5/10/16 (UPDATED 5/11/2016)

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.

Rescind Rules

- 4729-9-09: Removes rule requiring security and prescription blanks and controlled substance order forms. Rule language is in the process of being incorporated into OAC 4729-9-11.

Amended

- 4729-9-28: Clarifies that virtual wholesalers are not required to have a drug enforcement administration license.

Comments on the proposed rules will be accepted until close of business on May 24, 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

Please note this BIA was updated to reflect the removal of OAC 4729-16-01.

CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: State of Ohio Board of Pharmacy

Regulation/Package Title: Dangerous Drugs

Rule Number(s): Amend: 4729-9-28; 4729-16-01

Rescind: 4729-9-09

Date: 05/10/2016

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Amended	**Rescinded**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.

Rescind

- 4729-9-09: Removes rule requiring security and prescription blanks and controlled substance order forms. Rule language is in the process of being incorporated into OAC 4729-9-11.

Amended

- 4729-16-01: Provides definition section for drug compounding chapter. Adds the following:
    - Additional definitions for single and multidose vials and expiration dates;
    - Clarifies which licensed healthcare providers may conduct the final check of a drug prior to patient administration;
    - Defines immediate use and permits the practice when compounding drugs.
- 4729-9-28: Clarifies that virtual wholesalers are not required to have a drug enforcement administration license.

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: 4729.01, 4729.51, 4729.53, 4729.54, 4729.541 and 4729.55.

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 wholesale distributors and drug compounding (particularly by prescribers) is currently done at the state level 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 practice of pharmacy and 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 care 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 and the compounding of dangerous drugs.

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 originally reviewed by a number of stakeholders comprised of the Board's rules review committee in 2015. However, these updates are necessary in order to provide additional clarity to regulated entities.

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 did receive feedback and questions by several regulated entities including prescribers and virtual wholesalers regarding the need for additional clarity regarding the rules. Most notably, prescribers who conduct immediate use drug compounding or reconstitution (such as vaccines) expressed concern regarding the need to purchase unnecessary compounding equipment. Therefore, the Board felt it necessary to clarify that they may adhere to the immediate use provision in USP 797 in order to avoid having to purchase compounding hoods and other equipment required for more sophisticated drug compounding.

Additionally, 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?

For 4729-16-01, the Board did utilize scientific expertise in that the rule references The United States Pharmacopeial Convention (USP) drug compounding standards.

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 implementation of the drug compounding chapter and the licensure of virtual wholesalers, 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 rule package. It is the Board's responsibility to ensure that standard definitions for compounding and requirements for virtual wholesalers 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 rule 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 rule. In addition, the Board's compliance agents are trained to educate licensees on current and/or new regulations during on-site inspections.

Board of Pharmacy staff receive regular updates on rules via a monthly internal newsletter, biannual staff meetings featuring a regulatory update, mandatory all-day law reviews for new employees, email updates 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:

- Prescribers and pharmacists who are compounding dangerous drugs;
- Virtual wholesalers 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, terminal or wholesale distributor of dangerous drugs. Discipline might include reprimand, suspension of a license, required course work (pharmacists), monetary fine and/or revocation of a license.

c. Quantify the expected adverse impact from the regulation.

Rescind Rules

- 4729-9-09: Removes rule requiring security and prescription blanks and controlled substance order forms. Rule language is in the process of being incorporated into OAC 4729-9-11. This should have no adverse impact as the rule is being rescinded.

Amended

- 4729-16-01: Provides definition section for drug compounding chapter. Adds the following:
  - Additional definitions for single and multidose vials and expiration dates. This clarifies that single and multidose vials must be discarded after a certain amount of time in accordance with national compounding standards. Such definition also prohibits the use of single dose vials multiple times which may result in the need to purchase additional drug stock.

- Clarifies which licensed healthcare providers may conduct the final check of a drug prior to patient administration. It is expected through guidance to licensees that only nurses, pharmacists and prescribers should be conducting final checks of compounded drug products prior to administration. However, the addition of this language is intended to provide clarity. Those adhering to current Board guidance on the issue should not be negatively impacted by this definition.
- Defines immediate use and permits the practice when compounding drugs. This allows prescribers that compound sterile products to not have to purchase additional compounding equipment in order to mix immediate-use drugs (those administered within the hour) in their offices/pharmacies. This clarification means that prescribers will not have to adhere to more complex regulations on drug compounding that are required in Chapter 16.

- 4729-9-28: Clarifies that virtual wholesalers are not required to have a drug enforcement administration license. This amended rule language should not have any adverse impact on a virtual wholesaler.

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 patients deserve uniform standards to ensure that their drugs are compounded safely. Without such quality standards for pharmacists and physicians, the Board would not be fulfilling its mission to protect the health and safety of Ohioans.

Additionally, the need to clarify licensing requirements for virtual wholesalers 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 regulation is uniform across Ohio.

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

The State of Ohio Board of Pharmacy does not fine licensees or impose penalties for first-time paperwork violations. However, 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.

4729-9-09 Security of prescription blanks and D.E.A. controlled substance order forms. (RESCIND and include provision in OAC 4729-9-11)

~~For the purpose of aiding compliance with section 2925.23 of the Revised Code, a prescriber, responsible pharmacist, or responsible person shall provide security and control for their prescription blanks and D.E.A. controlled substance order forms by limiting their availability only to authorized persons.~~

~~R.C. 119.032 review dates: 11/22/2011 and 11/15/2016~~

4729-16-01 Definitions.

(A) As used in this chapter of the Administrative Code:

(1) "Compounding" has the same meaning as division (C) of section 4729.01 of the Revised Code.

(2) "Cytotoxic" means a drug that has been shown to be carcinogenic or mutagenic to humans through active or passive exposure.

(3) "Drug" has the same meaning as division (E) of section 4729.01 of the Revised Code.

(4) "Drug shortage" means a drug on the United States food and drug administration's drug shortage list that is not commercially available regardless of the reason that the drug is not available, including the absence of a manufacturer for the drug or the lack of a readily available supply of the drug from a manufacturer or wholesaler.

(5) "Fluid therapy pharmacy" means a pharmacy where the primary purpose is to compound and dispense parenteral compounded sterile product prescriptions.

(6) "Hazardous drugs" has the same meaning as defined in the United States pharmacopeia chapter <800> USP 39 - NF 34, or any official supplement thereto (5/1/2016).

(7) "In-state health care facility" means any of the following that are licensed as a terminal distributor of dangerous drugs in the state of Ohio:

(a) A hospital registered with the department of health under section 3701.07 of the Revised Code;

(b) Ambulatory surgical facility as defined in section 3702.30 of the Revised Code; or

(c) Emergency medical service (EMS) organization as defined in section 4765.01 of the Revised Code.

(8) "In-state pharmacy" means any pharmacy, as defined in section 4729.01 of the Revised Code, located inside of Ohio that ships, mails, or delivers, in any manner, drugs at retail in or out of Ohio. An in-state pharmacy does not include a nuclear pharmacy as defined in rule 4729-15-01 of the Administrative Code.

(9) "Licensed health professional authorized to prescribe drugs" or "prescriber" has the same meaning as defined in division (I) of section 4729.01 of the Revised Code.

(10) "Medical director" means the physician who is responsible for managing and directing the provision of medical services at an in-state health care facility.

(11) "Non-resident pharmacy" means any pharmacy, as defined in section 4729.01 of the Revised Code, located outside of Ohio that ships, mails, or delivers, in any manner, drugs at retail into Ohio. A non-resident pharmacy does not include a nuclear pharmacy as defined in rule 4729-15-01 of the Administrative Code.

(12) "Outsourcing facility" means a facility at one geographic location or address that is engaged in anticipatory compounding of sterile drugs and complies with the United States food and drug administration section 503B of the Federal Food, Drug, and Cosmetic Act (11/27/2013).

(13) "Parenteral" means a sterile preparation of drugs for injection through one or more layers of the skin.

(14) "Sterile" means a dosage form free of living microorganisms (aseptic).

(15) "Verified Pharmacy Program" means a program operated by the national association of boards of pharmacy that conducts inspections of pharmacies.

(16) "Licensed personnel approved by the responsible person" as used in paragraph (I) of rule 4729-16-04 and paragraph (G) of rule 4729-16-11 means an Ohio licensed pharmacist or individuals licensed or registered pursuant to Chapters 4723., 4730., and 4731. of the Revised Code.

(17) "Immediate-use" has the same meaning as defined in the United States pharmacopeia chapter <797> USP 39 - NF 34, or any official supplement thereto (5/1/2016). Notwithstanding paragraph (C)(2)(e) of rule 4729-16-04, immediate-use sterile compounded drugs may be prepared in accordance with the United States pharmacopeia chapter <797> USP 39 - NF 34, or any official supplement thereto (5/1/2016).

(18) "Single-Dose Container" means a single-unit container for articles or preparations intended for parenteral administration only. It is intended for a single use. A single-dose container is labeled as such. Single-dose containers shall be maintained and discarded in accordance the United States pharmacopeia chapter <797> USP 39 - NF 34, or any official supplement thereto (5/1/2016).

(19) "Multiple-Dose Container" means articles or preparations intended for parenteral administration only and usually containing antimicrobial preservatives. Multiple-dose containers shall be maintained and discarded in accordance the United States pharmacopeia chapter <797> USP 39 - NF 34, or any official supplement thereto (5/1/2016).

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 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. 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), 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~~ All criminal records checks conducted pursuant to 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 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 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.