Common Sense Initiative

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Business Impact Analysis

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

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

FYR 2024 (Drug Distributors)

Rule Number(s): 4729:6-2-03, 4729:6-2-04, 4729:6-2-06, 4729:6-3-01, 4729:6-3-03, 4729:6-3-04, 4729:6-3-05, 4729:6-3-06, 4729:6-3-07, 4729:6-3-08, 4729:6-5-01, 4729:6-5-02, 4729:6-6-01, 4729:6-7-01, 4729:6-8-01, 4729:6-8-02, 4729:6-9-01, 4729:6-9-02, 4729:6-10-01, 4729:6-10-02, 4729:6-11-01, 4729:6-11-02

Date of Submission for CSI Review: 2/13/2024

Public Comment Period End Date: 2/29/2024

Rule Type/Number of Rules:

New/___ rules
No Change/____ rules (FYR? ___)
Amended/_22_ 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Rescinded/____ rules (FYR?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.

Amend:

- 4729:6-2-03 – Specifies who must submit to a criminal records check when applying for a drug distributor license.
- 4729:6-2-04 – Provides the information for what must be included on a drug distributor license application.
- 4729:6-2-06 – Provides the procedures necessary to discontinue business as a drug distributor.
- 4729:6-3-01 – Provides the requirements for the destruction of controlled substances by a wholesale distributor of dangerous drugs, manufacturer of dangerous drugs, outsourcing facility, third-party logistics provider and repackager of dangerous drugs.
- 4729:6-3-03 – Provides the requirements for reporting the theft or loss of dangerous drugs by a wholesale distributor of dangerous drugs, manufacturer of dangerous drugs, outsourcing facility, third-party logistics provider and repackager of dangerous drugs.
- 4729:6-3-04 – Provides the requirements to verify licensure prior to the sale or purchase of dangerous drugs.
- 4729:6-3-05 – Requires drug distributors to report suspicious orders and customers who may present a diversion risk to the Board.

- 4729:6-3-06 – Implements controlled substance inventory requirements for all category III drug distributors.
- 4729:6-3-07 – Includes the requirements for drug distributors engaging in the sale of dangerous drugs online.
- 4729:6-3-08 – Provides the procedures for the sale/distribution of complementary supplies and drug samples.
- 4729:6-5-01 – Provides for the general operations of a wholesale distributor of dangerous drugs.
- 4729:6-5-02 – Includes the requirements for all records maintained by a wholesale distributor of dangerous drugs.
- 4729:6-6-01 – Provides for the general operations of a virtual wholesale distributor of dangerous drugs.
- 4729:6-7-01 – Provides for the general operations of a wholesale distributor of dangerous drugs with a broker classification.
- 4729:6-8-01 – Provides for the general operations of a manufacturer of dangerous drugs.
- 4729:6-8-02 – Includes the requirements for all records maintained by a manufacturer of dangerous drugs.
- 4729:6-9-01 – Provides for the general operations of a repackager of dangerous drugs.
- 4729:6-9-02 – Includes the requirements for all records maintained by a repackager of dangerous drugs.
- 4729:6-10-01 – Provides for the general operations of an outsourcing facility.
- 4729:6-10-02 – Includes the requirements for all records maintained by an outsourcing facility.
- 4729:6-11-01 – Provides for the general operations of a third-party logistics provider.
- 4729:6-11-02 – Includes the requirements for all records maintained by a third-party logistics provider.

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 3719.13 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.

   Rules 4729:6-3-01 and 4729:6-3-03 require adherence to federal rules regarding theft/loss and controlled substance drug destruction.

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.**

This rule package may exceed federal requirements because 4729.52 of the Revised Code authorizes the Board of Pharmacy to regulate the operation of drug distributors. Any regulations that may exceed provisions specified by the federal government are deemed necessary in order to protect the health and safety of Ohioans and to prevent the diversion of controlled substances and other dangerous drugs.

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 and distribution of dangerous drugs.

   Section 3719.28 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules establishing the manner of keeping and the form and content of records to be kept by persons authorized to manufacture, distribute, dispense, conduct research in, prescribe, administer, or otherwise deal with controlled substances.

   Section 3719.13 of the Ohio Revised Code authorizes employees of the Board of Pharmacy to inspect prescriptions, orders, records, and stocks of dangerous drugs and controlled substances.

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.

   No.

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.

   The rules in this package were distributed for public comment to all licensees and registrants of the Board.

   Prior to filing with CSI, the rules were also 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 questioned the extension of the record-keeping requirements from three to five years. By statute (ORC 3719.07), drug distributors are required to maintain records for five years, unless otherwise authorized by the Board.

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 this rule.

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 licensure and oversight of drug distributors, the State of 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 State of 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, 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**

- Ohio-licensed drug distributors (wholesaler, manufacturer, third-party logistics provider, outsourcing facility, and repackager).

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.

In general, violation of these rules may result in administrative licensure discipline for a licensee. Discipline might include reprimand, suspension of a license, monetary fine and/or revocation of a license.

Amend:

- 4729:6-2-03 – Specifies who must submit to a criminal records check when applying for a drug distributor license. Adds requirements for limited liability companies. The cost of a criminal records check (BCI and FBI) is $61.70 combined.
- 4729:6-2-04 – Provides the information for what must be included on a drug distributor license application. Add specific requirements for sole proprietorships and limited liability companies. Removes references to specific NABP accreditation programs. Restricts licensure to entities operating in the United States. The time to complete an application is estimated to be between 30-60 minutes.
- 4729:6-2-06 – Provides the procedures necessary to discontinue business as a drug distributor. Changes timeframe requirement to within 30 days and not 30 days prior to closing. The estimated cost to submit a discontinuation of business form is between 5-10 minutes (one-page form).
- 4729:6-3-01 – Provides the requirements for the destruction of controlled substances by a wholesale distributor of dangerous drugs, manufacturer of dangerous drugs, outsourcing facility, third-party logistics provider and repackager of dangerous drugs. Requires compliance with all federal requirements for disposal and specifies records must be maintained for five years. Drug distributors who do not maintain such records for 5 years will experience an increase in compliance costs.
- 4729:6-3-03 – Permits the Board to enter and inspect a licensee or applicant. Requires a corrective action response. The time to complete a corrective response is based on the number of violations observed by inspection staff.
- 4729:6-3-04 – Provides the requirements to verify licensure prior to the sale or purchase of dangerous drugs. Requires verification of licensure or an attestation that the entity is exempt from the Board's licensing requirements. Verification must be done electronically. It takes about 30 seconds to confirm licensure using Ohio's eLicensing system. To verify licensure exemptions, it requires an attestation from the purchaser. The Board developed a one-page form to assist licensees in meeting this

requirement: https://www.pharmacy.ohio.gov/documents/licensing/tddd/forms/general/tddd%20exemption%20attestation%20form.pdf

- 4729:6-3-05 – Requires drug distributors to report suspicious orders and customers who may present a diversion risk to the Board. Exempts the reporting of certain schedule I and II chemicals from suspicious order monitoring. Companies engaged in the sale of controlled substances and gabapentin will be required to operate a suspicious order monitoring system. This will result in an increase in administrative costs to ensure compliance with the reporting requirements of the rule.
- 4729:6-3-06 – Implements controlled substance inventory requirements for all category III drug distributors. Updates the rule to require records to be maintained for 5-years. Drug distributors may experience an increase in administrative costs to comply with the additional recordkeeping requirements.
- 4729:6-3-07 – Includes the requirements for drug distributors engaging in the sale of dangerous drugs online. Those selling drugs on the internet will experience additional administrative costs to ensure all information is present on the seller's website.
- 4729:6-3-08 – Provides the procedures for the sale/distribution of complementary supplies and drug samples. Amends to permit such samples to be provided to an entity exempted from licensure under ORC 4729.541.
- 4729:6-5-01 – Provides for the general operations of a wholesale distributor of dangerous drugs. Requires wholesalers to adhere to physical security requirements to prevent diversion. This may result in the need for additional investments to ensure they meet Board standards. Additionally, drug distributors may experience an increase in costs due to the extension of the recordkeeping requirements from three to five years.
- 4729:6-5-02 – Includes the requirements for all records maintained by a wholesale distributor of dangerous drugs. The rule does require notification for off-site storage. This is a one-page form that takes approximately 15 minutes to complete and submit. Additionally, drug distributors may experience an increase in costs due to the extension of the recordkeeping requirements from three to five years.
- 4729:6-6-01 – Provides for the general operations of a virtual wholesale distributor of dangerous drugs. The rule does require notification for off-site storage. This is a one-page form that takes approximately 15 minutes to complete and submit. Additionally, drug distributors may experience an increase in costs due to the extension of the recordkeeping requirements from three to five years.
- 4729:6-7-01 – Provides for the general operations of a wholesale distributor of dangerous drugs with a broker classification. Exempts brokers from licensure if they are engaged in the disposal of dangerous drugs.
- 4729:6-8-01 – Provides for the general operations of a manufacturer of dangerous drugs. Requires manufacturers to adhere to physical security requirements to prevent diversion and to manufacture in accordance with federal standards. Additionally, drug distributors may experience an increase in costs due to the extension of the recordkeeping requirements from three to five years.

- 4729:6-8-02 – Includes the requirements for all records maintained by a manufacturer of dangerous drugs. These are similar recordkeeping requirements to what currently exists in the rule so this should not adversely impact current licensees. The rule does require notification for off-site storage. This is a one-page form that takes approximately 15 minutes to complete and submit.
- 4729:6-9-01 – Provides for the general operations of a repackager of dangerous drugs. Requires repackagers to adhere to physical security requirements to prevent diversion and repackaging in accordance with federal standards. Additionally, drug distributors may experience an increase in costs due to the extension of the recordkeeping requirements from three to five years.
- 4729:6-9-02 – Includes the requirements for all records maintained by a repackager of dangerous drugs. The rule does require notification for off-site storage. This is a one-page form that takes approximately 15 minutes to complete and submit. These are similar recordkeeping requirements to what currently exists in the rule so this should not adversely impact current licensees.
- 4729:6-10-01 – Provides for the general operations of an outsourcing facility. Requires outsourcing facilities to adhere to physical security requirements to prevent diversion and to prepare compounded drugs in accordance with federal standards. Additionally, drug distributors may experience an increase in costs due to the extension of the recordkeeping requirements from three to five years.
- 4729:6-10-02 – Includes the requirements for all records maintained by an outsourcing facility. The rule does require notification for off-site storage. This is a one-page form that takes approximately 15 minutes to complete and submit. These are similar recordkeeping requirements to what currently exists in the rule so this should not adversely impact current licensees.
- 4729:6-11-01 – Provides for the general operations of a third-party logistics provider. Requires outsourcing to adhere to physical security requirements to prevent diversion and to prepare compounded drugs in accordance with federal standards. Additionally, drug distributors may experience an increase in costs due to the extension of the recordkeeping requirements from three to five years.
- 4729:6-11-02 – Includes the requirements for all records maintained by a third-party logistics provider. The rule does require notification for off-site storage. This is a one-page form that takes approximately 15 minutes to complete and submit. These are similar recordkeeping requirements to what currently exists in the rule so this should not adversely impact current licensees.

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).*

4729:6-3-05 – Exempts the reporting of certain schedule I and II chemicals from suspicious order monitoring.

4729:6-7-01 – Exempts drug distributors engaged in brokering dangerous drugs for the purpose of disposal from licensure requirements.

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 requirements for the licensure and regulation of drug distributors.

Regulatory Flexibility

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

These rules do not provide any exemptions or alternative means of compliance for small businesses. 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 State of Ohio Board of Pharmacy does not fine licensees or impose penalties for first-time paperwork violations. However, a significant deviation from the rules 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 is 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.

Furthermore, the Board also developed external inspection guides available to all licensees to ensure compliance with our regulations.

Rule 4729:6-2-03 – Criminal Records Checks. (AMEND)

(A) **Unless otherwise approved by the board, a** new distributor of dangerous drug license will not be issued until the following persons submit fingerprints to the Ohio bureau of criminal ~~identification and~~ investigation (BCI~~&I~~) for a criminal records check in accordance with paragraph (C) of this rule:

(1) The responsible person on the application for licensure; and

(2) The following persons based upon the drug distributor's business type:

(a) All partners of a partnership.

(b) The sole proprietor of a sole proprietorship.

(c) All members of a limited-liability company.

(i) If the limited liability company has a member which is not a natural person, the limited liability company's president, vice president, secretary, treasurer, and chief executive officer, or any equivalent position.

(ii) If the limited liability company's sole member is a publicly traded corporation, the limited-liability company may seek a waiver pursuant to paragraph (A)(3) of this rule.

(~~c~~ **d**) Except as provided in paragraph (A)(3) of this rule, the president, vice president, secretary, treasurer, and chief executive officer, or any equivalent position of a corporation and, if a corporation is not publicly traded on a major stock exchange, each shareholder owning ten percent or more of the voting stock of the corporation.

If the director or the director's designee determines other person(s) in the organizational structure have substantial control, such as the power to influence management and operational decision-making over the distribution of dangerous drugs, the director or designee may require a criminal records check of those with substantial control in addition to or in place of those persons set forth in this paragraph.

~~**(d) The agency director of a government agency.**~~

(e) The executive director or any equivalent position of a nonprofit organization.

(3) For publicly traded corporations, the board's executive director or the ~~**directors**~~ **director's** designee may waive the criminal records checks required in paragraph (A)(2)(c) of this rule under the following circumstances:

(a) The ~~**public**~~ **publicly** traded corporation submits a request to the executive director and includes the organizational structure of the corporation, including all corporate officer positions responsible for directing the distribution of dangerous drugs. The director or the ~~**directors**~~ **director's** designee may request additional information about the corporation's organizational structure.

(b) The executive director or the director's designee approves an alternate list of corporate officers ~~that~~ **who** are required to submit a criminal records check. If approval is not provided, the publicly traded corporation shall comply with paragraph (A)(2)(c) of this rule.

(B) The persons listed in paragraph (A)(2) of this rule shall be a natural person that owns and/or operates the business entity applying for licensure. In the event the applicant is not owned by a natural person, each business entity with an ownership interest in the applicant must be disclosed on the application up to and through the entity that is owned by a natural person, who shall be subject to a criminal records check in accordance with this rule.

(C) All criminal records checks conducted in accordance with this rule shall consist of both a BCI~~&I~~ criminal records check and a federal bureau of investigations records check (FBI) and shall comply with the following:

(1) Be based on electronic fingerprint impressions that are submitted directly to BCI~~&I~~ from a WebCheck provider agency or ink impressions. The state board of pharmacy may accept the results of a criminal records check based on ink impressions only in the following circumstances:

(a) Readable electronic fingerprint impressions cannot be obtained or are rejected by either BCI~~&I~~ or FBI;

(b) The person or persons listed in paragraph (A) of this rule reside outside of the state of Ohio; or

(c) The person or persons listed in paragraph (A) of this rule have a home address that is seventy-five miles or more from the nearest WebCheck location.

(2) Results will only be considered valid if the fingerprint impressions were obtained within one year of the date the application is received by the board.

(3) The results of the criminal records check must be sent directly to the state board of pharmacy from BCI~~&I~~.

(D) Only new persons listed in paragraphs (A)(1) and (A)(2) of this rule shall be required to submit to a criminal records check for a new application resulting from a change in the description of a distributor of dangerous drugs pursuant to rule 4729:6-2-05 of the Administrative Code.

Rule 4729:6-2-04 – Drug Distributor Applications. (AMEND)

(A) The following information shall be required on a form supplied by the state board of pharmacy from each person making application for a license as a distributor of dangerous drugs:

(1) The name, full physical business address (not a post office box), and telephone number.

(2) All trade, fictitious, or business names used by the licensee (e.g.**,** "doing business as" or "formerly known as"). ~~**Trade or business names shall not be identical to the name used by another, unrelated drug distributor permitted to purchase or sell drugs in this state.**~~

(3) Addresses, telephone numbers, and the full names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of dangerous drugs located in this state or used to distribute drugs into this state.

(4) The type of ownership or operation (i.e., sole proprietorship, partnership, **limited liability company,** corporation, ~~**or**~~ government agency**, or nonprofit organization**).

(5) The following information for the owner(s) and/or operator(s) of the drug distributor:

(a) For a partnership:

(i) The full name, business address, social security number, and date of birth of each partner. If the partner is not a natural person, each business entity that is a partner having an ownership interest must be disclosed on the application up to and through the entity that is owned by a natural person.

(ii) The name of the partnership.

(iii) The partnership's federal employer identification number.

(b) For a sole proprietorship: the full name, business address, social security number, and date of birth of the sole proprietor.

(c) For a limited lability company: the full name, business address, social security number, and date of birth of each member. If the member(s) is not a natural person, each business entity that is a member having an ownership interest must be disclosed on the application up to and through the entity that is owned by a natural person.

(~~**b**~~ **d**) For a corporation:

(i) The full name, business address, social security number**,** and date of birth of the corporation's president, vice-president, secretary, treasurer**,** and chief executive officer, or any equivalent position. For a publicly traded corporation that obtains a criminal records check waiver pursuant to paragraph (A)(3) of rule 4729:6-2-03 of the Administrative Code, the full name, business address, social security number**,** and date of birth of the corporate officers subject to a criminal records check as determined by the board**'**s executive director or director**'**s designee.

(ii) The name or names of the corporation.

(iii) The state of incorporation.

(iv) The corporation's federal employer identification number.

(v) The name of the parent company, if applicable.

(vi) If the corporation is not publicly traded on a major stock exchange, the full name, business address, and social security number of each shareholder owning ten percent or more of the voting stock of the corporation.

~~**(c) For a sole proprietorship: the full name, business address, social security number, and date of birth of the sole proprietor.**~~

(~~**d**~~ **e**) For a government agency: the full name, business address, social security number, and date of birth of the agency director.

(f) For a nonprofit organization: the full name, business address, social security number, and date of birth of the executive director or any equivalent position.

(6) If the entity submitting an application for a distributor of dangerous drugs license is located outside the boundaries of the state of Ohio, the licensing process shall include an inquiry to the licensing authority of the state ~~**or jurisdiction**~~ **where located** to determine if the entity possesses a current and valid license **or registration** to distribute dangerous drugs in that state ~~**or jurisdiction**~~ and any disciplinary action, including actions pending, the licensing authority is taking or may have taken against the entity. This information may be used to determine if the business entity should be granted a license by the state board of pharmacy. An entity located outside the boundaries of the state of Ohio that is making application for licensure as a third-party logistics provider or virtual wholesaler shall maintain **an applicable** ~~**verified-accredited wholesale distributors (VAWD)**~~ accreditation from the national association of boards of pharmacy if the state where the entity resides does not license such entities.

(7) If applicable, proof of the ~~**entitys**~~ **entity's** valid registration with the United States food and drug administration and/or the United States drug enforcement administration.

(8) Any information required on the application as determined by the board.

(9) Any follow-up information as deemed necessary by the board's executive director or the director's designee upon receipt of the application materials.

(B) Prior to the end of the licensing period established in rule 4729:6-2-02 of the Administrative Code, a renewal application requesting such information as the state board of pharmacy may require will be sent to the email or physical address of record to the attention of the responsible person. Such renewal application form shall be completed and returned with the applicable fee on or before the date established in rule 4729:6-2-02 of the Administrative Code.

(C) The Board shall not license an entity located outside of the United States.

(D) Except as provided in (D)(1) of this rule, an applicant or licensee engaged in the distribution of dangerous drugs shall obtain all applicable licenses issued in accordance with this division of the Administrative Code.

(1) This provision does not apply to a manufacturer who is also engaged in the wholesale distribution of dangerous drugs.

(2) An applicant or licensee engaged in activities requiring multiple licenses shall ensure that all requirements for each license can be maintained and all applicable drug records are segregated by license type.

Rule 4729:6-2-06 – Procedure for discontinuing business as a distributor of dangerous drugs. (AMEND)

(A) A distributor of dangerous drugs who plans to discontinue business activities shall file a notice with the state board of pharmacy. The notice shall be submitted, in a manner determined by the board, **within thirty days of discontinuation of business as a distributor of dangerous drugs.** ~~**at least thirty days in advance of the proposed date of discontinuing business, unless waived by the board's executive director or the director's designee due to extraordinary circumstances beyond the licensee's control.**~~ This notice shall include the following information:

(1) The name, address, and license number of the drug distributor discontinuing business.

(2) If applicable, the name, address, and license number of the drug distributor or other authorized entity where the dangerous drugs will be transferred.

(3) The name and address of the secured location where the records required to be maintained in accordance with this division will be stored.

(4) The proposed date of discontinuing business.

(B) Unless the licensee is informed by the executive director before the proposed date of discontinuing business that the transfer of dangerous drugs and records may not occur, the licensee discontinuing business may transfer the dangerous drugs and **drug** records**.** ~~**in accordance with the following:**~~

~~**(1)**~~ **(C)** On the date of discontinuing business, a complete inventory of all controlled substances being transferred or disposed of, in accordance with rule 4729:6-3-01 of the Administrative Code, shall be made. The inventory shall list the name, strength, dosage form, and quantity of all controlled substances transferred or disposed.

~~**(2)**~~ This inventory shall serve as the final inventory of the licensee discontinuing business and the initial inventory of the licensee to whom the controlled substances are being transferred. A copy of the inventory shall be included in the records of each licensee involved in the transfer.

Rule 4729:6-3-01 | Disposal of controlled substances. (AMEND)

(A) As used in this rule:

"Non-retrievable" means the condition or state to which a controlled substance shall be rendered following a process that permanently alters that controlled substance's physical or chemical condition or state through irreversible means and thereby renders the dangerous drugs which are controlled substances unavailable and unusable for all practical purposes. The process to achieve a non-retrievable condition or state may be unique to a substance's chemical or physical properties. A dangerous drug which is a controlled substance is considered non-retrievable when it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue. The purpose of destruction is to render the controlled substance(s) to a non-retrievable state and thus prevent diversion of any such substance to illicit purposes.

(B) A person licensed in accordance with section 4729.52 of the Revised Code or this division of the Administrative Code shall dispose of controlled substance dangerous drugs in accordance with 21 C.F.R. 1317 (~~**1/1/2016**~~ **9/25/2023**). The method of destruction must render the controlled substances to a state of non-retrievable. Records of controlled substance destruction that are required pursuant to 21 C.F.R. 1304 (~~**1/1/2016**~~ **9/25/2023**) shall be maintained for a minimum of ~~**three**~~ **five** years and made readily retrievable to the board of pharmacy upon request.

Rule 4729:6-3-03 | Inspections and corrective actions. (AMEND)

(A) Pursuant to section 3719.13 of the Revised Code, an entity licensed by state board of pharmacy in accordance with section 4729.52 of the Revised Code or this ~~**division**~~ **division** of the Administrative Code is subject to an on-site inspection by the board. An authorized board ~~**agent**~~ **employee** may, without notice, carry out an on-site inspection or investigation of an entity licensed by the board. Upon verification of the board ~~**agent's**~~ **employee's** credentials, the agent shall be permitted to enter the licensed entity.

(B) Submission of an application for a license, in accordance with section 4729.52 of the Revised Code or this ~~**division**~~ **division** of the Administrative Code, with the state board of pharmacy constitutes permission for entry and on-site inspection by an authorized board **employee** ~~**agent**~~.

(C) If an **employee** ~~**agent**~~ of the state board of pharmacy identifies a violation specified in paragraph (D) of this rule, the **employee** ~~**agent**~~ may provide written notice, in a manner determined by the board, of the nature of the observed violations to the responsible person on the license or application. The licensee or applicant may also be subject to disciplinary actions pursuant to Chapter 4729. of the Revised Code and this division of the Administrative Code.

(D) Violations may include any of the following:

(1) Violating any rule of the board;

(2) Violating any provision of Chapter 4729. of the Revised Code;

(3) Violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C. 301, or Chapter 3715. of the Revised Code; **or**

(4) Violating any provision of the federal drug abuse control laws or regulations or Chapter 2925. or 3719. of the Revised Code.

(E) The licensee or applicant shall submit to the board within thirty days of a written notice provided in accordance with paragraph (C) of this rule, in a manner determined by the board, either of the following:

(1) The action(s) the licensee or applicant has taken to correct the violation(s) and the date of implementation of the corrective action(s); or

(2) An explanation disputing the observed violations.

Rule 4729:6-3-04 | Verification of licensure prior to sale or purchase. (AMEND)

(A) As used in section 4729.60 of the Revised Code and in this rule, "roster" means any of the following:

(1) The online roster maintained as part of the board's ~~**elicensing**~~ **electronic licensing** system (available on the board's website: www.pharmacy.ohio.gov);

(2) An electronic list of licensees and registrants if maintained by the board; and

(3) Any other format capable of meeting the requirements of section 4729.60 of the Revised Code and this rule that has been approved by the board.

(B) Before a drug distributor may sell or distribute dangerous drugs to any person in this state, except as provided in paragraph (C) of this rule, the distributor shall conduct a documented query of a roster maintained by the board 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 drug distributor shall also review a current version of the licensee's drug list to ensure the purchaser is authorized to possess the drugs ordered.

(2) A distributor of dangerous drugs.

(C) Paragraph (B) of this rule does not apply when a drug distributor sells or distributes dangerous drugs to any of the following:

(1) A person specified in division (B)(4) of section 4729.51 of the Revised Code; or

(2) Any of the exempted persons listed in section 4729.541 of the Revised Code**.**

(D) A distributor of dangerous drugs may make a sale of a dangerous drug to any of the exempted persons listed in section 4729.541 of the Revised Code and shall ensure the purchaser meets the exemption criteria.

(1) To confirm a purchasing prescriber meets the exemption criteria pursuant to section 4729.541 of the Revised Code, the drug distributor shall comply with all the following:

(a) Provide the prescriber the requirements in Ohio law of when a prescriber is required to hold a license as a terminal distributor of dangerous drugs;

(b) Verify the prescriber is appropriately licensed in this state to prescribe dangerous drugs or drug therapy related devices in the course of the individual's professional practice;

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

(d) Ensure that all attestations are maintained by the drug distributor for a period of ~~three~~ **five** years after the sale or distribution of the dangerous drug.

(2) To confirm any other person purchasing dangerous drugs meets the exemption criteria pursuant to section 4729.541 of the Revised Code, the drug distributor shall comply with all the following:

(a) Provide the person the requirements in Ohio law of when a person is required to hold a license as a terminal distributor of dangerous drugs;

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

(c) Ensure that all attestations are maintained by the drug distributor for a period of ~~three~~ **five** years after the sale or distribution of the dangerous drug.

(E) Except as provided in paragraph (F) of this rule, before a drug distributor located in this state may purchase or receive dangerous drugs, the distributor shall conduct a documented query of a roster maintained by the board to determine if the seller is licensed as a distributor of dangerous drugs. If a licensed drug distributor conducts a documented query at least annually and relies on the results of the query in purchasing dangerous drugs, the distributor shall be deemed not to have violated this rule.

(F) A **third-party** ~~third party~~ logistics provider is exempt from the requirements of paragraph (B) of this rule if the licensee has access to documentation indicating the entity responsible for directing the sale or disposition of the drugs has complied with the requirements of this rule.

Rule 4729:6-3-05 | Suspicious Order Monitoring and Due Diligence. (AMEND)

(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 ~~administrations~~ **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.**~~

(**I** ~~**J**~~) 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.

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

Rule 4729:6-3-06 | Controlled Substances Inventory Requirements. (AMEND)

(A) All category III drug distributor licenses shall complete a controlled substances inventory in accordance with section 1304.11 of the Code of Federal Regulations (9/9/2014).

(B) The drug distributor's responsible person shall be responsible for completing and maintaining this inventory record.

(C) All inventory records shall be maintained for a period of ~~three~~ **five** years from the completion date of the inventory and made readily retrievable.

(D) When a drug or compound is added to the schedule of controlled substances by state or federal law, rule**,** or regulation, a drug distributor shall complete an inventory pursuant to paragraph (A) of this rule of all stocks of such substance no later than ten days after the drug is added to the schedule.

Rule 4729:6-3-07 | Sales of dangerous drugs on-line. (AMEND)

(A) All persons selling or offering to sell dangerous drugs at ~~**retail or**~~ wholesale **via the internet** into, out of, or within Ohio must be appropriately licensed by the state board of pharmacy.

(B) All drug distributors licensed with the state board of pharmacy and who sell or offer to sell dangerous drugs on the internet to persons located in Ohio or any other state must make such sales only in compliance with all state and federal laws, rules**,** and regulations governing the legal distribution of dangerous drugs.

(C) Websites owned and/or maintained by Ohio licensed dangerous drug distributors who sell or offer to sell dangerous drugs on the internet must provide the following information to the public:

(1) Name under which the dangerous drug distributor is licensed to do business as in Ohio.

(2) Full address of licensed location.

(3) Telephone number where the drug distributor may be contacted during regular business hours.

(4) A list of the states in which the dangerous drug distributor may legally sell dangerous drugs.

(5) The name, address**,** and how the state licensing agency and the drug enforcement administration may be contacted in each state in which the person is authorized to do business. This may include a link to the agency's and the drug enforcement ~~**administrations**~~ **administration's** website.

(D) Any Ohio licensed drug distributor requesting personal information from the public by way of the internet (**e.g.,** questionnaire forms or e-mail) must provide for security and confidentiality of the information. This portion of the website must also provide information regarding how the personal information will be used, pursuant to all federal and state laws, rules, and regulations, and ensure that such information is not used for purposes not disclosed without the written informed consent of the patient or person submitting personal information.

Rule 4729:6-3-08 | Distributor of dangerous drugs samples and complimentary supplies. (AMEND)

(A) As used in this rule:

(1) "Sample" means a dangerous drug or pharmaceutical preparation that would be hazardous to health or safety if used without the supervision of a licensed health professional authorized to prescribe drugs, or a drug of abuse, and that, at one time, had been placed in a container plainly marked as a sample by a manufacturer. Except as provided in paragraph (E) of this rule, samples may only be provided to and furnished by a licensed prescriber as defined in rule 4729:5-1-02 of the Administrative Code in accordance with paragraph (B) of this rule.

(2) "Complimentary supply" also known as "starter packs," "initial dose packs," "starter stocks," "replacement programs," or any other similar supply means a drug or pharmaceutical preparation that is distributed without charge by licensed drug distributors to pharmacies licensed as terminal distributors of dangerous drugs or prescribers to assist patients in the initiation of drug therapy. A complimentary supply shall not contain the markings or labeling of a sample drug.

(B) No drug distributor or distributor's representative, including sales representatives, may sell or distribute a sample of a drug to a licensed prescriber unless requested by the prescriber and the entity:

(1) Is licensed as a distributor of dangerous drugs **or is exempted from licensure in accordance with 4729.541 of the Revised Code**; and

(2) Maintains a record of such distribution for five years from the date of sale or distribution. Such records shall be made readily retrievable.

(C) Complimentary supplies are subject to the same requirements as stock shipments of dangerous drugs pursuant to agency 4729 of the Administrative Code and Chapters 4729., 3719., and 3715. of the Revised Code.

(D) A drug distributor shall comply with rule 4729:6-3-04 of the Administrative Code prior to the sale or distribution of complimentary supplies and samples.

(E) Nothing in this rule prohibits a pharmacist working, regardless of compensation, in a charitable pharmacy from dispensing a sample drug to a person in accordance with section 3719.811 of the Revised Code and agency 4729 of the Administrative Code.

(F) Paragraph (A)(1) of this rule does not permit a pharmacist who is authorized to manage drug therapy pursuant section 4729.39 of the Revised Code from ordering, dispensing**,** or personally furnishing a sample within a pharmacy licensed as a terminal distributor of dangerous drugs.

Rule 4729:6-5-01 | Wholesale Distributors - General Operations. (AMEND)

The following requirements shall apply to all persons licensed as a wholesale distributor of dangerous drugs:

(A) All facilities shall:

(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(3) Have a quarantine area for storage of dangerous drugs that are damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened. Such drugs shall be stored in accordance with paragraph (B) of this rule;

(4) Be maintained in a clean and orderly condition;

(5) Be free from infestation by insects, rodents, birds, or vermin of any kind;

(6) ~~**Shall be**~~ **Be** registered as a business entity with the appropriate state or local authority(s) and must operate out of a location that is zoned for commercial use and not out of a residence or personal dwelling.

(B) Adulterated drugs shall be stored in a separate and secure area apart from the storage of drugs used for distribution and sale.

(1) Adulterated drugs shall be stored no longer than two years from the date of adulteration or expiration. Adulterated drugs shall be stored in a manner that prohibits access by unauthorized persons.

(2) Dangerous drugs, other than controlled substances, may be destroyed utilizing proper methods of disposal and following the record keeping requirements noted in paragraph **(B)(3)** of this rule, or may be donated to a pharmacy school pursuant to sections 3715.88 to 3715.92 of the Revised Code. Methods of disposal of non-controlled dangerous drugs shall prevent the possession or use of the drugs by unauthorized persons.

(3) Records of dangerous drug destructions, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug destroyed, the date destroyed, the method of destruction, the positive identification of the responsible person that performed the destruction, and the positive identification of the person that witnessed the destruction.

(~~3~~ **4**) Dangerous drugs that are controlled substances shall be disposed of pursuant to rule 4729:6-3-01 of the Administrative Code.

(C) All facilities used for wholesale drug distribution shall be secure from unauthorized entry.

(1) Access from outside the premises shall be kept to a minimum and be well controlled.

(2) The outside perimeter of the premises shall be well lit.

(3) Entry into areas where dangerous drugs are stored shall be limited to authorized personnel.

(4) All facilities where dangerous drugs are stored shall be equipped with an alarm system to detect unauthorized entry after hours.

(5) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. The security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(D) All dangerous drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States pharmacopoeia/national formulary (USP/NF).

(1) If no storage requirements are established for a dangerous drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its strength, quality, and purity are not adversely affected.

(2) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to regularly document proper storage of dangerous drugs. Temperature and humidity documentation shall be made readily retrievable and maintained for a period of not less than ~~**three**~~ **five** years from the last documented temperature and humidity reading.

(E) All shipments of dangerous drugs shall be examined in accordance with the following:

(1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated dangerous drugs or dangerous drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(2) Each outgoing shipment shall be carefully inspected for identity of the dangerous drug products and to ensure that there is no delivery of dangerous drugs that have been damaged in storage or held under improper conditions.

(F) All returned, damaged, and expired dangerous drugs shall be handled in the following manner:

(1) Dangerous drugs that are expired, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other dangerous drugs until they are destroyed or returned to the supplier.

(2) Any dangerous drugs ~~whose~~ **where the** immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other dangerous drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a dangerous drug has been returned cast doubt on the drug's safety, **identity,** ~~identify,~~ strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling**,** as a result of storage or shipping.

(G) Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures which shall be followed for the receipt, security, storage, inventory, and distribution of dangerous drugs, including policies and procedures for identifying, recording, and reporting losses or thefts in accordance with rule 4729:6-3-02 of the Administrative Code, and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include in their written policies and procedures with all the following:

(1) A procedure to be followed for handling recalls and withdrawals of dangerous drugs. Such procedure shall be appropriate to deal with recalls and withdrawals due to:

(a) Any action initiated at the request of the food and drug administration or other federal, state, or local law enforcement or other government agency, including the state board of pharmacy;

(b) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market;

(c) Any action undertaken to promote public health and safety by replacing ~~of~~ existing merchandise with an improved product or new package design.

(2) A procedure to ensure that wholesale distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

(3) A procedure to ensure that any adulterated dangerous drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of adulterated dangerous drugs. This documentation shall be maintained for ~~three~~ **five** years after disposition of the adulterated drugs.

(H) Personnel employed in the wholesale distribution of dangerous drugs shall be required to have appropriate education, experience**,** and training to assume responsibility for positions related to compliance with the requirements of this division of the Administrative Code.

(I) Wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws, rules**,** and regulations. This shall include, but is not limited to, all applicable laws, regulations**,** and standards set forth by the United States food and drug administration and the United States drug enforcement administration.

(J) Wholesale drug distributors shall permit properly identified and authorized state board of pharmacy **employees** ~~**agents**~~ and federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit records and written operating procedures.

(K) Wholesale drug distributors shall be subject to the provisions of any applicable federal, state, or local laws, rules**,** or regulations that relate to dangerous drug salvaging or reprocessing.

(L) The state board of pharmacy shall be notified, in a manner specified by the Board, of any new facilities, work**,** or storage areas to be constructed or utilized for dangerous drugs in this state.

(M) The following minimum standards shall apply to the storage and transportation methods utilized by a wholesale distributor of dangerous drugs for the storage, transportation**,** and delivery of dangerous drugs:

(1) A licensee is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses.

(2) When storing dangerous drugs in a public warehouse, a licensee is responsible for selecting a facility which will provide adequate security to guard against storage losses. The licensee shall store controlled substances in a public warehouse which complies with the requirements set forth in **21 CFR 1301.72 (10/3/2023)** ~~**section 1301.72 of the code of federal regulations (2/28/2018)**~~. In addition, the licensee shall employ precautions (e.g., assuring that shipping containers do not indicate that contents are controlled substances) to guard against storage or **in-transit** losses.

(3) When distributing dangerous drugs through agents, a licensee is responsible for providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.

Rule 4729:6-5-02 | Wholesale distributors - recordkeeping. (AMEND)

(A) Wholesale distributors of dangerous drugs shall establish and maintain inventories and records of all transactions regarding the receipt, sale**,** and distribution or other disposition of dangerous drugs.

(1) The records shall include, but not be limited to, the following information:

(a) The source of the drugs, including the name and ~~**principle**~~ **principal** address of the seller or transferor, and the address of the location from which the drugs were shipped.

(b) The name, national drug code, quantity of the drugs received, distributed, sold, disposed**,** or returned.

(c) The dates of receipt, sale**,** and distribution of the drugs.

(d) The name and ~~**principle**~~ **principal** address of the purchaser or receiver and the address of the location where the drugs were shipped.

(e) A system of records and procedures shall be maintained which prevent the sale or other distribution of dangerous drugs to any person not authorized in accordance with section 4729.51 of the Revised Code. Such procedures and records shall meet the requirements set forth in rule 4729:6-3-04 of the Administrative Code.

(2) All records maintained in accordance with this rule shall be made readily retrievable for inspection and copying by properly identified and authorized state board of pharmacy agents and federal, state, or local law enforcement agency officials for a period of five years following disposition of the drugs.

(3) Wholesale distributors located in this state intending to maintain records at a location other than the place licensed by the state board of pharmacy must notify the board in a manner determined by the board. Any such alternate location shall be secured and accessible only to representatives or contractors of the wholesale distributor.

(4) A wholesale distributor maintaining records at location other than the location licensed by the state board of pharmacy or via a computerized recordkeeping system shall maintain an executed agreement with the company possessing or storing the records authorizing an agent of the board access to the records maintained in accordance with this division within three business days.

(B) The recordkeeping requirements in paragraph (A) of this rule shall be followed for all damaged, deteriorated, misbranded, or adulterated dangerous drugs.

(C) Wholesale distributors shall submit wholesale sale information to the drug database in accordance with section 4729.78 of the Revised Code.

Rule 4729:6-6-01 | Virtual wholesalers - general operations. (AMEND)

The following requirements shall apply to all persons licensed as a wholesale distributor of dangerous drugs with a virtual wholesaler classification:

(A) Virtual wholesalers shall establish and maintain inventories and records of all transactions regarding the receipt, sale**,** and distribution or other transfer of dangerous drugs.

(1) The records shall include, but not be limited to, the following information:

(a) The source of the drugs, including the name and ~~principle~~ **principal** address of the seller or transferor, and the address of the location from which the drugs were shipped.

(b) The name, national drug code, quantity of the drugs received, distributed, sold, disposed**,** or returned.

(c) The dates of receipt, sale**,** and distribution of the drugs.

(d) The name and ~~principle~~ **principal** address of the purchaser or receiver and the address of the location where the drugs were shipped.

(e) A system of records and procedures shall be maintained which prevent the sale or other distribution of dangerous drugs to any person not authorized in accordance with section 4729.51 of the Revised Code. Such procedures and records shall meet the requirements set forth in rule 4729:6-3-04 of the Administrative Code.

(2) All records maintained in accordance with this rule shall be made readily retrievable for inspection and copying by properly identified and authorized state board of pharmacy agents and federal, state, or local law enforcement agency officials for a period of five years following disposition of the drugs.

(3) Virtual wholesalers located in this state intending to maintain records at a location other than the place licensed by the state board of pharmacy must notify the board in a manner determined by the board. Any such alternate location shall be secured and accessible only to representatives or contractors of the wholesale distributor.

(4) A virtual wholesaler maintaining records at location other than the location licensed by the state board of pharmacy or via a computerized recordkeeping system shall maintain an executed agreement with the company possessing or storing the records authorizing an agent of the board access to the records maintained in accordance with this division within three business days.

(B) Virtual wholesalers shall establish, maintain, and adhere to written policies and procedures which shall be followed for the receipt, security, storage, inventory, and distribution of dangerous drugs, including policies and procedures for identifying, recording, and reporting losses or thefts in accordance with rule 4729:6-3-02 of the Administrative Code, and for correcting all errors and inaccuracies in inventories. At a minimum, virtual wholesalers shall include in their written policies and procedures with all the following:

(1) A procedure to be followed for handling recalls and withdrawals of dangerous drugs. Such procedure shall address recalls and withdrawals due to:

(a) Any action initiated at the request of the food and drug administration or other federal, state, or local law enforcement or other government agency, including the state board of pharmacy;

(b) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market;

(c) Any action undertaken to promote public health and safety by replacing ~~**of**~~ existing merchandise with an improved product or new package design.

(2) A procedure to ensure that virtual wholesalers prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

(3) A procedure to ensure that any adulterated dangerous drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of adulterated dangerous drugs. This documentation shall be maintained for ~~**three**~~ **five** years after disposition of the adulterated drugs.

(C) Personnel employed in the wholesale distribution of dangerous drugs shall be required to have appropriate education, experience**,** and training to assume responsibility for positions related to compliance with the requirements of this division of the Administrative Code.

(D) Virtual wholesalers shall operate in compliance with applicable federal, state, and local laws, rules**,** and regulations. This shall include, but is not limited to, all applicable laws, regulations**,** and standards set forth by the United States food and drug administration and the United States drug enforcement administration.

(E) Virtual wholesalers shall permit properly identified and authorized state board of pharmacy **employees** ~~**agents**~~ and federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit records and written operating procedures.

(F) Virtual wholesalers shall be subject to the provisions of any applicable federal, state, or local laws, rules**,** or regulations that relate to dangerous drug salvaging or reprocessing.

(G) Virtual wholesalers shall submit wholesale sale information to the drug database in accordance with section 4729.78 of the Revised Code.

(H) The following minimum standards shall apply to the storage and transportation methods utilized by virtual wholesalers for the storage, transportation**,** and delivery of dangerous drugs:

(1) A licensee is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses.

(2) When storing dangerous drugs in a public warehouse, a licensee is responsible for selecting a facility which will provide adequate security to guard against storage losses. The licensee shall store controlled substances in a public warehouse which complies with the requirements set forth in section 1301.72 of the code of federal regulations (2/28/2018). In addition, the licensee shall employ precautions (e.g., assuring that shipping containers do not indicate that contents are controlled substances) to guard against storage or **in-transit** losses.

(3) When distributing dangerous drugs through agents, a licensee is responsible for providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.

(I) A virtual wholesaler seeking to engage in any other activities relating to the distribution of dangerous drugs shall obtain additional licensure for the operations conducted pursuant to those rules.

(J) The requirement to obtain licensure as a **virtual** wholesaler pursuant to section 4729.52 of the Revised Code does not apply to any of the following:

(1) A board of health, as defined in section 3701.048 of the Revised Code, that is licensed as a terminal distributor of dangerous drugs for the purpose of distributing dangerous drugs to another terminal distributor during a declared public health emergency or emergency preparedness incident; or

(2) A board of health, as defined in section 3701.048 of the Revised Code, that is a certified covered entity as defined in Section 340B(a)(4) of the Public Health Service Act (1/24/2020) to perform the functions of a virtual wholesaler with a contracted pharmacy licensed as a terminal distributor of dangerous drugs that has a "ship to, bill to" arrangement in accordance with all applicable requirements of the federal health resources and services administration (HRSA). A certified covered entity shall be responsible for all of the following:

(a) Maintaining records of drug distribution in accordance with paragraph (A) of this rule; and

(b) Ensuring the contracted pharmacy is appropriately licensed as a terminal distributor of dangerous drugs in accordance with Chapter 4729. of the Revised Code.

Rule 4729:6-7-01 | Brokers - general operations. (AMEND)

The following requirements shall apply to all persons licensed as a wholesale distributor of dangerous drugs with a broker classification:

(A) Brokers shall establish and maintain records of all transactions regarding the transfer, sale**,** or other disposition of dangerous drugs.

(1) The records shall include, but shall not be limited to, the following information:

(a) The source of the drugs, including the name and ~~principle~~ **principal** address of the seller or transferor, and the address of the location from which the drugs were shipped.

(b) The name, national drug code and quantity of the drugs received, distributed, sold, disposed**,** or returned.

(c) The dates of receipt, sale**,** and distribution of the drugs.

(d) The name and ~~principle~~ **principal** address of the purchaser or receiver and the address of the location where the drugs were shipped.

(2) All records maintained in accordance with this rule shall be made readily retrievable for inspection and copying by properly identified and authorized state board of pharmacy agents and federal, state, or local law enforcement agency officials for a period of five years following disposition of the drugs.

(3) Brokers in this state intending to maintain records at a location other than the place licensed by the state board of pharmacy must notify the board ~~by~~ in a manner determined by the board. Any such alternate location shall be secured and accessible only to representatives or contractors of the broker.

(4) A broker maintaining records at location other than the location licensed by the state board of pharmacy or via a computerized recordkeeping system shall maintain an executed agreement with the company possessing or storing the records authorizing an agent of the board access to the records maintained in accordance with this division within three business days.

(B) Brokers shall only engage in the marketing, offering, or contracting for wholesale distribution and sale of dangerous drugs that are unopened (i.e.**,** no partial stock bottles) and packaged in the manufacturer's original container.

(C) Brokers shall operate in compliance with all applicable federal, state, and local laws, rules**,** and regulations.

(D) Brokers shall permit properly identified and authorized state board of pharmacy **employees** ~~agents~~, federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit records and written operating procedures.

(E) A broker seeking to engage in activities relating to the distribution of dangerous drugs other than those of a broker shall obtain additional licensure for the operations conducted pursuant to those rules.

(F) Brokers shall verify that the seller and buyer are appropriately licensed or exempt from licensure in accordance with rule 4729:6-3-04 of the Administrative Code.

(G) Brokers shall not engage in the marketing, offering, or contracting for wholesale distribution and sale of dangerous drugs that are controlled substances.

(H) Brokers shall operate in compliance with applicable federal, state, and local laws, rules, and regulations. This shall include, but is not limited to, all applicable laws, regulations, and standards set forth by the United States food and drug administration and the United States drug enforcement administration.

(I) An entity engaged in the brokering of dangerous drugs for the sole purpose of reverse distribution (e.g., disposal) shall not be required to obtain a license as a wholesale distributor of dangerous drugs with a broker classification.

Rule 4729:6-8-01 | Manufacturers - General Operations. (AMEND)

The following requirements shall apply to all persons licensed as a manufacturer of dangerous drugs:

(A) All facilities shall:

(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(3) Have a quarantine area for storage of dangerous drugs that are damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened. Such drugs shall be stored in accordance with paragraph (B) of this rule;

(4) Be maintained in a clean and orderly condition;

(5) Be free from infestation by insects, rodents, birds, or vermin of any kind;

(6) ~~**Shall be**~~ **Be** registered as a business entity with the appropriate state or local authority(s) and must operate out of a location that is zoned for commercial use and not out of a residence or personal dwelling.

(B) Adulterated drugs shall be stored in a separate and secure area apart from the storage of drugs used for manufacturing, distribution**,** and sale.

(1) Adulterated drugs shall be stored no longer than two years from the date of adulteration or expiration. Adulterated drugs shall be stored in a manner that prohibits access by unauthorized persons.

(2) Dangerous drugs, other than controlled substances, may be destroyed utilizing proper methods of disposal and following the record keeping requirements noted in paragraph **(B)(3)** of this rule, or may be donated to a pharmacy school pursuant to sections 3715.88 to 3715.92 of the Revised Code. Methods of disposal of non-controlled dangerous drugs shall prevent the possession or use of the drugs by unauthorized persons.

(3) Records of dangerous drug destructions, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug destroyed, the date destroyed, the method of destruction, the positive identification of the responsible person that performed the destruction, and the positive identification of the person that witnessed the destruction.

(~~3~~ **4**) Dangerous drugs that are controlled substances shall be disposed of pursuant to rule 4729:6-3-01 of the Administrative Code.

(C) All facilities used for manufacturing and drug storage shall be secure from unauthorized entry.

(1) Access from outside the premises shall be kept to a minimum and be well controlled.

(2) The outside perimeter of the premises shall be well lit.

(3) Entry into areas where dangerous drugs are stored shall be limited to authorized personnel.

(4) All facilities where dangerous drugs are stored shall be equipped with an alarm system to detect unauthorized entry after hours.

(5) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. The security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(D) All dangerous drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States pharmacopoeia/national formulary (USP/NF).

(1) If no storage requirements are established for a dangerous drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its strength, quality, and purity are not adversely affected.

(2) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of dangerous drugs.

(E) All shipments of dangerous drugs shall be examined in accordance with the following:

(1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated dangerous drugs or dangerous drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(2) Each outgoing shipment shall be carefully inspected for identity of the dangerous drug products and to ensure that there is no delivery of dangerous drugs that have been damaged in storage or held under improper conditions.

(F) All returned, damaged, and adulterated**,** dangerous drugs shall be handled in the following manner:

(1) Dangerous drugs that are damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other dangerous drugs until they are destroyed or returned to the supplier.

(2) Any dangerous drugs ~~**whose**~~ **where the** immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other dangerous drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a dangerous drug has been returned cast doubt on the drug's safety, **identity,** ~~**identify,**~~ strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(G) Manufacturers shall establish, maintain, and adhere to written policies and procedures which shall be followed for the receipt, security, storage, inventory, and distribution of dangerous drugs, including policies and procedures for identifying, recording, and reporting losses or thefts in accordance with rule 4729:6-3-02 of the Administrative Code, and for correcting all errors and inaccuracies in inventories. Manufacturers shall include in their written policies and procedures all of the following:

(1) A procedure to be followed for handling recalls and withdrawals of dangerous drugs. Such procedure shall be appropriate to deal with recalls and withdrawals due to:

(a) Any action initiated at the request of the food and drug administration or other federal, state, or local law enforcement or other government agency, including the state board of pharmacy;

(b) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market;

(c) Any action undertaken to promote public health and safety by replacing ~~**of**~~ existing merchandise with an improved product or new package design.

(2) A procedure to ensure that manufacturers prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

(3) A procedure to ensure that any adulterated dangerous drugs ~~**shall**~~ be segregated from other drugs and destroyed. This procedure shall provide for written documentation of the disposition of adulterated dangerous drugs. This documentation shall be maintained for ~~**three**~~ **five** years after disposition of the adulterated drugs.

(H) Personnel employed in the manufacture and distribution of dangerous drugs shall be required to have appropriate education, experience, and training to assume responsibility for positions related to compliance with the requirements of this division of the Administrative Code.

(I) Manufacturers of dangerous drugs shall operate in compliance with applicable federal, state, and local laws, rules, and regulations. This shall include, but is not limited to, all applicable laws, regulations and standards set forth by the United States food and drug administration and the United States drug enforcement administration.

(J) Manufacturers of dangerous drugs shall permit properly identified and authorized state board of pharmacy **employees** ~~**agents**~~ and federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit records and written operating procedures.

(K) Manufacturers of dangerous drugs shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to dangerous drug salvaging or reprocessing.

(L) The state board of pharmacy shall be notified, in a manner specified by the board, of any new facilities, work**,** or storage areas to be constructed or utilized for dangerous drugs in this state.

(M) The following minimum standards shall apply to the storage and transportation methods utilized by a manufacturer of distributor of dangerous drugs for the storage, transportation**,** and delivery of dangerous drugs:

(1) A licensee is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses.

(2) When storing dangerous drugs in a public warehouse, a licensee is responsible for selecting a facility which will provide adequate security to guard against storage losses. The licensee shall store controlled substances in a public warehouse which complies with the requirements set forth in section 1301.72 of the code of federal regulations (2/28/2018). In addition, the licensee shall employ precautions (e.g., assuring that shipping containers do not indicate that contents are controlled substances) to guard against storage or **in-transit** losses.

(3) When distributing dangerous drugs through agents, a licensee is responsible for providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.

(N) A manufacturer shall comply with current good manufacturing practices pursuant to **21 CFR Part 211 (1/1/2024)** ~~**Section 501 of the Federal Food, Drug and Cosmetic Act (5/28/2015)**~~.

Rule 4729:6-8-02 | Manufacturers - recordkeeping. (AMEND)

(A) Manufacturers of dangerous drugs shall establish and maintain inventories and records of all transactions regarding the manufacture, receipt, sale**,** and distribution or other disposition of dangerous drugs.

(1) The records shall include, but not be limited to, the following information:

(a) The source of the drugs, including the name and ~~**principle**~~ **principal** address of the seller or transferor, and the address of the location from which the drugs were shipped.

(b) The name, national drug code and quantity of the drugs received, distributed, sold, disposed**,** or returned.

(c) The dates of receipt, sale**,** and distribution of the drugs.

(d) The name and ~~**principle**~~ **principal** address of the purchaser or receiver and the address of the location where the drugs were shipped.

(e) A system of records and procedures shall be maintained which prevent the sale or other distribution of dangerous drugs to any person not authorized in accordance with section 4729.51 of the Revised Code. Such procedures and records shall meet the requirements set forth in rule 4729:6-3-04 of the Administrative Code.

(2) All records maintained in accordance with this rule shall be made readily retrievable for inspection and copying by properly identified and authorized state board of pharmacy agents and federal, state, or local law enforcement agency officials for a period of five years following disposition of the drugs.

(3) Manufacturers in this state intending to maintain records at a location other than the place licensed by the state board of pharmacy must notify the board in a manner determined by the board. Any such alternate location shall be secured and accessible only to representatives or contractors of the manufacturer.

(4) A manufacturer maintaining records at location other than the location licensed by the state board of pharmacy or via a computerized recordkeeping system shall maintain an executed agreement with the company possessing or storing the records authorizing an agent of the board access to the records maintained in accordance with this division within three business days.

(B) The recordkeeping requirements in paragraph (A) of this rule shall be followed for all damaged, deteriorated, misbranded, or adulterated dangerous drugs.

(C) Manufacturers shall submit applicable wholesale or retail sale information to the drug database in accordance with section 4729.78 of the Revised Code.

Rule 4729:6-9-01 | Repackagers - General Operations. (AMEND)

The following requirements shall apply to all persons licensed as a repackager of dangerous drugs:

(A) All facilities shall:

(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(3) Have a quarantine area for storage of dangerous drugs that are damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened. Such drugs shall be stored in accordance with paragraph (B) of this rule;

(4) Be maintained in a clean and orderly condition;

(5) Be free from infestation by insects, rodents, birds, or vermin of any kind;

(6) ~~**Shall be**~~ **Be** registered as a business entity with the appropriate state or local authority(s) and must operate out of a location that is zoned for commercial use and not out of a residence or personal dwelling.

(B) Adulterated drugs shall be stored in a separate and secure area apart from the storage of drugs used for repackaging, distribution**,** and sale.

(1) Adulterated drugs shall be stored no longer than two years from the date of adulteration or expiration. Adulterated drugs shall be stored in a manner that prohibits access by unauthorized persons.

(2) Dangerous drugs, other than controlled substances, may be destroyed utilizing proper methods of disposal and following the record keeping requirements noted in paragraph **(B)(3)** of this rule, or may be donated to a pharmacy school pursuant to sections 3715.88 to 3715.92 of the Revised Code. Methods of disposal of non-controlled dangerous drugs shall prevent the possession or use of the drugs by unauthorized persons.

(3) Records of dangerous drug destructions, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug destroyed, the date destroyed, the method of destruction, the positive identification of the responsible person that performed the destruction, and the positive identification of the person that witnessed the destruction.

(~~3~~ **4**) Dangerous drugs that are controlled substances shall be disposed of pursuant to rule 4729:6-3-01 of the Administrative Code.

(C) All facilities used for repackaging and storing drugs shall be secure from unauthorized entry.

(1) Access from outside the premises shall be kept to a minimum and be well controlled.

(2) The outside perimeter of the premises shall be well lit.

(3) Entry into areas where dangerous drugs are stored shall be limited to authorized personnel.

(4) All facilities where dangerous drugs are stored shall be equipped with an alarm system to detect unauthorized entry after hours.

(5) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. The security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(D) All dangerous drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States pharmacopoeia/national formulary (USP/NF).

(1) If no storage requirements are established for a dangerous drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its strength, quality, and purity are not adversely affected.

(2) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of dangerous drugs.

(E) All shipments of dangerous drugs shall be examined in accordance with the following:

(1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated dangerous drugs or dangerous drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(2) Each outgoing shipment shall be carefully inspected for identity of the dangerous drug products and to ensure that there is no delivery of dangerous drugs that have been damaged in storage or held under improper conditions.

(F) All returned, damaged, and adulterated**,** dangerous drugs shall be handled in the following manner:

(1) Dangerous drugs that are damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other dangerous drugs until they are destroyed or returned to the supplier.

(2) Any dangerous drugs ~~**whose**~~ **where the** immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other dangerous drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a dangerous drug has been returned cast doubt on the drug's safety, **identity,** ~~**identify**~~ strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling**,** as a result of storage or shipping.

(G) Repackagers shall establish, maintain, and adhere to written policies and procedures which shall be followed for the receipt, security, storage, inventory, and distribution of dangerous drugs, including policies and procedures for identifying, recording, and reporting losses or thefts in accordance with rule 4729:6-3-02 of the Administrative Code, and for correcting all errors and inaccuracies in inventories. Repackagers shall include in their written policies and procedures all of the following:

(1) A procedure to be followed for handling recalls and withdrawals of dangerous drugs. Such procedure shall be appropriate to deal with recalls and withdrawals due to:

(a) Any action initiated at the request of the food and drug administration or other federal, state, or local law enforcement or other government agency, including the state board of pharmacy;

(b) Any voluntary action by the manufacturer or repackager to remove defective or potentially defective drugs from the market;

(c) Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design.

(2) A procedure to ensure that repackagers prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

(3) A procedure to ensure that any adulterated dangerous drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of adulterated dangerous drugs. This documentation shall be maintained for ~~**three**~~ **five** years after disposition of the adulterated drugs.

(H) Personnel employed in the repackaging and distribution of dangerous drugs shall be required to have appropriate education, experience**,** and training to assume responsibility for positions related to compliance with the requirements of this division of the Administrative Code.

(I) Repackagers of dangerous drugs shall operate in compliance with applicable federal, state, and local laws, rules**,** and regulations. This shall include, but is not limited to, all applicable laws, regulations**,** and standards set forth by the United States food and drug administration and the United States drug enforcement administration.

(J) Repackagers of dangerous drugs shall permit properly identified and authorized state board of pharmacy **employees** ~~**agents**~~ and federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures.

(K) Repackagers of drug distributors shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to dangerous drug salvaging or reprocessing.

(L) The state board of pharmacy shall be notified, in a manner specified by the board, of any new facilities, work or storage areas to be constructed or utilized for dangerous drugs in this state.

(M) The following minimum standards shall apply to the storage and transportation methods utilized by a repackager of distributor of dangerous drugs for the storage, transportation**,** and delivery of dangerous drugs:

(1) A licensee is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses.

(2) When storing dangerous drugs in a public warehouse, a licensee is responsible for selecting a facility which will provide adequate security to guard against storage losses. The licensee shall store controlled substances in a public warehouse which complies with the requirements set forth in **21 CFR 1301.72 (10/3/2023)** ~~**section 1301.72 of the code of federal regulations (2/28/2018)**~~. In addition, the licensee shall employ precautions (e.g., assuring that shipping containers do not indicate that contents are controlled substances) to guard against storage or **in-transit** losses.

(3) When distributing dangerous drugs through agents, a licensee is responsible for providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.

Rule 4729:6-9-02 | Repackagers - recordkeeping. (AMEND)

(A) Repackagers of dangerous drugs shall establish and maintain inventories and records of all transactions regarding the repackaging, receipt, sale, and distribution or other disposition of dangerous drugs.

(1) The records shall include, but not be limited to, the following information:

(a) The source of the drugs, including the name and ~~principle~~ **principal** address of the seller or transferor, and the address of the location from which the drugs were shipped.

(b) The name, national drug code, and quantity of the drugs received, distributed, sold, disposed, or returned.

(c) The dates of receipt, sale, and distribution of the drugs.

(d) The name and ~~principle~~ **principal** address of the purchaser or receiver and the address of the location where the drugs were shipped.

(e) A system of records and procedures shall be maintained which prevent the sale or other distribution of dangerous drugs to any person not authorized in accordance with section 4729.51 of the Revised Code. Such procedures and records shall meet the requirements set forth in rule 4729:6-3-04 of the Administrative Code.

(2) All records maintained in accordance with this rule shall be made readily retrievable for inspection and copying by properly identified and authorized state board of pharmacy agents and federal, state, or local law enforcement agency officials for a period of five years following disposition of the drugs.

(3) Repackagers located in this state intending to maintain records at a location other than the place licensed by the state board of pharmacy must notify the board in a manner determined by the board. Any such alternate location shall be secured and accessible only to representatives or contractors of the repackager.

(4) A repackager maintaining records at location other than the location licensed by the state board of pharmacy or via a computerized recordkeeping system shall maintain an executed agreement with the company possessing or storing the records authorizing an agent of the board access to the records maintained in accordance with this division within three business days.

(B) The recordkeeping requirements in paragraph (A) of this rule shall be followed for all damaged, deteriorated, misbranded, or adulterated dangerous drugs.

(C) Repackagers shall submit applicable wholesale or retail sale information to the drug database in accordance with section 4729.78 of the Revised Code.

Rule 4729:6-10-01 | Outsourcing Facilities - General Operations. (AMEND)

The following requirements shall apply to all persons licensed as outsourcing facilities:

(A) All facilities shall:

(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(3) Have a quarantine area for storage of dangerous drugs that are damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened. Such drugs shall be stored in accordance with paragraph (B) of this rule;

(4) Be maintained in a clean and orderly condition;

(5) Be free from infestation by insects, rodents, birds, or vermin of any kind;

(6) ~~**Shall be**~~ **Be** registered as a business entity with the appropriate state or local authority(s) and must operate out of a location that is zoned for commercial use and not out of a residence or personal dwelling.

(B) Adulterated drugs shall be stored in a separate and secure area apart from the storage of drugs used for compounding, distribution**,** and sale.

(1) Adulterated drugs shall be stored no longer than two years from the date of adulteration or expiration. Adulterated drugs shall be stored in a manner that prohibits access by unauthorized persons.

(2) Dangerous drugs, other than controlled substances, may be destroyed utilizing proper methods of disposal and following the record keeping requirements noted in paragraph **(B)(3)** of this rule, or may be donated to a pharmacy school pursuant to sections 3715.88 to 3715.92 of the Revised Code. Methods of disposal of non-controlled dangerous drugs shall prevent the possession or use of the drugs by unauthorized persons.

(3) Records of dangerous drug destructions, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug destroyed, the date destroyed, the method of destruction, the positive identification of the responsible person that performed the destruction, and the positive identification of the person that witnessed the destruction.

(~~3~~ **4**) Dangerous drugs that are controlled substances shall be disposed of pursuant to rule 4729:6-3-01 of the Administrative Code.

(C) All outsourcing facilities shall be secure from unauthorized entry.

(1) Access from outside the premises shall be kept to a minimum and be well controlled.

(2) The outside perimeter of the premises shall be well lit.

(3) Entry into areas where dangerous drugs are stored shall be limited to authorized personnel.

(4) All facilities where dangerous drugs are stored shall be equipped with an alarm system to detect unauthorized entry after hours.

(5) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. The security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(D) All dangerous drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States pharmacopoeia/national formulary (USP/NF).

(1) If no storage requirements are established for a dangerous drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its strength, quality, and purity are not adversely affected.

(2) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of dangerous drugs.

(E) All shipments of dangerous drugs shall be examined in accordance with the following:

(1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated dangerous drugs or dangerous drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(2) Each outgoing shipment shall be carefully inspected for identity of the dangerous drug products and to ensure that there is no delivery of dangerous drugs that have been damaged in storage or held under improper conditions.

(F) All returned, damaged, and adulterated**,** dangerous drugs shall be handled in the following manner:

(1) Dangerous drugs that are damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other dangerous drugs until they are destroyed or returned to the supplier.

(2) Any dangerous drugs ~~**whose**~~ **where the** immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other dangerous drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a dangerous drug has been returned cast doubt on the drug's safety, **identity,** ~~**identify,**~~ strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(G) Outsourcing facilities shall establish, maintain, and adhere to written policies and procedures which shall be followed for the receipt, security, storage, inventory, and distribution of dangerous drugs, including policies and procedures for identifying, recording, and reporting losses or thefts in accordance with rule 4729:6-3-02 of the Administrative Code, and for correcting all errors and inaccuracies in inventories. Outsourcing facilities shall include in their written policies and procedures all of the following:

(1) A procedure to be followed for handling recalls and withdrawals of dangerous drugs. Such procedure shall be appropriate to deal with recalls and withdrawals due to:

(a) Any action initiated at the request of the food and drug administration or other federal, state, or local law enforcement or other government agency, including the state board of pharmacy;

(b) Any voluntary action by the outsourcing facility to remove defective or potentially defective drugs from the market;

(c) Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design.

(2) A procedure to ensure that outsourcing facilities prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

(3) A procedure to ensure that any adulterated dangerous drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of adulterated dangerous drugs. This documentation shall be maintained for ~~**three**~~ **five** years after disposition of the adulterated drugs.

(H) Personnel employed in the compounding, manufacturing, and distribution of dangerous drugs shall be required to have appropriate education, experience, and training to assume responsibility for positions related to compliance with the requirements of this division of the Administrative Code.

(I) Outsourcing facilities shall operate in compliance with applicable federal, state, and local laws, rules, and regulations. This shall include, but is not limited to, all applicable laws,

regulations, and standards set forth by the United States food and drug administration and the United States drug enforcement administration.

(J) Outsourcing facilities shall permit properly identified and authorized state board of pharmacy **employees** ~~**agents**~~ and federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures.

(K) Outsourcing facilities shall be subject to the provisions of any applicable federal, state, or local laws, rules or regulations that relate to dangerous drug salvaging or reprocessing.

(L) The state board of pharmacy shall be notified, in a manner specified by the Board, of any new facilities, work, or storage areas to be constructed or utilized for dangerous drugs in this state.

(M) The following minimum standards shall apply to the storage and transportation methods utilized by an outsourcing facility for the storage, transportation, and delivery of dangerous drugs:

(1) A licensee is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses.

(2) When storing dangerous drugs in a public warehouse, a licensee is responsible for selecting a facility which will provide adequate security to guard against storage losses. The licensee shall store controlled substances in a public warehouse which complies with the requirements set forth in **21 CFR 1301.72 (10/3/2023)** ~~**section 1301.72 of the code of federal regulations (2/28/2018)**~~. In addition, the licensee shall employ precautions (e.g., assuring that shipping containers do not indicate that contents are controlled substances) to guard against storage or **in-transit** losses.

(3) When distributing dangerous drugs through agents, a licensee is responsible for providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents. ~~**(N) An outsourcing facility shall comply with all labeling requirements pursuant to section 503B of the Federal Food, Drug, and Cosmetic Act (5/28/2015).**~~

(N) An outsourcing facility shall comply with current good manufacturing practices pursuant **to 21 CFR Part 211 (1/1/2024)** ~~**Section 501 of the Federal Food, Drug and Cosmetic Act (5/28/2015)**~~.

(O) If an entity licensed as an outsourcing facility sells or dispenses patient specific drugs, it must also maintain licensure as a terminal distributor of dangerous drugs. All laws and rules applicable to licensure as a terminal distributor of dangerous drugs shall apply to the dispensing of patient specific drugs.

Rule 4729:6-10-02 | Outsourcing facilities - recordkeeping. (AMEND)

(A) Outsourcing facilities shall establish and maintain inventories and records of all transactions regarding the compounding, manufacturing, sale, receipt, and distribution or other disposition of dangerous drugs.

(1) The records shall include, but not be limited to, the following information:

(a) The source of the drugs, including the name and ~~principle~~ **principal** address of the seller or transferor, and the address of the location from which the drugs were shipped.

(b) The name, formulation (i.e., active ingredients), dosage form, and quantity of the drugs received, distributed, sold, disposed, or returned.

(c) The dates of receipt, sale, and distribution of the drugs.

(d) The name and ~~principle~~ **principal** address of the purchaser or receiver and the address of the location where the drugs were shipped.

(e) A system of records and procedures shall be maintained which prevent the sale or other distribution of dangerous drugs to any person not authorized in accordance with section 4729.51 of the Revised Code. Such procedures and records shall meet the requirements set forth in rule 4729:6-3-04 of the Administrative Code.

(2) All records maintained in accordance with this rule shall be made readily retrievable for inspection and copying by properly identified and authorized state board of pharmacy agents and federal, state, or local law enforcement agency officials for a period of five years following disposition of the drugs.

(3) Outsourcing facilities located in this state intending to maintain records at a location other than the place licensed by the state board of pharmacy must notify the board in a manner determined by the board. Any such alternate location shall be secured and accessible only to representatives or contractors of the outsourcing facility.

(4) An outsourcing facility maintaining records at location other than the location licensed by the state board of pharmacy or via a computerized recordkeeping system shall maintain an executed agreement with the company possessing or storing the records authorizing an agent of the board access to the records maintained in accordance with this division within three business days.

(B) The recordkeeping requirements in paragraph (A) of this rule shall be followed for all damaged, deteriorated, misbranded, or adulterated dangerous drugs.

(C) Outsourcing facilities shall submit applicable wholesale or retail sale information to the drug database in accordance with section 4729.78 of the Revised Code.

(D) Outsourcing facilities shall comply with all recordkeeping requirements pursuant to section 503B of the Federal Food, Drug, and Cosmetic Act (5/28/2015).

Rule 4729:6-11-01 | Third-Party Logistics Providers - General Operations. (AMEND)

The following requirements shall apply to all persons licensed as third-party logistics providers:

(A) All facilities where dangerous drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(3) Have a quarantine area for storage of dangerous drugs that are damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened. Such drugs shall be stored in accordance with paragraph (B) of this rule;

(4) Be maintained in a clean and orderly condition;

(5) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(B) Adulterated drugs shall be stored in a separate and secure area apart from the storage of drugs used for distribution and sale.

(1) Adulterated drugs shall be stored no longer than two years from the date of adulteration or expiration. Adulterated drugs shall be stored in a manner that prohibits access by unauthorized persons.

(2) Dangerous drugs, other than controlled substances, may be destroyed utilizing proper methods of disposal and following the record keeping requirements noted in paragraph **(B)(3)** of this rule, or may be donated to a pharmacy school pursuant to sections 3715.88 to 3715.92 of the Revised Code. Methods of disposal of non-controlled dangerous drugs shall prevent the possession or use of the drugs by unauthorized persons.

(3) Records of dangerous drug destructions, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug destroyed, the date destroyed, the method of destruction, the positive identification of the responsible person that performed the destruction, and the positive identification of the person that witnessed the destruction.

(~~3~~ **4**) Dangerous drugs that are controlled substances shall be disposed of pursuant to rule 4729:6-3-01 of the Administrative Code.

(C) All facilities used by third-party logistics providers shall be secure from unauthorized entry.

(1) Access from outside the premises shall be kept to a minimum and be well controlled.

(2) The outside perimeter of the premises shall be well lit.

(3) Entry into areas where dangerous drugs are stored shall be limited to authorized personnel.

(4) All facilities where dangerous drugs are stored shall be equipped with an alarm system to detect unauthorized entry after hours.

(5) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. The security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(D) All dangerous drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States pharmacopoeia/national formulary (USP/NF).

(1) If no storage requirements are established for a dangerous drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its strength, quality, and purity are not adversely affected.

(2) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of dangerous drugs. Temperature and humidity documentation shall be made readily retrievable and maintained for a period of not less than ~~**three**~~ **five** years from the last documented temperature and humidity reading.

(E) All shipments of dangerous drugs shall be examined in accordance with the following:

(1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated dangerous drugs or dangerous drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(2) Each outgoing shipment shall be visually examined for identity and to prevent the shipping of contaminated dangerous drugs or dangerous drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(F) All returned, damaged, and adulterated~~,~~ dangerous drugs shall be handled in the following manner:

(1) Dangerous drugs that are damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other dangerous drugs until they are destroyed or returned to the supplier.

(2) Any dangerous drugs ~~**whose**~~ **where the** immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other dangerous drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a dangerous drug has been returned cast doubt on the drug's safety, ~~identify~~ **identity**, strength, quality, or purity, then the drug shall be destroyed~~;~~ or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling~~;~~ as a result of storage or shipping.

(G) Third-party logistics providers shall establish, maintain, and adhere to written policies and procedures which shall be followed for the receipt, security, storage, inventory, and distribution of dangerous drugs, including policies and procedures for identifying, recording, and reporting losses or thefts in accordance with rule 4729:6-3-02 of the Administrative Code, and for correcting all errors and inaccuracies in inventories. Third-party logistics providers shall include in their written policies and procedures all of the following:

(1) A procedure to be followed for handling recalls and withdrawals of dangerous drugs. Such procedure shall be appropriate to deal with recalls and withdrawals due to:

(a) Any action initiated at the request of the food and drug administration or other federal, state, or local law enforcement or other government agency, including the state board of pharmacy;

(b) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market;

(c) Any action undertaken to promote public health and safety by replacing ~~of~~ existing merchandise with an improved product or new package design.

(2) A procedure to ensure that third-party logistics providers prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

(3) A procedure to ensure that any adulterated dangerous drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of adulterated dangerous drugs. This documentation shall be maintained for ~~three~~ **five** years after disposition of the adulterated drugs.

(H) Personnel employed in the distribution of dangerous drugs shall be required to have appropriate education, experience**,** and training to assume responsibility for positions related to compliance with the requirements of this division of the Administrative Code.

(I) Third-party logistics providers shall operate in compliance with applicable federal, state, and local laws, rules**,** and regulations. This shall include, but is not limited to, all applicable laws, regulations**,** and standards set forth by the United States food and drug administration and the United States drug enforcement administration.

(J) Third-party logistics providers shall permit properly identified and authorized state board of pharmacy **employees** ~~**agents**~~ and federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit records and written operating procedures.

(K) Third-party logistics providers shall be subject to the provisions of any applicable federal, state, or local laws, rules, or regulations that relate to dangerous drug salvaging or reprocessing.

(L) The state board of pharmacy shall be notified, in a manner specified by the Board, of any new facilities, work, or storage areas to be constructed or utilized for dangerous drugs.

(M) The following minimum standards shall apply to the storage and transportation methods utilized by a third-party logistics provider for the storage, transportation, and delivery of dangerous drugs:

(1) A licensee is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses.

(2) When distributing dangerous drugs through agents, a licensee is responsible for providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.

Rule 4729:6-11-02 | Third-party logistics providers - recordkeeping. (AMEND)

(A) Third-party logistics providers shall establish and maintain inventories and records of all transactions regarding the receipt, sale, and distribution or other disposition of dangerous drugs.

(1) The records shall include, but not be limited to, the following information:

(a) The source of the drugs, including the name and ~~principle~~ **principal** address of the seller or transferor, and the address of the location from which the drugs were shipped.

(b) The name, national drug code, and quantity of the drugs received, distributed, sold, disposed, or returned.

(c) The dates of receipt, sale, and distribution of the drugs.

(d) The name and ~~principle~~ **principal** address of the purchaser or receiver and the address of the location where the drugs were shipped.

(e) A system of records and procedures shall be maintained which prevent the sale or other distribution of dangerous drugs to any person not authorized in accordance with section 4729.51 of the Revised Code. Such procedures and records shall meet the requirements set forth in rule 4729:6-3-04 of the Administrative Code.

(2) All records maintained in accordance with this rule shall be made readily retrievable for inspection and copying by properly identified and authorized state board of pharmacy agents and federal, state, or local law enforcement agency officials for a period of five years following disposition of the drugs.

(3) Third-party logistics providers located in this state intending to maintain records at a location other than the place licensed by the state board of pharmacy must obtain approval from the board in a manner determined by the board. Any such alternate location shall be secured and accessible only to representatives or ~~contractor~~ **contractors** of the third-party logistics provider.

(B) The recordkeeping requirements in paragraph (A) of this rule shall be followed for all damaged, deteriorated, misbranded, or adulterated dangerous drugs.