<u>4729:5-9-02.8</u> Labeling of prescriptions for patients.

- (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) Dosage form and route of administration;
 - (c) The strength and volume, where applicable, of the drug;
 - (d) The control number and expiration date;
 - (e) National drug code, universal product code, or formulary code, if applicable, which may be embedded in a barcode or quick response (QR) code on the label:
 - (f) 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; and
 - (g) Special storage conditions, if required.
 - (2) 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 or dispensed for outpatient use shall be labeled in accordance with rule 4729:5-5-06 of the Administrative Code.
- (C) Prior to dispensing, admixtures of parenteral solutions 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 pharmacy:
- (6) Cautionary statements, if required.
- (D) 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.

Replaces:	4729-17-10
Effective:	12/1/2021
Five Year Review (FYR) Dates:	12/01/2026

CERTIFIED ELECTRONICALLY

Certification

06/29/2021

Date

Promulgated Under: Statutory Authority: Rule Amplifies: Prior Effective Dates: 119.03 3715.69, 3719.28, 4729.26 3715.64, 3719.08 09/01/1985, 07/01/1991, 01/10/1996, 03/01/1999, 01/01/2009, 01/01/2010, 09/01/2016