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 July 26, 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
Summer.Corson@pharmacy.ohio.gov

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

License Verification

Rule Number(s): 4729:5-3-04

Date of Submission for CSI Review: 7/11/2024

Public Comment Period End Date: 7/26/2024

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 _Y__) **Rescinded/____ rules (FYR?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.

   Establishes the requirements for a terminal distributor to validate licensure (or licensure exemption) within the e-licensing system prior to conducting a sale or purchase. Makes small grammatical changes and adds requirements for terminal distributors restocking a licensed EMS vehicle.

3. **Please list the Ohio statute(s) that authorizes 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, 4729.60, 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.**

   The regulation of the practice of pharmacy, oversight of the sale of prescription drugs, and the operation of pharmacies 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 3719.28 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules prescribing the manner of keeping and the form and content of records to be kept by persons authorized to manufacture, distribute, dispense, conduct research in, prescribe, administer, or otherwise deal with controlled substances.

   Without these regulations, the Board would not be able to set uniform regulations to prevent unauthorized sales of dangerous drugs in this state.

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, the rule was reviewed and approved by the Board of Pharmacy. The Board has also heard from hospitals regarding the need to streamline the process for licensure verification for EMS.

10. **What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?**

    Stakeholders requested a streamlined process for licensure verification for providing drugs to EMS.

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 distribution 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 rule to ensure that the regulation 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

Terminal distributors of dangerous drugs who engage in occasional wholesale sales of dangerous drugs.

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.

The terminal distributor of dangerous drugs engaged in the occasional wholesale sale of dangerous drugs will be required to validate licensure using Ohio's eLicense system. The average time to confirm a licensed entity is approximately 1-2 minutes.

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 standards for the distribution of dangerous drugs. In particular, they ensure uniform regulations that allow for validation of licensure prior to the sale of dangerous drugs to prevent illegal sales and diversion.

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 4729:5-3-04 | Verification of licensure prior to sale or purchase. (AMEND)

(A) Before a terminal distributor of dangerous drugs may purchase dangerous drugs at wholesale, the terminal distributor shall query the ~~**boards**~~ **board's** online roster (available on the ~~**boards**~~ **board's** website: www.pharmacy.ohio.gov) to confirm any of the following:

(1) The seller is licensed to engage in the sale of dangerous drugs in accordance with section 4729.52 of the Revised Code; or

(2) The seller is licensed to engage in the occasional sale or distribution of dangerous drugs at wholesale in accordance with rule 4729:5-3-09 of the Administrative Code.

(B) If no documented query is conducted before a purchase is made, it shall be presumed that the purchase of dangerous drugs by the terminal distributor is in violation of section 4729.51 of the Revised Code.

If a licensed terminal distributor of dangerous drugs conducts a documented query at least annually and relies on the results of the query in purchasing dangerous drugs, the terminal distributor shall be deemed not to have violated section 4729.51 of the Revised Code in making the purchase.

(C) Before a terminal distributor of dangerous drugs may make a sale of dangerous drugs pursuant to rule 4729:5-3-09 of the Administrative Code, the terminal distributor shall query the ~~**boards**~~ **board's** online roster (available on the ~~**boards**~~ **board's** website: www.pharmacy.ohio.gov) to determine if the purchaser is licensed as either:

(1) A terminal distributor of dangerous drugs.

For a limited terminal distributor of dangerous drugs license, a terminal distributor shall also review a current version of the **licensee's** ~~**licensees**~~ drug list to ensure the purchaser is authorized to possess the drugs ordered.

(2) A distributor of dangerous drugs in accordance with division 4729:6 of the Administrative Code.

(D) Paragraph (C) of this rule does not apply when a terminal distributor sells or distributes dangerous drugs at wholesale to any of the following:

(1) A terminal distributor, manufacturer, outsourcing facility, third-party logistics provider, repackager, or wholesale distributor that is located in another state, is not engaged in the sale of dangerous drugs within this state, and is actively licensed to engage in the sale of dangerous drugs by the state in which the distributor conducts business; or

(2) Any of the exempted persons described in section 4729.541 of the Revised Code.

(3) The sale, transfer, or distribution of dangerous drugs to an EMS organization from an institutional pharmacy licensed as a terminal distributor of dangerous drugs that is owned or operated by a hospital for purposes of restocking an emergency medical services vehicle if the institutional pharmacy conducts an annual query to ensure the EMS organization is properly licensed as a terminal distributor of dangerous drugs.

(E) A terminal distributor of dangerous drugs may make a sale of a dangerous drug to any of the exempted persons described in section 4729.541 of the Revised Code in accordance with rule 4729:5-3-09 of the Administrative Code and shall ensure the purchaser meets the exemption criteria. To confirm a purchaser meets the exemption criteria, the terminal drug distributor shall comply with ~~**the**~~ **all** the following:

(1) Provide the purchaser, in a manner determined by the board, the requirements in Ohio law of when a purchaser shall hold a license as a terminal distributor of dangerous drugs;

(2) If the purchaser is a prescriber, verify the prescriber is appropriately licensed in this state to prescribe drugs or dangerous drugs or drug therapy related devices in the course of the individual's professional practice;

(3) Require the purchaser who claims an exemption to the terminal distributor of dangerous drug licensing requirement to annually attest in writing, which may include an electronic signature, that the purchaser meets the licensing exemptions in section 4729.541 of the Revised Code; and

(4) Ensure that all attestations are maintained by the terminal distributor for a period of three years following the date the attestation is signed by the purchaser.