Common Sense Initiative

Mike DeWine, *Governor*
Jon Husted, *Lt. Governor*
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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):

Zoning Requirements

Rule Number(s): 4729:5-2-06

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

Public Comment Period End Date: 11/1/2024

Rule Type/Number of Rules:

New/__1__ rules **No Change/____ rules (FYR? ___)**

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 ___) **Rescinded/____ rules (FYR?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.
   Lists the zoning requirements and exceptions to the requirements for terminal distributors of dangerous drugs.

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.

   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.**

   This rule package exceeds federal requirements because the regulation of dangerous drugs has 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 Board of Pharmacy to adopt rules governing the practice of pharmacy.

   In addition to this section, section 3719.28 of the Ohio Revised Code authorizes the state board of pharmacy to adopt rules to prevent the improper acquisition or use of controlled substances or their diversion into illicit channels.

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 rule written in plain language, licensee compliance with the rule, 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.

   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, this rule was 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 requested that veterinarians and veterinary clinics be exempted from this rule. Additionally, dentists who travel to provide anesthesia services requested an exemption for services provided off-site. Both exemptions were added to the rule due to the unique nature of services provided. The Board also removed certain provisions that prohibited the storage of personal items within a TDDD.

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 and Board staff, the Board did not consider any 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 rule 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 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 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**

       Terminal distributors of dangerous drugs who may be operating out of a personal residence.

    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.

Licensees who cannot meet the requirements of the rule will have to relocate their businesses to a location that is properly zoned for commercial or industrial use by March 31, 2027. New licensees will not be permitted to obtain licenses for their homes unless they meet the requirements of the rule.

16. **Are there any proposed changes to the rules that will <u>reduce</u> 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 believes that the regulatory intent of the proposed rules is necessary to protect the health and safety of all Ohioans by limiting the preparation of medications within a person's home. Additionally, the Board is considering the safety of its employees having to enter private homes where drugs tend to be co-mingled with other personal items and unauthorized access to medications by persons living within the home.

Regulatory Flexibility

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

    This rule package does exempt certain small businesses (veterinarians, dental anthologists) due to the unique nature of services offered. The Board also provides additional exemption on a case-by-case basis.

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 4729:5-2-06 | Zoning Requirements for Terminal Distributors of Dangerous Drugs. (NEW)

(A) This rule does not apply to the following:

(1) A veterinarian or veterinary clinic as defined in Chapter 4729:5-20 of the Administrative Code;

(2) A dentist providing anesthesia services to treat current or prospective patients outside of the location licensed as a terminal distributor of dangerous drugs; or

(3) Any other business type as determined by the board.

(B) Except as provided in paragraph (C) of this rule, a terminal distributor of dangerous drugs shall not operate out of a location that is zoned for residential use and/or is a residence or personal dwelling.

(C) A terminal distributor of dangerous drugs may operate in a location that is a residence or personal dwelling if it meets all the following conditions:

(1) Drugs and record storage areas are maintained in either:

(a) A structure or building that is detached or separate from the residence or personal dwelling; or

(b) There is clear delineation between the licensed location and the residence or personal dwelling where the licensed location has a separate means of egress and is physically secure from the rest of the residence.

(2) A terminal distributor license shall only be issued if the location is:

(a) Owned and occupied by a prescriber or pharmacist; or

(b) Occupied by a prescriber or pharmacist pursuant to a rental agreement.

(3) The licensed location shall be in compliance with applicable building, fire, safety, and zoning statutes, local ordinances, and rules and regulations adopted by the locality in which the licensee's property is located.

(4) The licensed location shall be able to demonstrate compliance with this rule and all other requirements pursuant to Chapter 4729. of the Revised Code and all rules adopted thereunder.

(D) Locations licensed as a terminal distributor of dangerous drugs on or before the effective date of this rule shall have until March 31, 2027, to comply with the requirements of this rule.

(E) Licensees that submit a change of business description in accordance with rule 4729:5-2-03 of the Administrative Code shall comply with the requirements of this rule.