



Common Sense Initiative

Mike DeWine, Governor
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Comments on the proposed rules will be accepted until close of business on June 24, 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 Corson
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Regulation/Package Title (a general description of the rules' substantive content):

Criteria for Pharmacist Licensure

Rule Number(s): 4729:1-2-01, 4729:1-2-02

Date of Submission for CSI Review: 6/6/2024

Public Comment Period End Date: 6/24/2024

Rule Type/Number of Rules:

New/___ rules

No Change/___ rules (FYR? ___)

Amended/ 2 rules (FYR? Y)

Rescinded/___ rules (FYR? ___)

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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.

Amend

- 4729:1-2-01 – Outlines the requirements for pharmacist licensure by examination. The rule is being amended to expand potential options for law examinations the Board will recognize for initial licensure.

- 4729:1-2-02 – Outlines the requirements for pharmacist licensure by reciprocity. The rule is being amended to expand potential options for law examinations the Board will recognize for initial licensure.

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 rules are authorized by section 4729.26 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 implements a federal requirement, but includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

N/A

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 licensure of pharmacists and the practice of pharmacy.

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/applicant compliance with the rules, and minimal questions from licensees/applicants regarding the provisions of the rules.

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.

The rules in this package were distributed for public comment to all licensees and registrants of the Board.

Prior to filing with CSI, the rules were also 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 received 6 comments from stakeholders that were generally positive, so the Board did not make changes to the draft regulation.

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.*

As the regulations are essential to protecting the public's safety by establishing licensure standards for pharmacists, 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 rules to ensure that the regulations do 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 rules will be posted on the Board of Pharmacy's web site, information concerning the rules 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 internal email updates, regular staff meetings featuring a regulatory update, mandatory all-day law reviews for new employees, 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

Applicants seeking to become pharmacist in Ohio.

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.

- 4729:1-2-01 – Pharmacy candidates that apply for the NAPLEX will pay a \$485 fee, and pharmacy candidates that apply for the MPJE will pay a \$200 fee. Candidates who need to retake these exams may have to pay additional fees.
- 4729:1-2-02 – The application to take the examinations for licensure as a pharmacist requires completing the application, which takes approximately one hour to complete. The reciprocity fee for candidates is \$337.50.

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 regulations are intended to protect and promote public safety. In particular, the rules ensure uniform regulations that allow for standards for the licensure of pharmacists and pharmacy interns.

Regulatory Flexibility

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

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 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 by pharmacists and pharmacy interns 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 are 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 4729:1-2-01 | Criteria for licensure by examination. (AMEND)

~~(A) Pursuant to sections [4729.07](#) and 4729.13 of the Revised Code, pharmacist licensure by examination shall consist of the "North American Pharmacist Licensure Examination" (NAPLEX) and the "Multistate Pharmacy Jurisprudence Examination" (MPJE) administered by the national association of boards of pharmacy (NABP).~~

(A) Pursuant to sections [4729.07](#) and 4729.13 of the Revised Code, pharmacist licensure by examination shall consist of:

(1) The "North American Pharmacist Licensure Examination" (NAPLEX) administered by the national association of boards of pharmacy (NABP); and

(2) A jurisprudence examination which shall be one of the following as determined by the board:

(a) The "Multistate Pharmacy Jurisprudence Examination" (MPJE) administered by the national association of boards of pharmacy (NABP); or

(b) A jurisprudence examination approved by the board.

(B)(1) Unless otherwise approved by the board, the minimum passing score on each examination shall be determined by NABP.

(a 1) Any candidate who fails to receive a passing score on the NAPLEX examination shall make application and remit the fee established by the state board of pharmacy for re-examination.

(b 2) Any candidate who fails to receive a passing score on the ~~MPJE~~ jurisprudence examination shall make application and remit the fee established by the state board of pharmacy for re-examination.

(B C) A candidate may use the NABP process to transfer the candidate's NAPLEX score to Ohio only after the candidate has met all of the requirements set by the board for examination and licensure in Ohio.

(C D) Pursuant to section [4729.08](#) of the Revised Code, graduates of unapproved schools or colleges of pharmacy located outside the United States who are using an approved examination to establish equivalency of their education shall:

(1) Obtain a passing score, as determined by NABP, on the "Foreign Pharmacy Graduate Equivalency Examination (FPGEE)"; and

(2) Show oral proficiency in English by successful completion of the "Test of English as a Foreign Language, Internet-based test" (TOEFL iBT) pursuant to rule [4729:1-2-04](#) of the Administrative Code.

(D E) Any examination candidate who fails to take both of the required examinations pursuant to paragraph (A) of this rule within twelve months from the date the board receives the application materials shall submit a new application for the required examination or examinations and remit the fee established by the board, as the original application shall be deemed abandoned.

(**E F**) The record of the passing score for an examination candidate who takes both of the required examinations pursuant to paragraph (A) of this rule, but successfully only completes one examination will:

(1) Be maintained up to three years if no more than twelve months has elapsed between attempts to successfully complete the remaining examination.

(2) Not be maintained if more than twelve months has elapsed between attempts to successfully complete the remaining examination. It will then be necessary for the examination candidate to repeat both examinations for Ohio licensure.

(**F G**) Any candidate who has requested to transfer their NAPLEX score to Ohio must **successfully complete** ~~take~~ the **MPJE jurisprudence examination** within twelve months from the date the candidate completed the NAPLEX examination or the score transfer will be denied.

(**G H**) Pursuant to section [4729.071](#) of the Revised Code, a candidate must submit electronic or ink fingerprint impressions for a criminal records check prior to receiving approval to take the required examinations. An examination candidate must submit fingerprint impressions no later than sixty days after the date the board receives the application materials. After sixty days, a candidate must submit a new application, the required fee, and fingerprint impressions, as the original application shall be deemed abandoned.

(**H I**) Candidates shall be limited to a total of five attempts to pass the NAPLEX and the **MPJE jurisprudence examination**. The board may grant one additional attempt to pass the NAPLEX and the **MPJE jurisprudence examination** in the event of extraordinary circumstances. A candidate that exceeds the limits set forth in this paragraph is no longer eligible to obtain licensure as a pharmacist by examination pursuant to this rule.

(**I J**) Pursuant to section [4729.16](#) of the Revised Code, a limited or restricted license may be issued to an applicant upon the determination of the board.

Rule 4729:1-2-02 | Criteria for licensure by reciprocity. (AMEND)

(A) An applicant seeking licensure as a pharmacist by reciprocity shall comply with all the following:

- (1) Be at least eighteen years of age.
- (2) Obtain a degree in pharmacy from a school of pharmacy approved by the state board of pharmacy.
- (3) Have met the applicable practical experience requirements by either:
 - (a) Successfully graduating after December 31, 2006 with a doctor of pharmacy degree (Pharm.D.) from a school of pharmacy approved by the state board of pharmacy; or
 - (b) Obtaining a total of at least one thousand seven hundred and forty hours of documented supervised practical experience in Ohio or any other state or jurisdiction in which the credentials are at least the equivalent of those required by this state at the time the experience was obtained. If the reciprocating state or jurisdiction requires less than the required hours, the board may grant internship credit for practice as a pharmacist.
- (4) Hold an active license or registration to practice pharmacy, which is in good standing, in a state or jurisdiction in which the credentials are at least the equivalent of those required by this state. Certification of these credentials shall be conducted by the national association of boards of pharmacy (NABP).

(B) An applicant who has met the requirements of the state or jurisdiction with which the applicant holds a certificate of good standing pursuant to a "Foreign Pharmacy Graduate Examination Commission (FPGEC)" certificate shall be required to establish proficiency in spoken English by providing evidence of the successful completion of the "Test of English as a Foreign Language, Internet-based test" (TOEFL iBT) pursuant to rule [4729:1-2-04](#) of the Administrative Code.

(C) Except as provided in rule [4729:1-2-09](#) of the Administrative Code, candidates who qualify for licensure by reciprocity shall successfully complete a course developed by the board **or approved by the board**, that includes a scored evaluation component, on ~~Ohio's~~ **Ohio's** law and rules governing the practice of pharmacy.

(1) Candidates who do not successfully complete this course within six months following the submission of a completed application shall file a new application and required fee for licensure by reciprocity, as the original application shall be deemed abandoned.

(2) Except as provided in paragraph (C)(3) of this rule, the board may require an applicant to complete **the jurisprudence examination as defined in rule 4729:1-2-01 of the Administrative Code the "Multistate Pharmacy Jurisprudence Examination" (MPJE)** in lieu of completing the course if the applicant has never obtained a passing score on the MPJE for any state or jurisdiction.

(3) Paragraph (C)(2) of this rule does not apply to applicant who either:

(a) Received initial licensure prior to January 1, 2018; or

(b) Successfully passed a board approved state jurisprudence examination.

(D) Pursuant to section [4729.071](#) of the Revised Code, a candidate must submit electronic or ink fingerprint impressions for a criminal records check prior to receiving an initial license to practice as a pharmacist. A reciprocity candidate must submit fingerprint impressions no later than six months after the date the board receives the application materials. After six months, a candidate must submit a new application, the required fee, and fingerprint impressions.

(E) Pursuant to division (B)(2) of section [4796.03](#) of the Revised Code, the board hereby waives the requirements set forth in division (B)(1) of section [4796.03](#) of the Revised Code.

(F) Pursuant to division (F)(3) of section [4796.03](#) of the Revised Code, the required fee for reciprocity shall be three hundred thirty-seven dollars and fifty cents and any transaction fee as required by section [125.18](#) of the Revised Code.

(G) Pursuant to section [4729.16](#) of the Revised Code, a limited or restricted license may be issued to an applicant upon the determination of the board.