



Common Sense Initiative

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Business Impact Analysis

Agency, Board, or Commission Name: State of Ohio Board of Pharmacy

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

Continuous Quality Improvement and Duty to Report

Rule Number(s): 4729:1-4-01, 4729:1-4-02, 4729:2-4-01, 4729:2-4-02, 4729:3-4-01, 4729:3-4-02, 4729:5-3-22, 4729:5-4-02

Date of Submission for CSI Review: 2/8/2024

Public Comment Period End Date: 3/1/2024

Rule Type/Number of Rules:

New/ 5 rules

No Change/ rules (FYR?)

Amended/ 3 rules (FYR? Y)

Rescinded/ 3 rules (FYR? Y)

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.

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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.

Amend:

- 4729:1-4-01 – Establishes the scope of disciplinary actions the Board of Pharmacy may impose on a pharmacist.
- 4729:2-4-01 – Establishes the scope of disciplinary actions the Board of Pharmacy may impose on pharmacy interns.
- 4729:3-4-01 – Establishes the Board of Pharmacy's authority to impose disciplinary actions on a pharmacy technician trainee, registered pharmacy technician or certified pharmacy technicians.

New:

- 4729:5-3-22 – Requires a pharmacy to develop a continuous quality improvement program in response to an error in dispensing.
- 4729:1-4-02 – Establishes the requirements for when and how pharmacists should notify the Board of Pharmacy of violations of Ohio laws and rules. Rescinds original rule.
- 4729:2-4-02 – Establishes the requirements for when and how pharmacy interns should notify the Board of Pharmacy of violations of Ohio laws and rules. Rescinds original rule.

- 4729:3-4-02 – Establishes the requirements for a pharmacy technician trainee, registered pharmacy technician or certified pharmacy technician to report a violation to the Board of Pharmacy. Rescinds original rule.
- 4729:5-4-02 – Requires terminal distributors of dangerous drugs to report errors in dispensing as well as employees who have resigned or been terminated by the pharmacy recklessness, unprofessional conduct, errors in dispensing, and issues related to substance use disorder or a mental health condition.

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, 3719.28, and 4729. of the Ohio Revised Code. Additionally, section 4729.10 of the Ohio Revised Code authorizes the Board to adopt rules requiring a licensee or registrant under Chapter 4729 to report to the Board a violation of state or federal law, including any rule adopted under this chapter.

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 distribution of dangerous drugs has traditionally been done at the state level by legislatively created state boards of pharmacy (ORC 4729). Additionally, section 4729.10 of the Ohio Revised Code authorizes the Board to adopt rules requiring a licensee or registrant under Chapter 4729 to report to the Board a violation of state or federal law, including any rule adopted under this chapter.

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)?

The regulations are necessary to:

- Strengthen regulations aimed at improving medication safety by requiring pharmacies to have a continuous quality improvement program for errors in dispensing.
- Require reporting by licensees of violations of Ohio laws and rules.
- Requires the reporting of errors in dispensing by a pharmacy that resulted in any of the following:
 - Initial or prolonged hospitalization and temporary patient harm.

- Permanent patient harm.
- A near-death event (e.g., anaphylaxis, cardiac arrest).
- Patient death.
- Exempts pharmacy personnel from disciplinary action related to an error in dispensing unless the individual engaged in reckless behavior.
- Encourages licensees and registrants to seek treatment by not penalizing them for voluntarily seeking treatment for a mental health condition or substance use disorder.

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 Board issued these rules for public comments on two separate occasions prior to filing with CSI. All licensees and pharmacy stakeholder organizations (OPA, Ohio Hospital Association, OSHP) were engaged to provide feedback on this rule package.

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

Stakeholder input that was incorporated into the rule included:

- Redefining what a prescription error is and providing specific examples in the rule.
- Permitting third parties to conduct quality assurance reviews for dispensing errors.
- Providing exceptions for contacting a patient who had a prescription error if the patient informed the pharmacy of the error.

- Limiting disciplinary action to reckless behavior for pharmacy personnel who are responsible for an error in dispensing.

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?

The Board did not use scientific data to develop the rule. However, it did rely on concept called “[Just Culture](#),” which recognizes that errors can occur and that such errors should be learning opportunities.

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 error reporting and the reporting of violation of Ohio law, the State of 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 State of 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 staff are trained to educate licensees on current and/or new regulations during on-site inspections. Furthermore, the Board plans to develop guidance materials prior to the final filing of the rule to ensure pharmacies and pharmacy personnel are aware of their responsibilities.

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.

- Pharmacists
- Pharmacy Interns
- Pharmacy Technicians
- Pharmacies licensed as terminal distributor of dangerous drugs

b. Quantify and identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance, etc.).

Amend:

- 4729:1-4-01 – Establishes the scope of disciplinary actions the Board of Pharmacy may impose on a pharmacist. The adverse impact of this rule applies to a pharmacist who violates Ohio laws and rules. Discipline might include reprimand, denial of a license, suspension of a license, monetary fine (\$500) and/or revocation of a license.
- 4729:2-4-01 – Establishes the scope of disciplinary actions the Board of Pharmacy may impose on pharmacy interns. The adverse impact of this rule applies to a pharmacy intern who violates Ohio laws and rules. Discipline might include reprimand, denial of a license, suspension of a license, monetary fine (\$500) and/or revocation of a license.
- 4729:3-4-01 – Establishes the Board of Pharmacy's authority to impose disciplinary actions on a pharmacy technician trainee, registered pharmacy technician or certified pharmacy technicians. The adverse impact of this rule applies to a pharmacy technician who violates Ohio laws and rules. Discipline might include reprimand, denial of a license, suspension of a license, monetary fine (\$500) and/or revocation of a license.

New:

- 4729:5-3-22 – Requires a pharmacy to develop a continuous quality improvement program in response to an error in dispensing. The costs of implementing this rule depend on the number of errors made by each pharmacy and the systems they've developed to prevent errors. Additional costs for implementing this rule are

- notification requirements if an error is discovered and the staff time to conduct an error review. Such time is dependent on the complexity and severity of the error. Additionally, failure to comply with the requirements of this rule may result in disciplinary action by the Board including reprimand, denial of a license, suspension of a license, monetary fine (\$1,000) and/or revocation of a license.
- 4729:1-4-02 – Establishes the requirements for when and how pharmacists should notify the Board of Pharmacy of violations of Ohio laws and rules. Requires proactive reporting by a pharmacist. The Board estimates that the notification requirements will take anywhere between 15-30 minutes to complete. Additionally, failure to comply with the requirements of this rule may result in disciplinary action by the Board including reprimand, denial of a license, suspension of a license, monetary fine (\$500) and/or revocation of a license.
 - 4729:2-4-02 – Establishes the requirements for when and how pharmacy interns should notify the Board of Pharmacy of violations of Ohio laws and rules. The Board estimates that the notification requirements will take anywhere between 15-30 minutes to complete. Additionally, failure to comply with the requirements of this rule may result in disciplinary action by the Board including reprimand, denial of a license, suspension of a license, monetary fine (\$500) and/or revocation of a license.
 - 4729:3-4-02 – Establishes the requirements for a pharmacy technician trainee, registered pharmacy technician or certified pharmacy technician to report a violation to the Board of Pharmacy. The Board estimates that the notification requirements will take anywhere between 15-30 minutes to complete. Additionally, failure to comply with the requirements of this rule may result in disciplinary action by the Board including reprimand, denial of a license, suspension of a license, monetary fine (\$500) and/or revocation of a license.
 - 4729:5-4-02 – Requires terminal distributors of dangerous drugs to report errors in dispensing as well as employees who have resigned or been terminated by the pharmacy recklessness, unprofessional conduct, errors in dispensing, and issues related to substance use disorder or a mental health condition. The Board estimates that the notification requirements will take anywhere between 15-30 minutes to complete. Additionally, failure to comply with the requirements of this rule may result in disciplinary action by the Board including reprimand, denial of a license, suspension of a license, monetary fine (\$1,000) and/or revocation of a license.

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*).

For the pharmacist, pharmacy intern, and pharmacy technician duty to report rules, the Board removed the requirement to self-report voluntarily treatment for mental health or a substance use disorder.

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 standards for the reporting of violations of Ohio laws and rules and responding to and reporting errors in dispensing.

Regulatory Flexibility

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

These 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 regulation is uniform across Ohio. The Board will provide an implementation window as well as guidance documents to ensure compliance.

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 State of Ohio Board of Pharmacy does not fine licensees or impose penalties for first-time paperwork violations. However, any failure to meet the Board's reporting standards 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.

The Board will also develop guidance documents on the implementation of the rules and will incorporate these changes into our [external inspection guides](#) available to all licensees.

4729:5-3-22 - Continuous Quality Improvement Programs in Pharmacy Services. (NEW)

(A) As used in this rule, “dispensing error” or “error in dispensing” means one or more of the following discovered after the dispensation (e.g., final verification) by the pharmacist or verification in accordance with rule 4729:5-3-17 of the Administrative Code, regardless of whether the patient received the drug:

(1) Variation from the prescriber's prescription or drug order, unless otherwise modified by the pharmacist in accordance with agency 4729 of the Administrative Code, including:

- (a) Incorrect drug;
- (b) Incorrect drug strength;
- (c) Incorrect dosage form;
- (d) Incorrect quantity;
- (e) Incorrect patient; or
- (f) Inadequate or incorrect packaging, labeling, or directions.

(2) Failure to exercise professional judgment in identifying and managing:

- (a) Known therapeutic duplication;
 - (b) Known drug-disease contraindications;
 - (c) Known drug-drug interactions;
 - (d) Incorrect drug dosage or duration of drug treatment;
 - (e) Known drug-allergy interactions;
 - (f) Any product quality issue attributed to a compounded drug preparation;
 - (g) A clinically significant, avoidable delay in therapy; or
 - (h) Any other significant, actual, or potential problem with a patient's drug therapy related to the practice of pharmacy.
- (3) Sale of a drug to the incorrect patient.
- (4) Variation in bulk repackaging or filling of automated devices, including:

(a) Incorrect drug;

(b) Incorrect drug strength;

(c) Incorrect dosage form; or

(d) Inadequate or incorrect packaging or labeling.

(B) A “dispensing error” or “error in dispensing,” as defined in paragraph (A) of this rule, may be considered a violation of division (A)(2) of section [3715.52](#) and section [3715.64](#) of the Revised Code.

(C) Each pharmacy licensed as a terminal distributor of dangerous drugs shall establish or participate in an established quality assurance program that documents and assesses dispensing errors to determine cause and an appropriate response to improve the quality of pharmacy service and prevent errors.

(D) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy to be made immediately available to an agent, inspector, or employee of the board.

(E) When a pharmacy determines or has been notified that a dispensing error has occurred, a representative of the terminal distributor of dangerous drugs shall as soon as possible:

(1) Communicate to the patient or the patient's caregiver the fact that an error in dispensing has occurred, and the steps required to avoid harm or mitigate the error.

(2) Communicate to the prescriber the fact that an error in dispensing has occurred only if the error could result in potential or actual patient harm.

(3) The communication requirement of this paragraph shall only apply when a patient receives a drug that was the result of a dispensing error.

(4) The pharmacy shall maintain documentation that the communications requirements of this rule were completed. Such documentation shall be maintained for three years from the date of creation in a readily retrievable manner.

(F) If a pharmacy is notified of a dispensing error by the patient, the patient's caregiver, or a prescriber, a representative of the terminal distributor of dangerous drugs is not required to communicate with that individual as required in paragraph (E) of this rule.

(G) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent errors in dispensing. An investigation of each error in dispensing shall commence as soon as is reasonably possible. All errors in dispensing discovered shall be subject to a quality assurance review within thirty days of identifying an error.

(F)

(1) The primary purpose of the quality assurance review (e.g., root cause analysis) shall be to advance error prevention by analyzing investigative and other pertinent data collected in response to an error in dispensing and to assess the cause and any contributing factors such as system or process failures or recklessness on the part of pharmacy staff. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:

(a) The date, location, and participants in the quality assurance review;

(b) The pertinent data and other information relating to the dispensing error(s) reviewed and documentation of any patient contact required;

(c) The findings and determinations generated by the quality assurance review; and

(d) Recommend changes to pharmacy policy, procedure, systems, or processes, if any.

(2) If applicable, a quality assurance review may be conducted by a quality assurance committee established in accordance with section 2305.24 of the Revised Code.

(H) In accordance with section 4729.23 of the Revised Code, the record of the quality assurance review, as established in paragraph (G) of this rule, shall be maintained for three years from the date of creation in a readily retrievable manner.

(I) The terminal distributor of dangerous drugs shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance review.

(J) Nothing in this section shall be construed to prevent a pharmacy from contracting or otherwise arranging for the provision of personnel or other resources, by a third party or administrative offices, with such skill or expertise as the pharmacy believes to be necessary to satisfy the requirements of this rule.

(K) The pharmacy shall comply with the reporting requirements for dispensing errors pursuant to rule 4729:5-4-02 of the Administrative Code.

Rule 4729:1-4-02 | Duty to report. (PHARMACISTS) (RESCIND ORIGINAL / NEW)

(A) As used in this rule, "error in dispensing" or "dispensing error" has the same meaning as 4729:5-3-22 of the Administrative Code.

(B) Pursuant to section [4729.10](#) of the Revised Code, a pharmacist who has knowledge, from direct observation or objective evidence, of violations described in paragraph (C) of this rule shall report such conduct to the state board of pharmacy.

(C) The following shall be reported to the board no later than ten days from discovery:

(1) Except as provided in paragraphs (C)(1)(a) and (C)(1)(b) of this rule, conduct indicating an individual licensed or registered by the board is addicted to or is suspected to be abusing alcohol, drugs or other chemical substances or impaired physically or mentally to such a degree as to render the individual unfit to carry out their professional duties.

(a) A pharmacist shall not be required to report in accordance with this rule if the pharmacist becomes aware of any condition described in paragraph (C)(1) of this rule as a result of either:

(i) The pharmacist's treatment of the individual for the condition; or

(ii) The pharmacist having access to the individual's protected health information.

(b) A pharmacist shall not be required to report in accordance with this rule if the individual voluntarily seeks treatment for a mental health condition or substance use disorder and there are no other violations of rule or law.

(2) Except as provided in paragraph (H) of this rule, violations, attempts to violate, or aiding and abetting in the violation of any of the provisions of Chapters 4729., 4752., 3715., 3719., 3796., 2925., and 2913. of the Revised Code, or any rule adopted by the board under those provisions, by an individual or entity licensed or registered by the board.

(3) Conduct by a pharmacy technician trainee, registered pharmacy technician, certified pharmacy technician, pharmacy intern or pharmacist that constitutes unprofessional conduct or dishonesty as defined in rule [4729:1-4-01](#) of the Administrative Code.

(D)

(1) Pursuant to section [4729.23](#) of the Revised Code, the identity of the pharmacist making a report in accordance with this rule shall remain confidential.

(2) Notwithstanding the confidentiality provided in accordance with paragraph (D)(1) of this rule, a pharmacist may be required to testify in a disciplinary proceeding as to the conduct or

violations listed in paragraph (C) of this rule without disclosing the pharmacist was the reporting individual.

(E) Reporting required in accordance with this rule shall be made by mail, using the board's online complaint form (available on the board's web site: www.pharmacy.ohio.gov), or by telephone and shall include the following information:

- (1) The name of the licensee, registrant or other individual who may have committed a violation listed in paragraph (C) of this rule;
- (2) The violation which is believed to have occurred; and
- (3) The date(s) of and place(s) of occurrence(s), if known.

(F) A licensed pharmacist shall notify the board of any of the following:

- (1) Any criminal conviction for, judicial finding of guilt of, or plea of guilty to a disqualifying offense within ten days after the date of conviction.
- (2) The pharmacist is convicted of, plead guilty to, is subject to a judicial finding of eligibility for intervention in lieu of conviction in this state under section [2951.041](#) of the Revised Code or the equivalent thereof in another jurisdiction within ten days after the individual is deemed eligible.
- (3) The pharmacist is granted entry into a diversion program, deferred prosecution program, or the equivalent thereof within ten days after the individual is granted entry into a program.
- (4) Any arrest for a felony within ten days after the arrest.

(G) A pharmacist shall notify the board of any disciplinary licensing or registration action taken by another state against the licensee within ten days of the notice action. This includes, but is not limited to, a disciplinary action that is stayed pending appeal.

(H) A dispensing error, as defined in rule 4729:5-3-22 of the Administrative Code, shall only be reported to the board by a pharmacy in accordance with rule 4729:5-4-02 of the Administrative Code.

(I) Pursuant to section [4729.10](#) of the Revised Code, in the absence of fraud or bad faith, a person who reports in accordance with this rule or testifies in any adjudication conducted under Chapter 119. of the Revised Code is not liable to any person for damages in a civil action as a result of the report or testimony.

Rule 4729:2-4-02 | Duty to report. (PHARMACY INTERNS) (RESCIND ORIGINAL / NEW)

(A) As used in this rule, "error in dispensing" or "dispensing error" has the same meaning as 4729:5-3-22 of the Administrative Code.

(B) Pursuant to section [4729.10](#) of the Revised Code, a pharmacy intern who has knowledge, from direct observation or objective evidence, of violations described in paragraph (C) of this rule shall report such conduct to the state board of pharmacy.

(C) The following shall be reported to the board no later than ten days from discovery:

(1) Except as provided in paragraphs (C)(1)(a) and (C)(1)(b) of this rule, conduct indicating an individual licensed or registered by the board is addicted to or is suspected to be abusing alcohol, drugs or other chemical substances or impaired physically or mentally to such a degree as to render the individual unfit to carry out their professional duties.

(a) A pharmacy intern shall not be required to report in accordance with this rule if the intern becomes aware of any condition described in paragraph (C)(1) of this rule as a result of either:

(i) The intern's treatment of the individual for the condition; or

(ii) The intern having access to the individual's protected health information.

(b) A pharmacy intern shall not be required to report in accordance with this rule if the individual voluntarily seeks treatment for a mental health condition or substance use disorder and there are no other violations of rule or law.

(2) Except as provided in paragraph (H) of this rule, violations, attempts to violate, or aiding and abetting in the violation of any of the provisions of Chapters 4729., 3715., 3719., 2925., and 2913. of the Revised Code, or any rule adopted by the board under those provisions, by an individual licensed or registered by the board.

(3) Conduct by a pharmacy technician trainee, registered pharmacy technician, certified pharmacy technician, pharmacy intern or pharmacist that constitutes unprofessional conduct or dishonesty as defined in rule [4729:2-4-01](#) of the Administrative Code.

(D)

(1) Pursuant to section [4729.23](#) of the Revised Code, the identity of the pharmacy intern making a report in accordance with this rule shall remain confidential.

(2) Notwithstanding the confidentiality provided in accordance with paragraph (D) (1) of this rule, a pharmacy intern may be required to testify in a disciplinary proceeding as to the conduct or violations listed in paragraph (C) of this rule without disclosing the intern was the reporting individual.

(E) Reporting required in accordance this rule shall be made by mail, using the board's online complaint form (available on the board's web site: www.pharmacy.ohio.gov), or by telephone and shall include the following information:

(1) The name of the licensee, registrant or other individual who may have committed a violation listed in paragraph (C) of this rule;

(2) The violation which is believed to have occurred; and

(3) The date(s) of and place(s) of occurrence(s), if known.

(F) A licensed pharmacy intern shall notify the board of any of the following:

(1) Any criminal conviction for, judicial finding of guilt of, or plea of guilty to a disqualifying offense within ten days after the date of conviction.

(2) The intern is convicted of, plead guilty to, is subject to a judicial finding of eligibility for intervention in lieu of conviction in this state under section [2951.041](#) of the Revised Code or the equivalent thereof in another jurisdiction within ten days after the individual is deemed eligible.

(3) The intern is granted entry into a diversion program, deferred prosecution program, or the equivalent thereof within ten days after the individual is granted entry into a program.

(4) Any arrest for a felony within ten days after the arrest.

(G) A pharmacy intern shall notify the board of any disciplinary licensing or registration action taken by another state against the licensee within ten days of the notice action. This includes, but is not limited to, a disciplinary action that is stayed pending appeal.

(H) A dispensing error, as defined in rule 4729:5-3-22 of the Administrative Code, shall only be reported to the board by a pharmacy in accordance with rule 4729:5-4-02 of the Administrative Code.

(I) Pursuant to section [4729.10](#) of the Revised Code, in the absence of fraud or bad faith, a person who reports in accordance with this rule or testifies in any adjudication conducted under Chapter 119. of the Revised Code is not liable to any person for damages in a civil action as a result of the report or testimony.

Rule 4729:3-4-02 | Duty to report. (PHARMACY TECHNICIANS) (RESCIND ORIGINAL / NEW)

(A) As used in this rule, "error in dispensing" or "dispensing error" has the same meaning as 4729:5-3-22 of the Administrative Code.

(B) Pursuant to section [4729.10](#) of the Revised Code, a pharmacy technician trainee, registered pharmacy technician or certified pharmacy technician who has knowledge, from direct observation or objective evidence, of violations described in paragraph (C) of this rule shall report such conduct to the board.

(C) The following shall be reported to the board no later than ten days from discovery:

(1) Except as provided in paragraph (C)(1)(a) of this rule, conduct indicating an individual licensed or registered by the board is addicted to or is suspected to be abusing alcohol, drugs or other chemical substances or impaired physically or mentally to such a degree as to render the individual unfit to carry out their professional duties.

(a) A registrant shall not be required to report in accordance with this rule if the registrant becomes aware of any condition described in paragraph (C)(1) of this rule as a result of either:

(i) The registrant or licensee is involved in the treatment of the individual for the condition; or

(ii) The registrant or licensee having access to the individual's protected health information.

(b) A registrant shall not be required to report in accordance with this rule if the individual voluntarily seeks treatment for a mental health condition or substance use disorder and there are no other violations of rule or law.

(2) Except as provided in paragraph (H) of this rule, violations, attempts to violate, or aiding and abetting in the violation of any of the provisions of Chapters 4729., 3715., 3719., 2925., and 2913. of the Revised Code, or any rule adopted by the board under those provisions, by an individual licensed or registered by the board.

(3) Conduct by a pharmacy technician trainee, registered pharmacy technician, certified pharmacy technician, pharmacy intern or pharmacist that constitutes unprofessional conduct or dishonesty as defined in rule [4729:3-4-01](#) of the Administrative Code.

(D)

(1) Pursuant to section [4729.23](#) of the Revised Code, the identity of the registrant making a report in accordance with this rule shall remain confidential.

(2) Notwithstanding the confidentiality provided in accordance with paragraph (D)(1) of this rule, a registrant may be required to testify in a disciplinary proceeding as to the conduct or violations listed in paragraph (C) of this rule without disclosing the registrant was the reporting individual.

(E) Reporting required in accordance with paragraph (C) this rule shall be made by mail, using the board's online complaint form (available on the board's web site: www.pharmacy.ohio.gov), or by telephone and shall include the following information:

(1) The name of the licensee or registrant or other individual who may have committed a violation listed in paragraph (C) of this rule;

(2) The violation which is believed to have occurred; and

(3) The date(s) of and place(s) of occurrence(s), if known.

(F) An individual registered pursuant to this division shall notify the board of any of the following:

(1) Any criminal conviction for, judicial finding of guilt of, or plea of guilty to a disqualifying offense within ten days after the date of conviction.

(2) The registrant is convicted of, plead guilty to, is subject to a judicial finding of eligibility for intervention in lieu of conviction in this state under section [2951.041](#) of the Revised Code or the equivalent thereof in another jurisdiction within ten days after the individual is deemed eligible.

(3) The registrant is granted entry into a diversion program, deferred prosecution program, or the equivalent thereof within ten days after the individual is granted entry into a program.

(4) Any arrest for a felony within ten days after the arrest.

(5) For a certified pharmacy technician, failure to maintain a current pharmacy technician certification from an organization that has been recognized by the board.

(G) An individual registered pursuant to this division shall notify the board of any disciplinary licensing or registration action taken by another state against the registrant within ten days of the notice of action. This includes, but is not limited to, a disciplinary action that is stayed pending appeal.

(H) A dispensing error, as defined in rule 4729:5-3-22 of the Administrative Code, shall only be reported to the board by a pharmacy in accordance with rule 4729:5-4-02 of the Administrative Code.

(I) Pursuant to section [4729.10](#) of the Revised Code, in the absence of fraud or bad faith, a person who reports in accordance with this rule or testifies in any adjudication conducted under Chapter 119. of the Revised Code is not liable to any person for damages in a civil action as a result of the report or testimony.

Rule 4729:5-4-02 | Duty to Report. (PHARMACIES) (NEW)

(A) As used in this rule:

(1) "Dishonesty" means any action by a licensee, registrant or applicant to include, but is not limited to, making any statement that deceives, misrepresents or misleads, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in the practice of pharmacy or in the operation or conduct of a pharmacy.

(2) "Dispensing error" or "error in dispensing" has the same meaning as 4729:5-3-22 of the Administrative Code.

(3) "Reckless behavior" means a person who acts recklessly or who is reckless. A person acts recklessly when, with heedless indifference to the consequences, the person disregards a substantial and unjustifiable risk that the person's conduct is likely to cause a certain result or is likely to be of a certain nature. A person is reckless with respect to circumstances when, with heedless indifference to the consequences, the person disregards a substantial and unjustifiable risk that such circumstances are likely to exist.

(4) "Unprofessional conduct" means conduct that is detrimental to the best interests of the public, including conduct that endangers the health, safety or welfare of a patient or client. Such conduct shall include, but not be limited to, the following acts: coercion, intimidation, harassment, sexual harassment, improper use of private health information, threats, degradation of character, indecent or obscene conduct, and theft.

(B) A pharmacy licensed as a terminal distributor of dangerous drugs shall be required to report, from direct observation or objective evidence, the following to the board in accordance with paragraph (C) of this rule:

(1) Any error in dispensing when the error is the result of reckless behavior.

(2) Any error in dispensing where the error results in any of the following per the National Coordinating Council for Medication Error Reporting and Prevention Medication Error Index (Revised 2/20/2001):

(a) Category F: An error occurred that resulted in initial or prolonged hospitalization and caused temporary patient harm.

(b) Category G: An error occurred that resulted in permanent patient harm.

(c) Category H: An error occurred that resulted in a near-death event (e.g., anaphylaxis, cardiac arrest).

(d) Category I: An error occurred that resulted in patient death.

(3) The termination or resignation of employment of any individual licensed or registered by the board that was based, in whole or in part, on an error or errors in dispensing.

(4) The termination or resignation of employment of any individual licensed or registered by the board that was based, in whole or in part, on engaging in unprofessional conduct, dishonesty, or reckless behavior.

(5) The termination or resignation of employment of any individual licensed or registered by the board that was based, in whole or in part, on the individual being addicted to or suspected of abusing alcohol, drugs or other chemical substances or impaired physically or mentally to such a degree as to render the individual unfit to carry out their professional duties.

(C) Reporting required in accordance with this rule shall be made by mail, using the board's online complaint form (available on the board's website: www.pharmacy.ohio.gov), **or telephone** and shall include the following information:

(1) The name of the employer and the employer's terminal distributor license number;

(2) The full name and license or registration number of the licensee or registrant for which a report is being made;

(3) If applicable, an explanation of the error in dispensing that occurred, including details regarding any patient harm;

(4) If applicable, an explanation of the circumstances that resulted in the individual's termination or resignation from employment; and

(5) The date(s) of and place(s) of occurrence(s), if known.

(D) All required reporting shall be submitted to the board no later than:

(1) For an error in dispensing pursuant to paragraphs (B)(1) through (B)(3) of this rule, ten days from the date the quality assurance program review in accordance with rule 4729:5-3-22 was completed; and

(2) For the termination or resignation of an employee pursuant to paragraphs (B)(4) and (B)(5) of this rule, ten days from the date the individual is terminated or resigns from employment.

(E) Notwithstanding any provision of agency 4729 of the Administrative Code, a pharmacist, pharmacy intern, certified pharmacy technician, registered pharmacy technician, or pharmacy technician trainee shall not be required to make a report to the board pursuant to the applicable

duty to report rules in divisions 4729:1, 4729:2, and 4729:3 of the Administrative Code if the licensee or registrant is employed by or under contract with a pharmacy licensed as a terminal distributor of dangerous drugs and the terminal distributor submits a report in accordance with paragraph (B) of this rule.

Rule 4729:1-4-01 | Disciplinary actions. (AMEND) [Pharmacists]

(A) As used in this rule:

(1) "Dishonesty" means any action by a licensee, registrant or applicant to include, but is not limited to, making any statement that deceives, misrepresents or misleads, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in the practice of pharmacy or in the operation or conduct of a pharmacy.

(2) "Unprofessional conduct" has the same meaning as defined in division (C) of section 4729.16 of the Revised Code and shall also include conduct that is detrimental to the best interests of the public, including conduct that endangers the health, safety or welfare of a patient or client. Such conduct shall include, but not be limited to, the following acts: coercion, intimidation, harassment, sexual harassment, improper use of private health information, threats, degradation of character, indecent or obscene conduct, and theft.

(3) "Reckless behavior" means a person who acts recklessly or who is reckless. A person acts recklessly when, with heedless indifference to the consequences, the person disregards a substantial and unjustifiable risk that the person's conduct is likely to cause a certain result or is likely to be of a certain nature. A person is reckless with respect to circumstances when, with heedless indifference to the consequences, the person disregards a substantial and unjustifiable risk that such circumstances are likely to exist.

(B)

(1) The state board of pharmacy, after notice and hearing in accordance with Chapter 119. of the Revised Code, may impose any one or more of the following sanctions on a pharmacist or applicant for a pharmacist license if the board finds the individual engaged in any of the conduct set forth in paragraph (B)(2) of this rule:

(a) Revoke, suspend, restrict, limit, or refuse to grant or renew a license;

(b) Reprimand or place the license holder on probation;

(c) Impose a monetary penalty or forfeiture not to exceed in severity any fine designated under the Revised Code for a similar offense, or in the case of a violation of a section of the Revised Code that does not bear a penalty, a monetary penalty or forfeiture of not more than five hundred dollars.

(2) The board may impose the sanctions listed in paragraph (B)(1) of this rule if the board finds a pharmacist or applicant for a pharmacist license:

(a) Has a criminal conviction for, judicial finding of guilt of, or plea of guilty to a disqualifying offense.

(b) Engaged in dishonesty or unprofessional conduct in the practice of pharmacy.

- (c) Is addicted to or abusing alcohol or drugs or is impaired physically or mentally to such a degree as to render the pharmacist unfit to practice pharmacy.
- (d) **Except as provided for in paragraph (B)(2)(r) of this rule,** violated, conspired to violate, attempted to violate, or aided and abetted the violation of any of the provisions of Chapter 4729. of the Revised Code, sections 3715.52 to 3715.72 of the Revised Code, Chapter 2925., 3796., 3719. or 4752. of the Revised Code, or any rule adopted by the board under those provisions.
- (e) Permitted someone other than a pharmacist or pharmacy intern to practice pharmacy.
- (f) Knowingly lent the pharmacist's name to an illegal practitioner of pharmacy or had a professional connection with an illegal practitioner of pharmacy.
- (g) Divided or agreed to divide remuneration made in the practice of pharmacy with any other individual, including, but not limited to, any licensed health professional authorized to prescribe drugs or any owner, manager, or employee of a health care facility, residential care facility, or nursing home.
- (h) Violated the terms of a consult agreement entered into pursuant to section 4729.39 of the Revised Code.
- (i) Committed fraud, misrepresentation, or deception in applying for or securing a license issued by the board under this chapter or under Chapter 3796., 3715., 3719., or 4752. of the Revised Code.
- (j) Failed to comply with an order of the board or a settlement agreement.
- (k) Violated any state or federal law, regulation, or rule regardless of the jurisdiction in which the acts were committed, except for minor traffic violations such as parking violations, speeding tickets and violations such as failure to obey a red light, failure to use a turn signal or expired vehicle registration.
- (l) Has been disciplined by the state board of pharmacy pursuant to section 4729.16 of the Revised Code.
- (m) Has been the subject of any of the following by the drug enforcement administration or licensing agency of any state or jurisdiction:
- (i) A disciplinary action that resulted in the suspension, probation, surrender or revocation of the person's license or registration.
- (ii) A disciplinary action that was based, in whole or in part, on the person's inappropriate prescribing, dispensing, diverting, administering, storing, securing, personally furnishing, compounding, supplying or selling a controlled substance or other dangerous drug.
- (n) Failed to conform to prevailing standards of care of similar pharmacists under the same or similar circumstances, whether or not actual injury to a patient is established.

(o) Has been subject to any of the following:

(i) A finding by a court of the person's eligibility for intervention in lieu of conviction; or

(ii) A finding by a court of the person's eligibility for treatment or intervention in lieu of conviction in another jurisdiction.

(p) Has been granted entry into a diversion program, deferred prosecution program, or the equivalent thereof.

(q) Cannot practice according to acceptable and prevailing standards of care by reason of mental illness or physical illness, including, but not limited to, physical deterioration that adversely affects cognitive, motor, or perceptive skills.

(r) Is responsible for any of the following but only as a result of reckless behavior:

(i) An error in dispensing as defined in rule 4729:5-3-22 of the Administrative Code;

(ii) A product quality issue for any compounded drug preparation as defined in rule 4729:7-2-03 of the Administrative Code.

Rule 4729:2-4-01 | Disciplinary actions. (AMEND) [Pharmacy Interns]

(A) As used in this rule:

(1) "Dishonesty" means any action by a licensee, registrant, or applicant to include, but is not limited to, making any statement that deceives, misrepresents or misleads, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in the practice of pharmacy or in the operation or conduct of a pharmacy.

(2) "Unprofessional conduct" has the same meaning as defined in division (C) of section [4729.16](#) of the Revised Code and shall also include conduct that is detrimental to the best interests of the public, including conduct that endangers the health, safety or welfare of a patient or client. Such conduct shall include, but not be limited to, the following acts: coercion, intimidation, harassment, sexual harassment, improper use of private health information, threats, degradation of character, indecent or obscene conduct, and theft.

(3) "Reckless behavior" means a person who acts recklessly or who is reckless. A person acts recklessly when, with heedless indifference to the consequences, the person disregards a substantial and unjustifiable risk that the person's conduct is likely to cause a certain result or is likely to be of a certain nature. A person is reckless with respect to circumstances when, with heedless indifference to the consequences, the person disregards a substantial and unjustifiable risk that such circumstances are likely to exist.

(B)

(1) The state board of pharmacy, after notice and hearing in accordance with Chapter 119. of the Revised Code, may impose any one or more of the following sanctions on a pharmacy intern or applicant for a pharmacy intern license if the board finds the individual engaged in any of the conduct set forth in paragraph (B)(2) of this rule:

(a) Revoke, suspend, restrict, limit, or refuse to grant or renew a license;

(b) Reprimand or place the license holder on probation;

(c) Impose a monetary penalty or forfeiture not to exceed in severity any fine designated under the Revised Code for a similar offense, or in the case of a violation of a section of the Revised Code that does not bear a penalty, a monetary penalty or forfeiture of not more than five hundred dollars.

(2) The board may impose the sanctions listed in paragraph (B)(1) of this rule if the board finds a pharmacy intern or applicant for a pharmacy intern license:

(a) Has a criminal conviction for, judicial finding of guilt of, or plea of guilty to a disqualifying offense.

(b) Engaged in dishonesty or unprofessional conduct in the practice of pharmacy.

- (c) Is addicted to or abusing alcohol or drugs or is impaired physically or mentally to such a degree as to render the pharmacy intern unfit to practice pharmacy.
- (d) **Except as provided for in paragraph (B)(2)(p) of this rule,** violated, conspired to violate, attempted to violate, or aided and abetted the violation of any of the provisions of Chapter 4729. of the Revised Code, sections [3715.52](#) to [3715.72](#) of the Revised Code, Chapter 2925., 3796., 3719. or 4752. of the Revised Code, or any rule adopted by the board under those provisions.
- (e) Knowingly lent the pharmacy intern's name to an illegal practitioner of pharmacy or had a professional connection with an illegal practitioner of pharmacy.
- (f) Divided or agreed to divide remuneration made in the practice of pharmacy with any other individual, including, but not limited to, any licensed health professional authorized to prescribe drugs or any owner, manager, or employee of a health care facility, residential care facility, or nursing home.
- (g) Committed fraud, misrepresentation, or deception in applying for or securing a license issued by the board under this chapter or under Chapter 3796., 3715., 3719. or 4752. of the Revised Code.
- (h) Failed to comply with an order of the board or a settlement agreement.
- (i) Violated any state or federal law, regulation, or rule regardless of the jurisdiction in which the acts were committed, except for minor traffic violations such as parking violations, speeding tickets and violations such as failure to obey a red light, failure to use a turn signal or expired vehicle registration.
- (j) Has been disciplined by the state board of pharmacy pursuant to section [4729.16](#) of the Revised Code.
- (k) Has been the subject of any of the following by the drug enforcement administration or licensing agency of any state or jurisdiction:
- (i) A disciplinary action that resulted in the suspension, probation, surrender or revocation of the person's license or registration.
- (ii) A disciplinary action that was based, in whole or in part, on the person's inappropriate prescribing, dispensing, diverting, administering, storing, securing, personally furnishing, compounding, supplying, or selling a controlled substance or other dangerous drug.
- (l) Failed to conform to prevailing standards of care of similar pharmacy interns under the same or similar circumstances, whether or not actual injury to a patient is established.
- (m) Has been subject to any of the following:
- (i) A finding by a court of the person's eligibility for intervention in lieu of conviction; or

- (ii) A finding by a court of the person's eligibility for treatment or intervention in lieu of conviction in another jurisdiction.
- (n) Has been granted entry into a diversion program, deferred prosecution program, or the equivalent thereof.
- (o) Cannot practice according to acceptable and prevailing standards of care by reason of mental illness or physical illness, including, but not limited to, physical deterioration that adversely affects cognitive, motor, or perceptive skills.

(p) Is responsible for any of the following but only as a result of reckless behavior:

(i) An error in dispensing as defined in rule 4729:5-3-22 of the Administrative Code;

(ii) A product quality issue for any compounded drug preparation as defined in rule 4729:7-2-03 of the Administrative Code.

Rule 4729:3-4-01 | Disciplinary actions. (AMEND) [Pharmacy Technicians]

(A) As used in this rule:

(1) "Dishonesty" means any action by a licensee, registrant, or applicant to include, but is not limited to, making any statement that deceives, misrepresents, or misleads, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in the practice of pharmacy or in the operation or conduct of a pharmacy.

(2) "Unprofessional conduct" means conduct that is detrimental to the best interests of the public, including conduct that endangers the health, safety or welfare of a patient or client. Such conduct shall include, but not be limited to, the following acts: coercion, intimidation, harassment, sexual harassment, improper use of private health information, threats, degradation of character, indecent or obscene conduct, and theft.

(3) "Reckless behavior" means a person who acts recklessly or who is reckless. A person acts recklessly when, with heedless indifference to the consequences, the person disregards a substantial and unjustifiable risk that the person's conduct is likely to cause a certain result or is likely to be of a certain nature. A person is reckless with respect to circumstances when, with heedless indifference to the consequences, the person disregards a substantial and unjustifiable risk that such circumstances are likely to exist.

(B) The state board of pharmacy, after notice and hearing in accordance with Chapter 119. of the Revised Code, may impose one or more of the following sanctions on a pharmacy technician trainee, registered pharmacy technician, certified pharmacy technician or applicant for such registration if the board finds the individual engaged in any of the conduct set forth in paragraph (C) of this rule:

(1) Revoke, suspend, restrict, limit, or refuse to grant or renew a registration;

(2) Reprimand or place the holder of the registration on probation;

(3) Impose a monetary penalty or forfeiture not to exceed in severity any fine designated under the Revised Code for a similar offense, or in the case of a violation of a section of the Revised Code that does not bear a penalty, a monetary penalty or forfeiture as specified in section [4729.96](#) of the Revised Code.

(C) The board may impose the sanctions listed in paragraph (B) of this rule if the board finds a pharmacy technician trainee, registered pharmacy technician, certified pharmacy technician or applicant for such registration:

(1) **Except as provided in paragraph (C)(9) of this rule,** has engaged in any of the conduct specified in division (A)(2) of section [4729.96](#) of the Revised Code.

- (2) Violated any state or federal law or rule regardless of the jurisdiction in which the acts were committed, except for minor traffic violations such as parking violations, speeding tickets and violations such as failure to obey a red light, failure to use a turn signal or expired registration.
- (3) Has been disciplined by the state board of pharmacy pursuant to section [4729.96](#) of the Revised Code.
- (4) Has been the subject of any of the following by the drug enforcement administration or licensing agency of any state or jurisdiction:
- (a) A disciplinary action that resulted in the suspension, probation, surrender or revocation of the person's license or registration.
- (b) A disciplinary action that was based, in whole or in part, on the person's inappropriate prescribing, dispensing, diverting, administering, storing, securing, personally furnishing, compounding, supplying or selling a controlled substance or other dangerous drug.
- (5) Has been subject to any of the following:
- (a) A finding by a court of the person's eligibility for intervention in lieu of conviction; or
- (b) A finding by a court of the person's eligibility for treatment or intervention in lieu of conviction in another jurisdiction.
- (6) Has been granted entry into a diversion program, deferred prosecution program, or the equivalent thereof.
- (7) Cannot conduct authorized activities according to acceptable and prevailing standards of care by reason of mental illness or physical illness, including, but not limited to, physical deterioration that adversely affects cognitive, motor, or perceptive skills.
- (8) Engaged in dishonesty or unprofessional conduct.
- (9) Is responsible for any of the following but only as a result of reckless behavior:**
- (a) An error in dispensing as defined in rule 4729:5-3-22 of the Administrative Code;**
- (b) A product quality issue for any compounded drug preparation as defined in rule 4729:7-2-03 of the Administrative Code.**
- (D) The board may require that an individual whose registration has been suspended may not be employed by or work in a facility licensed by the state board of pharmacy to possess or distribute dangerous drugs during such period of suspension.**