

1/25/22

CORRECTION: A previous version of this BIA had the incorrect rule number. The rule for review is OAC 4729:5-5-08.

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:

- 4729:5-5-08 – Provides requirements for pharmacist drug utilization review in outpatient pharmacies. Adds requirement for pharmacists to query the Ohio Automated Rx Reporting System (OARRS) prior to dispensing a prescription for gabapentin.

Comments on the proposed rules will be accepted until close of business on February 9, 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

Carrie Kuruc, Director

Business Impact Analysis

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

Rule Contact Name and Contact Information: Cameron McNamee
Cameron.mcnamee@pharmacy.ohio.gov

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

Drug Utilization Review

Rule Number(s): 4729:5-5-08

Date of Submission for CSI Review: 1/25/22

Public Comment Period End Date: 2/9/22

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Rescinded/ rules (FYR?)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,

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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):

- 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 this rule may result in administrative licensure discipline for a pharmacist. Discipline might include reprimand, continuing education, suspension of a license, monetary fine and/or revocation of a license.
- 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. Adds an additional check for pharmacists dispensing gabapentin prescriptions. However, the Board has integrated OARRS into the clinical workflow of 83% of Ohio pharmacies, which should reduce compliance costs associated with the rule. Integration is offered to all Ohio pharmacies at no-cost.

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:

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- 4729:5-5-08 – Provides requirements for pharmacist drug utilization review in outpatient pharmacies. Adds requirement for pharmacists to query the Ohio Automated Rx Reporting System (OARRS) prior to dispensing a prescription for gabapentin.

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.

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. Additionally, the Board has determined that gabapentin abuse is a significant public health issue. Therefore, implementing additional checks to reduce diversion is in the interest of public health (see Appendix A) of this document for a presentation providing detailed data regarding gabapentin diversion.

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.

Additionally, the Board has determined that gabapentin abuse is a significant public health issue. Therefore, implementing additional checks to reduce diversion is in the interest of public health (see Appendix A) of this document for a presentation providing detailed data regarding gabapentin diversion.

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

The success of the 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. The Board will also utilize OARRS data to determine compliance with 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.

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 one comment on this rule during the initial public comment process. The comments were not incorporated into the rule because they suggested expanding the category of drugs that must be reviewed in OARRS.

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?

The Board utilized a number of data sources to develop the rule. Those data sources are outlined in the presentation in Appendix A of this document.

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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 regulation is essential to protecting the public's safety by ensuring uniform standards for the practice of pharmacy, 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 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, external inspection guides, 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 staff 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:

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a. Identify the scope of the impacted business community; and

The rule package impacts the following:

- Pharmacists;
- Pharmacies.

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 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.

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.

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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 regulations protect and promote public safety by ensuring uniform requirements for pharmacists dispensing gabapentin prescriptions. Additionally, the Board contends that a review of these prescriptions in OARRS may reduce the diversion of this medication.

Regulatory Flexibility

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

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These 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 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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Rule 4729:5-5-08 | Prospective drug utilization review. (AMEND)

(A) Prior to dispensing any prescription, a pharmacist shall review the patient profile for the purpose of identifying the following:

- (1) Over-utilization or under-utilization;
- (2) Therapeutic duplication;
- (3) Drug-disease state contraindications;
- (4) Drug-drug interactions;
- (5) Incorrect drug dosage;
- (6) Drug-allergy interactions;
- (7) Abuse/misuse;
- (8) Inappropriate duration of drug treatment; and
- (9) Food-nutritional supplements-drug interactions.

(B) Upon identifying any issue listed in paragraph (A) of this rule, a pharmacist, using professional judgment, shall take appropriate steps to avoid or resolve the potential problem. These steps may include, but shall not be limited to, the following:

- (1) Requesting and reviewing an OARRS report or another state's prescription drug monitoring report;
- (2) Consulting with the prescriber; or
- (3) Counseling the patient.

(C) Prospective drug utilization review shall be performed using predetermined standards consistent with, but not limited to, any of the following:

- (1) Peer-reviewed medical literature (i.e. scientific, medical, and pharmaceutical publications in which original manuscripts are rejected or published only after having been critically reviewed by unbiased independent experts);

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(2) American hospital formulary service drug information; and

(3) United States pharmacopeia drug information.

(D) Prior to dispensing an outpatient prescription for a controlled substance dangerous drug **or a drug containing gabapentin**, at a minimum, a pharmacist shall request and review an OARRS report covering at least a one year time period in any of the following circumstances:

(1) A patient adds a new or different controlled substance dangerous drug **or a drug containing gabapentin** to the patient's therapy that was not previously included;

(2) An OARRS report has not been reviewed for that patient during the preceding twelve months, as indicated in the patient profile;

(3) A prescriber is located outside the usual pharmacy geographic area;

(4) A patient is from outside the usual pharmacy geographic area;

(5) A pharmacist has reason to believe the patient has received prescriptions for controlled substance dangerous drugs **or a drug containing gabapentin** from more than one prescriber in the preceding three months, unless the prescriptions are from prescribers who practice at the same physical location;

(6) Patient is exhibiting signs of potential abuse or diversion. This includes, but is not limited to, over-utilization, early refills, appears overly sedated or intoxicated upon presenting a prescription for a controlled substance dangerous drug, or an unfamiliar patient requesting a reportable drug by specific name, street name, color, or identifying marks.

(E) In the event an OARRS report is not immediately available, the pharmacist shall use professional judgment in determining whether it is appropriate and in the patient's best interest to dispense the prescription prior to reviewing a report.

(F) A pharmacist may use a delegate licensed or registered in accordance with Chapter 4729. of the Revised Code to request an OARRS report.

(G) Based upon information obtained during a prospective drug utilization review, a pharmacist shall use professional judgment when making a determination about the legitimacy of a prescription. A pharmacist shall not dispense a prescription of doubtful, questionable, or suspicious origin.

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