

**ARIZONA STATE BOARD OF PHARMACY  
POLICY GUIDELINES FOR  
UNIT DOSE PACKAGING AND DISPENSING**

**BACKGROUND:** The Board of Pharmacy recognizes unit dose packages as acceptable medication delivery systems for prescription drugs in proper applications.

**DEFINITION:** Unit Dose Package: A single-unit container for medications intended for administration by other than the parenteral route as a single dose, direct from the container, normally by someone other than the patient.

**LABELING:** Consistent with acceptable pharmacy practice, the label of each unit dose medication will contain: the drug name (generic and brand, if applicable), strength, and dosage form, the manufacturer's name and lot number, and a beyond-use-date of no more than one year or the manufacturer's expiration date if the expiration date is less than one year. The current Federal Poison Prevention Packaging Act provides no exemption for unit dose or patient med paks.

**POLICY:** For the purpose of establishing uniform use and handling of these packages, the Arizona Board of Pharmacy declares:

1. Unit dose packages are acceptable container systems for prescription drug delivery in certain applications.
2. Unit dose packages are intended to be administered to the patient by a third party, preferably a licensed professional nurse.
3. A unit dose package that is promptly returned to the dispensing pharmacy in "unopened-as issued" condition is permitted to be reused or redispensed if the requirements of R4-23-409 are met.
4. Careful attention must be given to avoid exposure of sensitive products to excessive heat during packaging and to excessive light during storage; always follow USP standards.
5. Collection of moisture within the package following exposure to heat or sudden changes in temperature is unacceptable.
6. When dispensed by a community pharmacy or limited-service pharmacy, the container in which the unit-dose packages are delivered to a facility must be properly labeled under A.R.S. §§ 32-1963.01(C) and (I), 32-1968, and 36-2525 and A.A.C. R4-23-402, applicable parts of R4-23-658(D), and R4-23-701.01(2).

This policy statement is prepared and circulated to protect the public health relevant to prescription drug packaging systems, their contents, labeling and use. Compliance is based on official compendium standards (see *current USP Containers-Physical Tests <66]>*).

This substantive policy statement is advisory only. A substantive policy statement does not include internal procedural documents that only affect the internal procedures of the agency and does not impose additional requirements or penalties on regulated parties or include confidential information or rules made in accordance with the Arizona Administrative Procedure Act. If you believe that this substantive policy statement does impose additional requirements or penalties on regulated parties you may petition the agency under A.R.S. § 41-1033 for a review of the statement.