Subject: 
Unit Dose Dispensing Systems  
(Formerly Preparation and Labeling of Extemporaneously Prepared Unit Dose Packages #3.12)

Purpose: 
To provide a policy on unit dose dispensing systems which are defined as a drug distribution system utilizing single unit, unit dose, or unit of issue packaging in a manner that helps reduce or remove traditional drug stocks from resident care areas and enables the selection and distribution of drugs to be pharmacy-based and controlled

Procedure: 
A. Unit Dose Dispensing Systems. 
   a. General Procedures 
      i. Policies and procedures specify the drug categories, specific drugs, or dosage forms which will NOT be dispensed under the particular unit dose dispensing system employed. 
         1. Example. When a non-formulary item is ordered for a patient and the provider determines that no alternative exists in the patient's best interest, and the patient's own medication is not available, and a sufficient supply of the medication obtained exceeds the patient's hospital usage, and the medication is determined to exceed appropriate non-formulary drug cost, and the medication is continued for home use 
         2. Example. InstyMeds – quantities for a 72-hour (NA) 
         3. Biological or other injectable supplied to a facility for health immunization or ongoing screening programs such as influenza vaccine, tuberculin skin test, or hepatitis-B and intended for use in the facility
   b. Labeling Requirements 
      i. Single Unit or Unit Dose Packaging 
         1. Doses packaged by the manufacturer or distributor shall be properly labeled according to federal Food and Drug Administration (FDA) requirements 
            a. Unit Dose (1" nitro, baby erythromycin, etc.) 
            b. Unit of Issue (cream, ointment, MDI, insulin, nitrotab, etc) 
         2. Doses packaged by the pharmacy for use beyond a 24-hour period shall be labeled (and packaged) according to the prepackaging requirements established in subrule 22.3 see below 
            a. Unit Dose (Medi-Dose and Medi-Dose Information Labeling Technology Software MILT) 
            b. Bulk Liquids (Ranitidine, Lactulose, etc.) 
         3. Those drugs NOT dispensed under a unit dose dispensing system shall be labeled in accordance with the requirements of subrule 657-6.10(1) 
      ii. Unit of Issue (NA) 
   c. Packaging Requirements. Packaging for all nonsterile drugs stored and dispensed in single unit, unit dose or unit of issue packages shall: 
      i. Preserve and protect the identity and integrity of the drug from the point of packaging to the point of patient administration 
      ii. When packaged by the manufacturer or distributor, be in accordance with federal Food and Drug Administration (FDA) requirements
iii. When in single unit and unit dose packages prepackaged by the pharmacy for use beyond 24 hours be in accordance with rule 22.3(126) Prepackaging (see below)
iv. Be clean and free of extraneous matter
d. Expiration Dating. Expiration dating for nonsterile drugs repackaged by the pharmacy into single unit, unit dose or unit of issue packages shall meet the following conditions:
i. Not to exceed 90 days from the date of repackaging (EXCEPT as below)
ii. Not exceed the manufacturer’s original expiration date
iii. May exceed 90 days from the date of repackaging provided that each of the following conditions are met
   1. The container is classified according to USP General Chapter 657 as being Class A or Class B for oral solid dosage forms or is a tight container for liquid dosage forms
      a. Medi-Dose = USP Class A Packaging System
   2. The container is light resistant when the manufacturer has labeled the product “sensitive to light”
   3. The expiration date is not greater than 12 months
   4. Drugs or dosage forms having known stability problems are assigned an expiration date of less than 90 days or are not repackaged as determined by this policy
e. Return of Drugs. A pharmacist shall NOT accept for reuse (except to the same patient) any previously dispensed controlled substances. Drugs excluding controlled substances, dispensed in single unit/ unit dose/ unit of issue packaging in compliance with subrules 22.1(2) to 22.1(5) (General Procedures, Labeling Requirements, Expiration Dating, Packaging Requirements) may be returned to the pharmacy stock and reissued provided:
   i. The expiration dating information is retrievable and identifiable
   ii. Drugs returned from unit of issue packaging are kept separate (NA)
   iii. Drugs were stored under proper storage conditions
   iv. Drugs are returned to pharmacy in the original packaging as when dispensed
   v. Pharmacy includes written policies and procedures that address the manner in which returned drugs will be recorded or identified
      1. See Pyxis MedStation 4000 System User Guide – Returning medication to a return bin

B. Prepackaging. 22.3(126)
a. Control Record. Pharmacies may prepackage and label drugs in convenient quantities for subsequent labeling and dispensing. Such drugs shall be prepackaged by or under the direct supervision of a pharmacist. The supervising pharmacist shall be responsible for the preparation and maintenance of a packaging control record containing the following information:
   i. Date
   ii. Identification of Drug
      1. Name of drug
      2. Dosage form
      3. Manufacturer
      4. Manufacturer’s lot number
      5. Strength
      6. Expiration date
   iii. Container Specification
   iv. Copy of a sample label
   v. Initials or unique identification of the packager
   vi. Initials or unique identification of the supervising pharmacist
   vii. Quantity per container
   viii. Internal control number or date
b. Label Information. Each prepackaged container shall bear a label containing the following information
   i. Name of drug
ii. Strength
iii. Internal control number or date
iv. Expiration date consistent with USP standards
v. Auxiliary labels, as needed

c. Labeling for Delivery. Prior to the delivery of a prepackaged drug to a patient, an appropriate label shall be affixed to the drug container pursuant to the labeling requirements of the appropriate pharmacy practice rules
i. See Policy Dispensing Emergency or Starter Supplies of Drugs IAC.657-7.12(3)

Additional Information:

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Jessica Rosenhamer, Pharmacy Director
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References:
Iowa Pharmacy Law