Ohio Administrative Code

Rule 4729:5-9-02.12 Drugs repackaged or relabeled by an institutional pharmacy.

Effective: February 1, 2022

(A) As used in this rule, "repackaging" means the act of taking a finished drug product from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the drug. Repackaging also includes the act of placing the contents of multiple containers (e.g., vials) of the same finished drug product into one container, as long as the container does not include other ingredients. If a drug is manipulated in any other way, including if the drug is reconstituted, diluted, mixed, or combined with another ingredient, that act is not considered repackaging.

(B) The following rule applies to dangerous drugs repackaged by an institutional pharmacy. The rule does not apply to any of the following:

(1) Repackaging drug products for use in animals;

(2) Repackaging non-dangerous drug products;

(3) Radiopharmaceuticals as defined in Chapter 4729:5-6 of the Administrative Code;

(4) Repackaging conducted by outsourcing facilities or repackagers licensed in accordance with section 4729.52 of the Revised Code;

(5) Removing a drug product from the original container at the point of care (e.g., patient's bedside) for immediate administration to a single patient after receipt of a valid patient-specific prescription or order for that patient (e.g., drawing up a syringe to administer directly to the patient);

(6) Upon receipt of, or in anticipation of, a valid patient-specific prescription or medication order, a licensed pharmacy removing from one container the quantity of non-sterile drug products (e.g., oral dosage forms) necessary to fill the prescription and placing it in a different container to dispense directly to the patient; and

(7) Investigational new drugs being studied under an investigational new drug application.

(C) Drugs repackaged by an institutional pharmacy shall comply with the following:

(1) Unless otherwise specified in the individual monograph or in the absence of stability data to the contrary, the beyond-use date shall be not later than the expiration date on the manufacturer's container or one-year from the date the drug is repackaged, whichever is earlier. Sterile compounded drug preparations shall comply with paragraph (C)(2) of this rule.

(2) Sterile compounded drug preparations shall comply with United States pharmacopeia chapter <797> as referenced in rule 4729:7-1-01 of the Administrative Code.

(D) Labels of drugs repackaged by and stored within a pharmacy prior to being dispensed shall contain, but not be limited to, the following:

(1) Name of drug, strength, and dosage form;

(2) National drug code or universal product code, if applicable, which may be embedded in a barcode or quick response (QR) code on the label;

(3) The identification of the repackager by name or by the final seven digits of their terminal distributor of dangerous drugs license number;

(4) Pharmacy control number; and

(5) The beyond-use date of the repackaged drug in accordance with the guidance listed in paragraph (C) of this rule.

(E) All drugs dispensed to inpatients for self-administration or dispensed for outpatient use shall also be labeled in accordance with rule 4729:5-5-06 of the Administrative Code.

(F) A record of all drugs repackaged and stored within a pharmacy prior to being dispensed shall be

kept for at least three years or one year past manufacturer's expiration date, whichever is greater. This record shall include, at a minimum, the following:

(1) Name of drug, strength, dosage form, and quantity;

(2) National drug code or universal product code (UPC), if applicable, which may be embedded in a barcode or quick response (QR) code on the label;

(3) Manufacturer's or distributor's control number;

(4) Manufacturer's or distributor's name, if a generic drug is used, or if not using NDC or UPC;

(5) Pharmacy control number;

(6) Manufacturer's or distributor's expiration date;

(7) The pharmacy's beyond-use date in accordance with the guidance listed in paragraph (C) of this rule;

(8) The positive identification of the individual responsible for the repackaging of the drug; and

(9) The positive identification of the pharmacist conducting the final verification of the repackaged drug to confirm the accuracy of the drug and conformity to the requirements of this rule prior to dispensing or distribution.

(G) Supplemental labels created by a pharmacy that contain a barcode or QR code for the purpose of identifying a drug shall contain a means of identifying the positive identification of the pharmacist responsible for:

(1) Association of the barcode to the drug product;

(2) Association of the label to the drug product.