8/1/2016

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.

Amended

- 4729-9-08: Requires a new application and fee for any change of ownership, business or trade name, category, or address of a terminal or wholesale distributor of dangerous drugs. The rule is being amended to clarify what a change of ownership includes and does not include.
- 4729-9-16: Specifies the minimum standards for wholesalers. The rule is being amended to specify the required information on an application as well as the individuals who are subject to a background check.
- 4729-9-28: Specifies the minimum standards for virtual wholesalers. The rule is being amended to specify the required information on an application as well as the individuals who are subject to a background check.
- 4729-9-29: Specifies the minimum standards for third party logistics providers. The rule is being amended to specify the required information on an application as well as the individuals who are subject to a background check.

Comments on the proposed rules will be accepted until close of business on August 19, 2016.

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

CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: State of Ohio Board of Pharmacy

Regulation/Package Title: Licensure

Rule Number(s): Amend: 4729-9-08; 9-16; 9-28; 9-29

Date: 08/01/2016

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Amended	Rescinded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.

Amended

- 4729-9-08: Requires a new application and fee for any change of ownership, business or trade name, category, or address of a terminal or wholesale distributor of dangerous drugs. The rule is being amended to clarify what a change of ownership includes and does not include.

- 4729-9-16: Specifies the minimum standards for wholesalers. The rule is being amended to specify the required information on an application as well as the individuals who are subject to a background check.
- 4729-9-28: Specifies the minimum standards for virtual wholesalers. The rule is being amended to specify the required information on an application as well as the individuals who are subject to a background check.
- 4729-9-29: Specifies the minimum standards for third party logistics providers. The rule is being amended to specify the required information on an application as well as the individuals who are subject to a background check.

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

The proposed rules are authorized by sections 4729.26 & 3719.28 of the Ohio Revised Code. The following sections of the Ohio Revised Code are also considered authorizing statutes for this rule package: 4729.51, 4729.52, 4729.54, 3719.03 and 4729.53.

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 wholesale distribution of dangerous drugs is authorized in statute to be conducted by the State of Ohio Board of Pharmacy.

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 distribution of 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 provisions in the above referenced chapters of the Ohio Revised Code to promote the public's safety and uniformity of drug distribution throughout Ohio. Without these regulations, the State of Ohio Board of Pharmacy would not be able to:

- set uniform requirements for licensure of virtual wholesale distributors, wholesale distributors and third party logistics providers; and
- require notification to the board, in the form of a new application, when a terminal or wholesale distributor makes operational changes to their business.

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 and prescribers regarding the provisions of the rules.

Development of the Regulation

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

The rules in this package were reviewed by a number of stakeholders comprised of the Board's Rules Review Committee. Members include individuals from hospital systems, specialty practice, academia and retail settings. The Board also received input from stakeholders who are operating as virtual wholesalers.

Prior to filing with CSI, the rules were reviewed and approved by the Board of Pharmacy.

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

The Board received feedback from virtual wholesalers regarding the requirement to obtain a Drug Enforcement Administration license. It was discovered that DEA is not licensing these facilities because they do not possess controlled substances. Therefore, it was necessary to adjust this requirement in rule.

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?**

The Board did not utilize scientific data to develop the rules in this package.

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 health and safety by ensuring the safe and effective licensure of entities distributing dangerous drugs, 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 reg*ulations 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 rule package. It is the Board's responsibility to ensure that standard definitions for compounding and preparation of compounded drugs by prescribers are consistent throughout the state.

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

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

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

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

- Virtual wholesalers of dangerous drugs;
- Terminal distributors of dangerous drugs;
- Wholesale distributors of dangerous drugs; and
- Third party logistic providers 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 terminal or wholesale distributor of dangerous drugs (includes virtual wholesalers and third party logistic providers). Discipline might include reprimand, suspension of a license, monetary fine and/or revocation of a license.

c. Quantify the expected adverse impact from the regulation.

- 4729-9-08: Requires a new application and fee for any change of ownership, business or trade name, category, or address of a terminal or wholesale distributor of dangerous drugs. The rule is being amended to clarify what a change of ownership includes and does not include. The cost of a terminal distributor license ranges from $112.50 – $150 per year based on the types of drugs stored at that facility. The time it takes to complete an application is approximately 30 minutes. Depending on whether the location will be shipping controlled or non-controlled drugs, the annual license cost for a wholesale distributor (includes virtual and third party logistics) ranges from $750 to $787.50. It also takes approximately one hour to complete the license application.
- 4729-9-16: Specifies the minimum standards for wholesalers. The rule is being amended to specify the required information on an application as well as the individuals who are subject to a background check. 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. 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).

- 4729-9-28: Specifies the minimum standards for virtual wholesalers. The rule is being amended to specify the required information on an application as well as the individuals who are subject to a background check. 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. 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).
- 4729-9-29: Specifies the minimum standards for third party logistics providers. The rule is being amended to specify the required information on an application as well as the individuals who are subject to a background check. 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. 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).

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

The Board determined that the regulatory intent justifies the impact on business because it is critical to the Board's mission to ensure that all entities are properly licensed and that they provide updated information to the Board in the event of any significant operational change. In addition, it is also important to the public to ensure that those who have access to a significant quantity of dangerous drugs are subject to background checks.

Furthermore, the need to clarify licensing requirements for virtual wholesalers, wholesalers and third party logistics providers is essential to avoid delays in the licensing process.

Regulatory Flexibility

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

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

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

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

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

Board of Pharmacy staff are available by telephone and e-mail to answer questions. Board staff members also provide presentations to groups and associations who seek updates on current regulations. Additionally, field staff (i.e. compliance officers) are trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

4729-9-16 **Minimum requirements for wholesalers.**

The following minimum requirements shall apply to all persons distributing dangerous drugs at wholesale in Ohio:

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

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

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

~~(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 following information for the owner(s) and/or operator(s) of the wholesale distributor:

(a) For a partnership:

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

(ii) the name of the partnership; and

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

(b) For a corporation:

(i) the full name, business address, Social Security number, date of birth, of the corporation's president, vice-president, secretary,

treasurer and chief executive officer, or any equivalent position;

(ii) the name or names of the corporation;

(iii) the state of incorporation;

(iv) the corporation's federal employer identification number;

(v) the name of the parent company, if applicable; andif a corporation is not publicly traded on a major stock exchange, the full name, business address, and Social Security number of each shareholder owning ten percent or more of the voting stock of the corporation.

(c) For a sole proprietorship:

(i) the full name, business address, Social Security number, and date of birth of the sole proprietor; and

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

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

~~(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) If the entity making application for a wholesale distributor of dangerous drugs license 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. This information will be used as part of the consideration in licensing the entity by the Ohio state board of pharmacy. The Ohio board will respond to inquiries of

a similar nature from other states about licensees in Ohio.

(7) Pursuant to division (A)(1) of section 4729.53 of the Revised Code, a new wholesale distributor of dangerous drug license will not be issued until the following submit fingerprints to the Ohio bureau of criminal identification and investigation (BCI&I) for a criminal records check:

(a) The responsible person on the application for licensure of a wholesale distributor pursuant to 4729-5-11; and

(b) The following persons based upon the wholesale distributors business type:

(i) All partners of a partnership;

(ii) The sole proprietor of a sole proprietorship;

(iii) The president, vice president, secretary, treasurer, and chief executive officer, or any equivalent position of a corporation and if a corporation is not publicly traded on a major stock exchange, each shareholder owning ten percent or more of the voting stock of the corporation;

(iv) The agency director of a government agency.

(c) The persons listed in paragraph (A)(7)(b) shall be a natural person that owns and/or operates the business entity applying for licensure. In the event the applicant is not owned by a natural person, each business entity with an ownership interest in the applicant must be disclosed on the application up to and through the entity that is owned by a natural person, who shall be subject to the background check in accordance with this rule.

(8) If there is a change in any of the following persons listed in paragraph (A)(7) of this rule, the new persons shall submit to a criminal records check within thirty days of the change.

(9) All criminal records check conducted in accordance with this rule shall consist of both a BCI&I criminal records check and a federal bureau of investigations records check (FBI). The results of the criminal records check must be sent directly to the 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 licensing process will proceed. The persons listed in paragraph (A)(7) of this rule may submit electronic fingerprint impressions

pursuant to rule 4729-5-12 of the Administrative Code, or if located outside of Ohio they may submit fingerprint impressions in a manner approved by the board.

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

(11) Any follow-up information as deemed necessary upon receipt of the application materials.

~~(7) Pursuant to division (A)(1) of section 4729.53 of the Revised Code, a new wholesale distributor of dangerous drug license will not be issued until the owner(s), the officers (if incorporated) or agency directors (if a government agency) 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, owners or agency directors, all new officers, owners or agency directors 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.~~

(B) Prior to the end of the licensing period, a renewal application requesting such information as the state board of pharmacy may require will be sent to the 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.

(C) 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 4729-9-17 of 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 carefully inspected for identity of the dangerous drug products and to ensure that there is no delivery of dangerous drugs that have been damaged in storage or held under improper conditions;

(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 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 of procedures shall be designed and operated to disclose orders for controlled substances and other dangerous drugs subject to abuse.

(i) The wholesaler shall inform the state board of pharmacy of suspicious orders for drugs, as described in paragraph (H)(1)(e) of this rule, when discovered. 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.

(ii) Reports, generated by the system as described in paragraph (H)(1)(e) of this rule, 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) Wholesalers intending to maintain records, described in this rule, at a location other than the place licensed by the state board of pharmacy must first send notification to the board.

(I) Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures which shall be followed for the receipt, security, storage, inventory, and distribution of dangerous drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, 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 wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

(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.

(J) 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. A wholesale distributor of dangerous drugs shall have a responsible person pursuant to rule 4729-5-11 of the Administrative Code.

(K) 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.

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

(1) Wholesale drug distributors 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 entity 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.

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

(N) The state board of pharmacy shall be notified 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.

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 physical 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;~~All trade, fictitious, or business names used by the licensee, e.g. "doing business as" or "formerly known as". Trade or business names shall not be identical to the name used by another, unrelated wholesale distributor permitted to purchase drugs in the state.

(3) Addresses, telephone numbers, and the full names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of dangerous drugs~~;~~.

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

(5) The following information for the owner(s) and/or operator(s) of the wholesale distributor with a virtual wholesale distributor/broker classification:

(a) For a partnership:

(i) the full name, business address, Social Security number, and date of birth of each partner; if the partner is not a natural person each

business entity that is a partner having an ownership interest must be disclosed on the application up to and through the entity that is owned by a natural person; and

(ii) the name of the partnership; and

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

(b) For a corporation:

(i) the full name, business address, Social Security number, date of birth, of the corporation's president, vice-president, secretary, treasurer and chief executive officer, or any equivalent position;

(ii) the name or names of the corporation;

(iii) the state of incorporation;

(iv) the corporation's federal employer identification number;

(v) the name of the parent company, if applicable; and

(vi) if a corporation is not publicly traded on a major stock exchange, the full name, business address, and Social Security number of each shareholder owning 10% or more of the voting stock of the corporation.

(c) For a sole proprietorship:

(i) the full name, business address, Social Security number, and date of birth of the sole proprietor; and

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

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

~~(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 applicable 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. This information will be used as part of the consideration in licensing the entity by the board of pharmacy. The board will respond to inquiries of a similar nature from other states regarding Ohio licnesed entitites. 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 following submit fingerprints to the Ohio bureau of criminal identification and investigation (BCI&I) for a criminal records check:

(a) The responsible person on the application for licensure of a wholesale distributor pursuant to 4729-5-11; and

(b) The following persons based upon the wholesale distributors business type:

(i) All partners of a partnership;

(ii) The sole proprietor of a sole proprietorship;

(iii) The president, vice president, secretary, treasurer, and chief executive officer, or any equivalent position of a corporation and

if a corporation is not publicly traded on a major stock exchange, each shareholder owning ten percent or more of the voting stock of the corporation;

(iv) The agency director of a government agency.

(c) The persons listed in paragraph (A)(9)(b) shall be a natural person that owns and/or operates the business entity applying for licensure. In the event the applicant is not owned by a natural person, each business entity with an ownership interest in the applicant must be disclosed on the application up to and through the entity that is owned by a natural person, who shall be subject to the background check in accordance with this rule.

(10) If there is a change in any of the following persons listed in paragraph (A)(9) of this rule, the new persons shall submit to a criminal records check within thirty days of the change.

~~(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), the officers (if incorporated) or agency directors (if a government agency) 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, owners or agency directors, all new officers, owners or agency directors 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.~~

(11) All criminal records check conducted in accordance with this rule shall consist of both a BCI&I criminal records check and a federal bureau of investigations records check (FBI). The results of the criminal records check must be sent directly to the 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 licensing process will proceed. The persons listed in paragraph (A)(9) of this rule may submit electronic fingerprint impressions pursuant to rule 4729-5-12 of the Administrative Code, or if located outside

of Ohio they may submit fingerprint impressions in a manner approved by the board.

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

(13) Any follow-up information as deemed necessary upon receipt of the application materials.

~~(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 attention of the responsible person. Such a renewal application shall be completed and returned with the applicable fee on or before the established deadline. As part of the renewal application, a person meeting the definition of a virtual wholesaler/broker that was licensed by the board as a wholesale distributor of dangerous drugs prior to the effective date of this rule shall demonstrate compliance with the requirements in paragraph (B)(8) of this rule. Failure to do so may result in a refusal by the board to renew the license.

(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.

(G) 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.

(H) 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.

(I) 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.

(J) 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.

(K) 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.

(L) The virtual wholesale distributors/brokers shall comply with Title II of the Drug Quality and Security Act (9/3/2015).

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

4729-9-08 **Change in description of terminal or wholesale dangerous drug facility.**

~~For the purpose of division (E) of section 4729.51 and division (D) of section 4729.52 of the Revised Code, any change in the ownership, business or trade name, category, or address of a terminal or wholesale distributor of dangerous drugs requires a new application, required fee, and license. The new application and required fee shall be submitted within thirty days of any change in the ownership, business or trade name, category, or address.~~

(A) For the purpose of division (E) of section 4729.51 and division (D) of section 4729.52 of the Revised Code, any change in the ownership, business or trade name, category, or address of a terminal or wholesale distributor of dangerous drugs requires a new application, required fee, and license. The new application and required fee shall be submitted within thirty days of any change in the ownership, business or trade name, category, or address.

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

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

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

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

(4) An existing corporation continues and there is a 100 percent stock purchase by another corporation or other business entity.

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

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

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

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

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

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

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

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

(C) For publicly traded corporations, a routine sale of stock is not a change of ownership. A publicly traded corporation is a corporation owned by stockholders who are members of the general public and who trade shares publicly, often through a listing on a stock exchange.

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

(E) Any change of ownership set forth in paragraphs (B)(2) and (B)(3) of this rule or as otherwise determined by the Board, shall require Board to issue a new license number.

(F) A change of credential class shall require notification to the Board. A change of credential class shall not require a full application fee, however, the Board may charge a nominal processing fee.

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 third party logistics provider classification:

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

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

~~(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 following information for the owner(s) and/or operator(s) of the wholesale distributor:

(a) For a partnership:

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

(ii) the name of the partnership; and

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

(b) For a corporation:

(i) the full name, business address, Social Security number, date of birth, of the corporation's president, vice-president, secretary, treasurer and chief executive officer, or any equivalent position;

(ii) the name or names of the corporation;

(iii) the state of incorporation;

(iv) the corporation's federal employer identification number;

(v) the name of the parent company, if applicable; and

(vi) if a corporation is not publicly traded on a major stock exchange, the full name, business address, and Social Security number of each shareholder owning 10% or more of the voting stock of the corporation.

(c) For a sole proprietorship:

(i) the full name, business address, Social Security number, and date of birth of the sole proprietor; and

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

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

~~(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 will not be issued until the following submit fingerprints to the Ohio bureau of criminal identification and investigation (BCI&I) for a criminal records check:

(a) The responsible person on the application for licensure of a wholesale distributor pursuant to 4729-5-11; and

(b) The following persons based upon the wholesale distributors business type:

(i) All partners of a partnership;

(ii) The sole proprietor of a sole proprietorship;

(iii) The president, vice president, secretary, treasurer, and chief executive officer, or any equivalent position of a corporation and if a corporation is not publicly traded on a major stock exchange, each shareholder owning ten percent or more of the voting stock of the corporation;

(iv) The agency director of a government agency.

(c) The persons listed in paragraph (A)(7)(b) shall be a natural person that owns and/or operates the business entity applying for licensure. In the event the applicant is not owned by a natural person, each business entity with an ownership interest in the applicant must be disclosed on the application up to and through the entity that is owned by a natural person, who shall be subject to the background check in accordance with this rule.

(10) All criminal records check conducted in accordance with this rule shall consist of both a BCI&I criminal records check and a federal bureau of investigations records check (FBI). The results of the criminal records check must be sent directly to the 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 licensing process will proceed. The persons listed in paragraph (A)(9) of this rule 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 in a manner approved by the board.

(11) If there is a change in any of the following persons listed in paragraph (A)(9) of this rule, the new persons shall submit to a criminal records check within thirty days of the change.

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

(13) Any follow-up information as deemed necessary upon receipt of the application materials.

~~(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), the officers (if incorporated) or agency directors (if a government agency) of the 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, owners or agency directors, all new officers, owners or agency directors 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 attention of the responsible person. Such a renewal application shall be completed and returned with the applicable fee on or before the established deadline. As part of the renewal application, a person meeting the definition of a third party logistics provider that was licensed by the board as a wholesale distributor of dangerous drugs prior to the effective date of this rule shall demonstrate compliance with the requirements in paragraph (B)(8) of this rule. Failure to do so may result in a refusal by the board to renew the license.

(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 4729-9-17 of 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.

(E) 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.

(F) 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.

(G) 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.

(H) 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.

(I) 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.

(J) 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.

(K) 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.

(L) 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.

(M) 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.

(N) 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.

(O) 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.

(P) 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.

(Q) The third party logistics providers shall comply with Title II of the Drug Quality and Security Act (9/3/2015).