Ohio Administrative Code

Rule 4729-17-10 Labeling of prescriptions for patients of an institutional facility.

Effective: September 1, 2016

(A) All dangerous drugs dispensed for use by inpatients in an institutional facility, whereby the drug is not in the possession of the ultimate user prior to administration, shall meet the following requirements:

(1) The label of a single unit package of an individual-dose or unit-dose system of packaging of drugs shall include:

(a) The non-proprietary or proprietary name of the drug;

(b) The route of administration, if other than oral;

(c) The strength and volume, where appropriate, expressed in the metric system whenever possible;

(d) The control number and expiration date;

(e) Identification of the manufacturer, packer or distributor, or if the repackager is the dispensing pharmacy identification of the repackager, shall be by name or by the final seven digits of their terminal distributor of dangerous drugs license number, and such identification shall be clearly distinguishable from the rest of the label;

(f) Special storage conditions, if required.

(2) When a multiple-dose drug distribution system is utilized, including dispensing of single unit packages, the drugs shall be dispensed in a container to which is affixed a label containing the following information:

(a) Identification of the dispensing pharmacy;

(b) The patient's full name;

(c) The date of dispensing;

(d) The non-proprietary and/or proprietary name of the drug;

(e) The strength, expressed in the metric system whenever possible.

(3) Multiple drugs may be packaged in the same container such that the different drugs are in contact with each other only under the following conditions:

(a) The number of drugs placed in one package cannot exceed the capability of the receptacle to prevent damage to the dosage forms.

(b) The quantity dispensed may not be more than a thirty-one-day supply.

(c) The labels must be of sufficient size to properly and clearly label a thirty-one-day or less supply with all information required by state and federal law including accessory labels.

(d) Each individual package must include a beyond-use date of not more than sixty days from the date the drugs were placed in the package.

(e) Medications which have been packaged in multi-dose packaging may not be returned to stock or redispensed when returned to the pharmacy for any reason.

(f) When the drugs are not in the possession of the ultimate user and any one drug within each individual package has been discontinued, all drugs in the individual package are deemed adulterated and they may not be administered unless otherwise approved by the board of pharmacy.

(g) The packaging is tamper-evident.

(h) Any pharmacist/pharmacy using multi-dose packaging must implement policies and procedures which will exclude drugs having the following characteristics from such packaging:

(i) The U.S.P. monograph or official labeling requires dispensing in the original container;

(ii) The drugs or dosage forms are incompatible with packaging components or each other;

(iii) The drugs are therapeutically incompatible when administered simultaneously;

(iv) The drug products require special packaging.

(4) At least the name of the patient must be placed on all medication containers too small to bear a complete label and dispensed in a container bearing a complete label.

(B) All drugs dispensed to inpatients for self-administration shall be labeled in accordance with paragraphs (A), (B), and (C) of rule 4729-5-16 of the Administrative Code.

(C) Whenever any drugs are added to parenteral solutions, such admixtures shall bear a distinctive label indicating:

(1) The patient's full name;

(2) The name and amount of the parenteral solution;

(3) The name and amount of the drug(s) added;

(4) The expiration date or beyond-use date;

(5) The name and address of the institutional facility pharmacy;

(6) Cautionary statements, if required.

(D) All drugs dispensed for use by outpatients of an institutional facility shall be labeled in accordance with paragraphs (A), (B), and (C) of rule 4729-5-16 of the Administrative Code except as noted in paragraph (A) of rule 4729-17-10 of the Administrative Code.