657—22.1 (155A) Unit dose dispensing systems.

22.1(1) *Definitions.* For the purpose of this rule, the following definitions shall apply:

"Single unit package" means a package that contains one discrete pharmaceutical dosage form.

"Unit dose dispensing system" means 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.

"Unit dose package" means a package that contains that particular dose of a drug ordered for the patient for one administration time. A unit dose package is not always a single unit package. "Unit dose package" does not include a strip pack prepared utilizing an automated medication distribution system (AMDS). A strip pack is a patient med pak subject to the requirements of rule 657—22.5(126,155A).

"Unit of issue package" means a package that provides multiple units or doses attached to each other but separated in a card or specifically designed container.

22.1(2) *General procedures*. The following will apply when a unit dose dispensing system is employed:

a. The pharmacist shall be responsible for determining the classification for containers, as set by USP General Chapter 671, used by the pharmacy to repackage nonsterile drugs into single unit, unit dose, or unit of issue packaging. This classification shall be used to determine maximum expiration dating for repackaging set forth in subrule 22.1(4).

b. Established written policies and procedures shall be available in the pharmacy for inspection by the board or its agents which specify the drug categories, specific drugs, or dosage forms which will not be dispensed under the particular unit dose dispensing system employed.

c. Those drugs not dispensed under a unit dose dispensing system shall be dispensed in accordance with the packaging requirements of the federal Food and Drug Administration (FDA).

22.1(3) *Labeling requirements.*

a. Labeling for single unit or unit dose packaging shall comply with the following:

(1) Doses packaged by the manufacturer or distributor shall be properly labeled according to federal Food and Drug Administration (FDA) requirements.

(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(2).

b. Labeling for unit of issue packages shall contain the following information:

(1) Name, strength, and expiration date of drug when the packages are utilized for floor stock in an institutional setting.

(2) Name and room or bed number of patient, the name of prescribing practitioner, the name and strength of drug, directions for use, and name and address of the dispensing pharmacy, when the packages are utilized for patients in an institutional setting. Room or bed number, the name of prescribing practitioner, and the name and address of the dispensing pharmacy are not required if this information appears on a medication administration record used by the institution.

(3) Unit of issue packages dispensed to patients on an outpatient basis or in a noninstitutional setting shall be considered prescription containers and shall be labeled in accordance with 657—subrule 6.10(1).

c. If a pharmacist selects a generically equivalent drug product for a brand name drug product prescribed by a practitioner, the label must identify the generic drug and may identify the brand name drug for which the selection is made. The dual identification allowed under this paragraph must take the form of the following statement on the label: "(generic name) Generic for (brand name product)".

d. The labeling requirements of paragraphs *"a"* and *"b"* of this subrule shall not apply to the special circumstances identified in rule 657—23.13(124,155A).

e. Those drugs not dispensed under a unit dose dispensing system shall be labeled in accordance with the requirements of subrule 22.5(5) or 657—subrule 6.10(1) as appropriate.

22.1(4) *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:

a. Not exceed 90 days from the date of repackaging except as provided in paragraph 22.1(4)*"c."*

b. Not exceed the manufacturer's original expiration date.

c. May exceed 90 days from the date of repackaging provided that each of the following conditions is met:

(1) The container is classified according to USP General Chapter 671 as being Class A or Class B for oral solid dosage forms or is a tight container for liquid dosage forms.

(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.

d. 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 policies developed by the pharmacy.

22.1(5) *Packaging requirements.* Packaging for all nonsterile drugs stored and dispensed in single unit, unit dose, or unit of issue packages shall:

a. Preserve and protect the identity and integrity of the drug from the point of packaging to the point of patient administration.

b. When packaged by the manufacturer or distributor, be in accordance with federal Food and Drug Administration (FDA) requirements.

c. When in single unit and unit dose packages prepackaged by the pharmacy for use beyond 24 hours, be in accordance with rule 657—22.3(126).

d. Be clean and free of extraneous matter.

22.1(6) *Return of drugs.* Under no circumstances shall a pharmacist accept for reuse, except to the same patient, any previously dispensed controlled substances. Drugs, excluding controlled substances, dispensed in single unit, unit dose, or unit of issue packaging in compliance with subrules 22.1(2) to 22.1(5) may be returned to the pharmacy stock and reissued provided that:

a. The expiration dating information is retrievable and identifiable.

b. Drugs returned from unit of issue packaging are kept separate according to manufacturer's lot number and the repackaged expiration date assigned pursuant to subrule 22.1(4). If, however, the pharmacy's recall policy states that all lots of a drug shall be considered part of the recall due to unknown manufacturer's lot numbers, drugs returned to stock from unit of issue packaging shall be kept separate according to the pharmacy's repackaged expiration date.

c. The drugs were stored under proper storage conditions.

d. The drugs are returned to the pharmacy in the original packaging as when dispensed.

e. The pharmacy includes in written policies and procedures the manner in which returned drugs will be recorded or identified.

This rule is intended to implement Iowa Code section 155A.36.

[**ARC 1309C**, IAB 2/5/14, effective 3/12/14]