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):

Electronic Product Verification

Rule Number(s): 4729:5-3-25

Date of Submission for CSI Review: 2/4/2026 (REVISED 2/5/2026)

Public Comment Period End Date: 2/20/2026

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 __) **Rescinded/____ rules (FYR?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

Specifies the procedure for conducting electronic product verification by a pharmacist. Includes training, technology, and other personnel requirements to ensure the practice can be conducted safely.

REVISED 2/5/2026: Replaced the "remote prescription dispensing" with "electronic product verification" in paragraph (B).

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 4729.285 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.

The 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 the practice of pharmacy 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 4729.285 of the Ohio Revised Code prohibits a pharmacist from using telehealth mechanisms or other virtual means to perform any of the actions involved in dispensing the dangerous drug unless the action is authorized by section 4729.554 of the Revised Code or by the state board of pharmacy through rules it adopts under section 4743.09 of the Revised Code.

Without these regulations, the Board would not be able to provide uniform procedures electronic product verification by pharmacists.

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 a rule written in plain language, licensee compliance with the rule, and minimal questions from licensees regarding the provisions of the rule.

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 rule in this package was put out for stakeholder comment on 12/8/25, with comments due on 1/15/2026. 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?

Commenters varied on the pixel requirements with some stating the image resolution is too high, while others argue it should be lower. The Board did not adjust the 300-pixel minimum because it mirrors the same standard for remote dispensing pharmacies.

Other commenters requested regular QA and to bar the use of quotas for these systems. There are already existing rules to address quotas, and the rule requires regular quality assurance testing. One hospital requested the addition of the National Drug Code (NDC). The rule was amended to require an image of NDC/GTIN, serial/lot number, and expiration date.

Some commenters questioned the need for assessments on how the systems operate. The Board contends that the use of such new technology should necessitate regular trainings to ensure patient safety.

One commenter requested the ability to have technicians perform electronic product verification. Ohio law does not permit a pharmacy technician to engage in such activities and limits dispensing to pharmacists and, with some limited exceptions, pharmacy interns.

The Board also modified the rule to have the images of the dispensed prescriptions be stored in a system that is readily retrievable rather than in the patient profile. This provides flexibility of where the images are storage but ensures the Board can investigate any errors or other system issues.

There were also concerns raised about the use of employee vs. contracted pharmacists. The Board amended to the rule to require the pharmacist conducting electronic product verification to be an employee or contractor of the pharmacy.

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 regulation is essential to protecting the public's safety by ensuring uniform standards for the practice of pharmacy using technology, 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 internal communications, 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

Terminal distributors of dangerous drugs that utilize electronic product verification.

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 this rule may result in administrative discipline for a Board of Pharmacy licensee. Discipline might include reprimand, denial of a license, suspension of a license, monetary fine, and/or revocation of a license.

This rule also requires the adoption of technology necessary to meet the standards in the rule. The costs associated with this rule will depend on how widely utilized the technology is by the pharmacy (e.g., moving to all EPV, or EPV for some products, etc.). Additional administrative burdens on pharmacies adopting this technology include the annual staff training requirements, pharmacist time to validate and conduct quality assurance, and ensuring proper record keeping.

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).*

No.

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 practice of pharmacy, including the use of electronic product verification. Furthermore, this rule is required by ORC 4729.285 to authorize this practice.

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 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 laws and rules.

Rule 4729:5-3-25 | Electronic product verification. (NEW)

(A) As used in this rule:

(1) "Electronic product verification" or “electronic verification” means the non-physical dispensation (“final check”) of a drug by a pharmacist using an electronic verification system to verify the accuracy of the final contents, or components in accordance with paragraph (F) of this rule, of the prepared drug or device and affixed label prior to dispensing. Electronic final verification does not include the following:

(a) Operation of a remote dispensing pharmacy pursuant to Chapter 4729:5-18 of the Administrative Code;

(b) The practice of remote outpatient prescription processing pursuant to rule 4729:5-5-20 of the Administrative Code;

(c) The practice of remote medication order processing pursuant to rule 4729:5-9-02.14 of the Administrative Code;

(d) The practice of personally furnishing by a prescriber pursuant to division 4729:5 of the Administrative Code; or

(e) The dispensation of a drug or device from an automated pharmacy system pursuant to rule 4729:5-3-17 of the Administrative Code.

(2) “Electronic verification system” means a system that complies with the requirements set forth in this rule.

(B) For a pharmacist to engage in electronic product verification, the pharmacist shall:

(1) Be licensed as a pharmacist in this state;

(2) Physically practice in a pharmacy licensed as a terminal distributor of dangerous drugs that is located in this state where the electronic product verification is being conducted;

(3) Complete the required training and competency evaluations in paragraph (G) of this rule; and

(4) Be a current or contracted employee of the pharmacy operating the electronic verification system.

(C) An electronic verification system shall allow the pharmacist to see an exact, clear, and unobstructed visual images of the drugs or devices dispensed and the label affixed to the container.

The system shall, at a minimum, have high-definition image resolution with variable viewing options to accurately and safely dispense a dangerous drug or drug device and sufficient data retention capabilities to investigate any quality-related events.

(1) The system shall use barcoding technology to ensure the accuracy of prescriptions or orders verified in accordance with this rule. Barcodes shall be scanned, and not manually typed, into the system. The board may waive or modify the barcode technology requirements listed in this paragraph if the electronic verification system can provide an alternative method to ensure the accuracy of prescriptions or orders dispensed in accordance with this rule.

(2) The system shall produce images that are high definition with image resolution of at least 300 pixels per inch and in full color.

(3) If multiple units are being dispensed, the pharmacist must be able to see and verify an image or images of each unit and each individual affixed label.

(4) The images shall contain the following to ensure the pharmacist is able to appropriately verify the prescription prior to dispensing.

(a) A clear image of the prescription label affixed to the medication or device;

(b) The full quantity of the filled prescription;

(c) Except as provided in paragraph (C)(5) of this rule, the medication stock bottle or container and label of a drug that has been returned to stock in accordance with rule 4729:5-5-22 of the Administrative Code used to fill the prescription, if applicable;

(d) Clear markings present on the drug (tablets, capsules, etc.), if applicable; and

(e) A clear image of the drug's national drug code (NDC) number or global trade item number (GTIN), serial number, lot number, and expiration date, if not otherwise captured or maintained in the pharmacy system.

(5) The board may waive or modify the requirements listed in paragraph (C)(4)(c) of this rule if the electronic verification system can provide an alternative method that accurately captures information from the medication stock bottle and/or container and label of a drug that has been returned to stock in accordance with rule 4729:5-5-22 of the Administrative Code.

(6) The system shall use stock images of the correct drug being dispensed, including markings, if applicable.

(7) Images associated with the verification and dispensing of a prescription or order shall be retained in a secure and readily retrievable format and maintained for one year from the date of verification.

(8) Use of an electronic verification system shall be terminated if the system is not properly functioning. Prior to resuming the use of the system, the pharmacy shall identify the root cause or causes of the malfunction and shall validate that the system is properly functioning. The pharmacy shall maintain documentation of the root cause or causes of the malfunction for a period of three years in a readily retrievable format.

(9) The electronic verification system shall be capable of clearly communicating that the pharmacist has verified the drug or device prior to distribution.

(10) Prior to dispensing, a pharmacist shall review and authorize overrides performed by a pharmacy technician or pharmacy intern of any technologically generated errors, warnings, alerts, or exceptions related to system functionality or verification/accuracy. Documentation of the pharmacist's review and authorization must be captured using electronic positive identification and maintained for three years from the date of review in a readily retrievable format.

(11) A pharmacist shall not be required to conduct electronic product verification if, in the pharmacist’s professional judgement, the system, personnel, or processes employed by the pharmacy present a danger to the health and safety of patients.

(D) All electronic product verifications shall be documented using an electronic form of positive identification in accordance with rule 4729:5-5-04 or rule 4729:5-9-02.3 of the Administrative Code.

(E) No further manipulation of the prescription or order shall occur after the pharmacist's electronic verification is complete other than applying the required container lid or seal. Manipulation does not include preparing a finished prescription/medication order for mailing, delivery, or storage.

(F) Except as provided for in this paragraph, a pharmacist shall not conduct electronic product verification of compounded drug preparations.

(1) All electronic product verification of compounded drug preparation shall comply with the requirements of this rule.

(2) Only components used for compounded drug preparations may be verified by a pharmacist using an electronic verification system.

(3) Reconstituted drugs may be used or manipulated for compounding after the pharmacist completes electronic verification.

(4) At the completion of the compounding process and prior to release or dispensation, the compounded drug preparation shall be visually inspected by a pharmacist in person to determine whether the physical appearance of the drug is as expected (e.g., free of inappropriate visible particulates or other foreign matter, discoloration, or other defects) and that the container closure integrity is in compliance with all applicable United States Pharmacopeia chapters referenced in rule 4729:7-1-01 of the Administrative Code. A pharmacist shall document this verification using positive identification.

(G) All pharmacy personnel utilizing electronic product verification must be trained and competent to perform the duties assigned and have a documented initial and annual assessment of competency using the pharmacy's electronic verification system.

(H) An electronic verification system shall be implemented and validated by an Ohio-licensed pharmacist prior to initial use to ensure proper functioning. The system shall be revalidated by an Ohio-licensed pharmacist in accordance with the pharmacy's policies and procedures at least once every six months.

(1) Proof of compliance with validation/revalidation requirements shall be documented by an Ohio-licensed pharmacist and maintained in a readily retrievable format for three years from the date of validation or revalidation.

(2) The records shall document the positive identification of the pharmacist performing the required validation, date(s) performed, and the results of the validation.

(I) Pharmacies using an electronic verification system as authorized by this rule shall maintain an ongoing and documented quality assurance system that monitors the performance of the electronic verification system to ensure proper and accurate functioning in accordance with rule 4729:5-3-22 of the Administrative Code. The quality assurance system shall also include procedures for reporting system malfunctions.

(J) Pharmacies utilizing an electronic verification system pursuant to this rule shall maintain and implement written policies and procedures governing all aspects of electronic verification activities. Such policies and procedures shall be maintained in a readily retrievable format and shall include, but are not limited to, the following:

(1) Staff training and competency assessments;

(2) Operation of the quality assurance system, including reporting, investigating and addressing errors, system malfunctions, and other quality assurance issues;

(3) Validation and revalidation of electronic verification technology to ensure proper functioning; and

(4) System maintenance, including any routine or preventive maintenance.

(K) Pharmacies using an electronic verification system shall comply with all applicable record keeping requirements pursuant to rule 4729:5-5-04 or rule 4729:5-9-02.3 of the Administrative Code.