Ohio Administrative Code

Rule 4729:5-9-02.11 Dispensing customized patient medication packages by an institutional pharmacy.

Effective: February 1, 2022

In lieu of dispensing two or more dangerous drugsin separate containers, a pharmacist practicing at an institutional pharmacymay dispense a customized patient medication package. A customized patientmedication package is a package for a specific patient comprising a series ofcontainers and containing two or more prescribed solid oral dosage forms thatcomplies with the following requirements:

(A) The package is designed, or each container is labeled, to indicate the day and time or period of time when the contents within each container are to be taken by the patient.

(B) The number of drugs placed in each container cannot exceed the capability of the container to prevent damage to the dosage forms.

(C) The quantity of the package dispensed may not be more than a thirty-one-day supply.

(D) The labels must be of sufficient size to properly and clearly label a thirty-one-day or less supply with all information required in accordance with this chapter of the Administrative Code, including the use of accessory labels. When a customized medication packaging is utilized, including dispensing of single unit packages, the drugs shall be dispensed in a container or package with an affixed label containing the following information:

(1) Identification of the dispensing pharmacy;

(2) The patient's full name;

(3) The date of dispensing;

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

(5) 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;

(6) The strength of the drug;

(7) The pharmacy's expiration date or beyond-use date, which shall not exceed the expiration date on the manufacturer's container or six months from the date the drug was originally packaged, whichever date is earlier. If multiple manufacturer containers are used, the expiration date shall not exceed the expiration date on the manufacturer's container that will expire first or six months from the date the drug was originally repackaged, whichever date is earlier.

(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) Dangerous drugs which have been dispensed in a customized patient medication package may only be returned to stock or re-dispensed in accordance with all the following:

(1) The drugs have not been in the possession of the ultimate user; and

(2) The drugs have not been placed in the same container with another dangerous drug (i.e. did not come into direct contact with a different drug within the same container).

(G) The containers of a package are sealed or secured in such a way that access to the drugs stored within is not possible without leaving visible proof that such access has been attempted or made.

(H) Any pharmacy dispensing customized patient medication packages in accordance with this rule must implement policies and procedures that will exclude drugs having any of the following characteristics from such packaging:

(1) The U.S.P. monograph or official labeling requires dispensing in the original container, unless there is documentation from the manufacturer stating otherwise;

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

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

(4) The drugs require special packaging.