



Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

Joseph Baker, Director

Comments on the proposed rules will be accepted until close of business on November 1, 2024. Please send all comments to the following email address:

RuleComments@pharmacy.ohio.gov

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

Business Impact Analysis

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

Rule Contact Name and Contact Information: Summer Reyburn

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

FYR 2024 Pharmacy Technicians

Rule Number(s): 4729:3-5-03

Date of Submission for CSI Review: 10/15/2024

Public Comment Period End Date: 11/1/2024

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

CSIPublicComments@governor.ohio.gov

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Rescinded/___ rules (FYR?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.

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.

Grants extension periods and waivers for the completion of continuing education requirements for active-duty members and their spouses. Amended to replace the director of licensing with the executive director or director's designee.

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 5903.12 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.

The regulation of the practice of pharmacy, including pharmacy technicians, 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 and distribution of dangerous drugs.

Section 4729.94 of the Ohio Revised Code requires the Board of Pharmacy to adopt rules governing registration of registered pharmacy technicians, certified pharmacy technicians, and pharmacy technician trainees.

Section 5903.12 of the Ohio Revised Code requires the Board to develop a process to grant extension periods and waivers for the completion of continuing education requirements for active-duty veteran members and their spouses.

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.

N/A.

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?

Stakeholders did not provide any comments on the proposed rules in this package.

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?
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 necessary to carry out the Board's responsibilities under ORC 5903.12.

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 it 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 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 and quarterly webinars from the Director of Policy, and feedback from the Board's legal department for every citation submitted.

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

Registered and certified pharmacy technicians who are active-duty military or spouses of active-duty members.

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.

There is no cost to submit a waiver or extension request. However, the process will require the submission of a required information that may take an estimated five minutes to complete.

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*).

N/A

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 so it can establish uniform processes to comply with ORC 5903.12.

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 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 preparation/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 4729:3-5-03 | Veteran and military family provisions related to continuing education. (AMEND)

(A) Extension of continuing education requirements.

(1) In accordance with section 5903.12 of the Revised Code, the state board of pharmacy shall grant extension periods and waivers for the completion of continuing education requirements for active duty veteran members and the spouses of active duty veterans. If a registered pharmacy technician or their spouse is called to active duty for military service, the time period allowed for completion of any continuing education requirements will be extended by the amount of time that the technician or the technician's spouse was on active duty.

(2) Upon receiving the application and proper documentation, the board's **director of licensing executive director or director's designee** shall extend the continuing education reporting period by an amount of time equal to the total number of months that the registrant or their spouse spent on active duty during the current reporting period. For purposes of this division, any portion of a month served on active duty shall be considered one full month.

(3) The registrant shall submit proper documentation certifying the active duty service and the length of that active duty service. Documentation required to obtain an extension or waiver pursuant to paragraph (A)(1) of this rule will be published on the state board of pharmacy's website: www.pharmacy.ohio.gov.

(B) Determining fulfillment of continuing education.

(1) If a registered pharmacy technician is a veteran, the state board of pharmacy shall consider relevant military education, training or service that has been completed by the registration holder no more than two years prior to the thirty first of march of the year in which a technician's registration must be renewed when determining the fulfillment of any continuing education requirements.

(2) For the board to consider relevant education, training, or service completed by a registered technician, the registrant shall submit a request for consideration and evidence or

documentation of the education, training, or service to the ~~director of licensing executive~~ **director or director's designee** at least thirty days prior to the required continuing education reporting period pursuant to rule 4729:3-5-02 of the Administrative Code.