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 Prescription Drug Collection

Rule Number(s): 4729:10-1-02

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/__1__ 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 ___) **Rescinded/_____ rules (FYR?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.
   - 4729:10-1-02: Provides the requirements for approved collectors, other than law enforcement agencies, to collect unwanted and unused prescription drugs from ultimate users for disposal.

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, 3719.28, and 4729.69 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 implement a federal requirement as it incorporates federal regulations for prescription drug collection.

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 in that it specifically prohibits the disposal of medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers). These substances can be harmful and are prohibited to protect employees who collect the disposed medications.

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. Section 4729.69 of the Ohio Revised Code requires the state board of pharmacy, in collaboration with the director of mental health and addiction services and attorney general, to adopt rules regarding drug take-back

programs under which drugs are collected from the community for the purpose of destruction or disposal of the drugs. 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.

Without these regulations, the Ohio Board of Pharmacy would not be able to provide uniform drug collection and destruction procedures for entities authorized under state and federal law.

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 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, this rule was distributed for public comment and was 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?**

    Stakeholders did not provide any comments on the proposed rule 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.*

    As the regulations are essential to protecting the public's safety by ensuring uniform standards for the disposal of dangerous drugs, 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 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 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**
Pharmacies collecting prescription medications for disposal.

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.
Provides the requirements for approved collectors, other than law enforcement agencies to collect unwanted and unused prescription drugs from ultimate users for disposal. Requires collectors to be authorized by the Drug Enforcement Administration. This application takes approximately an hour to complete, and there is no cost for the application.

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 protects and promotes public safety by ensuring uniform drug destruction standards to prevent diversion.

Regulatory Flexibility

18. **Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.**
This rule package does not provide any exemptions or alternative means of compliance for small businesses when it comes to the handling or destruction of controlled substance medications. 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 collection of dangerous drugs for disposal 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 4729:10-1-02 | Authorized collectors. (NO CHANGE)

(A) An authorized collector may operate a drug collection receptacle if they meet the requirements specified in 21 CFR Part 1300, 21 CFR Part 1301, 21 CFR Part 1304, 21 CFR Part 1305, 21 CFR Part 1307 and 21 CFR Part 1317 (4/1/2018).

(B) If an authorized collector operates a drug collection receptacle for the collection of non-controlled substances only, the collector shall meet all of the requirements specified in paragraph (A) of this rule.

(C) A long-term care facility may dispose of prescription medications, including controlled substances, dangerous drugs, and over-the-counter medications on behalf of an ultimate user who resides, or has resided, at that long-term care facility pursuant to 21 CFR 1317.80 (4/1/2018).

(D) An authorized collector may operate a mail-back program if they meet the requirements specified in 21 CFR Part 1300, 21 CFR Part 1301, 21 CFR Part 1304, 21 CFR Part 1305, 21 CFR Part 1307 and 21 CFR Part 1317 (4/1/2018).

(E) If an authorized collector operates a mail-back program for the collection of non-controlled substances only, the collector shall meet all of the requirements specified in paragraph (D) of this rule.

(F) An authorized collector shall indicate on a drug collection receptacle or with written materials accompanying a mail-back package that the collection of any of the following is prohibited:

(1) Medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers); and

(2) Schedule I controlled substances.

(G) An authorized collector shall not dispose of the collector's inventory or stock of controlled substances, dangerous drugs or over-the-counter medications in a drug collection receptacle or through a mail-back program.

(H) An authorized collector shall maintain the confidentiality of the ultimate user pursuant to all applicable state and federal laws, rules, and regulations.

(I) An authorized collector shall not operate a take-back event as defined in rule 4729:10-1-01 of the Administrative Code.