5/4/2018

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

- 4729:2-3-02: Allows a pharmacy intern under the direct supervision of a pharmacist to administer certain laboratory tests.
- 4729:3-3-05: Allows a certified pharmacy technician under the direct supervision of a pharmacist to administer certain laboratory tests.
- 4729:2-3-03: Establishes the required training for a pharmacy intern under the direct supervision of a pharmacist to administer immunizations and outlines informed consent requirements.
- 4729:2-3-04: Specifies the protocols under which a pharmacy intern may dispense naloxone without a prescription.

Comments on the proposed rules will be accepted until close of business on **May 21, 2018**. Please send all comments to the following email address: **Ali.Simon@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: Pharmacy Interns & Technicians

Rule Number(s):

New:

- 4729:2-3-02
- 4729:3-3-05
- 4729:2-3-03
- 4729-2-3-04

Date: 5/4/2018

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Amended	Rescinded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

- 4729:2-3-02: Allows a pharmacy intern under the direct supervision of a pharmacist to administer certain laboratory tests.
- 4729:3-3-05: Allows a certified pharmacy technician under the direct supervision of a pharmacist to administer certain laboratory tests.
- 4729:2-3-03: Establishes the required training for a pharmacy intern under the direct supervision of a pharmacist to administer immunizations and outlines informed consent requirements.
- 4729:2-3-04: Specifies the protocols under which a pharmacy intern may dispense naloxone without a prescription.

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

The proposed rule is authorized by sections 4729.26, 4729.44 and 4729.41 of the Ohio Revised Code.

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?

These rules do not implement a federal requirement. However, the testing approved for administration pursuant to 4729:2-3-02, 4729:3-3-05 are approved by the US Food and Drug Administration.

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 practice of pharmacy (including technicians and interns) has traditionally been done at the state level by legislatively created state boards 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 Board of Pharmacy to adopt rules governing the practice of pharmacy, which includes a pharmacist, pharmacy intern, and pharmacy technician's scope of practice.

Section 4729.41 of the Ohio Revised Code requires the Board of Pharmacy to adopt rules pertaining to the administration of immunizations by pharmacy professionals.

Section 4729.44 of the Ohio Revised Code requires the Board of Pharmacy to adopt rules pertaining to the dispensing of naloxone by pharmacists and pharmacy interns pursuant to a physician-approved protocol.

Without these regulations, the Board of Pharmacy would not be able to ensure uniform standards for the following activities performed by pharmacy interns: immunization administration, dispensing of naloxone pursuant to a physician protocol, and the administration of certain testing at the pharmacy.

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

The success of these regulations will be measured by having rules written in plain language, licensee compliance with the rules, and minimal questions from licensees regarding the provisions of the rule.

Development of the Regulation

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

This rule package was 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 date.

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?**

For the proposed rules, the Board of Pharmacy Rules Review Committee reviewed the proposed changes. The Committee recommended and the Board approved waiving the required naloxone patient training if someone had received training within the previous 12-months.

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

Scientific data was not used to develop or review these rules.

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

As the regulations are essential to protecting the public's safety by ensuring uniform standards for the practice of pharmacy, 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 practice standards across Ohio. At this juncture, it was the determination of the Board that the rule package did not lend itself to performance-based regulations.

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

The Board of Pharmacy's Director of 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 are trained to educate licensees on current and/or new regulations during on-site inspections.

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

- Pharmacies;
- Pharmacy interns; and
- Certified pharmacy technicians.

b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and

Violation of this rule may result in administrative licensure discipline for a terminal distributor of dangerous drugs, pharmacy intern or certified pharmacy technician. 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

- 4729:2-3-02, 4729:3-3-05 Allows a pharmacy intern or certified pharmacy technician to administer certain laboratory tests. These requirements are set forth currently in rule 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 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 all staff conducting CLIA waived tests receive appropriate training to conduct safe testing. A pharmacy intern and certified pharmacy technician will only be able to administer CLIA waived tests under the direct supervision of a pharmacist.
- 4729:2-3-03 Establishes the required training for a pharmacy intern under the direct supervision of a pharmacist to administer immunizations and outlines informed consent requirements. Currently, these requirements are set forth in 4729-5-40. Pharmacy interns will have to complete an ACPE-accredited course meeting the requirements specified in the rule. A similar course for vaccine administration costs up to $390 (*https://www.ohiopharmacists.org/aws/OPA/pt/sp/education_immunization*).
- 4729:2-3-04: Specifies the protocols under which a pharmacy intern may dispense naloxone without a prescription. Interns that dispense naloxone will be required to obtain training as well as provide patient training. The provision of patient training takes an estimated 15-20 minutes depending on the training program utilized.

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

The Board believes that the regulatory intent of the proposed rules is necessary to protect the health and safety of all Ohioans by providing uniform regulations for the administration of certain testing by pharmacy professional and the dispensing of naloxone without a prescription.

Regulatory Flexibility

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

This rule package does 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 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 and host regional meetings to discuss changes to Ohio laws and rules. Additionally, staff are trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

4729:2-3-02 – Pharmacy intern administration of diagnostic tests.

(A) A pharmacy intern under the direct supervision of a pharmacist may administer CLIA waived diagnostic 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 United States department of health and human services (HHS), as a clinical laboratory through the clinical laboratory improvement amendments (CLIA);

(2) The pharmacy or facility licensed as a terminal distributor of dangerous drugs has obtained a CLIA certificate of waiver from HHS; and

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

(B) A pharmacy intern under the direct supervision of a pharmacist may evaluate the results of a test administered under this rule when advising a patient or a health care professional treating a patient if the test relates to the patient's drug therapy.

(C) This rule applies only to the administration and evaluation of laboratory testing by individuals licensed or registered in accordance with Chapter 4729. of the Revised Code.

4729:3:3-05 – Certified pharmacy technician administration of diagnostic tests.

(A) A certified pharmacy technician under the direct supervision of a pharmacist may administer CLIA waived diagnostic 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 United States department of health and human services (HHS), as a clinical laboratory through the clinical laboratory improvement amendments (CLIA);

(2) The pharmacy or facility licensed as a terminal distributor of dangerous drugs has obtained a CLIA certificate of waiver from HHS; and

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

(B) This rule applies only to the administration and evaluation of laboratory testing by individuals licensed or registered in accordance with Chapter 4729. of the Revised Code.

4729:2-3-03 – Immunization administration by pharmacy interns.

(A) Pharmacy interns working under the direct supervision of a pharmacist may administer immunizations listed in paragraph (C) of this rule if an intern complies with the following:

(1) Successfully completes a course in the administration of immunizations that meets the requirements set forth in rule 4729:1-3-02 of the Administrative Code.

(2) Practices in accordance with a definitive set of treatment guidelines specified in a protocol established by a physician that complies with the requirements of rule 4729:1-3-02 of the Administrative Code.

(3) Receives and maintains certification to perform basic life-support procedures by successfully completing a basic life-support training course certified by the American red cross, American heart association or other training course approved by the board. Certification shall be obtained and maintained through courses that are conducted in-person or, at a minimum, offer an in-person training component.

(4) The supervising pharmacist has completed all of the training necessary to administer immunizations in accordance with rule 4729:1-3-02 of the Administrative Code.

(B)

(1) Pharmacy interns working under the direct supervision of a pharmacist seeking to administer any immunization listed in paragraph (C) of this rule that was added after the completion of an initial immunization course approved pursuant to rule 4729:1-3-02 of the Administrative Code shall, at a minimum, conduct a review of appropriate clinical resources to familiarize themselves with all the following prior to the administration of the immunization:

(a) Disease states associated with the immunization;

(b) Type or nature of activity of the immunization;

(c) Appropriate administration schedules;

(d) Appropriate routes of administration;

(e) Appropriate injection sites;

(f) Appropriate dosages;

(g) Appropriate monitoring and treatment of the patient for adverse reactions;

(h) Appropriate patient populations;

(i) Precautions and contraindications; and

(j) Proper storage requirements for the immunization.

(2) Failure to adhere to the appropriate standard of care for administration of an immunization shall be consider a violation of this rule and may subject a pharmacy intern to discipline in accordance with rule 4729:2-4-01 of the Administrative Code.

(C) A pharmacy intern working under the direct supervision of a pharmacist may administer the same immunizations authorized for pharmacist administration listed in paragraph (G) of rule 4729:1-3-02 of the Administrative Code.

(D) A pharmacy intern shall obtain informed consent pursuant to rule 4729:5-5-04 of the Administrative Code to administer an immunization.

(E) A pharmacy intern shall comply with the vaccine information statement requirements of the National Vaccine Childhood Injury Act, 42 U.S.C. Section 300aa-26 (12/14/1993).

(F) An immunization specified in this rule shall not be administered to any individual who is less than thirteen years of age, except in the following situations:

(1) The immunization for influenza is administered to individuals who are seven years of age or older; or

(2) Pursuant to a prescription from a licensed prescriber, an immunization or vaccine is administered to individuals who are seven years of age or older but not more than thirteen years of age.

(G) For each immunization administered to an individual by a pharmacy intern, other than an immunization for influenza administered to an individual eighteen years of age or older, the pharmacy intern shall notify the individual's family physician or, if the individual has no family physician, the board of health of the health district in which the individual resides or the authority having the duties of a board of health for that district under section 3709.05 of the Revised Code. The notice shall be given not later than thirty days after the immunization is administered. Notification of may be conducted using one of the following methods that is capable of confirming delivery of the required notification:

(1) Electronic mail;

(2) Interoperable electronic medical records system;

(3) Facsimile;

(4) Electronic prescribing system;

(5) Electronic pharmacy record system;

(6) Documented verbal communication;

(7) Any other method of notification that might reasonably be expected to allow for the confirmed transmission of the required notification.

4729:2-3-04 – Dispensing of naloxone by pharmacy interns.

(A) A pharmacy intern under the direct supervision of a pharmacist may dispense naloxone without a prescription to either of the following in accordance with an approved protocol specified in paragraph (B) of rule 4729:1-3-04 of the Administrative Code:

(1) An individual who there is reason to believe is experiencing or at risk of experiencing an opioid-related overdose;

(2) A family member, friend, or other person in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose.

(B) A pharmacy intern under the direct supervision of a pharmacist who dispenses naloxone pursuant to this rule shall instruct the individual to whom naloxone is dispensed verbally or in writing to summon emergency services as soon as practicable either before or after administering naloxone.

(C) Except as provided in paragraph (E) this rule, a pharmacy intern shall personally provide in-person training and written educational materials, unless otherwise approved by the board, to the individual to whom naloxone is dispensed, appropriate to the dosage form of naloxone dispensed, including, but not limited to, all the following:

(1) Risk factors of opioid overdose;

(2) Strategies to prevent opioid overdose;

(3) Signs of opioid overdose;

(4) Steps in responding to an overdose;

(5) Information on naloxone;

(6) Procedures for administering naloxone;

(7) Proper storage and expiration of naloxone product dispensed; and

(8) Information on where to obtain a referral for substance abuse treatment.

(D) Patient training as required by paragraph (C) of this rule is not required if the patient has previously received training and all the following apply:

(1) The patient is offered training and refuses; and

(2) The pharmacy intern has documentation confirming training pursuant to this rule has been provided within the previous twelve months.

(3) A pharmacy intern under the direct supervision of a pharmacist who dispenses naloxone pursuant to this rule shall still instruct the individual to whom naloxone is dispensed verbally or in writing to summon emergency services as soon as practicable either before or after administering naloxone.

(E) A terminal distributor of dangerous drugs shall ensure that all pharmacy interns that dispense naloxone pursuant to this rule are appropriately trained on the use of naloxone and can meet the training requirements listed in paragraphs (B) and (C) of this rule.

(F) A pharmacy intern may document the dispensing of naloxone by the pharmacy intern on a prescription form. The form may be assigned a number for record-keeping purposes.