Common Sense Initiative

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Business Impact Analysis

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

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

Naloxone TDDD Requirements

Rule Number(s): 4729:5-3-19

Date of Submission for CSI Review: 9/16/2025

Public Comment Period End Date: 10/17/2025

Rule Type/Number of Rules:

New/___ rules
No Change/____ rules (FYR? ___)
Amended/____ rules (FYR? ___)
Rescinded/__1__ rules (FYR? _N_)

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.

   Specifies the requirements for maintaining naloxone for emergency use and for distribution via an automated mechanism. This rule is being rescinded to comply with the new requirements in ORC 3715.50, which removed most Ohio Board of Pharmacy licensure requirements for locations that store overdose reversal medications (such as naloxone) for use in emergency situations and for distribution through an automated mechanism (such as a vending machine); ORC 3715.50 implemented requirements for all persons maintaining overdose reversal medications for use in emergency situations and for distribution through an automated mechanism.

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 rule is authorized by sections 4729.26, 4729.54, and 4729.55 of the Ohio 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.

No, this rule does 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)?**

The public purpose of this regulation was to meet the statutory requirements of section 4729.515 of the Revised Code (which is now rescinded) and to ensure naloxone is regularly replenished and maintained in accordance with the manufacturer's storage instructions; however, because of the new requirements in ORC 3715.50, this rule is being rescinded.

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

The success of the regulation will be measured by having compliance with ORC 3715.50.

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.

Initially, this rule was distributed to all Board stakeholders (including ODH's Project DAWN programs) and licensees for public comment. The proposed rescission of the rule was sent to stakeholders for public comment between August 29, 2025, and September 15, 2025.

Prior to filing with CSI, the rule was 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?

The Board did not receive any comments regarding the recission of this rule.

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 this rule, except the rule requires adherence to the temperature and storage standards developed by the drug's manufacturer.

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.***

This regulation is being rescinded, and all requirements will fall under ORC 3715.50 so the agency didn't consider any 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 rule to ensure that the regulation does 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.

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.

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**

Board of Pharmacy licensed facilities that seek to maintain naloxone at off-site locations for emergency use (similar to an AED) or those that operate automated distribution machines to dispense naloxone.

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 its current form it would impose an administrative sanction on a licensee. However, this is not applicable as the rule is being rescinded. Facilities will need to follow the requirements laid out in ORC 3715.50.

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).***

Not applicable—the rule is being rescinded.

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

Not applicable—this rule is being rescinded.

Regulatory Flexibility

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

The rule 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 regulation is 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 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.

Rule 4729:5-3-19 | Naloxone for emergency use and distribution via automated mechanisms. (RESCIND – DEFER BACK TO REQUIREMENTS IN ORC 3715.50)

(A) As used in this rule, "tamper-evident" means a package, storage container or other physical barrier that is sealed or secured in such a way that access to the drugs stored within is not possible without leaving visible proof that such access has been attempted or made.

(B) In accordance with section 4729.515 of the Revised Code, a terminal distributor of dangerous drugs may acquire and maintain a supply of naloxone for use in emergency situations and for distribution through an automated mechanism. The naloxone may be maintained at a location other than the location licensed as a terminal distributor of dangerous drugs.

(C) In the case of naloxone for use in emergency situations, a terminal distributor of dangerous drugs shall do all of the following:

(1) Provide written materials regarding the emergency administration of naloxone to any individual who accesses the naloxone, to include:

(a) Specific instruction to summon emergency services pursuant to division (D)(2) of section 4729.515 of the Revised Code.

(b) Procedures for administering naloxone contained within the kit, including the possible administration of multiple doses.

(c) Performing rescue breathing and the use of a face shield or other rescue breathing barrier device, which shall be provided with the naloxone.

(d) Proper method for placing an individual into the recovery position.

(2) Specify a process to be used to notify the terminal distributor that the naloxone has been accessed within a reasonable time of its being accessed, which may include any of the following:

(a) Documented checks of the emergency naloxone and its required components, to be conducted at least every thirty days, by an employee of the terminal distributor of dangerous drugs. The terminal distributor shall include a telephone number where persons can report that the emergency naloxone has been used and needs replenishment.

(b) An automated alert that notifies the terminal distributor when the emergency naloxone is accessed.

(c) Any other method approved by the board's executive director or the director's designee.

(3) Except in instances where naloxone is not commercially 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, a terminal distributor of dangerous drugs shall replace any naloxone and, if missing or used, any required components (instructions, rescue breathing barrier device, etc.) no later than forty-eight hours following notification that naloxone has been accessed in accordance with paragraph (C)(2) of this rule.

(4) Maintain the naloxone in accordance with the manufacturer's or distributor's instructions.

(a) All naloxone maintained for emergency use in accordance with this paragraph shall be sealed in a tamper-evident manner to ensure the integrity of the drug.

(b) Any naloxone that shows sign of tampering or adulteration shall be immediately removed by the terminal distributor of dangerous drugs and replaced within forty-eight hours of discovering the naloxone has been tampered with or is adulterated.

(c) A terminal distributor shall develop and implement a policy to ensure that naloxone that exceeds its manufacturer's expiration date is removed and properly disposed.

(5) A terminal distributor maintaining naloxone in accordance with this paragraph shall:

(a) Maintain a complete list that includes the address and description of the location (e.g. first floor hallway, second floor conference room, etc.) of where the terminal distributor maintains the naloxone for emergency use. The list shall be immediately available for inspection upon request of an employee of the board.

(b) Keep a record of the naloxone maintained for emergency use that includes the name, strength, dosage form, national drug code and expiration date. Records shall be readily retrievable and maintained for a period of three years.

(c) Ensure the naloxone is maintained in a container or device that is securely fastened to a permanent structure and is clearly marked to indicate naloxone is available for emergency use.

(6) The requirements of this paragraph shall not apply to a service entity that maintains naloxone for emergency administration in accordance section 4729.514 of the Revised Code.

(D) In the case of naloxone for distribution through an automated mechanism, a terminal distributor of dangerous drugs shall do all the following:

(1) Ensure the mechanism is securely fastened to a permanent structure or is of an appropriate size and weight to reasonably prevent it from being removed from its intended location.

(2) Develop a process to be used to monitor and replenish the inventory of naloxone maintained in the automated mechanism, which may include any of the following:

(a) Documented checks of the mechanism, to be conducted at least every thirty days, by an employee of the terminal distributor of dangerous drugs.

(b) An electronic system to monitor the inventory of naloxone within the mechanism.

(c) Any other method approved by the Board's executive director or the director's designee.

(3) Provide written educational materials to the person accessing the naloxone appropriate to the dosage form of naloxone distributed, including, but not limited to, all of the following:

(a) Risk factors of opioid overdose.

(b) Strategies to prevent opioid overdose.

(c) Signs of opioid overdose.

(d) Steps in responding to an overdose, including:

(i) The proper method for placing an individual into the recovery position.

(ii) Specific instruction to summon emergency services pursuant to division (D)(2) of section 4729.515 of the Revised Code.

(e) Information on naloxone.

(f) Procedures for administering naloxone.

(g) Proper storage and expiration of naloxone product distributed.

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

(i) Information, as required in paragraph (D)(4) of this rule, on where individuals may call for additional questions regarding naloxone administration. The telephone number must include the hours where an appropriately trained representative is available to answer questions.

(4) Provide a telephone number where individuals can call representatives with the requisite training necessary to answer questions regarding naloxone administration.

(5) Maintain the naloxone in accordance with the manufacturer's or distributor's instructions.

(a) Any naloxone that shows sign of tampering or adulteration shall be immediately removed by the terminal distributor of dangerous drugs.

(b) A terminal distributor shall develop and implement a policy to ensure that naloxone that exceeds its manufacturer's expiration date is removed and properly disposed.

(6) A terminal distributor maintaining naloxone in accordance with this paragraph shall:

(a) Maintain a complete list that includes the address and description of the location (e.g. first floor hallway, second floor conference room, etc.) of where the terminal distributor maintains an automated mechanism. The list shall be immediately available for inspection upon request of an employee of the board.

(b) Maintain a record of the naloxone stored within the automated mechanism that includes the name, strength, dosage form, national drug code and expiration date. Records shall be readily retrievable and maintained for a period of three years.

(7) Naloxone removed from an automated mechanism shall not be returned to the mechanism or transferred in accordance with rule 4729:5-3-09 of the Administrative Code, except if it was removed by an employee of the terminal distributor of dangerous drugs.

(E) The state board of pharmacy may grant variances from this rule in cases in which:

(1) The applicable provision is not statutorily mandated.

(2) Granting the variance would not:

(a) Be contrary to public interest; or

(b) Compromise the integrity of the drug.

(3) No party will be injured by the granting of the variance.

(F) An approval for a variance pursuant to paragraph (E) of this rule may be revocable, may be granted for a limited period or may be granted subject to the conditions as the state board of pharmacy may prescribe.