Common Sense Initiative

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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):

FYR Pharmacy Technicians

Rule Number(s): 4729:3-3-01, 4729:3-5-01

Date of Submission for CSI Review: 1/12/2026

Public Comment Period End Date: 2/10/2026

Rule Type/Number of Rules:

New/___ rules

No Change/____ rules (FYR? ___)

Amended/__2__ 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Rescinded/____ rules (FYR?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.

4729:3-3-01: Establishes the activities pharmacy technician trainees may perform. Adds stocking an automated drug storage system to the list of activities.

4729:3-5-01: Definitions section for a rule chapter on registered pharmacy technician continuing education requirements. Makes small grammatical changes and updates cross references.

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 4729.94 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.

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 and the licensure of pharmacy staff have 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 4729.94 of the Ohio Revised Code requires the Board of Pharmacy to adopt rules governing the registration and scope of practice of registered pharmacy technicians, certified pharmacy technicians, and pharmacy technician trainees.

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 reviewed by the Board's Rules Review Committee. The Committee, composed of pharmacists and pharmacy technicians from a number of practice settings, is responsible for reviewing and approving rules prior to their legislatively mandated five-year review date.

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 Rules Review Committee had no comments or concerns about the changes made in these rules, so no additional amendments were made.

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 licensure and practice of pharmacy technician trainees, registered pharmacy technicians, and certified pharmacy technicians, 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 they 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

- Registered pharmacy technicians
- Certified pharmacy technicians
- Pharmacy technician trainees
- Pharmacists

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.

In general, violation of these rules may result in administrative discipline for a licensee. Discipline might include reprimand, denial of a license, suspension of a license, required coursework, monetary fine, and/or revocation of a license.

4729:3-3-01: This rule restricts the number of technician trainees that can be supervised by a pharmacist at one time. Thus, a pharmacy that has more than two technician trainees may incur additional costs to ensure another pharmacist is on-site to provide supervision. It should be noted that the expansion of the trainee's scope of practice under the rule was already authorized under a Board resolution issued during the COVID-19 pandemic.

4729:3-5-01: The rule is a definition section and should have no adverse impact.

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).***

Not Applicable.

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 protect and promote public safety by ensuring uniform licensing and training standards of pharmacy technicians.

Regulatory Flexibility

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

The 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 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 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. Additionally, staff are trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

Additionally, to assist our licensees, including those representing small businesses, the Board developed inspection guides. These guides align with internal guidance used by Board inspectors and allow licensees to conduct self-inspections to maintain compliance. The guides also include links to the rules, important definitions, and reminders of when a licensee is required to submit notification or additional information to the Board. The guides may be accessed by visiting: www.pharmacy.ohio.gov/inspection. The Board also has a number of resources on its licensing and continuing education websites to educate our licensees.

Rule 4729:3-3-01 | Pharmacy Technician Trainees. (AMEND)

(A) A pharmacy technician trainee shall wear a name tag or badge which contains the designation "Pharmacy Technician Trainee." The required designation may be added to an existing name tag or badge. The name tag or badge and the required designation shall contain lettering of a legible size.

(B) A pharmacy technician trainee may, under the direct supervision of a pharmacist, engage in the following activities at a location licensed as a terminal distributor of dangerous drugs to the extent that the activities do not require the exercise of professional judgment:

(1) Accepting new written, faxed or electronic prescription orders from a prescriber or a prescriber's agent but shall not include verbal orders;

(2) Entering information into and retrieving information from a database or patient profile;

(3) Preparing and affixing labels;

(4) Stocking dangerous drugs and retrieving those drugs from inventory;

(5) Counting and pouring dangerous drugs into containers;

(6) Placing dangerous drugs into containers prior to dispensing by a pharmacist;

(7) Non-sterile drug compounding following the completion of site-specific training pursuant to rule 4729:3-3-02 of the Administrative Code;

(8) Sterile drug compounding following the completion of a site-specific training pursuant to rule 4729:3-3-02 of the Administrative Code;

(9) Packaging and selling a dangerous drug to a patient or patient representative; ~~**and**~~

(10) Sending or receiving electronic prescriptions between pharmacies accessing the same prescription records in a centralized database or pharmacy computers linked in any other manner~~**;.**~~ **and**

(11) Stocking automated drug storage systems, floor stock, and crash carts at a location licensed as a terminal distributor of dangerous drugs if either of the following applies:

(a) The terminal distributor utilizes barcode administration for restocking the drugs and develops and implements a quality assurance program to ensure the accuracy of the personnel stocking the dangerous drugs; or

(b) For restocking automated drug storage systems only: a pharmacist verifies the final dispensing of a dangerous drug removed from the automated drug storage system.

(C) A pharmacist is not permitted to supervise more than three pharmacy technician trainees engaging in the activities pursuant to paragraph (B) of this rule at any time, unless otherwise approved by the board.

(D) The number of pharmacy technician trainees supervised by a pharmacist does not limit the number of pharmacy interns that can be supervised by a pharmacist in accordance with rule 4729:2-1-01 of the Administrative Code.

Rule 4729:3-5-01 | Continuing Education – Definitions. (AMEND)

As used in Chapter 4729:3-5 of the Administrative Code.

(A) "A.C.P.E." means the accreditation council for pharmacy education.

(B) "Continuing education unit" or "C.E.U." means ten contact hours of participation in an organized continuing pharmacy education experience presented by an approved provider.

(C) "Continuing pharmacy education" or "continuing education", as required in section 4729.12 of the Revised Code, means post-registration pharmacy education undertaken to maintain professional competency to practice as a pharmacy technician, improve professional skills, and preserve uniform qualifications for continuing the practice of the profession for the purpose of protecting public health and welfare. Continuing pharmacy education may be obtained from any of the following providers:

(1) A pharmacy jurisprudence program pursuant to paragraph (**~~D~~E**) of this rule;

(2) An approved in-state provider of volunteer healthcare services in accordance with section 4745.04 of the Revised Code and **~~agency 4729~~Chapter 4729-6** of the Administrative Code;

(3) An A.C.P.E. accredited continuing education provider.

(D) "One-third of a licensee's continuing education requirement" as used in division (C) of section 4745.04 of the Revised Code and paragraph (C) of rule 4729:3-5-02 of the Administrative Code, means the total number of required C.E.U.s for licensure renewal divided by three and rounded down to the nearest whole number.

(E) "Pharmacy jurisprudence" means continuing education the includes any of the following:

(1) An A.C.P.E. law program as identified by A.C.P.E numbering convention "03";

(2) A board of pharmacy approved continuing education program provided by an in-state approved jurisprudence provider pursuant to **~~agency 4729~~Chapter 4729-6** of the Administrative Code that pertains to current or recent changes to laws, rules, and regulations relating to the practice of pharmacy; or

(3) A program presented by the state board of pharmacy that pertains to current or recent changes to laws, rules, and regulations relating to the practice of pharmacy.

(F) "Patient or medication safety" means an A.C.P.E. continuing education program identified by the A.C.P.E. numbering convention "05" that ~~**deals with**~~ **pertains to** the prevention of healthcare errors and the elimination or mitigation of patient injury caused by healthcare errors.

(G) "Veteran" means anyone who is serving or has served under honorable conditions in any component of the armed forces, including the national guard and reserve.