1/17/2017

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

New Rules

- 4729-5-25: Allows for a pharmacist, pharmacy intern under the direct supervision of a pharmacist or a qualified pharmacy technician under the direct supervision of a pharmacist to administer certain laboratory tests.
- 4729-5-14: Allows a pharmacy to return dangerous drugs that have been dispensed, but not picked up by or delivered to patients and have never left the prescription department of the pharmacy or the control of the pharmacy delivery agent, to stock shelves.

Amended

- 4729-9-10: Adds condition that drugs sold under rule must be unopened, sealed and in the original manufacturer's packaging.
- 4729-9-13: Adds definitions of sample and complimentary supply. Adds condition that complimentary samples are subject to the same requirements as stock shipments of dangerous drugs. Allows pharmacists working in a charitable pharmacy to dispense a sample drug.

Comments on the proposed rules will be accepted until close of business on February 2, 2017. 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: Dangerous Drugs & Pharmacists, Interns and Technicians

Rule Number(s): New: 4729-5-25; 5-14

Amend: 4729-9-10; 9-13

Date: 1/17/2017

Rule Type:

New	5-Year Review
Amended	Rescinded

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

Regulatory Intent

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

New Rules

- 4729-5-25: Allows for a pharmacist, pharmacy intern under the direct supervision of a pharmacist or a qualified pharmacy technician under the direct supervision of a pharmacist to administer certain laboratory tests.
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- 4729-9-13: Adds definitions of sample and complimentary supply. Adds condition that complimentary samples are subject to the same requirements as stock shipments of dangerous drugs. Allows pharmacists working in a charitable pharmacy to dispense a sample drug.

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

The proposed rules are authorized by sections 4729.26 and 3719.28 of the Ohio Revised Code. The following sections of the Ohio Revised Code are also considered authorizing statutes for this rule package: 4729.51, 4729.95 and 3719.81.

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 proposed rules do not implement a federal requirement. However, the testing approved for administration pursuant to 4729-5-25 are approved by the US Food and Drug Administration (FDA).

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 dangerous drugs, the pharmacy profession (including technicians and interns) and the records associated with the distribution of prescription drugs has traditionally been done at the state level by legislatively created state boards of pharmacy, such as 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 governing records for the distribution of controlled substances.

The rules proposed under this statutory authority are necessary to facilitate compliance with the provisions in the previously 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:

- Ensure drugs that are returned to stock are not expired;
- Patient lab testing is performed safely;
- Drugs are sold and maintained in conditions to ensure the integrity of the drug stock; and
- There are clear regulations regarding the distribution of samples and complimentary supplies.

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 the Board's Rules Review Committee. The Committee, composed of pharmacists from a number of practice settings, is responsible for reviewing and approving all rules prior to their legislatively mandated five-year review date.

Prior to filing with CSI, the rules were also 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?

For the proposed rules, the Board of Pharmacy Rules Review Committee reviewed the proposed changes/additions. The feedback agreed to by the committee and approved by the Board included the following:

- Permitting qualified technicians to administer testing until the new technician registration law is implemented. (4729-5-25)

- Changing the expiration date on drugs returned to stock from 6 months to one year. (4729-5-14)
- Removing pharmacist positive identification requirements for verifying drug contents. (4729-5-14)

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 United States Pharmacopeial Convention (USP) was used to develop rule 4729-5-14, specifically the one-year expiration date stated in the rule.

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

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

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

The agency did not consider a performance-based regulation for this rule package. It is the Board's responsibility to ensure uniform regulations across Ohio. At this juncture, it was the determination of the Board and the Rules Review Committee that the rule package did not lend itself to performance-based regulations.

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

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

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

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

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

- Pharmacists;
- Pharmacy interns;
- Pharmacy technicians;
- Terminal distributors of dangerous drugs;
- Wholesale distributors of dangerous drugs; and
- Drug manufacturers.

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, intern, terminal distributor or wholesale distributor. 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.

New Rules

- 4729-5-25: The pharmacy or facility licensed as a terminal distributor of dangerous drugs must be certified as a clinical laboratory under the Clinical Laboratory Improvement Amendments (CLIA) if it wishes to administer certain testing. CLIA waived certification

fees are $150.00 biennially. Laboratories up for certification must also meet CLIA standards to become certified. The responsible person of the terminal distributor of dangerous drugs and the terminal distributor of dangerous drugs must take the time to ensure that all staff conducting CLIA waived tests receive appropriate training to conduct safe testing.

- 4729-5-14: Allows a pharmacy to return dangerous drugs that have been dispensed, but not picked up by or delivered to patients and have never left the prescription department of the pharmacy or the control of the pharmacy delivery agent, to stock shelves. The regulation may require upgrades to pharmacy computer systems to ensure the proper expiration date is included on the prescription label. Furthermore, entities that add new labeling (which is optional) will be required to have pharmacists conduct additional checks of medications that are returned to stock. Depending on volume, this will require additional pharmacist hours to meet this requirement.

Amended

- 4729-9-10: Adds condition that drugs sold under rule must be unopened, sealed and in the original manufacturer's packaging. This regulation may prohibit the practice of selling open stock bottles. Therefore, a pharmacy that needs to purchase medication from another pharmacy will be required to purchase the entire stock bottle, which will increase overall costs.
- 4729-9-13: Adds definitions of sample and complimentary supply. Adds condition that complimentary samples are subject to the same requirements as stock shipments of dangerous drugs. Allows pharmacists working in a charitable pharmacy to dispense a sample drug. Specifies that any entity selling a sample or complimentary drug in Ohio shall be licensed as a wholesale distributor of dangerous drugs. Depending on whether the location will be shipping controlled or non-controlled drugs, the annual license cost ranges from $750 to $787.50. It also takes approximately one hour to complete the license application. Additionally, the rule imposes recordkeeping and background check requirements on licensees. The cost of a background check per officer of the company is: BCI&I - $22, FBI - $24, and some agencies may charge a processing fee (e.g. $5-$40).

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

The Board determined that the regulatory intent justifies the impact on business because the regulations are intended to protect and promote public safety. In particular, they ensure uniform regulations that allow for:

- The safety and security of dangerous drugs returned to stock shelves;
- Safe laboratory testing at pharmacies;

- Protection of the integrity of drugs that are sold between pharmacies; and
- Common definitions and enforcement of safety standards for drug samples and complimentary supplies.

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

4729-9-10 Occasional sale.

(A) The term "occasional sale" as used in section 4729.51 of the Revised Code means a wholesale sale to a wholesale distributor of dangerous drugs, terminal distributor of dangerous drugs, ~~prescriber as defined in section 4729.01 of the Revised Code,~~ or any entity or person exempted from licensure as a terminal distributor of dangerous drugs pursuant to section 4729.541 of the Revised Cod by either:

(1) a ~~pharmacist~~ pharmacy licensed as a terminal distributor of dangerous drugs; ~~who is a terminal distributor of dangerous drugs~~; or

(2) A licensed terminal distributor of dangerous drugs that is not a pharmacy, but only with respect to naloxone.

B) The total value of all dangerous drugs distributed by the terminal distributor of dangerous drugs pursuant to this rule shall not exceed five percent of the total value of dangerous drugs purchased by the terminal distributor of dangerous drugs during the same calendar year. In addition, the total amount of controlled substances sold pursuant to this rule shall not exceed the allowable amount as specified in 21 C.F.R. 1307.11 (3/16/2016).

(1) The value of the dangerous drugs shall be based on the cost of the dangerous drugs to the terminal distributor of dangerous drugs.

(C) The limits set forth in this rule do not apply to terminal distributors of dangerous drugs that conduct occasional sales of naloxone at wholesale to a state or local law enforcement agency.

(D) The limits set forth in this rule do not apply to ~~pharmacies~~ terminal distributors of dangerous drugs that conduct occasional sales of naloxone at wholesale.

(E) Sales conducted in accordance with this rule shall only consist of the sale of dangerous drugs that are unopened, sealed and in the original manufacturer's packaging.

4729-9-13 Distributor of dangerous drugs samples and complimentary supplies.

(A) As used in this rule:

(1) "Sample" means a dangerous drug or pharmaceutical preparation that would be hazardous to health or safety if used without the supervision of a licensed health professional authorized to prescribe drugs, or a drug of abuse, and that, at one time, had been placed in a container plainly marked as a sample by a manufacturer. Except as provided in paragraph (D) of this rule, samples may only be provided to and furnished by a licensed prescriber as defined in rule 4729-5-15 of the Administrative Code in accordance with paragraph (B) of this rule.

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

(B) No manufacturer, manufacturer's representative, or wholesale dealer in pharmaceuticals may furnish a sample of a drug ~~of abuse as defined in section 3719.011 of the Revised Code~~ to a licensed prescriber unless requested by the prescriber and unless the company is registered as a wholesale distributor of dangerous drugs and maintains a record of such distribution which will be available to the state board of pharmacy.

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

(D) Nothing in this rule prohibits a pharmacist working, whether or not for compensation, in a charitable pharmacy from dispensing a sample drug to a person in accordance with section 3719.811 of the Revised Code and chapter 4729-36 of the Administrative Code.

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

4729-5-25 Pharmacist, Pharmacy Intern and Technician Administered Testing (NEW)

(A) A pharmacist, pharmacy intern under the direct supervision of a pharmacist or a qualified pharmacy technician under the direct supervision of a pharmacist may administer laboratory testing provided the following conditions are met:

(1) The pharmacy or facility licensed as a terminal distributor of dangerous drugs is certified by the US Department of Health and Human Services, as a clinical laboratory under the Clinical Laboratory Improvement Amendments (CLIA);

(2) The tests do not otherwise require a prescriber's order and the pharmacy or facility licensed as a terminal distributor of dangerous drugs has obtained a CLIA Certificate of Waiver from the US Department of Health and Human Services;

(3) The responsible person of the terminal distributor of dangerous drugs and the terminal distributor of dangerous drugs shall ensure and document that all pharmacists, pharmacy interns, qualified pharmacy technicians and certified pharmacy technicians conducting CLIA waived tests pursuant to this rule receive appropriate training to conduct testing in a safe and effective manner.

(B) A pharmacist or pharmacy intern may evaluate the results of a test administered under this rule when advising an individual and the health care professionals treating an individual regarding the individual's drug therapy.

(C) This rule does not restrict a pharmacist's ability to order and evaluate tests under a consult agreement pursuant to section 4729.39 of the Revised Code.

(D) Upon the effective date of section 4729.95 of the Revised Code, only a pharmacist, pharmacy intern under the direct supervision of a pharmacist or a certified pharmacy technician under the direct supervision of a pharmacist may administer laboratory testing in accordance with this rule.

4729-5-14 Return to Stock in a Pharmacy (NEW)

(A) As used in this rule, "pharmacy delivery agent" means an employee of the pharmacy who delivers dangerous drugs that have been dispensed. It does not include the United States Postal Service or common or contract carrier.

(B) A pharmacy may return dangerous drugs to stock shelves that have been dispensed, but not picked up by or delivered to patients and have never left the prescription department of the pharmacy or the control of the pharmacy delivery agent, if the pharmacy complies with the following:

(1) The pharmacy has the capability to place the expiration date, as required by this rule, on the prescription label.

(2) The expiration date on the label shall not exceed the expiration date on the manufacturer's container or one year from the date the drug was originally dispensed and placed in the prescription vial, whichever date is earlier. If the prescription container is the manufacturer's original sealed packaging, the expiration date is the expiration date listed on the packaging.

(3) The dangerous drug products returned to the shelf shall be maintained in the container in which they were filled and shall maintain their original prescription label containing the original expiration date assigned. This label shall not be removed, altered, or replaced with another label or have any other label added, except as follows:

(a) Adding a barcode label to identify the product for inventory control or documenting a future dispensing of the product;

(b) The pharmacist allows for the removal of the name, address and phone number of the patient if, in their professional judgement, there are concerns regarding patient confidentiality. If the patient's name is removed, all other information shall remain on the label; or

(c) A new label or modification to the existing label may be placed on the container if the drug is verified by a pharmacist following the application of the new or modified label.

(d) A prescription label may be removed if the prescription container is the manufacturer's original sealed packaging and the removal of the label does not remove or otherwise cause to make unreadable the expiration date and lot number on the manufacturer's packaging.

(4) The contents of a prescription container shall not be returned to the manufacturer's stock bottle.

(5) When dispensing medication that was previously returned to stock to another patient, a new container shall be used.

(6) The pharmacy shall develop and implement a policy to ensure that the drugs and packaging (i.e. prescription vials) are stored within the proper temperature range in the pharmacy and during delivery via a pharmacy delivery agent. The policy shall include a requirement for the pharmacy's responsible person to conduct routine temperature control monitoring at least annually.

(7) In the case of recalls, any dangerous drugs returned to stock shelves containing the drug affected by the recall shall be removed from the shelves immediately, unless the lot number can be determined.

(8) A dangerous drug that leaves the prescription department of the pharmacy in the custody of a pharmacy delivery agent may only be returned to stock shelves if the drug meets any of the following prior to initially leaving the prescription department:

(a) Each dangerous drug prescription is dispensed in a tamper evident container or package prior to leaving the pharmacy; or

(b) The dangerous drug prescription is dispensed in the manufacturer's original tamper evident packaging.

(9) A dangerous drug prescription that is dispensed and shows any signs of tampering or adulteration shall not be returned to stock shelves.

(C) A dangerous drug that exceeds its assigned expiration date as described in paragraph (A) of this rule, shall be removed from ~~stock~~ the area for the storage of drugs used for dispensing and administration in accordance with rule 4729-9-17.

(D) No compounded or reconstituted prescriptions may be returned to stock.

(E) This rule does not apply to drugs dispensed for inpatients pursuant to paragraph (C) of rule 4729-17-01 of the Administrative Code. Drugs dispensed for inpatients shall may be returned to stock in accordance with rule 4729-9-04 of the Administrative Code.