

11/9/23

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:

- 4729:5-2-05 – Notification of Accessible Services.

Comments on the proposed rule will be accepted until close of business on **November 27, 2023**. Please send all comments to the following email address: RuleComments@pharmacy.ohio.gov

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

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Business Impact Analysis

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

Rule Contact Name and Contact Information: Summer Corson
summer.corson@pharmacy.ohio.gov

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

Accessible Pharmacy Services

Rule Number(s): 4729:5-2-05

Date of Submission for CSI Review: 11/9/23

Public Comment Period End Date: 11/27/23

Rule Type/Number of Rules:

New/ 1 rules

No Change/ rules (FYR?)

Amended/ rules (FYR?)

Rescinded/ rules (FYR?)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

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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.
 - Violation of the proposed rule may result in administrative discipline against a license holder.
- c. ☒ Requires specific expenditures or the report of information as a condition of compliance.
 - The proposed rule requires every outpatient pharmacy to report information on the accessible services provided by the pharmacy.
- 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.

New:

- 4729:5-3-05 – Notification of Accessible Services. Requires every outpatient pharmacy in the state of Ohio to report to the Board the type of language translation services (for example, translated prescription labels) available for patients whose first language is not English, as well as report to
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the Board on the types of services available for patients who are hard of hearing or patients who have low vision. The outpatient pharmacy must submit this information as part of the licensure and renewal process and must also notify the Board of any change to their accessible services as listed above within thirty days of the change. The outpatient pharmacy shall be required to provide the services they report to offer to their patients upon request, unless there is a temporary software or equipment failure of the service offered.

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 includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

This rule does not specifically exceed federal requirements. Rather, this rule requires outpatient pharmacies notify the Board what services are offered, as the ADA has public requirements for accommodations in the provision of pharmacy services.

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.

Without this regulation, the Board of Pharmacy would not be able to provide Ohio patients with access to information on what accessible services are available in their area.

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

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- 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.

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?**

The Board did receive comments on this rule during the initial public comment process. The Board did amend the rule to account for software or equipment failure based upon feedback from the Ohio Council of Retail Merchants.

- 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.

- 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?**

As the regulations are essential to promoting patient safety, the State of Ohio Board of Pharmacy did not consider any regulatory alternatives.

- 13. 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. It is the Board's responsibility to ensure standards across Ohio. At this juncture, it was the determination of the Board that the rule did not

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lend itself to a performance-based regulation.

14. 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 regulations do not duplicate another State of Ohio Board of Pharmacy regulation.

15. 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 rule. 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

16. 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; and

The rule impacts the following:

- Outpatient pharmacies

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

Violation of this rule may result in administrative discipline for a Board of Pharmacy licensee. Discipline might include reprimand, denial of a license, 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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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.

An additional 3-5 minutes would be required for an employee of an outpatient pharmacy to fill out an online form describing the accessible services their pharmacy provides.

17. 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 people with disabilities covered under the ADA need services accessible to them, especially when it comes to something as important as their medications. This GAO report discusses challenges and best practices for prescription labels that could help people who are blind or visually impaired:

<https://www.gao.gov/products/gao-17-115>

Regulatory Flexibility

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

This 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 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 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. Additionally, staff are trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

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4729:5-2-05 - Notification of Accessible Services. (NEW)

(A) Every outpatient pharmacy providing pharmacy services in this state shall report to the state board of pharmacy, in a manner determined by the board, the following information on accessible services provided by the pharmacy within ninety days of the effective date of this rule:

- (1) The type of language translation services, including translated prescription labels, for patients who are of limited English proficiency;
- (2) The type of services available for patients who are hard of hearing; and
- (3) The type of services available for patients with low vision.

(B) As part of the licensure and renewal process established in rule 4729:5-2-02 of the Administrative Code, an outpatient pharmacy providing pharmacy services in this state shall submit information on the accessible services listed in paragraph (A) of this rule that are provided by the pharmacy.

(C) An outpatient pharmacy required to submit notification to the board in accordance with this rule shall notify the board within thirty days of any change in the accessible services provided by the pharmacy.

(D) Except as provided in paragraph (E) of this rule, a pharmacy that reports it offers accessible services shall be required to provide those services to patients upon request.

(E) Paragraph (D) does not apply if the pharmacy experiences a temporary software or equipment failure of the accessible service offered.