7/27/15

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 Ohio State 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 Rules

- **4729-9-27:** In accordance with federal law, prohibits a terminal distributor or wholesale distributor of dangerous drugs that possess controlled substances from the employment of an individual who has been convicted of a felony drug crime or administrative action by the United States Drug Enforcement Administration (DEA), unless granted a waiver by the DEA.
- **4729-9-28:** Specifies requirements for licensure as a wholesale distributor of dangerous drugs for virtual wholesale distributors/brokers.
- **4729-9-29:** Specifies requirements for licensure as a wholesale distributor of dangerous drugs for third party logistics providers.

Amended Rules

- **4729-9-18:** Requires all locations licensed with the board to maintain the license at that site. The rule is amended to correct a typo.

No Change (5-Year Review)

- **4729-9-20:** Specifies the procedures for discontinuing business as a wholesale or terminal distributor of dangerous drugs.
- **4729-9-07:** Provides the labeling and recordkeeping requirements for drugs that are repackaged or relabeled by a pharmacy.
- **4729-9-03:** Provides minimum standards for a first-aid department that stores dangerous drugs.

Comments on the proposed rules will be accepted until close of business on August 11, 2015. Please send all comments to the following email address:
Cameron.mcnamee@pharmacy.ohio.gov

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

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117
CSIOhio@governor.ohio.gov

CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: State of Ohio Board of Pharmacy

Regulation/Package Title: Charitable Pharmacies and Drug Repositories

Rule Number(s): New: 4729-9-28; 4729-9-29; 4729-9-27;

Amended: 4729-9-18;

No Change: 4729-9-20; 4729-9-07; 4729-9-03;

Date: 07/27/2015

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Amended	Rescinded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 Rules

- **4729-9-27:** In accordance with federal law, prohibits a terminal distributor or wholesale distributor of dangerous drugs that possess controlled substances from the employment of an individual who has been convicted of a felony drug crime or administrative action by

the United States Drug Enforcement Administration (DEA), unless granted a waiver by the DEA.

- **4729-9-28:** Specifies requirements for licensure as a wholesale distributor of dangerous drugs for virtual wholesale distributors/brokers.
- **4729-9-29:** Specifies requirements for licensure as a wholesale distributor of dangerous drugs for third party logistics providers.

Amended Rules

- **4729-9-18:** Requires all locations licensed with the board to maintain the license at that site. The rule is amended to correct a typo.

No Change (5-Year Review)

- **4729-9-20:** Specifies the procedures for discontinuing business as a wholesale or terminal distributor of dangerous drugs.
- **4729-9-07:** Provides the labeling and recordkeeping requirements for drugs that are repackaged or relabeled by a pharmacy.
- **4729-9-03:** Provides minimum standards for a first-aid department that stores dangerous drugs.

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

The proposed rules are authorized by sections 3719.28 and 4729.26 of the Ohio Revised Code. The following sections of the Ohio Revised Code are also considered authorizing statutes for this rule package: 4729.01, 4729.51, 4729.52, 4729.54, 4729.55 and 4729.56.

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?

The rule does 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 exceeds federal requirements because the regulation of the pharmacy profession has traditionally been done at the state level by legislatively created state boards of

pharmacy, such as the State of Ohio Board of Pharmacy. The State of Ohio Board of Pharmacy regulates all aspects of pharmacy practice, including drug distribution within the state.

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 state board of pharmacy to adopt rules governing the practice of pharmacy, which includes a pharmacist's scope of practice and the regulation of entities that store, ship and sell dangerous drugs.

Section 3719.28 of the Ohio Revised Code authorizes the state 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.

The rules proposed under this statutory authority are necessary to facilitate compliance with the above referenced provisions of the Ohio Revised Code to promote the public's safety and uniformity of care throughout Ohio. Without these regulations, the Ohio State Board of Pharmacy would not be able to:

- Provide uniform licensure and oversight of virtual wholesalers and third party logistics providers.
- Provide uniform requirements for repackaging and relabeling by pharmacies.
- Ensure that pharmacies comply with federal law regarding the employment of individuals with felony drug convictions or are subject to administrative action by the DEA.
- Enforce policies to aid in the regulation of dangerous drug distributors licensed with the Board.

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 were reviewed and approved by the State of Ohio Board of Pharmacy's Rules Review Committee. The committee is comprised of a broad array of stakeholders including:

- Select Specialty Hospital – Akron
- Berger Health System
- The Kroger Company
- Meijer
- Nationwide Children's Hospital
- Fort Hamilton Hospital
- Central Ohio Compounding Pharmacy
- Healthspan Physicians and Integrated Care
- Cedarville University School of Pharmacy
- Fairview Hospital – Cleveland Clinic
- OhioHealth
- Wal-Mart
- Pharmacy Systems, Inc.

All rules are subject to final approval by the state board of pharmacy prior to filing with the Joint Committee on Agency Rule Review.

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

For the proposed rules, the Board of Pharmacy Rules Review Committee reviewed the proposed changes. Any proposed feedback agreed to by the committee and approved by the Board was incorporated into the rule package.

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 the 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, 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 Board did not consider a performance-based regulation for the rules in this package. It is the Board's responsibility to ensure that regulations are consistent throughout the state. 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 Legal Affairs and Pharmacist Compliance Supervisor reviewed the proposed rules to ensure that the regulations do not duplicate another State of Ohio Board of Pharmacy regulation.

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

Pharmacy Board 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, monthly email updates from the legislative affairs liaison and feedback from the Board's legal director for every citation submitted.

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:

- Entities that operate as third party logistics providers or virtual wholesalers.
- Terminal distributors of dangerous drugs.
- Wholesale distributors of dangerous drugs.

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 licensure discipline for a pharmacist, pharmacy intern, terminal or wholesale distributor of dangerous drugs. Discipline might include reprimand, suspension of a license, required course work (pharmacists/interns), monetary fine and/or revocation of a license.

c. Quantify the expected adverse impact from the regulation.

New Rules

- **4729-9-27:** In accordance with federal law, prohibits a terminal distributor or wholesale distributor of dangerous drugs that possess controlled substances from the employment of an individual who has been convicted of a felony drug crime or administrative action by the United States Drug Enforcement Administration (DEA), unless granted a waiver by the DEA. This mirrors an existing federal rule and should have no adverse impact on a licensee.
- **4729-9-28:** Specifies requirements for licensure as a wholesale distributor of dangerous drugs for virtual wholesale distributors/brokers. Requires licensure as a wholesale distributor of dangerous drugs with a wholesale distributor/broker classification. Depending on whether the location will be shipping controlled or non-controlled drugs, the annual license cost ranges from $750 to $787.50. It also takes approximately one hour to complete the license application. Additionally, the rule imposes recordkeeping and background check requirements on licensees. The cost of a background check per officer of the company is: BCI&I - $22, FBI - $24, and some agencies may charge a processing fee (e.g. $5-$40). This rule also requires a recent state inspection report if the entity is not located in Ohio. If no inspection report is available or the state does not license this type of facility, the rule requires the entity 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.
- **4729-9-29:** Specifies requirements for licensure as a wholesale distributor of dangerous drugs for third party logistics providers. Requires licensure as a wholesale distributor of dangerous drugs with a third party logistics provider classification. Depending on whether the location will be shipping controlled or non-controlled drugs, the annual

license cost ranges from $750 to $787.50. It also takes approximately one hour to complete the license application. Additionally, the rule imposes recordkeeping and background check requirements on licensees. The cost of a background check per officer of the company is: BCI&I - $22, FBI - $24, and some agencies may charge a processing fee (e.g. $5-$40). This rule also requires a recent state inspection report if the entity is not located in Ohio. If no inspection report is available or the state does not license this type of facility, the rule requires the entity 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.

Amended Rules

- **4729-9-18:** Requires all locations licensed with the board to maintain the license at that site. The rule is amended to correct a typo. This rule may result in minimal administrative costs to print and have the license on-file.

No Change (5-Year Review)

- **4729-9-20:** Specifies the procedures for discontinuing business as a wholesale or terminal distributor of dangerous drugs. Requires the submission of a one page form. This form takes approximately 10 minutes to complete.
- **4729-9-07:** Provides the labeling and recordkeeping requirements for drugs that are repackaged or relabeled by a pharmacy. This will result in increased administrative costs to ensure compliance with the recordkeeping and labeling requirements for pharmacies that relablel/repackage drugs.
- **4729-9-03:** Provides minimum standards for a first-aid department that stores dangerous drugs. Requires a first aid department that stores dangerous drugs to obtain licensure as a terminal distributor of dangerous drugs. Depending on whether the location will be dispensing controlled or non-controlled drugs, the annual license cost ranges from $112.50 to $150.00. It also takes approximately 30 minutes to complete the license application.

Regulatory Flexibility

15. 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.

16. 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, any failure of a standard of care in the practice of pharmacy is not considered a paperwork error but a quality assurance issue by the licensee that is necessary for the protection of the public.

17. 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. Additionally, field staff (i.e. compliance officers) is trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

4729-9-28 Licensure as a Virtual Wholesale Distributor/Broker

(A) "Virtual Wholesale Distributor/Broker" means any person engaged in wholesale distribution of dangerous drugs in or into Ohio which:

(1) Has title but does not take physical possession of dangerous drugs;

(2) Shall be licensed by the state board of pharmacy as a wholesale distributor pursuant to section 4729.52 of the Revised Code with a virtual wholesale distributor/broker classification; and

(3) 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) 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 wholesale distributor of dangerous drugs with a virtual wholesale distributor/broker classification:

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

(2) All trade or business names used by the licensee, any trade or business names under which licensee was previously or is presently licensed;

(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;

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

(5) The full name(s) of the owner and/or operator of the licensee, including:

(a) If a sole proprietorship, the full name of the sole proprietor, and the name of the business entity;

(b) If a partnership, the full name of each partner, and the name of the partnership;

(c) If a corporation, the full name and title of each corporate officer and director, the corporate names, the name of the state of incorporation, the corporation number, and a copy of the corporation papers;

(d) If a government agency, the name of the agency, and the full name of each officer and director of the agency.

(6) A copy of any existing licensure the entity has from the state in which it is located or a letter from a state entity where it is located that indicates that the state does not license such entities;

(7) A copy of any federal licensure or registration, including a drug enforcement agency registration if distributing controlled substances;

(8) If the entity making application for a wholesale distributor of dangerous drugs license with a virtual wholesale distributor/broker classification is located outside the boundaries of the state of Ohio, part of the licensing process shall be an inquiry to the licensing authority of the state in which that entity is located. This inquiry will determine whether the entity possesses a current and valid license to distribute dangerous drugs in that state and the experience the licensing authority has had with the entity. If a state does not license Virtual Wholesale Distributor/Brokers as defined in paragraph (A) of this rule, the facility must maintain Verified-Accredited Wholesale Distributors (VAWD) accreditation from the National Association of Boards of Pharmacy.

(9) Pursuant to division (A)(1) of section 4729.53 of the Revised Code, a new wholesale distributor of dangerous drug license with a virtual wholesale distributor/broker classification will not be issued until the owner(s), if incorporated the officers or if government agency the agency directors or officers, of the wholesale operation submit fingerprints to the Ohio bureau of criminal identification and investigation (BCI&I) for a criminal records check. If there is a change in officers, all new officers shall submit to a criminal records check. The criminal records check shall consist of both a BCI&I criminal records check and a federal bureau of investigations records check (FBI). The results of the criminal records check must be sent directly to the Ohio state board of pharmacy from BCI&I. To be considered valid, the criminal records check must have been performed within the past twelve months. After the board receives the results of all of the required criminal records checks the license process will proceed. The owner(s) or officers may submit electronic fingerprint impressions pursuant to rule 4729-5-12 of the Administrative Code, or if located outside of Ohio they may submit ink fingerprint impressions as instructed on a form provided by the board.

(10) Any additional information as the state board of pharmacy may require.

(C) 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 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 established deadline.

(D) Virtual Wholesale Distributors/Brokers shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of dangerous drugs.

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

(a) The source of the drugs, including the all of the following:

(i) name and principle address of the seller or transferor;

(ii) the address of the location from which the drugs were shipped; and

(iii) verification that the seller or transferor is appropriately licensed to sell or transfer dangerous drugs at wholesale.

(b) The identity and quantity of the drugs received and distributed or disposed of.

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

(d) A system of records and procedures shall be maintained which prevent the sale or other distribution of dangerous drugs to any person not authorized by division (B) of section 4729.51 of the Revised Code.

(e) A system shall be designed and operated to disclose orders for controlled substances and other dangerous drugs subject to abuse. Reports, generated by the system, shall be furnished to the state board of pharmacy within three working days of receipt of a request from the board. The reports shall include the name and address of the purchaser, date of purchases, product trade name, national drug code (NDC) number, size of package, and quantity purchased.

(2) Inventories and records shall be made available for inspection and photocopying by properly identified and authorized state board of pharmacy designated agents, federal, state, or local law enforcement agency officials for a period of three years following disposition of the drugs.

(3) Records described in this rule that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period.

(a) Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by properly identified and authorized state board of pharmacy designated agents, federal, state, or local law enforcement agency officials.

(b) Virtual wholesale distributors/brokers intending to maintain records, described in this rule, at a location other than the place licensed by the state board of pharmacy must obtain approval from the board.

(E) The virtual wholesale distributors/broker shall inform the state board of pharmacy of suspicious orders for controlled substances and other dangerous drugs subject to abuse, immediately upon discovery. Suspicious orders are those which, in relation to the wholesaler's records as a whole, are of unusual size, unusual frequency, or deviate substantially from established buying patterns.

(F) Virtual wholesale distributors/brokers 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, and for correcting all errors and inaccuracies in inventories. At a minimum, virtual wholesale distributors/brokers shall include in their written policies and procedures the following:

(1) A procedure whereby the oldest approved stock of a dangerous drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.

(2) 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.

(3) A procedure to ensure that virtual wholesale distributors/brokers 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.

(4) 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 outdated dangerous drugs.

(5) This documentation shall be maintained for three years after disposition of the outdated drugs.

(F) Wholesale distributors of dangerous drugs shall establish and maintain accurate and current lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications. When there is a change in the designated contact person to whom communications with the state board of pharmacy may be directed, the board shall be notified of the new contact person within thirty days on a board approved form. This notice to the board shall be sent by certified mail, return receipt requested, or by verified facsimile transmission.

(G) Personnel employed in the wholesale distribution of dangerous drugs shall be required to have appropriate education and/or experience to assume responsibility for positions related to compliance with the licensing regulations.

(H) Wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations.

(1) Virtual wholesale distributors/brokers shall permit properly identified and authorized state board of pharmacy designated agents, 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 at reasonable times and in a reasonable manner, to the extent authorized by law.

(2) Any virtual wholesale distributor/broker making a wholesale sale of a controlled substance shall be required to possess a license as a wholesale distributor of dangerous drugs with a virtual wholesale distributor/broker classification and a license as a wholesaler or manufacturer of controlled substances, except that a licensed terminal distributor of dangerous drugs may make an occasional sale of a controlled substance pursuant to rule 4729-9-10 of the Administrative Code.

(I) Virtual wholesale distributors/brokers shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to dangerous drug salvaging or reprocessing.

(J) The state board of pharmacy shall be notified within thirty days of any new facilities, work or storage areas to be constructed or utilized for dangerous drugs or of any changes in operation of the registrant being used or implemented.

(K) The virtual wholesale distributors/brokers shall comply with Title II of the Drug Quality and Security Act (5/26/2015).

(L) Virtual wholesale distributors/brokers shall submit wholesale sale information to the board of pharmacy in accordance with Chapter 4729-37 of the Administrative Code.

4729-9-29 Licensure as a Third Party Logistics Provider

(A) "Third party logistics provider" means any person who:

(1) Contracts with a manufacturer or wholesale distributor of dangerous drugs to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer, but does not take title to the dangerous drug or have general responsibility to direct the dangerous drug's sale or disposition;

(2) Is licensed by the state board of pharmacy as a wholesale distributor pursuant to section 4729.52 of the Revised Code with a third party logistics provider classification; and

(3) 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) 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 wholesale distributor of dangerous drugs with a virtual wholesale distributor/broker classification:

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

(2) All trade or business names used by the licensee, any trade or business names under which licensee was previously or is presently licensed;

(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;

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

(5) The full name(s) of the owner and/or operator of the licensee, including:

(a) If a sole proprietorship, the full name of the sole proprietor, and the name of the business entity;

(b) If a partnership, the full name of each partner, and the name of the partnership;

(c) If a corporation, the full name and title of each corporate officer and director, the corporate names, the name of the state of incorporation, the corporation number, and a copy of the corporation papers;

(d) If a government agency, the name of the agency, and the full name of each officer and director of the agency.

(6) A copy of any existing licensure the entity has from the state in which it is located or a letter from a state entity where it is located that indicates that the state does not license such entities;

(7) A copy of any federal licensure or registration;

(8) If the entity making application for a wholesale distributor of dangerous drugs license with a third party logistics provider classification is located outside the boundaries of the state of Ohio, part of the licensing process shall be an inquiry to the licensing authority of the state in which that entity is located. This inquiry will determine whether the entity possesses a current and valid license to distribute dangerous drugs in that state and the experience the licensing authority has had with the entity. If a state does not license such entities, the facility must maintain Verified-Accredited Wholesale Distributors (VAWD) accreditation from the National Association of Boards of Pharmacy.

(9) Pursuant to division (A)(1) of section 4729.53 of the Revised Code, a new wholesale distributor of dangerous drug license with a third party logistics provider classification will not be issued until the owner(s), if incorporated the officers or if government agency the agency directors or officers, of the wholesale operation submit fingerprints to the Ohio bureau of criminal identification and investigation (BCI&I) for a criminal records check. If there is a change in officers, all new officers shall submit to a criminal records check. The criminal records check shall consist of both a BCI&I criminal records check and a federal bureau of investigations records check (FBI). The results of the criminal records check must be sent directly to the Ohio state board of pharmacy from BCI&I. To be considered valid, the criminal records check must have been performed within the past twelve months. After the board receives the results of all of the required criminal records checks the license process will proceed. The owner(s) or officers may submit electronic fingerprint impressions pursuant to rule 4729-5-12 of the Administrative Code, or if located outside of Ohio they may submit ink fingerprint impressions as instructed on a form provided by the board.

(10) Any additional information as the state board of pharmacy may require.

(C) 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 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 established deadline.

(D) 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 outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened. Such drugs shall be stored no longer than two years pursuant to rule 4729-9-17of the Administrative Code;

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

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

(D) 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 lighted.

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

(4) All facilities where dangerous drugs are held shall be equipped with a state board of pharmacy approved 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. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(E) 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 prescription drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, 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.

(3) The recordkeeping requirements in paragraph (H) of this rule shall be followed for all stored drugs.

(F) 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;

(3) The recordkeeping requirements in paragraph (H) of this rule shall be followed for all incoming and outgoing dangerous drugs.

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

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

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

(H) Wholesale drug distributors with a third party logistics provider classification shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of dangerous drugs.

(1) These 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 identity and quantity of the drugs received and distributed or disposed of.

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

(d) A system of records and procedures shall be maintained which prevent the sale or other distribution of dangerous drugs to any person not authorized by division (B) of section 4729.51 of the Revised Code.

(e) A system shall be designed and operated to disclose orders for controlled substances and other dangerous drugs subject to abuse. Reports, generated by the system, shall be furnished to the state board of pharmacy within three working days of receipt of a request from the board. The reports shall include the name and address of the purchaser, date of purchases, product trade name, national drug code (NDC) number, size of package, and quantity purchased.

(2) Inventories and records shall be made available for inspection and photocopying by properly identified and authorized state board of pharmacy designated agents, federal, state, or local law enforcement agency officials for a period of three years following disposition of the drugs.

(3) Records described in this rule that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period.

(a) Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by properly identified and

authorized state board of pharmacy designated agents, federal, state, or local law enforcement agency officials.

(b) Third party logistics provider intending to maintain records, described in this rule, at a location other than the place licensed by the state board of pharmacy must obtain approval from the board.

(I) Third party logistics provider shall inform the state board of pharmacy of suspicious orders for controlled substances and other dangerous drugs subject to abuse, immediately upon discovery. Suspicious orders are those which, in relation to the wholesaler's records as a whole, are of unusual size, unusual frequency, or deviate substantially from established buying patterns.

(J) 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, and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include in their written policies and procedures the following:

(1) A procedure whereby the oldest approved stock of a dangerous drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.

(2) A procedure to be followed for handling recalls and withdrawals of dangerous drugs. Such procedure shall be adequate 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.

(3) 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.

(4) A procedure to ensure that any outdated 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 outdated dangerous drugs. This documentation shall be maintained for three years after disposition of the outdated drugs.

(K) Third party logistics providers shall establish and maintain accurate and current lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications. When there is a change in the designated contact person to whom communications with the state board of pharmacy may be directed, the board shall be notified of the new contact person within thirty days on a board approved form. This notice to the board shall be sent by certified mail, return receipt requested, or by verified facsimile transmission.

(L) Personnel employed by the third party logistics providers shall be required to have appropriate education and/or experience to assume responsibility for positions related to compliance with the licensing regulations.

(M) Third party logistics providers shall operate in compliance with applicable federal, state, and local laws and regulations.

(1) Third party logistics providers shall permit properly identified and authorized state board of pharmacy designated agents, 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 at reasonable times and in a reasonable manner, to the extent authorized by law.

(2) A third party logistics provider making a wholesale sale of a controlled substance shall be required to possess a license as a wholesale distributor of dangerous drugs and a license as a wholesaler or manufacturer of controlled substances, except that a licensed terminal distributor of dangerous drugs may make an occasional sale of a controlled substance pursuant to rule 4729-9-10 of the Administrative Code.

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

(O) The state board of pharmacy shall be notified within thirty days of any new facilities, work or storage areas to be constructed or utilized for dangerous drugs or of any changes in operation of the registrant being used or implemented.

(P) The third party logistics providers shall comply with Title II of the Drug Quality and Security Act (5/26/2015).

4729-9-03 Minimum standards for a first-aid department.

(A) A first-aid department is any entity which stocks, administers, and/or uses dangerous drugs in conjunction with the treatment of medical emergencies, except that this does not include the offices of a prescriber as defined in section 4729.01 of the Revised Code or an entity licensed in any other manner as a terminal distributor of dangerous drugs pursuant to section 4729.54 of the Revised Code.

(B) Each first-aid department which stocks, administers, and/or provides dangerous drugs must obtain a limited category I, II, or III terminal distributor of dangerous drugs license pursuant to section 4729.54 of the Revised Code. The license and the addendum shall be maintained in a readily available place in the principal location of such business for inspection by a state board of pharmacy designated agent. The application and license shall be signed by a person licensed pursuant to Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery. This person shall maintain supervision and control over the possession and custody of the dangerous drugs and is responsible for their legal use and distribution in accordance with state and federal laws and rules.

(C) When one first-aid department purchases dangerous drugs for first-aid departments in other locations and redistributes them, this supplying first-aid department must also be registered as a wholesale distributor of dangerous drugs.

All purchase, sale, and distribution records for dangerous drugs and inventory for controlled substances shall be kept for at least three years and shall be available for inspection during regular business hours by a state board of pharmacy designated agent. The first-aid department must be able to account for the acquisition, administration, and distribution of all dangerous drugs.

(D) All purchase orders or requisitions for dangerous drugs must be signed by the responsible person who signed the dangerous drug license pursuant to paragraph (B) of this rule and who is in charge of the first-aid department.

(E) Dangerous drugs which are not controlled substances shall be administered only by certified/licensed health care personnel who are functioning within the scope of their practice in accordance with written standing orders or protocol filed with the state board of pharmacy pursuant to section 4729.54 of the Revised Code. Controlled substances may be administered only after personally contacting a prescriber and obtaining an oral order. No dangerous drugs are to be administered except pursuant to the written standing orders or protocol or where a written or oral order is issued by such prescriber for the particular patient. Oral orders shall be immediately recorded in writing,

Including the name and strength of drug, dosage form, quantity used, name of patient, name of prescriber, name of person receiving order, name of person administering drug, time of administration, and the date. This record shall be kept on file at the first-aid department and be co-signed by the prescriber within thirty days.

(F) All dangerous drugs are to be kept in a safe and secure place, such as an enclosure or cabinet, which is to be kept locked.

(G) The responsible prescriber shall visit the first-aid department at least once each month and shall review the records, accountability procedures, controls, and security.

4729-9-07 Procedure for discontinuing business as a wholesale or a terminal distributor of dangerous drugs.

(A) A wholesale or terminal distributor of dangerous drugs who plans to discontinue business activities shall file a written notice with the board of pharmacy. The written notice shall be submitted to the board of pharmacy in person, by verified facsimile, or by registered or certified mail, return receipt requested, at least fourteen days in advance of the proposed date of discontinuing business, unless the board waives this time limitation in individual instances. This notice shall include the following information:

(1) The name, address, and wholesale or terminal distributor of dangerous drugs number of the registrant discontinuing business.

(2) The name, address, and wholesale or terminal distributor of dangerous drugs number to whom 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. The storage of dispensing records must comply with the confidentiality requirements of rule 4729-5-29 of the Administrative Code.

(4) The proposed date of discontinuing business.

(B) Unless the registrant 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 registrant 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 of according to rule 4729-9-06 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 registrant discontinuing business and the initial inventory of the registrant to whom the controlled substances are being transferred. A copy of the inventory shall be included in the records of each registrant involved in the transfer.

(C) Upon discontinuing business, the registrant shall return to the board of pharmacy, in person or by registered or certified mail, return receipt requested, the wholesale distributor of dangerous drugs license or the terminal distributor of dangerous drugs license for cancellation.

4729-9-18 Availability of terminal, wholesale, or manufacturer license.

Each entity possessing a current license as a terminal distributor of dangerous drugs, wholesale distributor of dangerous drugs, wholesaler of controlled substances, or manufacturer of controlled substances shall maintain such license in a readily available place in the principal location of such business~~;~~.

4729-9-20 Drugs repackaged or relabeled by a pharmacy.

(A) Labels of drugs repackaged by and stored within a pharmacy prior to being dispensed shall contain, but not be limited to, the following:

(1) Name of drug, strength, and dosage form;

(2) The identification of the repackager by name or by the final seven digits of their terminal distributor of dangerous drugs license number;

(3) Pharmacy control number;

(4) Pharmacy's expiration date or beyond-use date, which shall be within the proven period of stability of the drug. This expiration or beyond-use date shall be no later than the manufacturer's expiration date of a not previously opened manufacturer's container.

(B) A record of all drugs repackaged and stored within a pharmacy prior to being dispensed shall be kept for at least three years or one year past manufacturer's expiration date, whichever is greater. This record shall include at least the following:

(1) Name of drug, strength, dosage form, and quantity;

(2) Manufacturer's or distributor's control number;

(3) Manufacturer's or distributor's name, if a generic drug is used;

(4) Pharmacy control number;

(5) Manufacturer's or distributor's expiration date;

(6) The pharmacy's expiration date or beyond-use date;

(7) Positive identification of the pharmacist responsible for the repackaging of the drug.

(C) Supplemental labels created by a pharmacy that contain a barcode for the purpose of identifying a drug shall contain a means of identifying the positive identification of the pharmacist responsible for:

(1) The creation of the barcode; and

(2) Affixing the barcode label to the drug product.

4729-9-27 Employment of Individuals with Felony Convictions

(A) Pursuant to 21 C.F.R. § 1301.76 (5/18/2015), a terminal or wholesale distributor of dangerous drugs that is a united states drug enforcement administration registrant shall not employ in a position which allows access to controlled substances any person who has been convicted of a felony relating to controlled substances, or who, at any time, has had an application for drug enforcement administration registration denied, revoked, or surrendered for cause. "For cause" means surrendering a registration in lieu of, or as a consequence of, any federal or state administrative, civil, or criminal action resulting from an investigation of the individual's handling of controlled substances.

(B) Paragraph (A) of this rule does not apply if a waiver is obtained by a registrant pursuant to 21 C.F.R. § 1307.03.