



Continuous Quality Improvement & Duty to Report Rules

Comments Due 11.30.23

Earlier this year, the Board issued rules to address error reporting and continuous quality improvement processes in the operation of a pharmacy.

The rule package can be accessed by visiting:
www.pharmacy.ohio.gov/CQIComment

Comments are due by **November 30, 2023** and shall be submitted to
rulecomments@pharmacy.ohio.gov

After significant feedback from the initial round of public comment, the Board is re-issuing the rules that make the following changes:

- **Rule 4729:5-3-22 (Continuous Quality Improvement Programs in Pharmacy Services):**
 - Defines an “error in dispensing” in the context of the [National Coordinating Council for Medication Error Reporting and Prevention Medication Error Index](#) (Revised 2/20/2001). NOTE: Category A is not included in the definition of an error because it reads as, “Category A: Circumstances or events that have the capacity to cause error.”
 - If applicable, allows the required quality assurance review to be conducted by a quality assurance committee established under ORC [2305.24](#).
 - Removes timeframe to begin investigation of an error in dispensing and instead requires licensees to complete “as soon as is reasonable possible.”
 - Removes the requirement for the pharmacist to communicate any errors to the patient. Rather, a representative of the licensee is required to communicate errors to patients under certain conditions.
- **Rule 4729:1-4-02 (Duty to Report – Pharmacists):**
 - Provides a new definition of error in dispensing to coincide with the definition in proposed rule 4729:5-3-22 of the Administrative Code.
- **Rule 4729:2-4-02 (Duty to Report – Pharmacy Interns):**
 - Provides a new definition of error in dispensing to coincide with the definition in proposed rule 4729:5-3-22 of the Administrative Code.
- **Rule 4729:3-4-02 (Duty to Report – Pharmacy Technicians):**
 - Provides a new definition of error in dispensing to coincide with the definition in proposed rule 4729:5-3-22 of the Administrative Code.

- **Rule 4729:5-4-02 (Duty to Report – Pharmacies):**
 - Requires pharmacies to report the following errors 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 F: An error occurred that resulted in initial or prolonged hospitalization and caused temporary patient harm.
 - 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.
- **Rule 4729:1-4-01 Disciplinary actions. (AMEND) [Pharmacists]:**
 - Adds definition of “reckless” and “at-risk” behavior.
 - Exempts a pharmacist from any disciplinary action related to an error in dispensing or compounding product quality (OAC 4729:7-2-03) issue except in the case of “reckless” or “at-risk” behavior.
- **Rule 4729:2-4-01 Disciplinary actions. (AMEND) [Pharmacy Intern]:**
 - Adds definition of “reckless” and “at-risk” behavior.
 - Exempts a pharmacy intern from any disciplinary action related to an error in dispensing or compounding product quality issue except in the case of “reckless” or “at-risk” behavior.
- **Rule 4729:3-4-01 Disciplinary actions. (AMEND) [Pharmacy Technicians]:**
 - Adds definition of “reckless” and “at-risk” behavior.
 - Exempts a pharmacy technician from any disciplinary action related to an error in dispensing or compounding product quality issue (OAC 4729:7-2-03) except in the case of “reckless” or “at-risk” behavior.

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