# Ohio Administrative Code

## Rule 4729:5-3-22 Continuous Quality Improvement Programs in Pharmacy Services.

Effective: March 1, 2025

(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 a 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 patient; or

(e) 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.

(5) 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.

(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.

(1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy to be made readily retrievable 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.

(4) Any record reviewed in accordance with this paragraph shall be for investigation or inspection purposes and shall be subject to confidentiality protections pursuant to section 4729.23 of the Revised Code.

(5) 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.

(D) 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 and the error poses harm to the patient. Harm includes impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom.

(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.

(E) 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.

(F) 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 by the quality assurance program.

(G) 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.

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