11/6/19

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.

Amend:

- 4729:6-3-08 - Provides the procedures for the sale/distribution of complementary supplies and drug samples. The rule is being amended to require records to be maintained for five years from the date of sale or distribution.
- 4729:6-5-02 - Includes the requirements for all records maintained by a wholesale distributor of dangerous drugs. The rule is being amended to require records to be maintained for five years for wholesale distributors.
- 4729:6-6-01 - Provides for the general operations of a virtual wholesale distributor of dangerous drugs. The rule is being amended to require records to be maintained for five years for virtual wholesale distributors.
- 4729:6-7-01 - Provides for the general operations of a wholesale distributor of dangerous drugs with a broker classification. The rule is being amended to require records to be maintained for five years for brokers.
- 4729:6-8-02 - Includes the requirements for all records maintained by a manufacturer of dangerous drugs. The rule is being amended to require records to be maintained for five years for manufacturers.
- 4729:6-9-02 - Includes the requirements for all records maintained by a repackager of dangerous drugs. The rule is being amended to require records to be maintained for five years for repackagers.
- 4729:6-10-02 - Includes the requirements for all records maintained by an outsourcing facility. The rule is being amended to require records to be maintained for five years for outsourcing facilities.
- 4729:6-11-02 - Includes the requirements for all records maintained by a third-party logistics provider. The rule is being amended to require records to be maintained for five years for third-party logistics providers.

Comments on the proposed rules will be accepted until close of business on November 22, 2019. Please send all comments to the following email address: RuleComments@pharmacy.ohio.gov

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

Business Impact Analysis

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

Rule Contact Name and Contact Information: Cameron McNamee
Cameron.mcnamee@pharmacy.ohio.gov

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

Drug Distributor Record Keeping

Rule Number(s): 4729:6-3-08, 4729:6-5-02, 4729:6-6-01, 4729:6-7-01, 4729:6-8-02, 4729:6-9-02, 4729:6-10-02, 4729:6-11-02

Date of Submission for CSI Review: 11/5/19

Public Comment Period End Date: 11/22/19

Rule Type/Number of Rules:

New/___ rules
No Change/____ rules (FYR? ___)
Amended/__8__rules (FYR? _N_)
Rescinded/____ rules (FYR? ___)

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

Reason for Submission

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

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

   The rule(s):

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

4729:6-3-08 - Requires verification of licensure or exemption of licensure prior to sale of a sample or complimentary supply.

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

Violation of the rule may result in administrative discipline for a distributor of dangerous drugs. Discipline might include reprimand, suspension/denial of a license, monetary penalty and/or revocation/denial of a license.

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

4729:6-5-02, 4729:6-6-01, 4729:6-7-01, 4729:6-8-02, 4729:6-9-02, 4729:6-10-02, 4729:6-11-02 – These rules require notification for off-site storage for in-state licensees. This is a one-page form that takes approximately 15 minutes to complete and submit.

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

Drug distributors may experience increased storage costs to maintain records for an additional two years. However, drug distributors operating in 20 other states must already maintain records for a five-year period.

Regulatory Intent

2. **Please briefly describe the draft regulation in plain language.**
   Please include the key provisions of the regulation as well as any proposed amendments.

Amend:

- 4729:6-3-08 - Provides the procedures for the sale/distribution of complementary supplies and drug samples. The rule is being amended to require records to be maintained for five years from the date of sale or distribution.
- 4729:6-5-02 - Includes the requirements for all records maintained by a wholesale distributor of dangerous drugs. The rule is being amended to require records to be maintained for five years for wholesale distributors.
- 4729:6-6-01 - Provides for the general operations of a virtual wholesale distributor of dangerous drugs. The rule is being amended to require records to be maintained for five years for virtual wholesale distributors.
- 4729:6-7-01 - Provides for the general operations of a wholesale distributor of dangerous drugs with a broker classification. The rule is being amended to require records to be maintained for five years for brokers.
- 4729:6-8-02 - Includes the requirements for all records maintained by a manufacturer of dangerous drugs. The rule is being amended to require records to be maintained for five years for manufacturers.
- 4729:6-9-02 - Includes the requirements for all records maintained by a repackager of dangerous drugs. The rule is being amended to require records to be maintained for five years for repackagers.
- 4729:6-10-02 - Includes the requirements for all records maintained by an outsourcing facility. The rule is being amended to require records to be maintained for five years for outsourcing facilities.
- 4729:6-11-02 - Includes the requirements for all records maintained by a third-party logistics provider. The rule is being amended to require records to be maintained for five years for third-party logistics providers.

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

The proposed rules are authorized by sections 4729.26 and 3719.28 of the Ohio Revised Code. In addition, section 3719.07 already authorizes records to maintained for five years (unless otherwise approved by the Board).

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

These rules do not implement a federal requirement.

5. **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.

6. **What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**

Section 4729.26 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules governing the practice of pharmacy and distribution of dangerous drugs.

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

7. **How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

The success of the regulations will be measured by having rules written in plain language, Licensee/registrant compliance with the rules, and minimal questions from licensees/registrants regarding the provisions of the rules.

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

No.

Development of the Regulation

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

The rule in this package was distributed to all Ohio licensed drug distributors for review and comment. It was also posted to the Board's website as part of a public comment period.

Prior to filing with CSI, the rule was also reviewed and approved by the Board of Pharmacy.

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

The Board did not receive any input from stakeholders during the comment period. It did receive a question from a licensee that was already addressed in the definition section of division 4729:6.

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

Scientific data was not used to develop or review this rule.

12. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?

As the regulations are essential to protecting the public's safety by ensuring uniform standards for the licensure and oversight of drug distributors, the State of Ohio Board of Pharmacy did not consider any regulatory alternatives.

13. 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 performance-based regulations for this rule package. It is the Board's responsibility to ensure uniform practice standards across Ohio. At this juncture, it was the determination of the Board that the rule package did not lend itself to a performance based regulations.

14. 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 regulation does not duplicate another State of Ohio Board of Pharmacy regulation.

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

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

trained to educate licensees on current and/or new regulations during on-site inspections.

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

Adverse Impact to Business

16. 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; and

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 all adverse impact (e.g., 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.
The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a "representative business." Please include the source for your information/estimated impact.

Amend:

- 4729:6-3-08 - Provides the procedures for the sale/distribution of complementary supplies and drug samples. The rule is being amended to require records to be maintained for five years from the date of sale or distribution. This will result in administrative costs to distributors to conduct verification. Drug distributors may experience increased storage costs to maintain records for an additional two years. However, drug distributors operating in 20 other states must already maintain records for a five-year period.
- 4729:6-5-02 - Includes the requirements for all records maintained by a wholesale distributor of dangerous drugs. The rule is being amended to require records to be maintained for five years for wholesale distributors. The rule does require notification for off-site storage if the licensee is located in Ohio. This is a one-page form that takes approximately 15 minutes to complete and submit. Drug distributors may experience increased storage costs to maintain records for an additional two years. However, drug

distributors operating in 20 other states must already maintain records for a five-year period.

- 4729:6-6-01 - Provides for the general operations of a virtual wholesale distributor of dangerous drugs. The rule is being amended to require records to be maintained for five years for virtual wholesale distributors. The rule does require notification for off-site storage if the licensee is located in Ohio. This is a one-page form that takes approximately 15 minutes to complete and submit. Drug distributors may experience increased storage costs to maintain records for an additional two years. However, drug distributors operating in 20 other states must already maintain records for a five-year period.
- 4729:6-7-01 - Provides for the general operations of a wholesale distributor of dangerous drugs with a broker classification. The rule is being amended to require records to be maintained for five years for brokers. The rule does require notification for off-site storage if the licensee is located in Ohio. This is a one-page form that takes approximately 15 minutes to complete and submit. Drug distributors may experience increased storage costs to maintain records for an additional two years. However, drug distributors operating in 20 other states must already maintain records for a five-year period.
- 4729:6-8-02 - Includes the requirements for all records maintained by a manufacturer of dangerous drugs. The rule is being amended to require records to be maintained for five years for manufacturers. The rule does require notification for off-site storage if the licensee is located in Ohio. This is a one-page form that takes approximately 15 minutes to complete and submit. Drug distributors may experience increased storage costs to maintain records for an additional two years. However, drug distributors operating in 20 other states must already maintain records for a five-year period.
- 4729:6-9-02 - Includes the requirements for all records maintained by a repackager of dangerous drugs. The rule is being amended to require records to be maintained for five years for repackagers. The rule does require notification for off-site storage if the licensee is located in Ohio. This is a one-page form that takes approximately 15 minutes to complete and submit. Drug distributors may experience increased storage costs to maintain records for an additional two years. However, drug distributors operating in 20 other states must already maintain records for a five-year period.
- 4729:6-10-02 - Includes the requirements for all records maintained by an outsourcing facility. The rule is being amended to require records to be maintained for five years for outsourcing facilities. The rule does require notification for off-site storage if the licensee is located in Ohio. This is a one-page form that takes approximately 15 minutes to complete and submit. Drug distributors may experience increased storage costs to maintain records for an additional two years. However, drug distributors operating in 20 other states must already maintain records for a five-year period.

- 4729:6-11-02 - Includes the requirements for all records maintained by a third-party logistics provider. The rule is being amended to require records to be maintained for five years for third-party logistics providers. The rule does require notification for off-site storage if the licensee is located in Ohio. This is a one-page form that takes approximately 15 minutes to complete and submit. Drug distributors may experience increased storage costs to maintain records for an additional two years. However, drug distributors operating in 20 other states must already maintain records for a five-year period.

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

The Board determined that the regulatory intent justifies the impact on business because the regulations protect and promote public safety by ensuring licensees maintain records for a sufficient period of time in order for the Board to conduct a thorough investigation of a violation of Ohio laws and regulations.

Regulatory Flexibility

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

These rules do not provide any exemptions or alternative means of compliance for small businesses. The law does not differentiate on the size of the business and therefore the regulation is uniform across Ohio.

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

The State of Ohio Board of Pharmacy does not fine licensees or impose penalties for first-time paperwork violations. However, failure by a licensee to maintain appropriate records of drug distribution, as is required by law, is not considered a paperwork error but a quality assurance issue by the licensee that is necessary for the protection of the public.

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

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

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 (E) of this rule, samples may only be provided to and furnished by a licensed prescriber as defined in rule 4729:5-1-02 of the Administrative Code in accordance with paragraph (B) of this rule.

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

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

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

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

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

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

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

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

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, 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~~ rule shall be made readily retrievable for inspection and copying by properly identified and authorized state board of pharmacy agents and federal, state, or local law enforcement agency officials for a period of ~~three~~ five years following disposition of the drugs.

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

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

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

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

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, 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~~ paragraph (A) of this rule shall be made readily retrievable for inspection and copying by properly identified and authorized state board of pharmacy agents and federal, state, or local law enforcement agency officials for a period of ~~three~~ five years following disposition of the drugs.

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

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

(B) Virtual wholesalers shall establish, maintain, and adhere to written policies and procedures which shall be followed for the receipt, security, storage, inventory, and distribution

of dangerous drugs, including policies and procedures for identifying, recording, and reporting losses or thefts in accordance with rule 4729:6-3-02 of the Administrative Code, and for correcting all errors and inaccuracies in inventories. At a minimum, virtual wholesalers shall include in their written policies and procedures with all the following:

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

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

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

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

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

(3) A procedure to ensure that any adulterated dangerous drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of adulterated dangerous drugs. This documentation shall be maintained for three 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 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~~ paragraph (A) of this rule shall be made readily retrievable for inspection and copying by properly identified and authorized state board of pharmacy agents and federal, state, or local law enforcement agency officials for a period of ~~three~~ five years following disposition of the drugs.

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

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

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

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

(D) Brokers shall permit properly identified and authorized state board of pharmacy

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.

4729:6-8-02 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 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~~ rule shall be made readily retrievable for inspection and copying by properly identified and authorized state board of pharmacy agents and federal, state, or local law enforcement agency officials for a period of ~~three~~ five years following disposition of the drugs.

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

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

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

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

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 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~~ rule shall be made readily retrievable for inspection and copying by properly identified and authorized state board of pharmacy agents and federal, state, or local law enforcement agency officials for a period of ~~three~~ five years following disposition of the drugs.

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

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.

4729:6-10-02 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, formulation (i.e. active ingredients), dosage form and quantity of the drugs received, distributed, sold, disposed or returned.

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

(d) The name and principle 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~~ rule shall be made readily retrievable for inspection and copying by properly identified and authorized state board of pharmacy agents and federal, state, or local law enforcement agency officials for a period of ~~three~~ five years following disposition of the drugs.

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

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

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

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

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

4729:6-11-02 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 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~~ rule shall be made readily retrievable for inspection and copying by properly identified and authorized state board of pharmacy agents and federal, state, or local law enforcement agency officials for a period of ~~three~~ five years following disposition of the drugs.

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