

**11/21/2017**

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**

- 4729:1-3-05: Allows a pharmacist to fit, measure and dispense therapeutic diabetic shoes and shoe inserts. Rescinds current rule 4729-5-23.
- 4729:2-3-01: Lists the professional functions that may be performed by a pharmacy intern. Rescinds current rule 4729-5-08.
- 4729:2-3-02: Allows a pharmacy intern to fit, measure and dispense therapeutic diabetic shoes and shoe inserts. Rescinds current rule 4729-5-23.

Comments on the proposed rules will be accepted until close of business on **December 8, 2017**. Please send all comments to the following email address:

[Cameron.mcnamee@pharmacy.ohio.gov](mailto:Cameron.mcnamee@pharmacy.ohio.gov)

In addition, please copy your comments to:

[CSIPublicComments@governor.ohio.gov](mailto:CSIPublicComments@governor.ohio.gov)

## Business Impact Analysis

Agency Name: State of Ohio Board of Pharmacy

Regulation/Package Title: Pharmacy interns and diabetic shoes

Rule Number(s): New: 4729:1-3-05; 4729:2-3-01; 4729:2-3-02

Date: 11/21/2017

**Rule Type:**

New

Amended

5-Year Review

Rescinded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**

- 4729:1-3-05: Allows a pharmacist to fit, measure and dispense therapeutic diabetic shoes and shoe inserts. Rescinds current rule 4729-5-23.
- 4729:2-3-01: Lists the professional functions that may be performed by a pharmacy intern. Rescinds current rule 4729-5-08.
- 4729:2-3-02: Allows a pharmacy intern to fit, measure and dispense therapeutic diabetic shoes and shoe inserts. Rescinds current rule 4729-5-23.

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

The proposed rules are authorized by section 4729.26 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.

**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 has traditionally been done at the state level by legislatively created state boards of pharmacy. The regulation of the pharmacy practice includes valid requirements for the practice of pharmacy by pharmacists and pharmacy interns.

**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 and distribution of dangerous drugs. Without this regulation, the Board would not be able to permit pharmacists and interns to perform specific functions relating to the practice of pharmacy.

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

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

**Development of the Regulation**

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

The rules 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. Any proposed feedback agreed to by the committee and approved by the Board was incorporated into the rule package.

The committee did recommend permitting a pharmacy intern to transfer a controlled substance prescription in rule 4729:2-3-01. However, that revision would conflict with federal regulations set forth by the Drug Enforcement Administration.

**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 this rule.

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

As the regulations are essential to protecting the public's safety by ensuring uniform standards for the practice of pharmacy by pharmacists and pharmacy interns, 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. Corresponding rules in Chapter 4729. are being rescinded to avoid duplicate regulations.

**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:

- Pharmacists; and
- Pharmacy interns.

**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 or pharmacy intern. 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.**

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## **New**

- 4729:1-3-05: Allows a pharmacist to fit, measure and dispense therapeutic diabetic shoes and shoe inserts. This rule should have no adverse as it permits pharmacists to engage in specific activities.
- 4729:2-3-01: Lists the professional functions that may be performed by a pharmacy intern. This rule should have no adverse impact as it establishes a scope of practice for pharmacy interns.
- 4729:2-3-02: Allows a pharmacy intern to fit, measure and dispense therapeutic diabetic shoes and shoe inserts. This rule should have no adverse as it permits pharmacy interns to engage in specific activities.

### **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 protect and promote public safety by ensuring uniform standards for the practice of pharmacy by pharmacists and pharmacy interns.

## **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 by pharmacists and pharmacy interns 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?**

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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.

**4729:2-3-01 Practice as a pharmacy intern.**

In addition to assisting a pharmacist with technical functions, a pharmacy intern may perform the following professional functions under the direct supervision of a pharmacist.

- (A) The sale of schedule V controlled substances pursuant to agency 4729 of the Administrative Code.
- (B) The receipt of oral prescriptions pursuant to rule 4729:5-5-10 of the Administrative Code.
- (C) The transfer of a non-controlled prescription copy pursuant to rule 4729:5-5-11 of the Administrative Code.
- (D) The act of patient counseling pursuant to rule 4729-5:5-09 of the Administrative Code.
- (E) The administration of immunizations pursuant to section 4729.41 of the Revised Code.
- (F) The documentation of informed consent to administer an immunization pursuant to section 4729.41 of the Revised Code and rule 4729:5-5-04 of the Administrative Code.
- (G) The dispensing of naloxone in pursuant to section 4729.44 of the Revised Code.



**4729:1-3-05 Therapeutic diabetic shoes.**

(A) Pursuant to section [4779.02](#) of the Revised Code, a pharmacist may fit and measure individuals for therapeutic diabetic shoes and shoe inserts and may dispense those shoes and shoe inserts.

(B) A pharmacist shall not provide any other services that are authorized under Chapter 4779. of the Revised Code.

**4729:2-3-02 Therapeutic diabetic shoes.**

(A) Pursuant to section 4779.02 of the Revised Code, a pharmacy intern acting under the direct supervision of a pharmacist, may fit and measure individuals for therapeutic diabetic shoes and shoe inserts and may dispense those shoes and shoe inserts.

(B) A pharmacy intern acting under the direct supervision of a pharmacist shall not provide any other services that are authorized under Chapter 4779. of the Revised Code.