Ohio Administrative Code

Rule 4729:5-5-22 Return to stock in an outpatient pharmacy.

Effective: December 1, 2020

(A) As used in this rule:

(1) "Pharmacy delivery agent" means an employee of the pharmacy, United States postal service, or common or contract carrier who delivers dangerous drugs that have been dispensed.

(2) "Psychiatric outpatient facility" means a facility where psychiatric evaluation and treatment is provided on an outpatient basis.

(B) An outpatient pharmacy may return dangerous drugs to stock shelves that have been dispensed, but have never left the pharmacy (i.e. never picked up by a patient or caregiver) or the control of a pharmacy delivery agent (i.e. never delivered to a patient or caregiver), if the pharmacy complies with all of the following:

(1) The pharmacy has the capability to place the expiration date, as required by this rule, on the prescription label.

(2) The expiration date on the label shall not exceed the expiration date on the manufacturer's container or one year from the date the drug was originally dispensed and placed in the prescription vial, whichever date is earlier. If multiple manufacturer containers are used, the expiration date shall not exceed the expiration date on the manufacturer's container that will expire first or one year from the date the drug was originally dispensed and placed in the prescription vial, whichever date is earlier. If the prescription container is the manufacturer's original sealed packaging, the expiration date is the expiration date listed on the packaging.

(3) The dangerous drug products returned to stock shelves shall be maintained in the container in which they were filled and shall maintain their original prescription label containing the original expiration date assigned. The label on the container shall not be removed, altered, or replaced with another label or have any other label added, except as follows:

(a) Adding to or modifying the existing label, if the drug name, dose, and original expiration date are maintained.

(b) Adding a new label over the existing label on the container. In this instance, the drug shall be verified by a pharmacist or an electronic verification system following the application of the new label. The new label shall include the expiration date assigned on the original label.

(c) A prescription label may be removed if the prescription container is the manufacturer's original sealed packaging and the removal of the label does not remove or otherwise cause to make unreadable the expiration date and lot number on the manufacturer's packaging.

(4) The contents of a prescription vial or container shall not be returned to the manufacturer's stock bottle.

(5) When dispensing a dangerous drug that was previously returned to stock to another patient, a new container shall be used or, in the case of unit dose or unit of use products, all previous patient information shall be removed.

(6) Drugs returned to stock shelves shall be stored in accordance with rule 4729:5-5-02 of the Administrative Code. The pharmacy shall develop and implement a policy to ensure that drugs are maintained by pharmacy delivery agents within temperatures as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling.

(7) In the case of recalls, any drugs returned to stock shelves containing the drug affected by the recall shall be removed from the shelves immediately, unless the lot number can be determined.

(8) A dangerous drug that leaves the prescription department of the pharmacy in the custody of a pharmacy delivery agent may only be returned to stock shelves if the drug meets either of the following prior to initially leaving the prescription department:

(a) Each dangerous drug prescription is dispensed in a tamper evident container or package prior to leaving the pharmacy; or

(b) The dangerous drug prescription is dispensed in the manufacturer's original tamper evident packaging.

(9) A dangerous drug that is dispensed and shows any signs of tampering or adulteration shall not be returned to stock shelves.

(C) A dangerous drug that exceeds its assigned expiration date, as described in paragraph (B) of this rule, shall be removed from the area for the storage of drugs used for dispensing and administration in accordance with rule 4729:5-3-06 of the Administrative Code.

(D) Non-controlled drugs dispensed by a government entity and delivered for outpatients to a psychiatric outpatient facility or to any service provider licensed as a terminal distributor of dangerous drugs may be returned to stock if all the following apply:

(1) The drugs are packaged in unopened, single-dose or tamper-evident containers; and

(2) The drugs have not been in the possession of the ultimate user.

(E) This rule does not apply to drugs dispensed for inpatients pursuant to agency 4729 of the Administrative Code. Drugs dispensed for inpatients may be returned to stock in accordance with the applicable provisions of agency 4729 of the Administrative Code.

(F) A pharmacy may transfer dangerous drugs that are returned to stock shelves that meet the requirements of this rule to another pharmacy if the transfer is conducted in accordance with paragraph (E) of rule 4729:5-3-09 of the Administrative Code.