Pharmacy Duty to Report Requirements – Effective 3/1/25

Updated 2/27/2025

Effective March 1, 2025, **Ohio** pharmacies licensed as terminal distributors of dangerous drugs will be required to submit certain information to the Board per OAC 4729:5-4-02. ***This rule does not apply to non-resident pharmacies (e.g., out-of-state pharmacies).***

REMINDER: Per section 4729.23 of the Ohio Revised Code, information submitted to the Board in accordance with this rule shall be deemed confidential, is not a public record, and is not subject to discovery in any civil action.

DISPENSING ERROR REPORTING

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 (also 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.**

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See Q1 and Q2 of this document for the definition of a dispensing error and reckless behavior.

REPORTING TERMINATIONS OR RESIGNATIONS

The rule also includes provisions requiring an Ohio pharmacy to report to the Board any of the following:

1. The termination or resignation of employment of any individual licensed or registered by the Board (e.g., pharmacists, pharmacy interns, and pharmacy technicians) that was based, in whole or in part, on an error or errors in dispensing.

2. 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.

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 conduct indicating an individual licensed or registered by the Board was practicing pharmacy while physically or mentally impaired by 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.

See Q3 for the definition of unprofessional conduct and dishonesty.

For questions regarding these requirements, please review the following frequently asked questions. Other questions not addressed here may be emailed to the Board by visiting: http://www.pharmacy.ohio.gov/contact.aspx.

Q1) How does the Board define a dispensing error or error in dispensing?

OAC 4729:5-3-22 (effective March 1, 2025) 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).

Q2) How does the Board define reckless behavior?

"Reckless behavior" as defined in OAC 4729:5-4-02 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.

Q3) How does the Board determine if an error needs to be reported in accordance with this rule?

Effective March 1, 2025, OAC 4729:5-3-22 requires any pharmacy licensed as a terminal distributor of dangerous drugs to implement a continuous quality improvement (CQI) program for pharmacy services. Included in the CQI program is a quality assurance review for dispensing errors. This process should be utilized to determine whether or not the error meets the criteria for reporting to the Board.

Q4) How does the Board define unprofessional conduct and dishonesty?

The terms are defined in rule 4729:5-4-02 of the Ohio Administrative Code:

"Unprofessional conduct" means conduct unbecoming of a licensee, registrant or applicant, or 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.

"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.

Q5) How do I submit a report for my pharmacy and what information is required to be submitted?

Reporting required in accordance with this rule must be made using any of the following methods:

- In writing, either by mail or using the Board's online complaint form (available on the Board's web site: www.pharmacy.ohio.gov/complaint); or

- By telephone during normal business hours (614-466-4143 – ask to speak with the Compliance and Enforcement Department).

IMPORTANT: Reporting can be made by any representative of the pharmacy. It is ultimately the pharmacy's terminal distributor of dangerous drugs license to ensure compliance with the reporting requirements of the rule.

The following information must be included in the pharmacy's report:

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.

REMINDER: By rule, all reports submitted must protect the confidentiality of patients. No patient-identifying information should be disclosed as part of an initial report. The Board may request additional information, including patient information, as part of its investigation.

Q5) What is the required timeframe for reporting?

For reporting errors in dispensing: The rule states that all reporting to the Board must be conducted within ten (10) days from the date the quality assurance program review in accordance with rule 4729:5-3-22 is completed.

For reporting termination or resignation of employee: The rule states that all reporting to the Board must be conducted within ten (10) days from the date the individual is terminated or resigns from employment.

Q6) Is the identity of the individual submitting the report confidential?

Yes. By law, the identity of the representative submitting the report, and the contents of the report, are confidential.

Q7) Are there legal protections for an individual submitting a report?

Yes. Pursuant to section 4729.10 of the Ohio 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 Ohio Revised Code is not liable to any person for damages in a civil action as a result of the report or testimony.

Q8) Does this rule apply to non-resident pharmacies?

No. Currently, the rule does not apply to non-resident pharmacies (e.g. those outside of the state).

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.