Ohio Administrative Code

Rule 4729-5-16 Labeling of drugs dispensed on prescription.

Effective: October 1, 2016

(A) No drug may be dispensed on prescription unless a label is affixed to the container in which such drug is dispensed and such label includes:

(1) The name and address of the pharmacy as it appears on the terminal distributor of dangerous drugs license;

(2) The full name of the patient for whom the drug is prescribed; or, if the patient is an animal, the full name of the owner and identification of the animal;

(3) The full name of the prescriber;

(4) Directions for use of the drug;

(5) The date of dispensing;

(6) Any cautions which may be required by federal or state law;

(7) The serial number of the prescription;

(8) The proprietary name, if any, or the generic name and the name of the distributor of the drug dispensed; and the strength, if more than one strength of the drug is marketed. The dispensing pharmacist may omit the name and strength of the drug only if the prescriber specifically requests omission in writing in the case of a written prescription, or verbally in the case of an orally transmitted prescription;

(9) The quantity of drug dispensed;

(10) If the drug is compounded, the statement "Compounded Drug Product" or other similar

statement shall also be displayed prominently on the label.

(B) The term "affix" means the prescription label must be attached or fastened to the container.

(C) At least the prescription number and the name of the patient must be placed on all prescription containers too small to bear a complete prescription label and dispensed in a container bearing a complete prescription label. The label bearing only the prescription number and the name of the patient does not need to be applied to any product whose function would be impaired by such a label. In all cases, a complete prescription label meeting the requirements of paragraph (A) of this rule must be applied to the container in which such product is dispensed.

(D) This rule does not apply to drugs which are dispensed for use by inpatients of an institutional facility whereby the drug is not in the possession of the ultimate user prior to administration. Such drugs shall be labeled in accordance with rule 4729-17-10 of the Administrative Code.

(E) Labels for a compounded drug products that are prepared in anticipation of a prescription drug order shall comply with the requirements in rule 4729-16-03 of the Administrative Code.

(F) The inclusion of the statement "Compounded Drug Product" or other similar statement as required by paragraph (A)(10) of this rule and paragraphs (L) and (O) of rule 4729-16-03 of the Administrative Code does not apply to non-sterile compounded drugs that are reconstituted in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.