Common Sense Initiative

Mike DeWine, *Governor*
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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):

CLIA Waived Diagnostic Testing by Pharmacy Personnel

Rule Number(s): 4729:1-3-01, 4729:2-3-05, 4729:3-3-05

Date of Submission for CSI Review: 4/8/2025

Public Comment Period End Date: 5/2/2025

Rule Type/Number of Rules:

New/___ rules
No Change/__3__ 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Rescinded/____ rules (FYR?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.

   - 4729:1-3-01: Allows a pharmacist to administer certain laboratory tests.
   - 4729:2-3-05: Allows a pharmacy intern under the direct supervision of a pharmacist to administer certain laboratory tests.
   - 4729:3-3-05: Allows a certified pharmacy technician under the direct supervision of a pharmacist to administer certain laboratory tests.

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 of the 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. However, the testing approved for administration pursuant to these rules is cleared by the US Food and Drug Administration.

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 the practice of pharmacy (including pharmacists, technicians, and interns) 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.

Without these regulations, the Board of Pharmacy would not be able to ensure uniform standards regarding the administration of certain laboratory testing at a 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 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.

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 three comments. One was supportive of the rules. The other two raised concerns regarding the ability of pharmacy personnel to perform these tests. The Board reviewed these concerns, but asserts that since such tests have been cleared by FDA for home use by patients, they can safely be administered by pharmacy personnel. Therefore, stakeholder input did not affect these regulations, as they are currently no change rules under their five-year review.

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. However, such tests have been cleared by FDA for home use by patients.

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 administering certain laboratory tests, 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, 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

- Pharmacies;
- Pharmacists;
- Pharmacy interns; and
- Certified pharmacy technicians.

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.

These rules allow a pharmacist, pharmacy intern, or certified pharmacy technician to administer certain laboratory tests. The pharmacy or facility licensed as a terminal distributor of dangerous drugs must be certified as a clinical laboratory under the Clinical Laboratory Improvement Amendments (CLIA) if it wishes to administer certain testing. CLIA waived certification fees are $150 biennially. Laboratories up for certification must also meet CLIA standards to become certified. The responsible person of the terminal distributor of dangerous drugs and the terminal distributor of dangerous drugs must take the time to ensure all staff conducting CLIA waived tests receive appropriate training to conduct safe testing. A pharmacy intern and certified pharmacy technician will only be able to administer CLIA waived tests under the direct supervision of a pharmacist.

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).***

No.

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 providing uniform regulations for the administration of certain testing by pharmacy professionals.

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. The law does not differentiate on the size of the business and therefore the regulations are 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.

Furthermore, the Board also developed external inspection guides available to all licensees to ensure compliance with our regulations.

Rule 4729:1-3-01 - Pharmacist administration of diagnostic tests. (NO CHANGE)

(A) A pharmacist may administer clinical laboratory improvement amendments (CLIA) waived diagnostic laboratory testing provided the following conditions are met:

(1) The pharmacy or facility licensed as a terminal distributor of dangerous drugs is certified by the United States department of health and human services (HHS), as a clinical laboratory through the CLIA;

(2) The pharmacy or facility licensed as a terminal distributor of dangerous drugs has obtained a CLIA certificate of waiver from HHS; and

(3) The responsible person of the terminal distributor of dangerous drugs and the terminal distributor of dangerous drugs ensures and documents that all pharmacists conducting CLIA waived tests pursuant to this rule receive appropriate training to conduct testing in a safe and effective manner.

(B) A pharmacist may evaluate the results of a test administered under this rule when advising a patient or a health care professional treating a patient if the test relates to the patient's drug therapy.

(C) This rule applies only to the administration and evaluation of laboratory testing by individuals licensed or registered in accordance with Chapter 4729. of the Revised Code.

Rule 4729:2-3-05 - Pharmacy intern administration of diagnostic tests. (NO CHANGE)

(A) A pharmacy intern under the direct supervision of a pharmacist may administer clinical laboratory improvement amendments (CLIA) waived diagnostic laboratory testing provided the following conditions are met:

(1) The pharmacy or facility licensed as a terminal distributor of dangerous drugs is certified by the United States department of health and human services (HHS), as a clinical laboratory through the CLIA;

(2) The pharmacy or facility licensed as a terminal distributor of dangerous drugs has obtained a CLIA certificate of waiver from HHS; and

(3) The responsible person of the terminal distributor of dangerous drugs and the terminal distributor of dangerous drugs shall ensure and document that all pharmacy interns conducting CLIA waived tests pursuant to this rule receive appropriate training to conduct testing in a safe and effective manner.

(B) A pharmacy intern under the direct supervision of a pharmacist may evaluate the results of a test administered under this rule when advising a patient or a health care professional treating a patient if the test relates to the patient's drug therapy.

(C) This rule applies only to the administration and evaluation of laboratory testing by individuals licensed or registered in accordance with Chapter 4729. of the Revised Code.

Rule 4729:3-3-05 - Certified pharmacy technician administration of diagnostic tests. (NO CHANGE)

(A) A certified pharmacy technician under the direct supervision of a pharmacist may administer clinical laboratory improvement amendments (CLIA) waived diagnostic laboratory testing provided the following conditions are met:

(1) The pharmacy or facility licensed as a terminal distributor of dangerous drugs is certified by the United States department of health and human services (HHS), as a clinical laboratory through the CLIA;

(2) The pharmacy or facility licensed as a terminal distributor of dangerous drugs has obtained a CLIA certificate of waiver from HHS; and

(3) The responsible person of the terminal distributor of dangerous drugs and the terminal distributor of dangerous drugs shall ensure and document that all certified pharmacy technicians conducting CLIA waived tests pursuant to this rule receive appropriate training to conduct testing in a safe and effective manner.

(B) This rule applies only to the administration and evaluation of laboratory testing by individuals licensed or registered in accordance with Chapter 4729. of the Revised Code.