# Common Sense Initiative

Mike DeWine, *Governor*
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## Business Impact Analysis

**Agency, Board, or Commission Name:** Ohio Board of Pharmacy

**Rule Contact Name and Contact Information:** Summer Reyburn, summer.reyburn@pharmacy.ohio.gov

**Regulation/Package Title (a general description of the rules' substantive content):**

FYR Pharmacy Interns

**Rule Number(s):** 4729:2-2-07, 4729:2-3-04, 4729:2-3-06

**Date of Submission for CSI Review:** 1/12/2026

**Public Comment Period End Date:** 2/10/2026

**Rule Type/Number of Rules:**

**New/___ rules**

**No Change/____ rules (FYR? ___)**

**Amended/__3__ rules (FYR? _Y_)**

**Rescinded/____ rules (FYR? ___)**

**The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations**

**that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.**

## Reason for Submission

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

   **Which adverse impact(s) to businesses has the agency determined the rule(s) create?**

   **The rule(s):**

   a. ☐ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**

   b. ☒ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**

   c. ☒ **Requires specific expenditures or the report of information as a condition of compliance.**

   d. ☒ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

## Regulatory Intent

2. **Please briefly describe the draft regulation in plain language.**

***Please include the key provisions of the regulation as well as any proposed amendments.***

**4729:2-2-07:** Provides the passing scores for the Test of English as a Foreign Language, Internet-based Test. Updates the passing scores to be twenty-two for writing, twenty-five for speaking, twenty-two for listening, and twenty-one for reading. This reflects national changes by the National Association of Boards of Pharmacy: https://nabp.pharmacy/programs/foreign-pharmacy/

**4729:2-3-04:** Specifies the protocols under which a pharmacy intern may dispense naloxone without a prescription. Updates instances of "naloxone" to "overdose reversal drug" as defined in rule 4729-8-02 of the Administrative Code. Updates instances of "physician-established protocol" to "prescriber-established protocol." Removes training requirements.

**4729:2-3-06:** Specifies the protocols and other requirements under which a pharmacy intern may dispense an epinephrine autoinjector without a prescription. Clarifies that the epinephrine must be an autoinjector or any formulation authorized in chapter 4729. of the Revised Code and removes further instances of "autoinjector" from the rule. Adds definitions for "epinephrine" and "pharmacy affiliated with the pharmacist."

3. **Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

The proposed rules are authorized by sections 3719.28, 4729.26, and 4729.47 of the Revised Code.

4. **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?**
***If yes, please briefly explain the source and substance of the federal requirement.***

These rules do not implement a federal requirement.

5. **If the regulation implements a federal requirement, but includes provisions not specifically required by the federal government, please explain the rationale for**

**exceeding the federal requirement.**

Not Applicable.

6. **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.

Section 4729.47 of the Ohio Revised Code requires the Board of Pharmacy to adopt rules pertaining to the dispensing of epinephrine autoinjectors by pharmacists and pharmacy interns pursuant to a physician-approved protocol.

Section 3715.502 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 prescriber-approved protocol.

Without these regulations, the Board of Pharmacy would not be able to ensure uniform standards for the dispensing of overdose reversal drugs (naloxone) and epinephrine pursuant to a prescriber protocol as well as successful passage of the Test of English as a Foreign Language by foreign pharmacy students.

7. **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 rules.

8. **Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**
***If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.***

No.

## Development of the Regulation

**9. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**
***If applicable, please include the date and medium by which the stakeholders were initially contacted.***

Changes to rule 4729:2-2-07 were put out for stakeholder comment between the dates of 10/23-11/14/2025.

This rule package was also reviewed by the Board's Rules Review Committee. The Committee, composed of pharmacists and pharmacy technicians from a number of practice settings, is responsible for reviewing and approving 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.

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

No changes were suggested either through public comment or by the Board of Pharmacy, so no additional changes were made to the rules.

**11. 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.

**12. 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?**
***Alternative regulations may include performance-based regulations, which define the required outcome, but do not dictate the process the regulated stakeholders must use to comply.***

As the regulations are essential to protecting the public's safety by ensuring uniform standards for the practice of pharmacy and the licensure of pharmacists, the Ohio Board of Pharmacy did not consider any regulatory alternatives.

**13. 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 Ohio Board of Pharmacy regulation.

**14. 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, webinars from the Director of Policy and Communications, and feedback from the Board's legal department for every citation submitted.

## Adverse Impact to Business

**15. Provide a summary of the estimated cost of compliance with the rule(s). Specifically, please do the following:**

**a. Identify the scope of the impacted business community, and**

- Pharmacy interns

**b. Quantify and identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance, etc.).**

***The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a representative business. Please include the source for your information/estimated impact.***

In general, violation of these rules may result in administrative licensure discipline for a pharmacist, intern, or terminal distributor of dangerous drugs. Discipline might include reprimand, suspension of a license, required coursework (intern/pharmacist), monetary fine, and/or revocation of a license.

**4729:2-2-07:** Those who do not meet these updated scores will be required to retake the examination. In the US, the examination costs a total of $270.

**4729:2-3-04:** This rule reduces the overall burden on the pharmacy intern by streamlining the training requirements for pharmacists who distribute overdose reversal medications. This will result in overall reduction in time for interns dispensing these medications.

**4729:2-3-06:** This rule requires a pharmacy intern to conduct patient training on the proper method of administering epinephrine. It is estimated that this required training may take between 2-5 minutes per dispensing.

16. **Are there any proposed changes to the rules that will reduce a regulatory burden imposed on the business community? Please identify.** ***(Reductions in regulatory burden may include streamlining reporting processes, simplifying rules to improve readability, eliminating requirements, reducing compliance time or fees, or other related factors).***

**4729:2-3-04:** This rule reduces the overall burden on the pharmacy intern by streamlining the training requirements for pharmacists who distribute overdose reversal medications. This will result in overall reduction in time for interns dispensing these medications.

17. **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 dispensing of overdose reversal drugs and epinephrine, and the licensure of pharmacy interns. Additionally, some rules are required by Ohio law.

## Regulatory Flexibility

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

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

**19. 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 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.

**20. 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. Staff are trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

Additionally, to assist our licensees, including those representing small businesses, the Board developed inspection guides. These guides align with internal guidance used by Board inspectors and allow licensees to conduct self-inspections to maintain compliance. The guides also include links to the rules, important definitions, and reminders of when a licensee is required to submit notification or additional information to the Board. The guides may be accessed by visiting: www.pharmacy.ohio.gov/inspection. The Board also has a number of resources on its licensing and continuing education websites to educate our licensees.

**Rule 4729:2-2-07 - Successful completion of the Test of English as a Foreign Language, Internet-based Test. (AMEND)**

Successful completion of the "Test of English as a Foreign Language, Internet-based test" (TOEFL iBT) shall be the following minimum scores or higher:

(A) Writing: **twenty-two** ~~**twenty-four**~~;

(B) Speaking: **twenty-five** ~~**twenty-six**~~;

(C) Listening: **twenty-two** ~~**twenty-one**~~; and

(D) Reading: **twenty-one** ~~**twenty-two**~~.

**Rule 4729:2-3-04 | Dispensing of ~~naloxone~~ overdose reversal drugs by pharmacy interns. (AMEND)**

(A) A pharmacy intern under the direct supervision of a pharmacist may dispense **~~naloxone~~ an overdose reversal drugs as defined in rule 4729-8-02 of the Administrative Code** 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~~ individual** 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~~ an overdose reversal drug** pursuant to this rule shall**:**

**(1)** Instruct the individual to whom **~~naloxone~~ the overdose reversal drug** is dispensed verbally or in writing to summon emergency services as soon as practicable either before or after administering **~~naloxone~~ an overdose reversal drug; and**

**(2) Offer to counsel the patient in accordance with rule 4729:5-5-09 of the Administrative Code.**

**(C) All overdose reversal drugs dispensed pursuant to this rule shall be in packaging that contains the manufacturer's instructions for use.**

**(D) Nothing in this rule shall prohibit the sale or distribution of an overdose reversal drug by pharmacy personnel in accordance with section 3715.50 of the Revised Code.**

**~~(C) Except as provided in paragraph (D) this rule, a pharmacy intern shall provide in-person training, unless the in-person requirement is waived by the board, and written educational materials to the individual to whom naloxone is dispensed that includes 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 the naloxone dispensed;~~

~~(6) Procedures for administering the naloxone dispensed;~~

~~(7) Proper storage and expiration of the naloxone 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;~~

~~(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 trained on the use of naloxone and can meet the training requirements listed in paragraphs (B) and (C) of this rule.~~

**Rule 4729:2-3-06 | Dispensing of epinephrine ~~autoinjectors~~ by pharmacy interns. (AMEND)**

(A) A pharmacy intern under the direct supervision of a pharmacist may dispense epinephrine**, which shall be an epinephrine autoinjector or any other formulation authorized pursuant to Chapter 4729. of the Revised Code,** ~~**autoinjector**~~ without a prescription to either of the following in accordance with an approved protocol specified in paragraph (B) of rule 4729:1-3-06 of the Administrative Code:

(1) An individual who there is reason to believe is experiencing or at risk of experiencing anaphylaxis if the pharmacy affiliated with the pharmacist has a record of previously dispensing epinephrine to the individual in accordance with a prescription issued by a licensed health professional authorized to prescribe drugs;

(2) An individual acting on behalf of a qualified entity, as defined in section 3728.01 of the Revised Code.

(B)

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

(2) A pharmacy intern who dispenses an epinephrine autoinjector to an individual identified in paragraph (A) of this rule shall provide notification of the dispensing to the individual's primary care provider, if known, or to the prescriber who issued the individual the initial prescription for an epinephrine ~~**autoinjector**~~. Notification shall be conducted using one of the following methods that is capable of confirming delivery of the required notification:

(a) Electronic mail;

(b) Interoperable electronic medical records system;

(c) Facsimile;

(d) Electronic prescribing system;

(e) Electronic pharmacy record system;

(f) Documented verbal communication;

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

(C) When a pharmacy intern dispenses ~~**an**~~ epinephrine ~~**autoinjector**~~ pursuant to this rule, the pharmacy intern shall provide to the person receiving the ~~**device**~~ **medication** instruction on the proper method of administering epinephrine ~~**with the device**~~.

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

(E) This rule does not affect the authority of a pharmacy intern to contact a prescriber to obtain a new oral prescription for ~~**an**~~ epinephrine ~~**autoinjector**~~ in accordance with the applicable provisions of division 4729:5 of the Administrative Code.

**(F) As used in this rule:**

**(1) "Epinephrine" means an epinephrine autoinjector or any other formulation authorized pursuant to Chapter 4729. of the Revised Code.**

**(2) "Pharmacy affiliated with the pharmacist" as used in paragraph (A)(1) of this rule means the pharmacy that dispensed the epinephrine autoinjector or another pharmacy under common ownership of the pharmacy that dispensed the epinephrine autoinjector.**