3/6/2018

The following information is being provided pursuant to the requirements of Executive Order 2011-01K and Senate Bill 2 of the 129th General Assembly, which require state agencies, including the State of Ohio Board of Pharmacy, to draft rules in collaboration with stakeholders, assess and justify an adverse impact on the business community (as defined by S.B. 2), and provide an opportunity for the affected public to provide input on the following rules.

New

- 4729:6-1-01 – Provides definitions section for new drug distributor division of the Ohio Administrative Code. **(NOTE: Drug distributor includes an Ohio-licensed wholesaler, manufacturer, third-party logistics provider, outsourcing facility and repackager)**
- 4729:6-2-01 – Outlines the requirements for serving as the responsible person for an Ohio-licensed drug distributor.
- 4729:6-2-02 – Provides the licensing cycle and fees for initial licensure and renewal of a drug distributor license.
- 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.
- 4729:6-2-05 – Outlines the requirements when there is a change in ownership, business name, category or address of a drug distributor. (Rescinds existing rule 4729-9-08)
- 4729:6-2-06 – Provides the procedures necessary to discontinue business as a drug distributor. (Rescinds existing rule 4729-9-07)
- 4729:6-3-04 – Provides the requirements to verify licensure prior to the sale or purchase of dangerous drugs. (Rescinds existing rule 4729-9-12)
- 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. (Rescinds existing rule 4729-9-24)
- 4729:6-3-08 – Provides the procedures for the sale/distribution of complementary supplies and drug samples. (Rescinds existing rule 4729-9-13)
- 4729:6-4-01 – Outlines the instances where the Board may impose a disciplinary action against a drug distributor. (Rescinds existing rule 4729-9-19)
- 4729:6-5-01 – Provides for the general operations of a wholesale distributor of dangerous drugs. (Rescinds existing rule 4729-9-16)

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- 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. (Rescinds existing rule 4729-9-28)
- 4729:6-7-01 – Provides for the general operations of a wholesale distributor of dangerous drugs with a broker classification. (Rescinds existing rule 4729-9-30)
- 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. (Rescinds existing rule 4729-16-02)
- 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. (Rescinds existing rule 4729-9-29)
- 4729:6-11-02 – Includes the requirements for all records maintained by a third-party logistics provider.

Rescind (if not stated above)

- 4729-9-18 – Requires Board of Pharmacy license to be maintained on-site in a readily retrievable location.
- 4729-9-27 – Requires compliance with DEA regulations regarding employment of individuals with felony convictions.

Comments on the proposed rules will be accepted until close of business on **March 21, 2018**. Please send all comments to the following email address:
Ali.Simon@pharmacy.ohio.gov

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

CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: State of Ohio Board of Pharmacy

Regulation/Package Title: Drug Distributors

Rule Number(s):

New

- **4729:6-1-01**
- **4729:6-2-01**
- **4729:6-2-02**
- **4729:6-2-03**
- **4729:6-2-04**
- **4729:6-2-05 (Rescinds existing rule 4729-9-08)**
- **4729:6-2-06 (Rescinds existing rule 4729-9-07)**
- **4729:6-3-04 (Rescinds existing rule 4729-9-12)**
- **4729:6-3-05**
- **4729:6-3-06**
- **4729:6-3-07 (Rescinds existing rule 4729-9-24)**
- **4729:6-3-08 (Rescinds existing rule 4729-9-13)**
- **4729:6-4-01 (Rescinds existing rule 4729-9-19)**
- **4729:6-5-01 (Rescinds existing rule 4729-9-16)**
- **4729:6-5-02**
- **4729:6-6-01 (Rescinds existing rule 4729-9-28)**
- **4729:6-7-01 (Rescinds existing rule 4729-9-30)**
- **4729:6-8-01**
- **4729:6-8-02**
- **4729:6-9-01**
- **4729:6-9-02**
- **4729:6-10-01 (Rescinds existing rule 4729-16-02)**
- **4729:6-10-02**
- **4729:6-11-01 (Rescinds existing rule 4729-9-29)**
- **4729:6-11-02**

Rescind (if not indicated above)

- **4729-9-27**
- **4729-9-18**

Date: 3/6/2018

Rule Type:

New	5-Year Review
Amended	**Rescinded**

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

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

New

- 4729:6-1-01 – Provides definitions section for new drug distributor division of the Ohio Administrative Code. **(NOTE: Drug distributor includes an Ohio-licensed wholesaler, manufacturer, third-party logistics provider, outsourcing facility and repackager)**
- 4729:6-2-01 – Outlines the requirements for serving as the responsible person for an Ohio-licensed drug distributor.
- 4729:6-2-02 – Provides the licensing cycle and fees for initial licensure and renewal of a drug distributor license.
- 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.
- 4729:6-2-05 – Outlines the requirements when there is a change in ownership, business name, category or address of a drug distributor. (Rescinds existing rule 4729-9-08)
- 4729:6-2-06 – Provides the procedures necessary to discontinue business as a drug distributor. (Rescinds existing rule 4729-9-07)
- 4729:6-3-04 – Provides the requirements to verify licensure prior to the sale or purchase of dangerous drugs. (Rescinds existing rule 4729-9-12)
- 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. (Rescinds existing rule 4729-9-24)
- 4729:6-3-08 – Provides the procedures for the sale/distribution of complementary supplies and drug samples. (Rescinds existing rule 4729-9-13)
- 4729:6-4-01 – Outlines the instances where the Board may impose a disciplinary action against a drug distributor. (Rescinds existing rule 4729-9-19)
- 4729:6-5-01 – Provides for the general operations of a wholesale distributor of dangerous drugs. (Rescinds existing rule 4729-9-16)
- 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. (Rescinds existing rule 4729-9-28)
- 4729:6-7-01 – Provides for the general operations of a wholesale distributor of dangerous drugs with a broker classification. (Rescinds existing rule 4729-9-30)
- 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. (Rescinds existing rule 4729-16-02)
- 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. (Rescinds existing rule 4729-9-29)
- 4729:6-11-02 – Includes the requirements for all records maintained by a third-party logistics provider.

Rescind (if not stated above)

- 4729-9-18 – Requires Board of Pharmacy license to be maintained on-site in a readily retrievable location.
- 4729-9-27 – Requires compliance with DEA regulations regarding employment of individuals with felony convictions.

2. Please list the Ohio statute authorizing the Agency to adopt this regulation.

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

3. 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?

These rules do not implement a federal requirement.

4. If the regulation 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.

5. 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 distribution of dangerous drugs.

Section 3719.28 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules prescribing 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.

Without these regulations, the Board would not be able to ensure uniformity for drug distributors operating in Ohio, as it pertains to the following:

- Licensure;
- Security;
- Recordkeeping;
- Reporting of suspicious orders;
- Verification of licensure prior to sale or purchase;
- Background checks for owners and responsible persons;

Additionally, the rules are necessary to establish specific violations for which the Board may take disciplinary action against a drug distributor.

6. 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.

Development of the Regulation

7. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.

The rules in this package were distributed to all Ohio licensed drug distributors and posted to the Board's website as part of a public comment period. As part of this process, the Board received comments from the following entities:

- Celegene
- Kroger Co.
- Healthcare Distribution Alliance
- Cardinal Health
- AmerisourceBergen
- Independent Pharmacy Cooperative
- PhRMA
- Pfizer
- Association for Accessible Medicines
- International Warehouse Logistics Association

8. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

The Board incorporated the following changes to the rules based upon feedback provided from stakeholders:

- 4729:6-2-04: Clarified that only facilities in Ohio or used to ship drugs into Ohio must be indicated on a drug distributor's application.
- 4729:6-2-05: Requires new application *within* 30 days of a change of business description rather than 30 days *prior* to a change of business description.

- 4729:6-2-06: Specified the circumstances where the executive director or the director's designee may waive the requirement to file a discontinuation of business form with the Board 30 days prior to ceasing operations.
- 4729:6-3-04: Modified the license verification provision to only require the purchasing drug distributor to verify licensure of the seller annually.
- 4729:6-3-08: Clarified that website requirements in the rule only apply to drug distributors who sell or offer to sell dangerous drugs online.
- Transportation and storage requirements: Modified provisions throughout the division to require adherence to federal requirements.
- Suspicious order reporting: Removed provisions related to what constitutes a suspicious order and created a new requirement related to reporting of customers who may be engaged in possible drug diversion (including potential customers).

9. 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.

10. 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?

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.

11. Did the Agency specifically consider a performance-based regulation? Please explain. ***Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.***

The agency did not consider a performance-based regulation for this rule package. It is the Board's responsibility to ensure uniform standards for the licensure and oversight of drug distributors. At this juncture, it was the determination of the Board that the rule package did not lend itself to performance-based regulations.

12. 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. Corresponding rules in Chapter 4729. are being rescinded to avoid duplicate regulations.

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

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

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

Additionally, the Board will work closely with the regulated entities to provide additional guidance, including the issuance of frequently asked questions and other guidance materials.

Adverse Impact to Business

14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

a. Identify the scope of the impacted business community;

The rule package impacts the following:

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

b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and

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

c. Quantify the expected adverse impact from the regulation.

New

- 4729:6-1-01 – Provides definitions section for new drug distributor division of the Ohio Administrative Code. This rule contains definitions related to the division and should not have an adverse cost on business, except that an applicant does forfeit their licensure fee if their application is deemed abandoned. Depending on the category type of the license, the fee ranges from $1,900 – $2,000.
- 4729:6-2-01 – Outlines the requirements for serving as the responsible person for an Ohio-licensed drug distributor. The adverse impact of this regulation is on the distributor to ensure the responsible person on the license (or application) is not excluded from serving as the responsible person, unless they are seeking an exception from the Board. This requires the employer to have a screening policy in place. In the event of a change in responsible person, the rule does require the new responsible person to conduct a controlled substance inventory. As reported during the stakeholder comment period, this could disrupt operations of the distributor depending on the amount of controlled substances possessed at the facility and the frequency with which the facility gets a new responsible person. The Board welcomes suggestions of how to provide accountability to ensure the responsible person is aware of the operations taking place at the drug distributor, including the detection of controlled substance diversion. It should be noted that this is the current requirement in rule 4729-5-11 of the Administrative Code.
- 4729:6-2-02 – Provides the licensing cycle and fees for initial licensure and renewal of a drug distributor license. This rule establishes the maximum 24-month renewal cycle as permitted in law, as opposed to the current 12-month cycle. It does not have an impact on cost because fees are set per the Revised Code but prohibits operations if a facility fails to renew their license.
- 4729:6-2-03 – Specifies who must submit to a criminal records check when applying for a drug distributor license. The cost of a criminal records check (BCI&I/FBI) includes the following fees: BCI&I - $22, FBI - $24, and some agencies may charge a processing fee (e.g. $5-$40).
- 4729:6-2-04 – Provides the information for what must be included on a drug distributor license application. The estimated time to complete an initial application is approximately 1-2 hours. A renewal application takes approximately 30 minutes to complete. If the applicant is a virtual wholesaler or third-party logistics provider and is not licensed in their home state, the rule requires the entity to obtain and maintain Verified-Accredited Wholesale Distributors (VAWD) accreditation from the National Association of Boards of Pharmacy. VAWD accreditation is $5,500 in the first year and $7,500 every three years.
- 4729:6-2-05 – Outlines the requirements when there is a change in ownership, business name, category or address of a drug distributor. This requires the submission of a new application if there is a change in ownership, business name, category or address of a drug distributor. The overall cost of this regulation is the biennial licensure fee ($1,900 – $2,000) and the 1-2 hours to complete the new application.

- 4729:6-2-06 – Provides the procedures necessary to discontinue business as a drug distributor. This requires the submission of a one-page form to the Board. It takes approximately 20 minutes to complete the form.
- 4729:6-3-04 – Provides the requirements to verify licensure prior to the sale or purchase of dangerous drugs. Confirmation of licensure prior to sale is a requirement of section 4729.60 of the Revised Code. The rule does have a requirement to verify licensure prior to purchase or to confirm exemption from licensure but this verification must only be conducted on an annual basis. Verification of licensure can be completed by using the state's online e-licensing system. It takes approximately 1 minute to verify a license. The Board has also made available a downloadable spreadsheet that can also be used for verification.
- 4729:6-3-05 – Requires drug distributors to report suspicious orders and customers who may present a diversion risk to the Board. This will require distributors to make modifications to their existing suspicious order monitoring system to identify the additional drugs (i.e. gabapentin) and categories of suspicious orders stipulated in the rule. In addition, distributors will have to ensure proper staff capacity to conduct the required review of suspicious orders to ensure that fulfillment does not result in diversion. Furthermore, all distributors will be required to implement customer screening policies and obtain specific information on an annual basis to identify possible diversion risk. This information must also be reported to the Board. Overall, the rule will result in an increased administrative burden on drug distributors operating in the state and may necessitate investments in IT upgrades. It should be noted that the Board is attempting to mitigate some costs and achieve efficiencies in reporting by integrating the reporting of suspicious orders/customers into the same system used for reporting sales information to OARRS.
- 4729:6-3-06 – Implements controlled substance inventory requirements for all category III drug distributors. This should not result in any additional costs because this rule copies existing U.S. Drug Enforcement Administration regulations.
- 4729:6-3-07 – Includes the requirements for drug distributors engaging in the sale of dangerous drugs online. This does require modifications to websites only for those distributors engaged in online sales and will result in some initial administrative costs in order to meet the notification requirements of the rule.
- 4729:6-3-08 – Provides the procedures for the sale/distribution of complementary supplies and drug samples. Requires maintaining records of sales for three years and to comply with all licensure verification requirements of rule 4729:6-3-04. This will result in administrative costs to distributors to conduct verification.
- 4729:6-4-01 – Outlines the instances where the Board may impose a disciplinary action against a drug distributor. Violation of the provisions of this rule could result in a maximum fine of $2,500, probation, suspension or revocation of a license.
- 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. It should be noted that the security requirements have not changed from rule 4729-9-16 and current licensees should not experience any additional costs.

- 4729:6-5-02 – Includes the requirements for all records maintained by a wholesale distributor of dangerous drugs. These are similar recordkeeping requirements to what currently exists in 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.
- 4729:6-6-01 – Provides for the general operations of a virtual wholesale distributor of dangerous drugs. These are similar recordkeeping requirements to what currently exists for virtual wholesalers in rule 4729-9-28 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.
- 4729:6-7-01 – Provides for the general operations of a wholesale distributor of dangerous drugs with a broker classification. These are similar recordkeeping requirements to what currently exists for virtual wholesalers in rule 4729-9-30 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.
- 4729:6-8-01 – 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. It should be noted that the security requirements have not changed from rule 4729-9-16 (when manufacturers were licensed as wholesalers) and current licensees should not experience any additional costs.
- 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 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. It should be noted that the security requirements have not changed from rule 4729-9-16 (when repackagers were licensed as wholesalers) and current licensees should not experience any additional costs.
- 4729:6-9-02 – Includes the requirements for all records maintained by a repackager of dangerous drugs. These are similar recordkeeping requirements to what currently exists in 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.
- 4729:6-10-01 – Provides for the general operations of an outsourcing facility. Requires outsourcing to adhere to physical security requirements to prevent diversion and to prepare compounded drugs in accordance with federal standards. It should be noted that the security requirements have not changed from rule 4729-9-16 (when outsourcing

facilities were licensed as wholesalers) and current licensees should not experience any additional costs.

- 4729:6-10-02 – Includes the requirements for all records maintained by an outsourcing facility. These are similar recordkeeping requirements to what currently exists in 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.
- 4729:6-11-01 – Provides for the general operations of a third-party logistics provider. Requires third party logistics providers to adhere to physical security requirements to prevent diversion. This may result in the need for additional investments to ensure they meet Board standards. It should be noted that the security requirements have not changed from rule 4729-9-29 and current licensees should not experience any additional costs.
- 4729:6-11-02 – Includes the requirements for all records maintained by a third-party logistics provider. These are similar recordkeeping requirements to what currently exists in 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.

Rescind (if not stated above)

- 4729-9-18 – Requires Board of Pharmacy license to be maintained on-site in a readily retrievable location. Rule is being rescinded and should have no adverse impact.
- 4729-9-27 – Requires compliance with DEA regulations regarding employment of individuals with felony convictions. Rule is being rescinded and should have no adverse impact. Rule text is being moved to proposed rule 4729:5-3-10 (CSI BIA filed on 2/08/2018).

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

The Board determined that the regulatory intent justifies the impact on business because the regulations protect and promote public safety by ensuring uniform standards for the security and control of dangerous drugs and identifying and reporting possible drug diversion.

Regulatory Flexibility

16. 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.

17. 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.

18. 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.

4729:6-1-01 – Definitions

As used in this division:

(A) “Distributor of Dangerous Drugs” or “Drug Distributor” means the following persons licensed in accordance with section 4729.52 of the Revised Code:

(1) Wholesale distributors of dangerous drugs, including:

(a) Brokers; and

(b) Virtual wholesalers.

(2) Manufacturers of dangerous drugs.

(3) Outsourcing facilities.

(4) Third-party logistics providers.

(5) Repackagers of dangerous drugs.

(B) "Abandoned application" means an application submitted for licensure in accordance with this division that meets the requirements in paragraph (B)(1) of this rule. An applicant forfeits all fees associated with an abandoned application. The board shall not be required to act on any abandoned application and the application may be destroyed by board staff. If the application is abandoned, the applicant shall be required to reapply for licensure or registration, submit the required fee and comply with the requirements in effect at the time of reapplication.

(1) An application shall be deemed abandoned if any of the following apply:

(a) An applicant fails to demonstrate compliance with rule 4729:6-2-01 of the Administrative Code and the applicable licensing rules pursuant to this division within ninety days of receipt of a completed application. The applicant may submit a request to the director of licensing for a one-time ninety-day extension.

(b) An applicant fails to complete all application requirements within thirty days after being notified of the incomplete application by the board.

(2) An application shall not be deemed abandoned if the application is subject to any of the following:

(a) An administrative proceeding; or

(b) If there is discipline pending against the applicant.

(C) “Access to drug stock” includes not only physical access, but also any influence over the handling of dangerous drugs such as purchases, inventories, issuance of medical orders, etc. It does not include employees or contractors such as maintenance, janitorial, IT or other staff that may need limited supervised access to areas where dangerous drugs or D.E.A. controlled substance order forms are kept.

(D) “Act of moral turpitude” means an act or behavior that gravely violates moral sentiment or accepted moral standards of the community and is a morally culpable quality held to be present in some criminal offenses as distinguished from others.

(E) "Adulterated drug" includes a dangerous drug to which any of the following applies:

(1) A compounded dangerous drug if it exceeds the beyond use date as indicated in United States pharmacopeia chapters 795 and 797, USP 41 - NF 36, or any official supplement thereto (5/1/2018).

(2) Meets any of the requirements described in section 3715.63 of the Revised Code.

(3) Is beyond the expiration date as stated by the manufacturer, repackager, or distributor in its labeling. This does not apply to expired drugs that are donated pursuant to sections 3715.88 to 3715.92 of the Revised Code.

(4) Is not stored, dispensed or personally furnished according to the requirement of the federal act as indicated in the product labeling.

(F) "Broker" means any person engaged in the marketing, offering, or contracting for wholesale distribution and sale of a dangerous drug in or into Ohio who does not take physical possession of dangerous drugs. A broker shall be licensed a wholesale distributor pursuant to section 4729.52 of the Revised Code with a broker classification.

(G) “Dangerous drug” has the same meaning as in section 4729.01 of the Revised Code.

(H) "Manufacturer of dangerous drugs" or "manufacturer" means a person, other than a pharmacist or prescriber, that meets the following criteria:

(1) Meets the definition of a manufacturer pursuant in section 21 U.S. Code § 360eee (11/27/2013); and

(2) Manufactures dangerous drugs and who is engaged in the sale or distribution of dangerous drugs in or into Ohio.

(I) "Outsourcing facility" means a facility that is engaged in the compounding and sale of sterile drugs and is registered as an outsourcing facility with the United States food and drug administration.

(J) "Person" has the same meaning as in division (S) of section 4729.01 of the Revised Code and includes any individual member, regardless of the percentage of ownership, of any partnership, association, limited liability company, or corporation.

(K) "Place on probation", as used in Chapter 4729. of the Revised Code, means to take action against a license or registration suspending some or all of the sanctions imposed by the board against that license or registration. The terms of the probation shall state the period of time covered by the probation and may include other conditions as determined by the state board of pharmacy.

(L) “Positive identification” means a method of identifying an individual who disposes of or destroys a dangerous drug in accordance with this division.

(1) A method of positive identification may not rely solely on the use of a private personal identifier such as a password, but must also include a secure means of identification such as the following:

(a) A manual signature on a hard copy record;

(b) A magnetic card reader;

(c) A bar code reader;

(d) A biometric method;

(e) A proximity badge reader;

(f) A board approved system of randomly generated personal questions; or

(g) Other effective methods for identifying individuals that have been approved by the board.

(2) A method of positive identification relying on a magnetic card reader, a bar code reader, a proximity badge reader, or randomly generated questions for identification must also include a private personal identifier, such as a password, for entry into a secure mechanical or electronic system.

(M) “Readily retrievable” means that records maintained in accordance with this division shall be kept in such a manner that they can be separated out from all other records and produced for review by an agent of the board within three business days.

(N) "Refuse to grant or renew" means to deny original or continued licensure for a period of at least twenty-four months. After twenty-four months, or such period of time as the individual board order may require, a person licensed by the board or a person seeking to attain such status by licensure, and whose license the state board of pharmacy has refused to grant or renew, may make application to the board for issuance of a new license. A person that seeks to attain such

status by licensure, whose license the state board of pharmacy has refused to grant or renew, must meet any requirements established by the board.

(O) "Repackager of dangerous drugs" or "repackager" means a person that meets the following:

(1) Repacks and relabels dangerous drugs for sale or distribution; and

(2) Is required to register with the United States food and drug administration to engage in the repackaging or relabeling of dangerous drugs.

(P) “Reverse distribute” or “reverse distribution” means to acquire dangerous drugs for the purpose of:

(1) Return to a manufacturer or entity authorized by the manufacturer to accept returns on the manufacturer's behalf; or

(2) Destruction or disposal.

(Q) "Revoke" means to take action against a license rendering such license void and such license may not be reissued. "Revoke" is an action that is permanent against the licensee.

(R) "Sale" or "sell", except as provided for in paragraph (Q)(1) of this rule, includes any transaction made by any person, whether as principal proprietor, agent, or employee, to do or offer to do any of the following: deliver, distribute, broker, exchange, gift or otherwise give away, or transfer, whether the transfer is by passage of title, physical movement, or both.

(1) The shipment of dangerous drugs to a reverse distributor in this state licensed as a wholesaler in accordance with section 4729.52 of the Revised Code for the sole purpose of destruction or wasting of dangerous drugs does not constitute a sale and does not require the person shipping the dangerous drugs to the reverse distributor to possess an Ohio license in accordance with Chapter 4729. of the Revised Code.

(S) “State” means a state of the United States, the District of Columbia, the Commonwealth of Puerto Rico or a territory or insular possession subject to the jurisdiction of the United States.

(T) "Suspend" means to take action against a license rendering such license without force and effect for a period of time as determined by the state board of pharmacy.

(U) "Summary suspension" means to take immediate action against a license or registration without a prior hearing rendering such license without force and effect for a period of time as indicated in section 4729.561 of the Revised Code. The board may suspend a license issued pursuant to Chapter 4729. of the Revised Code by utilizing a telephone conference call to review the allegations and take a vote.

(V) "Third-party logistics provider" means a person that provides or coordinates warehousing or other logistics services pertaining to dangerous drugs including distribution, on behalf of a manufacturer, wholesale distributor, or terminal distributor of dangerous drugs, but does not take ownership of the drugs or have responsibility to direct the sale or disposition of the drugs.

(W) “Virtual wholesaler” or “virtual wholesaler distributor” means any person engaged in wholesale distribution of dangerous drugs in or into Ohio who has title but does not take physical possession of dangerous drugs. A virtual wholesale distributor shall be licensed as a wholesale distributor pursuant to section 4729.52 of the Revised Code with a virtual wholesale distributor classification.

(X) "Wholesale distributor of dangerous drugs" or "wholesale distributor" means a person engaged in the sale of dangerous drugs at wholesale or the reverse distribution of dangerous drugs and includes any agent or employee of such a person authorized by the person to engage in the sale of dangerous drugs at wholesale.

(Y) "Wholesale sale" and "sale at wholesale" mean any sale in which the purpose of the purchaser is to resell the article purchased or received by the purchaser.

4729:6-2-01 – Responsible Person – Drug Distributor.

(A) A location licensed as a distributor of dangerous drugs in accordance with section 4729.52 of the Revised Code shall have a responsible person at all times.

(B) When there is a change of responsible person, the state board of pharmacy shall be notified by the new responsible person within ten days of the effective date of the appointment of the new responsible person in a manner determined by the board.

(C) For all category III drug distributor licenses, a complete inventory, pursuant to rule 4729:6-3-06 of the Administrative Code shall be taken of the controlled substances on site by the new responsible person on the effective date of the change of responsible person. The new responsible person shall be responsible for completing and maintaining this inventory record at the location licensed as a drug distributor.

(D) The responsible person for a location licensed as a distributor of dangerous drugs shall be responsible for compliance with all applicable state and federal laws, regulations, and rules governing the manufacture, sale and distribution of dangerous drugs.

(E) The responsible person shall be physically present at the location for a sufficient amount of time to provide supervision and control of dangerous drugs on-site.

(F) The board of pharmacy shall issue a resolution providing the credential types or qualifications required for the responsible person of each license/classification/business type of a distributor of dangerous drugs licensed in accordance with section 4729.52 of the Revised Code. Only individuals that meet the credentials specified may be the responsible person for that license/classification/business type. The resolution shall be updated as necessary and made available on the board's web site, www.pharmacy.ohio.gov.

(G) Unless otherwise approved by the board, a drug distributor shall not have a responsible person who:

(1) Has been denied the right to work in any facility by the state board of pharmacy as part of an official order of the board.

(2) Has been denied the right to work in such a facility by another professional licensing agency as part of an official order of that agency.

(3) Has committed an act that constitutes a misdemeanor theft offense, regardless of the jurisdiction in which the act was committed.

(4) Has committed an act that constitutes a misdemeanor drug offense, except for a minor misdemeanor drug offense, regardless of the jurisdiction in which the act was committed.

(5) Has committed an act that constitutes a felony, regardless of the jurisdiction in which the act was committed.

(6) Has been subject to any of the following:

(a) A finding by a court of the person's eligibility for intervention in lieu of conviction; or

(ii) A finding by a court of the person's eligibility for treatment or intervention in lieu of conviction in another jurisdiction.

(7) Has been granted entry into a diversion program, deferred prosecution program, or the equivalent thereof.

(8) Cannot practice according to acceptable and prevailing standards of care by reason of mental illness or physical illness, including, but not limited to, physical deterioration that adversely affects cognitive, motor, or perceptive skills.

(9) Is addicted to or abusing alcohol or drugs;

(10) Has been disciplined by the state board of pharmacy pursuant to Chapter 4729. of the Revised Code, except for a disciplinary action related to the failure to timely obtain continuing education required pursuant to agency 4729. of the Administrative Code.

(11) Has been excluded from participation in Medicare or a state health care program.

(12) Has been denied a license or registration by the drug enforcement administration or appropriate issuing body of any state or jurisdiction.

(13) Has been the subject of any of the following by the drug enforcement administration or licensing agency of any state or jurisdiction:

(a) A disciplinary action that resulted in the suspension, probation, surrender or revocation of the person's license or registration; or

(b) A disciplinary action that was based, in whole or in part, on the person's inappropriate prescribing, dispensing, diverting, administering, storing, securing, personally furnishing, compounding, supplying or selling a controlled substance or other dangerous drug.

(14) Has committed an act that constitutes a misdemeanor that is related to, or committed in, the employee’s professional practice.

(15) Has committed an act of moral turpitude that constitutes a felony or misdemeanor in this state, regardless of the jurisdiction in which the act was committed.

4729:6-2-02 – Distributor of dangerous drugs licensing and renewal.

(A) Upon the effective date of this rule:

(1) All drug distributor licenses issued pursuant to section 4729.52 of the Revise Code shall be effective for a period of twelve months from the first day of July of each year. A license shall be renewed by the board for a like period, annually, according to the provisions of sections 4729.52 and 4729.53 of the Revised Code, and the standard renewal procedure of Chapter 4745. of the Revised Code.

(2) A person who seeks to renew a license shall submit an application for renewal and pay the required fee in accordance with section 4729.52 of the Revised Code on or before the thirtieth day of June each year.

(3) The required fees for initial licensure and annual renewal of a distributor of dangerous drug licensure are as follows:

(a) For a category II license: nine hundred and fifty dollars;

(b) For a category III license: one thousand dollars.

(B) Effective July 1, 2019:

(1) All drug distributor licenses issued pursuant to section 4729.52 of the Revised Code shall be effective for a period of twenty-four months from the first day of July of every odd-numbered year. A license shall be renewed by the board for a like period, biennially, according to the provisions of sections 4729.52 and 4729.53 of the Revised Code, and the standard renewal procedure of Chapter 4745. of the Revised Code.

(2) A person who seeks to renew a license shall submit an application for renewal and pay the required fee in accordance with section 4729.52 of the Revised Code on or before the thirtieth day of June of every odd-numbered year.

(3) The required fees for initial licensure and biennial renewal of a distributor of dangerous drug licensure shall be in accordance with section 4729.52 of the Revised Code.

(C) Paragraph (A) of this rule is no longer applicable effective July 1, 2019.

(D) Licensure pursuant to section 4729.52 of the Revised Code is not applicable to any facility owned or operated by the following:

(1) The United States department of defense;

(2) The United States department of veterans affairs; or

(3) Any other federal agency.

(E) A person licensed pursuant section 4729.52 of the Revised Code that fails to renew licensure in accordance with this section and rules adopted by the board is prohibited from engaging in manufacturing, repackaging, compounding, or distributing as a third-party logistics provider or wholesale distributor until a valid license is issued by the board.

4729:6-2-03 – Criminal Records Checks.

(A) Pursuant to section 4729.53 of the Revised Code, 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 pursuant to rule 4729:6-2-02 of the Administrative Code; 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) 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;

(d) The agency director of a government agency.

(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 background 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 are from out-of-state; 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 paragraph (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.

4729:6-2-04 – Drug Distributor Applications.

(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 the 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 distribute drugs into this state.

(4) The type of ownership or operation (i.e., sole proprietorship, partnership, corporation, or government agency).

(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 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.

(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:

(i) The full name, business address, social security number, and date of birth of the sole proprietor.

(ii) If applicable, the federal employer identification number of the business entity.

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

(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 to determine if the entity possesses a current and valid license to distribute dangerous drugs in that state or jurisdiction and any disciplinary action, including actions pending, the licensing authority 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 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 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 of the director's designee upon receipt of the application materials.

(B) Prior to the end of the licensing period, 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.

4729:6-2-05 - Change in description of a distributor of dangerous drugs.

(A) Any change in the ownership, business or trade name, category, or address of a distributor of dangerous drugs requires a new application, required fee, and license. The new application and required fee shall be submitted within thirty days of any change in the ownership, business or trade name, category, or address.

(B) A change of ownership includes any of the following:

(1) A change of controlling interest of ten percent or more of a licensed corporation's outstanding shares of voting stock.

(2) Any business entity change from its original form, as licensed, to a sole proprietor ownership, partnership, limited liability company, corporation or any other business entity.

(3) An existing corporation ceases and a new corporation or other business entity is formed.

(4) An existing corporation continues and there is a one hundred percent stock purchase by another corporation or other business entity.

(5) Two wholly-owned subsidiaries of a parent company are merged.

(6) A currently licensed drug distributor is purchased or operated by a different business entity than what is listed on the original application, even if the location maintains the original "doing business as" (DBA) and/or responsible person.

(7) Any partnership change other than that which was originally licensed.

(a) A partnership change is deemed to have occurred when:

(i) There is an addition or removal of one or more partners in a partnership to which a license is issued.

(ii) The entity is sold and the sale becomes final.

(b) For partnerships, a transfer of a proportion of ownership among existing partners is not a change of ownership, if there is no addition or removal of a partner.

(8) Any other business model change as determined by the board to be a change of ownership.

(C) For publicly traded corporations, a routine sale of stock is not a change of ownership.

A publicly traded corporation is a corporation owned by stockholders who are members of the general public and who trade shares publicly, often through a listing on a stock exchange.

(D) If any change of ownership in accordance with paragraph (B) of this rule results in a new or different DBA, or a new or different employer identification number (EIN), a new application fee and new license number are required.

(E) A change of ownership set forth in paragraphs (B)(2) and (B)(3) of this rule or as otherwise determined by the board's executive director or the director's designee, shall require the board to issue a new license number.

(F) A change of ownership as described in paragraph (B) of this rule of a licensee's parent or holding company shall not require a new application, required fee, and license.

(G) A change of credential class shall require notification to the board. A change of credential class shall not require a full application fee but the board may charge a nominal processing fee.

4729:6-2-06 - Procedure for discontinuing business as a distributor of dangerous drugs.

(A) A distributor of dangerous drugs who plans to discontinue business activities shall file a notice with the board of pharmacy. The notice shall be submitted, in a manner determined by the board, 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) The name, address, and licensed 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 of purchase and dispensing will be kept in accordance with section 4729.37 of the Revised Code and this division of the Administrative Code.

(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 records in accordance with the following:

(1) On the date of discontinuing business, a complete inventory of all controlled substances being transferred, or disposed pursuant to 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 of.

(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.

4729:6-3-04 - Verification of licensure prior to sale or purchase.

(A) Before a drug distributor may sell or distribute dangerous drugs to any person in this state, except as provided in paragraph (B) of this section, the distributor shall query the board's online roster (available on the board's website: www.pharmacy.ohio.gov) to determine if the purchaser is licensed as either:

(1) A terminal distributor of dangerous drugs.

(a) 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.

(B) Paragraph (A) 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.

(C) 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, on an annual basis, comply with all the following:

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

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

(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; and

(d) Ensure that all attestations are maintained by the drug distributor for a period of three 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, on an annual basis, comply with all the following:

(a) Provide the person, in a manner determined by the Board, the requirements in Ohio law of when a person shall 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 prescriber meets the licensing exemptions in section 4729.541 of the Revised Code; and

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

(D) Before a drug distributor located in this state may purchase or receive dangerous drugs, the distributor shall query the board's online roster (available on the board's website: www.pharmacy.ohio.gov) 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.

(E) A third party logistics provider is exempt from the requirements 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.

4729:6-3-05 - Suspicious Order Monitoring and Due Diligence.

(A) As used in this rule:

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

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

(b) A person who possesses, or possesses for sale or sells, at retail, a dangerous drug in accordance with Chapters 3719., 4715., 4723., 4725., 4729., 4730., 4731., and 4741. of the Revised Code.

(2) “Reported drug” means any dangerous drug whose sale is required to be reported to the drug database pursuant to agency 4729 of the Administrative Code.

(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 not be limited to, any of the following:

(1) Orders of unusual size;

(2) Orders deviating substantially from a normal pattern;

(3) Orders of unusual frequency;

(4) Orders by a prescriber that do not correspond to the prescriber’s specialty (family practice, oncology, geriatrics, pain management) or type (physician, dentist, veterinarian);

(5) Orders by a prescriber exceeding 2,500 unit doses of controlled substances in a single month;

(6) Orders consisting of significant quantity of a limited type of controlled substances together with few, if any, other controlled or non-controlled dangerous drugs.

(D) All suspicious orders shall be subject to an independent analysis by at least two persons designated by the drug distributor's responsible person prior to completing a sale to determine whether the reported drugs are 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 thirty 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) A drug distributor listed in paragraph (B) of this rule shall exercise due diligence to identify customers ordering or seeking to order reported drug 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 to be conducted prior to an initial sale and on an annual basis:

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

(2) On-site visits.

(3) If applicable, confirmation of prescriber type and specialty practice area.

(4) Review of drug utilization reports.

(5) To determine possible diversion risk, the drug distributor shall, at a minimum, ascertain and review the following information on all customers:

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

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

(c) Orders for reported drugs from other drug distributors (i.e. the ratio supplied compared to other drug distributors);

(d) In the case of a pharmacy, if there are particular prescribers who constitute most of the prescriptions it dispenses (i.e. small number of prescribers contributing to a large quantity of reported drugs dispensed);

(e) The number of out-of-state patients served; and

(f) Any additional information to identify possible reported drug diversion and/or risk of diversion as determined by the drug distributor.

(H) Any customer identified as a possible diversion risk, including those to whom the drug distributor refuses to sell, shall be submitted electronically 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 thirty days of the order being identified as a possible diversion risk by the drug distributor.

(I) Within ninety days of the effective date of this rule, a drug distributor shall provide, in a manner determined by the board, a complete list of all persons in this state the distributor has refused a sale of a reported drug to within the past three years. The list shall contain the name of the person, address, drug enforcement administration registration (if applicable), the name of the drugs requested, the quantity requested, the date of request and a detailed explanation of why a sale was refused.

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

(1) The design and operation of the 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 possible diversion risks to the state board of pharmacy; and

(d) Information on submitting a confidential report of a suspicious order by using the board's online electronic complaint form that can accessed by visiting: www.pharmacy.ohio.gov. The training shall remind all employees that complaints and all information submitted that identifies a complainant shall remain confidential pursuant to section 4729.23 of the Revised Code.

(K) All policies and procedures maintained in accordance with paragraph (J) of this rule shall be reviewed and updated on an annual basis. Updates shall include any guidance issued by the

board regarding the identification of suspicious orders or customers who may be engaged in drug diversion.

4729:6-3-06 – Controlled Substances Inventory Requirements

(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 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.

4729:6-3-07 – Sales of dangerous drugs on-line.

(A) All persons selling or offering to sell dangerous drugs at retail or wholesale into, out of, or within Ohio must be appropriately licensed 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 administration's website.

(D) Any Ohio licensed drug distributor requesting personal information from the public by way of the internet (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.

4729:6-3-08 - Distributor of dangerous drugs samples and complimentary supplies.

(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 (D) 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 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 company:

(1) Is licensed as a distributor of dangerous drugs; and

(2) Maintains a record of such distribution which 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.

4729:6-4-01 – Disciplinary Actions

(A) The state board of pharmacy, in accordance with Chapter 119. of the Revised Code, may impose any one or more of the following sanctions on a person licensed as a distributor of dangerous drugs for any of the causes set forth in paragraph (B) of this rule:

(1) Suspend, revoke, restrict, limit, or refuse to grant or renew a license;

(2) Reprimand or place the license holder on probation;

(3) Impose a monetary penalty or forfeiture as set forth in section 4729.56 of the Revised Code.

(B) The board may impose the sanctions set forth in paragraph (A) of this rule for any of the following:

(1) Making any false material statements in an application for licensure or licensure renewal under section 4729.52 of the Revised Code.

(2) Violating any federal, state, or local drug law; any provision of this chapter or Chapter 2925., 3715., or 3719. of the Revised Code; or any rule of the board.

(3) A conviction of a felony.

(4) Commission of an act that constitutes a felony in this state, regardless of the jurisdiction in which the act was committed.

(5) Failing to satisfy the qualifications for licensure under section 4729.53 of the Revised Code or the rules of the board or ceasing to satisfy the qualifications after the license is granted or renewed.

(6) Falsely or fraudulently promoting to the public a drug that is a controlled substance included in schedule I, II, III, IV, or V, except that nothing in this division prohibits a manufacturer, outsourcing facility, third-party logistics provider, repackager, broker, virtual wholesaler or wholesale distributor of dangerous drugs from furnishing information concerning a controlled substance to a health care provider or licensed terminal distributor.

(7) Violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), United States Code Title 21 (10/22/2017), or Chapter 3715. of the Revised Code.

(8) Failing to comply with the requirements 4729:6-3-05 of the Administrative Code.

(9) Conducting the sale of a suspicious order without conducting an independent analysis prior to completing a sale to determine whether the reported drugs are likely to be diverted from legitimate channels in accordance with rule 4729:6-3-05 of the Administrative Code.

(10) Commission of an act of moral turpitude that constitutes a felony or misdemeanor, regardless of the jurisdiction in which the act was committed.

(11) Commission of a crime of moral turpitude as defined in section 4776.10 of the Revised Code.

(12) Violation of any restrictions placed by the state board of pharmacy on a license or violating any terms of a board order issued against the licensee.

(13) Exclusion from participation in Medicare or a state health care program.

(14) Being denied a license or registration by the drug enforcement administration or appropriate issuing body of any state or jurisdiction.

(15) Being the subject of any of the following by the drug enforcement administration or licensing agency of any state or jurisdiction:

(a) A disciplinary action that resulted in the suspension or revocation of the person's license or registration; or

(b) A disciplinary action that was based, in whole or in part, on the person's inappropriate prescribing, dispensing, diverting, administering, storing, personally furnishing, compounding, supplying or selling a controlled substance or other dangerous drug.

(16) Commission of an act that constitutes a misdemeanor theft offense, regardless of the jurisdiction in which the act was committed.

(17) Commission of an act that constitutes a misdemeanor drug offense, except for a minor misdemeanor drug offense, regardless of the jurisdiction in which the act was committed.

(18) Has been subject to any of the following:

(a) A finding by a court of the person's eligibility for intervention in lieu of conviction; or

(b) A finding by a court of the person's eligibility for treatment or intervention in lieu of conviction in another jurisdiction.

(19) Has been granted entry into a diversion program, deferred prosecution program, or the equivalent thereof.

(20) Is addicted to or abusing alcohol or drugs.

(21) Commission of an act that constitutes a misdemeanor that is related to, or committed in, the person's professional practice.

(22) Employs a responsible person that does not meet the requirements set forth in rule 4729:6-2-01 of the Administrative Code.

(23) Retaliating against or disciplining an employee for filing a complaint with a board of pharmacy or other licensing body or reporting a violation of state or federal statute or any ordinance or regulation of a political subdivision that the employee's employer has authority to correct. As used in this section, retaliation or discipline of an employee includes, but is not limited to, the following:

(a) Removing or suspending the employee from employment;

(b) Withholding from the employee salary increases or employee benefits to which the employee is otherwise entitled;

(c) Transferring or reassigning the employee;

(d) Denying the employee a promotion that otherwise would have been received;

(e) Reducing the employee in pay or position.

(24) The method used by the drug distributor to store, possess or distribute dangerous drugs poses serious harm to others.

(25) The ownership of such entity has been transferred from a person whose license issued in accordance with Chapter 4729. of the Revised Code has been revoked or disciplined by the state board of pharmacy or any other state or federal professional licensing or regulatory agency to the spouse or other family member.

(26) The ownership of such facility has been transferred from a licensee whose license has been revoked or disciplined by the state board of pharmacy or any other state or federal professional licensing or regulatory agency to another who employs the former owner or who allows the former owner to be present within the physical confines of the location to be licensed.

(27) Unless otherwise approved by the board, a distributor knowingly employs a person with access to drug stock who:

(a) Has been denied the right to work in any facility by the state board of pharmacy as part of an official order of the board.

(b) Has been denied the right to work in such a facility by another professional licensing agency as part of an official order of that board.

(c) Has committed an act that constitutes a misdemeanor theft offense, regardless of the jurisdiction in which the act was committed.

(d) Has committed an act that constitutes a misdemeanor drug offense, except for a minor misdemeanor drug offense, regardless of the jurisdiction in which the act was committed.

(e) Has committed an act that constitutes a felony, regardless of regardless of the jurisdiction in which the act was committed.

(f) Has been subject to any of the following:

(i) A finding by a court of the person's eligibility for intervention in lieu of conviction; or

(ii) A finding by a court of the person's eligibility for treatment or intervention in lieu of conviction in another jurisdiction.

(g) Has been granted entry into a diversion program, deferred prosecution program, or the equivalent thereof.

(h) Is addicted to or abusing alcohol or drugs.

(i) Has been disciplined by the state board of pharmacy pursuant to Chapter 4729. of the Revised Code, except for a disciplinary action related to the failure to timely obtain continuing education required pursuant to agency 4729. of the Administrative Code.

(j) Has been excluded from participation in Medicare or a state health care program.

(k) Has been denied a license or registration by the drug enforcement administration or appropriate issuing body of any state or jurisdiction.

(l) Has been the subject of any of the following by the drug enforcement administration or licensing agency of any state or jurisdiction:

(i) A disciplinary action that resulted in the suspension, probation, surrender or revocation of the person's license or registration; or

(ii) A disciplinary action that was based, in whole or in part, on the person's inappropriate prescribing, dispensing, diverting, administering, storing, securing, personally furnishing, compounding, supplying or selling a controlled substance or other dangerous drug.

(m) Has committed an act that constitutes a misdemeanor that is related to, or committed in, the employee’s professional practice.

4729:6-5-01 – Wholesale Distributors – General Operations

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 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)(2) (a) 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.

(a) 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) 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 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 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, 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 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 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 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.

4729:6-5-02 – Wholesale Distributors – Recordkeeping

(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 address of the seller or transferor, and the address of the location from which the drugs were shipped.

(b) The name, national drug code, lot number 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 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 division 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 three 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.

4729:6-6-01 – Virtual Wholesalers – General Operations

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 address of the seller or transferor, and the address of the location from which the drugs were shipped.

(b) The name, national drug code, lot number 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 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 division 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 three 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 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 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.

4729:6-7-01 – Brokers – General Operations

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 address of the seller or transferor, and the address of the location from which the drugs were shipped.

(b) The name, national drug code, lot number 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 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 division 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 three 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 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.

4729:6-8-01 – Manufacturers – General Operations

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 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)(2) (a) 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.

(a) 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) 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 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, 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 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 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 Section 501 of the Federal Food, Drug and Cosmetic Act (5/28/2015).

4729:6-8-02 – Manufacturers – Recordkeeping

(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 address of the seller or transferor, and the address of the location from which the drugs were shipped.

(b) The name, national drug code, lot number 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 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 division 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 three 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.

4729:6-9-01 – Repackagers – General Operations

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 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)(2)(a) 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.

(a) 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) 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 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, 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 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 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 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.

4729:6-9-02 – Repackagers – Recordkeeping

(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 address of the seller or transferor, and the address of the location from which the drugs were shipped.

(b) The name, national drug code, lot number 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 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 division 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 three 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.

(c) 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.

4729:6-10-01 – Outsourcing Facilities – General Operations

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 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)(2) (a) 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.

(a) 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) 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 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, 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 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 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 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).

(O) An outsourcing facility shall comply with current good manufacturing practices pursuant to Section 501 of the Federal Food, Drug and Cosmetic Act (5/28/2015).

(P) 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.

4729:6-10-02 – Outsourcing Facilities – Recordkeeping

(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 address of the seller or transferor, and the address of the location from which the drugs were shipped.

(b) The name, national drug code, lot number 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 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 division 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 three 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).

4729:6-11-01 – Third Party Logistic Providers – General Operations

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)(2) (a) 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.

(a) 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) 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 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 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, 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 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 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.

4729:6-11-02 – Third Party Logistics Providers – Recordkeeping

(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 address of the seller or transferor, and the address of the location from which the drugs were shipped.

(b) The name, national drug code, lot number 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 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 division 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 three 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 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.