Common Sense Initiative

Mike DeWine, *Governor*
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Business Impact Analysis

Comments on the proposed rule will be accepted until close of business on October 3, 2025. Please send all comments to the following email address: rulecomments@pharmacy.ohio.gov.

In addition, please copy your comments to: CSIPublicComments@governor.ohio.gov.

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):

Manner of Issuance

Rule Number(s): 4729:5-5-15

Date of Submission for CSI Review: 9/19/2025 (REVISED 9/23/2025)

Public Comment Period End Date: 10/3/2025

Rule Type/Number of Rules:

New/___ rules	No Change/____ rules (FYR? ___)
Amended/_1___ 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 _Y_)	Rescinded/___ rules (FYR?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.

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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.

4729:5-5-15: Requires a prescriber to include a patient's weight if the patient is under the age of 18 and the drug being prescribed is dosed based upon a patient's weight. Clarifies paragraph (G) by deferring back to the statute.

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 rule is authorized by sections 4729.26 and 3719.28 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.

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.**

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, such as the Ohio Board of Pharmacy.

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 distribution of dangerous drugs.

Section 3719.28 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules for the administration and enforcement of Chapter 3719. of the Revised Code in order to prescribe the manner of keeping and the form and content of records to be kept by persons authorized to manufacture, distribute, dispense, prescribe, or administer controlled substances.

Without these regulations, the Board of Pharmacy would not be able to ensure the necessary information to treat a pediatric patient.

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 it written in plain language, licensee compliance with the rule, and minimal questions from licensees regarding the provisions of the rule.

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.

This rule package was distributed for initial public comment by posting the rule package to the Board's proposed rules website and sending a notification to all licensees via email.

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

The Board incorporated the following suggestions into the rule draft:

- Allowing any pharmacy staff to obtain the patient's weight, not just the pharmacist;
- Allows for pediatric patients to provide their own weight (ex. 16 year olds); and
- Allow for pharmacy staff who have access to an electronic medical record to access the patient's weight information and add that to the prescription.

Also, while not incorporated into the rule, the Board has also committed to a six-month implementation window to allow for any required system upgrades.

Additionally, the Board received comments that weight should be able to be reported using metric units or the imperial system. This is already feasible under the rule, as the pharmacist would simply need to convert imperial into metric to comply with the rule.

The Board also received a number of positive comments about how this would improve patient safety and could potentially save time for the pharmacist.

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?

This rule was developed in response to the Institute for Safe Medication Practices' (ISMP) 2025-2026 Targeted Medication Safety Best Practices for Community Pharmacy report. One of the best practices recommended is to obtain and use a patient's weight to verify dosing of weight-based medications. The ISMP report specifically highlights obtaining and using patient weight for pediatric dosing.

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 administration and distribution of dangerous drugs, 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 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.

The rule will be posted on the Board of Pharmacy's web site; 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 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.

Additionally, the Board has developed inspection guides that licensees can use to conduct self-inspections. 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.

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

- Pharmacies licensed as terminal distributors of dangerous drugs;
- Prescribers; and
- Pharmacists.

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 terminal distributor of dangerous drugs or pharmacist. Discipline might include reprimand, continuing education, suspension of a license, monetary fine, and/or revocation of a license.

It will also require prescribers and/or pharmacies to update or turn on electronic fields in their electronic prescribing systems to capture patient weight. This cost is variable depending on the system purchased by the prescriber or pharmacy. However, cost concerns were not raised during the early stakeholder outreach.

Lastly, pharmacies could experience a reduction in costs if there is widespread compliance with this amended rule. Pharmacists will no longer have to call prescriber offices and track down the information necessary to treat a pediatric patient.

16. Are there any proposed changes to the rules that will <u>reduce</u> 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).*

As stated previously, pharmacies could experience a reduction in costs if there is widespread compliance with this amended rule. Pharmacists will no longer have to call prescriber offices and track down the information necessary to treat a pediatric patient.

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 justifies the impact on business because the regulations are intended to protect and promote public safety. The rule ensures pharmacists have the necessary information to treat pediatric patients.

Regulatory Flexibility

18. 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.

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 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.

The Board has also developed inspection guides that licensees can use to conduct self-inspections. 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.

Rule 4729:5-5-15 | Manner of issuance of a prescription. (AMEND)

(A) A prescription, to be valid, must be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of the prescriber's professional practice. The responsibility for the proper prescribing is upon the prescriber, but a corresponding responsibility rests with the pharmacist who dispenses the prescription. An order purporting to be a prescription issued not in the usual course of bona fide treatment of a patient is not a prescription and the person knowingly dispensing such a purported prescription, as well as the person issuing it, shall be subject to the penalties of law.

(B) All outpatient prescriptions issued by a prescriber shall:

(1) Be dated as of and on the day when issued.

(2) Contain the manually printed, typewritten, or preprinted full name, professional title, and address of the prescriber. The prescriber's address shall include the physical address of the prescriber's practice location.

(3) Indicate a telephone number where the prescriber can be contacted during normal business hours.

(4) Indicate the full name and residential address of the patient; or, if the patient is an animal, the last name of the owner, name of animal (if applicable), and species of the animal or animals. The patient or owner's residential address shall include a physical street address.

(5) Indicate the drug name and strength.

(6) Indicate the quantity to dispense.

(7) Indicate the appropriate and explicit directions for use.

(8) For patients under the age of eighteen, indicate the patient's actual body weight in metric units if the dosing of the drug being prescribed is based upon a patient's weight. If not indicated on the prescription, this information may be added to the prescription by pharmacy personnel using any of the following methods:

(a) Contacting the issuing prescriber;

(b) If the pharmacy has the necessary equipment on-site, obtaining the weight of the patient;

(c) Accessing the patient's medical record, provided the patient's weight has been obtained from the patient within one month of the prescription being issued; or

(d) Contacting the patient, patient's parent, or caregiver.

(**9** ~~**8**~~) Specify the number of times or the period of time for which the prescription may be refilled. If no such authorization is given, the prescription may not be refilled except in accordance with section 4729.281 of the Revised Code.

(a) Prescriptions for non-controlled substance dangerous drugs bearing "PRN," "Ad lib," or other similar prescription refill designation permitting the pharmacist to refill the prescription as needed by the patient, shall be refilled only in keeping with the number of doses ordered and according to the directions for use, and, in no instance, shall such prescription be refilled beyond one year from the date of issue. The prescription shall not be refilled out of context with the dosage schedule indicated in the directions for use unless specifically authorized by the prescriber.

(b) Prescriptions for controlled substance dangerous drugs bearing "PRN," "Ad lib," or other similar prescription refill designation are not considered a valid refill authorization.

(**10** ~~**9**~~) Not authorize any refills for schedule II controlled substances.

(**11** ~~**10**~~) Authorize refills for schedules III and IV controlled substances only as permitted by section 3719.05 of the Revised Code.

(**12** ~~**11**~~) Not authorize a refill beyond one year from the date of issuance for schedule V controlled substances and for dangerous drugs that are not controlled substances.

(**13** ~~**12**~~) Identify the trade name or generic name of the drug(s) in a compounded prescription.

(**14** ~~**13**~~) Not be coded in such a manner that it cannot be dispensed by any pharmacy of the patient's choice.

(**15** ~~**14**~~) For a controlled substance:

(a) Indicate the drug enforcement administration registration number of the prescriber pursuant to 21 CFR 1306.05 (3/31/2010).

(b) Except for veterinarians licensed pursuant to Chapter 4741. of the Revised Code, indicate either:

(i) The ICD-10-CM medical diagnosis code of the primary disease or condition that the controlled substance is being used to treat. The code shall, at a minimum, include the first four alphanumeric characters of the ICD-10-CM medical diagnosis code, sometimes referred to as the category and the etiology (ex. M 16.5).

(ii) For dentists licensed pursuant to Chapter 4715. of the Revised Code, the Code on Dental Procedures and Nomenclature (CDT Code), as published by the American dental association, of the dental treatment requiring the controlled substance prescription.

(**16** ~~**15**~~) Except for veterinarians licensed under Chapter 4741. of the Revised Code, for all controlled substances and products containing gabapentin: indicate the prescriber's intended days' supply of the prescription.

(**17** ~~**16**~~) For a managing pharmacist acting as an agent of a physician pursuant to section 4729.39 of the Revised Code and Chapter 4729:1-6 of the Administrative Code, the prescription shall include the full name of the managing pharmacist.

(**18** ~~**17**~~) Be issued in compliance with all applicable federal and Ohio laws, rules, and regulations.

(C) Failure of a prescription to contain the requirements set forth in paragraphs (B)(~~**14**~~**15**)(b) and (B)(~~**15**~~**16**) of this rule or of the pharmacist to obtain the information set forth in paragraphs (B)(~~**14**~~ **15**)(b) and (B)(~~**15**~~**16**) of this rule shall not render the prescription, if dispensed in good faith, to be invalid.

(D) All prescriptions issued on paper to a patient by a prescriber shall be:

(1) Manually signed on the day issued by the prescriber in the same manner as the prescriber would sign a check or legal document.

(2) Issued in compliance with rule 4729:5-5-05 of the Administrative Code.

(E) When forms are used that create multiple copies of a prescription issued to a patient by a prescriber, the original prescription that includes the actual signature of the prescriber must be issued to the patient for dispensing by a pharmacist.

(F) Pursuant to section 4729.38 of the Revised Code, a pharmacist shall not select a generically equivalent drug or interchangeable biological product if either of the following applies:

(1) In the case of a written or electronic prescription, including a computer-generated prescription, the prescriber handwrites or actively causes to display on the prescription "dispense as written," "D.A.W.," "do not substitute," "brand medically necessary," or any other statement or numerical code that indicates the prescriber's intent to prevent substitution. Such a designation shall not be preprinted or stamped on the prescription, but a reminder to the prescriber of the designation procedure may be preprinted or displayed on the prescription form or electronic system the prescriber uses to issue the prescription.

(2) In the case of an oral prescription, the prescriber or the prescriber's agent specifies that the drug as prescribed is medically necessary or otherwise indicates the prescriber's intent to prevent substitution.

(G) **~~Pursuant to section 4729.40 of the Revised Code, a~~ A** pharmacist shall **comply with the requirements of section 4729.40 of the Revised Code when converting prescriptions authorizing refills. ~~not dispense a quantity or amount of drug that varies from the quantity or amount of the drug that otherwise would be dispensed unless all the conditions are met in accordance with that section and either of the following applies:~~**

~~(1) The prescriber includes "dispense as written" or another phrase having a similar meaning on the prescription. Such a designation shall not be preprinted or stamped on the prescription, but a reminder to the prescriber of the designation procedure may be preprinted or displayed on the prescription form or electronic system the prescriber uses to issue the prescription.~~

~~(2) When issuing a prescription electronically or orally, the prescriber specifies that the quantity or amount of the drug to be dispensed may not vary from the quantity or amount specified in the prescription.~~

(H) Pursuant to section 4729.382 of the Revised Code, a pharmacist shall not make the substitution of an epinephrine autoinjector if either of the following applies to the prescription:

(1) In the case of a written or electronic prescription, including a computer-generated prescription, the prescriber handwrites or actively causes to display on the prescription "dispense as written," "D.A.W.," "do not substitute," "medically necessary as prescribed," or any other statement or numerical code that indicates the prescriber's intent to prevent substitution. Such a designation shall not be preprinted or stamped on the prescription, but a reminder to the prescriber of the designation procedure may be preprinted or displayed on the prescription form or electronic system the prescriber uses to issue the prescription.

(2) In the case of an oral prescription, the prescriber specifies that the epinephrine autoinjector as prescribed is medically necessary or otherwise indicates the prescriber's intent to prevent substitution.

(I) A patient or patient's caregiver shall have the exclusive right to freedom of choice for any pharmacy to dispense prescriptions.

(J) A pharmacist may dispense a prescription from a prescriber practicing outside of Ohio, if all the following apply:

(1) The prescriber who issued the prescription would ordinarily be entitled to issue prescriptions under Ohio law and the state where the prescription was issued;

(2) The prescription meets all the requirements of this rule, including whether the prescription is for a legitimate medical purpose in accordance with paragraph (A) of this rule.

(3) The prescription is transmitted in accordance with rule 4729:5-3-11 of the Administrative Code; and

(4) For a controlled substance prescription, the prescriber holds a valid drug enforcement administration registration number in the state of origin of the prescription.