

6/22/22

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.

Amend:

- 4729:5-9-03.6: Point of care locations in an institutional facility. Clarifies that recordkeeping requirements for point of care locations apply to both controlled and non-controlled drugs.

Comments on the proposed rules will be accepted until close of business on July 11, 2022. 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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Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

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Business Impact Analysis

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

Rule Contact Name and Contact Information: Kylynne Johnson
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Regulation/Package Title (a general description of the rules' substantive content):

Point of care locations in an institutional facility.

Rule Number(s): 4729:5-9-03.6

Date of Submission for CSI Review: 6/22/22

Public Comment Period End Date: 7/11/22

Rule Type/Number of Rules:

New/ __ rules

No Change/ __ rules (FYR? __)

Amended/ 1 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Rescinded/ __ rules (FYR?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,

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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):

- Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**
 - Requires active DEA registration to store controlled substances on site. However, this is a requirement of federal law.
- 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 this rule may result in administrative licensure discipline for a terminal distributor of dangerous drugs. Discipline might include reprimand, suspension of a license, monetary fine and/or revocation of a license.
- Requires specific expenditures or the report of information as a condition of compliance.**
- 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.

Amend:

4729:5-9-03.6: Clarifies that recordkeeping requirements for point of care locations apply to both controlled and non-controlled drugs.

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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 and 3719.28 of the Ohio Revised Code. The rule is amplified by sections 3719.09, 4729.28 and 4729.51 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.

These rules do 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.

These rules exceed federal requirements because the regulation of the pharmacy profession has traditionally been done at the state level by legislatively created state boards 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 practice of pharmacy. The language will provide necessary operational clarification to reduce drug diversion and promote patient safety.

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 a rule 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.

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This rule was sent for initial public stakeholder comment to the public via the Board's website.

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 comments from its public stakeholder posting.

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 protecting the public's safety by providing operational clarification, 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 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 a performance-based regulations.

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 regulation does 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.

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Board of Pharmacy staff receive regular updates on rules via a monthly internal newsletter, regular compliance 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 package impacts the following:

- Point of care locations; and
- Institutional facilities.

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

- Violation of these rules may result in administrative discipline for a 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.

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.

- A licensee operating a point of care location may experience administrative costs (recordkeeping and developing policies/procedures) to comply with the requirements of the rule.

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 the regulation protects and promotes public safety by establishing operational clarification of point of care locations in an institutional facility.

Regulatory Flexibility

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

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

Institutional Facilities.

4729:5-9-03.6 - Point of care locations in an institutional facility. (AMEND)

(A) "Point of care location" has the same meaning as in rule [4729:5-9-01](#) of the Administrative Code.

(B) Dangerous drugs maintained at a point of care location shall be in a securely locked, substantially constructed cabinet, including an automated drug storage system, or safe to deter and detect unauthorized access.

(C) The responsible person for the point of care location shall be an employee of the institutional pharmacy that owns the drug stock and shall be responsible for all the following:

- (1) Designating those who may obtain access to the drug stock;
- (2) Determining, in conjunction with the appropriate interdisciplinary committees, the drugs that are to be included at the point of care location;
- (3) Providing controls to prevent the diversion of the drug stock;
- (4) Instituting record keeping procedures to account for drugs removed from the point of care location and for capturing the positive identification of the person who obtained the drugs from the point of care location; and
- (5) Providing procedures for the inspection of the point of care location to ensure proper utilization and replacement of the drug stock.

(D) If dangerous drugs that are controlled substances are stored at the point of care location, the owner of the drug stock shall either:

- (1) Obtain a drug enforcement administration (DEA) registration for the point of care location; or
- (2) Utilize the DEA registration of the institutional facility where the point of care location is located. The institutional facility where the point of care location is located shall be responsible for compliance with all federal and state laws, rules, and regulations relating to the possession and use of controlled substances.

(E) This rule does not apply to pharmacy-supplied contingency drugs in an institutional facility licensed as a terminal distributor of dangerous drugs.

(F) An institutional point of care location ~~that contains controlled substances~~ shall comply with the

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requirements of rules [4729:5-9-03.2](#) and [4729:5-9-03.3](#) of the Administrative Code.

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