CHAPTER 49

Repackaging Medications

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LEARNING OBJECTIVES

- Discuss the unit-dose system used in hospital pharmacies.
- Recognize important concepts relating to personnel, equipment, and supply requirements for repackaging medications.
- Describe the labeling requirements for repackaging medications.
- Discuss the quality assurance, process controls, and record-keeping requirements for repackaging medications.

The Unit-Dose System

Most health-system pharmacies utilize a *unit-dose medication distribution system*. A unit-dose medication distribution system uses medications packaged in unit-dose or single-unit packages. A *single-unit package* contains one dosage form of medication (e.g., one capsule, one 5 mL volume of liquid, etc.). A *unit-dose package* contains the dose of a medication ordered for a patient (e.g., two 250 mg tablets for a 500 mg dose). However, not all medications are available from the manufacturer in single-unit or unit-dose packages. Therefore, pharmacies often purchase medications in bulk containers and repackage them in unit-dose or single-unit packages.

Pharmacies that repackage medications must employ procedures that ensure the quality and integrity of the medications. You should carefully review your department's policy and procedures for repackaging. It outlines your facility's guidelines for the important elements of repackaging operations, such as the following:

- Space or facility requirements
- Cleanliness
- Labeling format
- Assignment of beyond-use dates (BUDs)
- Setup, operation, and cleaning of equipment
- Required records
- Quality assurance
- Selection of repackaging containers and other materials

You should be oriented to the procedures (including operation of repackaging equipment) and demonstrate competence before performing this activity. Documentation of orientation and competence should be

maintained as part of your personnel records. Documentation is required by your facility for accreditation, Medicare reimbursement, and compliance with regulations in some states.

For more on information on the unit-dose system and repackaging, refer to Appendix A: ASHP Technical Assistance Bulletin on Single Unit and Unit Dose Packages of Drugs and Appendix B: ASHP Technical Assistance Bulletin on Repackaging Oral Solids and Liquids in Single Unit and Unit Dose Packages.

Personnel, Equipment, and Supplies

Personnel

Both pharmacists and technicians are involved in the repackaging operation. The customary responsibilities of technicians include repackaging medications; maintaining repackaging control records; and maintaining equipment, supplies, and the repackaging area. Pharmacists obtain and evaluate data on repackaging materials and the repackaging requirements of specific medications and conduct the final check of the repackaged medications before release for distribution. Although technicians perform certain tasks, the ultimate responsibility for the repackaging operations belongs to the pharmacist. All personnel involved in the repackaging operations are required to adhere to the facility's infection control procedures. It is essential that good hand hygiene practices are observed during repackaging operations.

Facility

The repackaging area should be separate from other pharmacy work areas and designed to limit traffic and reduce distractions. The area should be clean with adequate lighting and ventilation, as well as temperature and humidity controls. Food and beverages must not be allowed in the repackaging area. These measures are necessary to ensure that required standards of sanitation, sterility, infection control, and quality assurance are maintained.

Equipment

It is important that repackaging equipment be operated and maintained according to the manufacturer's instructions. Written procedures should be developed and kept current for the operation, cleaning, and maintenance of equipment. Certain automated equipment must be routinely calibrated or inspected to ensure proper performance. Equipment must be emptied, cleaned, sanitized, and inspected before each repackaging run. All activities related to the maintenance, cleaning, inspection, and calibration of equipment must be documented and maintained in the pharmacy's records.

Repackaging Materials

Repackaging materials (e.g., containers, seals, and closures) must be selected to maintain the integrity of the medication. The type of package selected for a specific drug product must meet all applicable FDA and USP requirements. Information regarding these requirements can be found in the U.S. Pharmacopeia and the FDA's website (http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation). Data on the characteristics of repackaging materials—including chemical composition, light transmission, moisture permeability, recommended sealing temperature, and storage requirements—should be obtained from the manufacturers. Plastic bags, prescription vials, and paper envelopes/boxes do not meet FDA and USP requirements and must not be used for repackaging medications.

Desirable properties of repackaging materials include the following:

- Protects contents from light, moisture, heat, air and handling, as required
- Does not absorb, adsorb, or chemically react with the medication
- Does not deteriorate during the shelf life of the medication
- Allows inspection of contents, unless protection from light is required
- Allows easy identification of evidence of entry
- Easy to open and use
- Preferably recyclable or biodegradable
- Maintains the sterility of the medication for sterile products
- Should not allow attachment of needles for oral syringes used to repackage orally administered liquids

Repackaging materials should be stored according to the manufacturer's recommendations and in a manner to prevent contamination or degradation.