Pharmacy Continuous Quality Improvement Programs for Dispensing Errors

Updated 2/27/2025

Effective March 1, 2025, rule 4729:5-3-22 of the Administrative Code requires any pharmacy licensed as a terminal distributor of dangerous drugs to implement a continuous quality improvement program for pharmacy services.

For questions regarding the rule, please review the frequently asked questions in this document. If you need additional information, the most expedient way to have your questions answered will be to e-mail the Board office by visiting: http://www.pharmacy.ohio.gov/contact.aspx.

Frequently Asked Questions

Q1) Does this apply to all pharmacies licensed as a terminal distributor of dangerous drugs?

A1) Yes. This applies to all **Ohio** pharmacies licensed as terminal distributors of dangerous drugs. It does not apply to terminal distributors that are not pharmacies (for example, prescriber clinics, veterinarian office, EMS, or opioid treatment programs). Additionally, it does not apply to pharmacies where pharmacists are not engaged in the dispensation of drugs (e.g., MTM or consulting pharmacies).

NOTE: This rule does not apply to non-resident pharmacies (e.g., out-of-state pharmacies).

REMINDER: "Dispense" means the final association (sometimes referred to as the "final check") of a drug with a particular patient pursuant to a prescription, medication order, or other lawful order of a prescriber and the professional judgment of and the responsibility for interpreting, preparing, compounding, labeling, and packaging a specific drug (OAC 4729:5-5-01 (B) & 4729:5-9-01 (F)).

Q2) How does the Board define a dispensing error or error in dispensing?

A2) The rule defines a dispensing error or error in dispensing to mean one or more of the following discovered ***AFTER*** dispensation (e.g., final verification) by a pharmacist:

- **Any 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 patient; or (e) Inadequate or incorrect packaging, labeling, or directions.

- **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.

- **Sale of a drug to the incorrect patient (e.g., that patient leaves the pharmacy with the incorrect medication).**

- **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.

IMPORTANT:

- A dispensing error does not include the delivery of an incorrect drug to a patient by a pharmacy delivery agent as defined in rule 4729:5-5-22 of the Administrative Code (e.g., a courier delivers to the wrong house).

- Nothing in this rule prohibits a pharmacy from implementing a quality assurance program for medication errors (ex., near misses) that are identified *prior* to the dispensation of a drug by a pharmacist.

Q3) What are the requirements of the rule as it relates to a quality assurance program?

A3) The rule requires that each pharmacy 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.

Specifically, the rule requires all of the following:

1. Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy to be made readily retrievable (e.g., can be produced within 3 business days upon request of an agent, inspector, or employee of the Board).

2. The quality assurance program shall include necessary documentation, internal reporting, and assessment of dispensing errors to determine the cause and an appropriate response to prevent future dispensing errors.

3. All records of the quality assurance program for each pharmacy shall be maintained for three years from the date of creation in a readily retrievable manner.

IMPORTANT CONFIDENTIALITY PROTECTIONS: Any record reviewed by the Board related to a quality assurance program shall be deemed for inspection or investigation purposes and is subject to confidentiality protections under Ohio law (ORC 4729.23). Therefore, nothing reviewed upon a routine inspection will be subject to public disclosure under Ohio public records laws.

REMINDER: The quality assurance review may be conducted by a quality assurance committee established in accordance with section 2305.24 of the Ohio Revised Code.

Q4) How often must quality assurance program policies and procedures be reviewed and updated?

A4) There is no set timeframe for reviewing and updating the quality assurance policies and procedures. Rather, it is the expectation of the Board that reviews will be conducted as needed to meet the requirements of the rule.

Q5) If a pharmacy determines a dispensing error has occurred, what are the requirements under the rule?

A5) The rule requires a representative of pharmacy to do the following:

- **Patient/Caregiver Notification:** Communicate* to the patient or patient's caregiver the fact that an error in dispensing has occurred, and the steps required to avoid harm or mitigate the error.

- **Prescriber Notification:** Communicate* to the prescriber the fact that an error in dispensing has occurred.
- **Notification Documentation:** 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.

***IMPORTANT:** The communication requirements listed above only apply if a patient receives the drug that was the result of a dispensing error **and** the error poses harm to the patient. The rule defines harm as any of the following: impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom.

Additionally, if the pharmacy is notified of the error by the patient, patient's caregiver, or prescriber, a representative of the pharmacy is not required to comply with the notification requirements for that individual. For example, if a patient notifies the pharmacy, the pharmacy is not required to notify the patient (or patient's caregiver) but is still required to notify the prescriber if it meets the criteria listed above (e.g., patient received the drug and the error could result in harm).

Q6) Is the pharmacy responsible for communicating changes made as a result of the quality assurance program to staff?

A6) Yes. The pharmacy is required to inform pharmacy personnel (pharmacists, interns, technicians, and support personnel) of changes to pharmacy policies, procedures, systems, or processes made as a result of recommendations generated by the quality assurance program.

Q7) Can a pharmacy's quality assurance program be contracted to third party?

Yes. The rule specifically allows for pharmacies to contract or otherwise arrange 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.

Additionally, the rule also permits the use of a quality assurance committee established in accordance with section 2305.24 of the Ohio Revised Code.

IMPORANT: Please be advised that the pharmacy, and not a contracted third party, is ultimately responsible for ensuring compliance with this rule.

Q8) Are errors in dispensing required to be reported to the Board?

The current pharmacist duty to report rule requires the reporting of errors in dispensing in certain circumstances. For more information on this requirement, visit: www.pharmacy.ohio.gov/PharmReport.

However, on March 1, 2025, OAC 4729:5-4-02 will move that responsibility from the pharmacist to the pharmacy.

Effective 3/1/2025, an Ohio pharmacy licensed as a terminal distributor of dangerous drugs shall be required to report the following to the Board:

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):
    - Category G: An error occurred that resulted in permanent patient harm.
    - Category H: An error occurred that resulted in a near-death event (e.g., anaphylaxis, cardiac arrest).
    - Category I: An error occurred that resulted in patient death.

IMPORTANT: The Board recognizes that errors in dispensing are an opportunity to make system/process improvements to promote safer patient care and can occur in any pharmacy setting. To encourage internal reporting pursuant to OAC 4729:5-3-22, the Board updated its disciplinary rules (effective 3/1/2025) for pharmacists, pharmacy interns, and pharmacy technicians that prohibits the Board from taking disciplinary action against an individual licensee/registrant for an error in dispensing, **UNLESS the error is the result of reckless behavior.**

For more information on error reporting, visit: www.pharmacy.ohio.gov/PharmacyReport

Q9) Are compounded product quality issues required to be reported to the Board and how to they differ from error reporting?

Yes. OAC 4729:7-2-03 and 4729:5-8-04 require any pharmacy (whether in-state or out-of-state), to report compounded product quality issues to the Board. A product quality issue means any of the following:

(1) Any incident that causes the compounded drug preparation or its labeling to be mistaken for, or applied to, another article;
(2) Contamination of the compounded drug preparation, including but not limited to mold, fungal, bacterial, or particulate contamination; or
(3) Any significant chemical, physical, or other change or deterioration of the dispensed compounded drug preparation within the compounded drug preparation's assigned beyond-use date.

Please be advised that compounded product quality issues must be reported regardless of patient harm or recklessness as this is a separate requirement from error reporting. Product quality issues must be reported within seventy-two hours upon discovery using the Board's reporting form: www.pharmacy.ohio.gov/CompoundReport.

IMPORTANT: For non-resident (e.g. out-of-state) pharmacies, the reporting of compounded product quality issues is only applicable if the drug was dispensed to a patient residing in this state.