

DRUGS REPACKAGED OR RELABELED BY A PHARMACY

Rule 4729-9-20 [Update Effective 01/01/2009]

- (A) 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) The identification of the repackager by name or by the final seven digits of their terminal distributor of dangerous drugs license number;
 - (3) Pharmacy control number;
 - (4) Pharmacy's expiration date or beyond-use date, which shall be within the proven period of stability of the drug. This expiration or beyond-use date shall be no later than the manufacturer's expiration date of a not previously opened manufacturer's container.
- (B) 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 least the following:
- (1) Name of drug, strength, dosage form, and quantity;
 - (2) Manufacturer's or distributor's control number;
 - (3) Manufacturer's or distributor's name, if a generic drug is used;
 - (4) Pharmacy control number;
 - (5) Manufacturer's or distributor's expiration date;
 - (6) The pharmacy's expiration date or beyond-use date;
 - (7) Positive identification of the pharmacist responsible for the repackaging of the drug.
- (C) Supplemental labels created by a pharmacy that contain a barcode for the purpose of identifying a drug shall contain a means of identifying the positive identification of the pharmacist responsible for:
- (1) The creation of the barcode; and
 - (2) Affixing the barcode label to the drug product.

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