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

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

FYR 2024 Probation

Rule Number(s): 4729:4-1-03, 4729:4-1-06

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

Public Comment Period End Date: 11/1/2024

Rule Type/Number of Rules:

New/___ rules **No Change/__2__ rules (FYR? _Y_)**

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 ___) **Rescinded/_____ rules (FYR?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 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.
   - 4729:4-1-03: Provides requirements to become an approved treatment provider for pharmacy professionals.
   - 4729:4-1-06: Provides requirements for approved monitoring programs.
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 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 implements a federal requirement, but includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

   This rule package exceeds federal requirements because the regulation of pharmacy professionals has traditionally been done at the state level by legislatively created state boards of pharmacy, such as the Ohio Board 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 state board of pharmacy to adopt rules governing the practice of pharmacy and distribution of dangerous drugs.

   Section 3719.28 of the Ohio Revised Code authorizes the state board of pharmacy to adopt rules to facilitate surveillance of traffic in drugs, to prevent the improper acquisition or use of controlled substances or their diversion into illicit channels.

   The rules proposed under this statutory authority are necessary to facilitate compliance with the provisions in the above referenced chapters of the Ohio Revised Code to promote the public's safety and uniformity of care throughout Ohio. Without these regulations, the

Ohio Board of Pharmacy would not be able to ensure pharmacy professionals are monitored to ensure that they are complying with required substance abuse treatment plans.

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.

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.

   Prior to filing with CSI, these rules were posted to the Board's website for public comment and 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 these rules.

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 ensuring uniform standards for the practice of pharmacy, 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 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 Communications, 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**
       Treatment providers and treatment monitors.
    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.

- 4729:4-1-03: The regulation would require the approved treatment provider to monitor and report certain infractions to the Board. Such requirements would result in administrative costs incurred by the provider.
- 4729:4-1-06: Provides requirements for approved monitoring programs. It will take an estimated 20 to 30 minutes to submit the required information to the Board of Pharmacy.

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, they ensure uniform regulations that allow for the monitoring of pharmacy professionals who suffer from substance abuse or mental illness to ensure that they comply with all requirements of their treatment plan.

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 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 4729:4-1-03 | Requirements for approved treatment providers. (NO CHANGE)

(A) An approved treatment provider, as defined in rule 4729:4-1-01 of the Administrative Code, shall meet or exceed the following requirements:

(1) Certification, as determined by the board, by the Ohio department of mental health and addiction services pursuant to Chapter 5119. of the Revised Code.

(2) Any other treatment provider approved by the board, to include:

(a) An out-of-state provider, when treatment has already been initiated or completed; or

(b) Any provider not certified in accordance with paragraph (A)(1) of this rule.

(3) Any treatment provider must be approved prior to a licensee or registrant participating in the program, unless the board finds exceptional circumstances exist, in which case the board may approve the treatment provider during or after treatment.

(B) An intervenor associated with an approved treatment provider shall:

(1) Respond to information from concerned individuals;

(2) Ascertain validity of the information received;

(3) Assess the situation and, if the licensee or registrant is showing evidence of impairment, the intervenor shall refer the individual for evaluation;

(4) If the licensee or registrant fails to comply within one week to a referral for evaluation, the intervenor must report the name of the individual to the board within one business day.

(C) A treatment assessor associated with an approved treatment provider shall evaluate a licensee or registrant referred to the approved treatment provider to determine if the licensee or registrant has a substance use disorder related impairment.

(1) If such an impairment exists, the approved treatment provider shall formulate the licensee or registrant's individualized treatment plan as defined in rule 4729:4-1-01 of the Administrative Code. The specific requirements shall be determined by an assessment of psychological, physical, developmental, family, social, environmental, recreational, and professional needs. The individualized treatment plan shall be part of a treatment contract

which the impaired licensee or registrant must sign. If the impaired licensee or registrant fails to sign the treatment contract and enter treatment within forty-eight hours of the determination that the licensee or registrant needs treatment, the approved treatment provider must report the name of the licensee or registrant to the board within one business day.

(D) The designated person for the approved treatment provider shall:

(1) Establish a system of records that will provide for complete information about an impaired licensee or registrant from intervention through the rehabilitation stage;

(2) Establish treatment contracts meeting the requirements of this division and a system of follow up to determine compliance by the impaired licensee or registrant with the treatment contract;

(3) Ensure the confidentiality of the impaired licensee or registrant, except:

(a) If the licensee or registrant fails to comply within one week to a referral for evaluation;

(b) If the impaired licensee or registrant fails to sign the contract and enter treatment within forty-eight hours of the determination that the licensee or registrant needs treatment;

(c) If the impaired licensee or registrant does not suspend practice on entering treatment;

(d) If the impaired licensee or registrant does not comply with the terms of the treatment contract;

(e) If the impaired licensee or registrant resumes practice before the approved treatment provider or monitoring program has made a clear determination that the licensee or registrant is capable of practicing;

(f) If the impaired licensee or registrant suffers a relapse at any time.

(4) Notify the state board of pharmacy within one business day if the licensee or registrant violates any provision of this rule.

Rule 4729:4-1-06 | Requirements for approved monitoring programs. (NO CHANGE)

(A) An approved monitoring program, as defined in rule 4729:4-1-01 of the Administrative Code, must be approved by the state board of pharmacy and shall meet or exceed the following requirements:

(1) Have board approved policies and procedures which shall include, but not be limited to, the following:

(a) The program's standards and procedures for care;

(b) The program's standards and training/approval process for personnel.

(2) Have personnel including, but not limited to, an intervenor and a designated person as defined in rule 4729:4-1-01 of the Administrative Code.

(B) An intervenor associated with an approved monitoring program shall:

(1) Respond to information from concerned individuals;

(2) Ascertain validity of the information received;

(3) Assess the situation and, if the licensee or registrant is showing evidence of impairment, the intervenor shall refer the individual for evaluation;

(4) If the licensee or registrant fails to comply within one week to a referral for evaluation, the intervenor must report the name of the licensee or registrant to the board within one business day.

(C) The designated person for the limited approved treatment provider shall:

(1) Ensure confidentiality of the impaired licensee or registrant, except:

(a) If the licensee or registrant fails to comply within one week to a referral for evaluation; or

(b) If the impaired licensee or registrant suffers a relapse at any time during or following rehabilitation.

(2) Notify the state board of pharmacy within one business day if the licensee or registrant violates any portion of this rule.