

CHAPTER 22
UNIT DOSE, ALTERNATIVE PACKAGING, AND EMERGENCY BOXES

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 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 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.

657—22.2 Reserved.

657—22.3(126) Prepackaging.

22.3(1) 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:

a. Date.

b. Identification of drug.

(1) Name of drug.

(2) Dosage form.

(3) Manufacturer.

(4) Manufacturer’s lot number.

(5) Strength.

(6) Expiration date.

c. Container specification.

d. Copy of a sample label.

e. Initials or unique identification of the packager.

- f. Initials or unique identification of the supervising pharmacist.
- g. Quantity per container.
- h. Internal control number or date.

22.3(2) Label information. Each prepackaged container shall bear a label containing the following information:

- a. Name of drug.
- b. Strength.
- c. Internal control number or date.
- d. Expiration date consistent with USP standards.
- e. Auxiliary labels, as needed.

22.3(3) 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.

This rule is intended to implement Iowa Code sections 126.10 and 126.11.

657—22.4 Reserved.

657—22.5(126,155A) Patient med paks. In lieu of dispensing prescribed drug products in conventional prescription containers, a pharmacist may, with the consent of the patient, the patient's caregiver, or the prescriber, provide a customized patient medication package (patient med pak) pursuant to the requirements of this rule.

22.5(1) Definition. A patient med pak is a customized patient medication package prepared for a specific patient which comprises a series of immediate containers containing prescribed solid oral dosage forms, each container being labeled with the time or the appropriate period for the patient to take its contents.

22.5(2) General procedures. The following shall apply when patient med paks are employed:

a. The pharmacist shall be responsible for determining the classification, as directed by USP General Chapter 671, for containers used by the pharmacy to repackage nonsterile drugs into patient med paks.

b. Packaging for all nonsterile solid oral dosage forms stored and dispensed in patient med paks shall:

(1) Preserve and protect the identity and integrity of the drug from the point of packaging to the point of administration, and

(2) Be clean and free of extraneous matter when the drugs are placed into the package.

c. Drugs dispensed in patient med paks to patients may not be returned to the pharmacy stock and reissued except to the same patient as provided in subrule 22.5(4).

d. There is no special exemption for patient med paks from the requirements of the Poison Prevention Packaging Act. Thus, the patient med pak, if it does not meet child-resistant standards, shall be placed in an outer package that does comply, or the necessary consent of the purchaser or physician to dispense in a container not intended to be child-resistant shall be obtained.

22.5(3) Reuse of containers. Notwithstanding requirements that all prescription drugs be dispensed in a new container conforming with standards established in the official compendia, a pharmacist may dispense and refill a prescription for nonliquid oral products in a clean patient med pak provided:

a. A patient med pak is reused only for the same patient; and

b. No more than a one-month supply is dispensed at one time.

22.5(4) Repackaging of patient med paks. In the event a drug is added to or discontinued from a patient's drug regimen, the pharmacist may repackage the patient's med pak and either add to or remove from the patient's drugs packaged as ordered by the prescriber. Drugs returned by the patient for repackaging shall be reused by the pharmacist in the design of the new patient med pak, and any drug removed from the new drug regimen shall either be disposed of in compliance with board rules or returned, properly labeled, to the patient. Under no circumstances shall a drug within a container of a patient med pak be returned to the pharmacy stock.

22.5(5) Labeling requirements.

a. Except as provided in subrule 22.5(6), the patient med pak shall be labeled with the following:

- (1) The name of the patient;
- (2) The unique identification number for the patient med pak itself and a separate unique identification number for each of the prescription drug orders for each of the drug products contained therein;

- (3) The name, strength, dosage form, and total quantity of each drug product contained therein;
- (4) The directions for use for each drug product contained therein;
- (5) The name of the prescriber of each drug product;
- (6) The date of preparation of the patient med pak and the beyond-use date assigned to the patient med pak;

- (7) The name, address, and telephone number of the pharmacy; and
- (8) The initials or unique identification of the responsible pharmacist.

b. The patient med pak shall be accompanied by a patient package insert, in the event that any drug contained therein is required to be dispensed with such insert as accompanying labeling. Alternatively, such required information may be incorporated into a single, overall educational insert provided by the pharmacist for the total patient med pak.

c. If the patient med pak allows for the removal or separation of the intact containers therefrom, each individual container shall bear a label identifying the patient, the unique identification number for the patient med pak, and the name and telephone number of the dispensing pharmacy.

d. 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)”.

22.5(6) Alternate labeling. If the patient med pak container is not of sufficient size to accommodate the label information as required in subrule 22.5(5) in a legible font, a patient package insert shall be prepared and delivered with the patient med pak. The patient package insert shall contain all label information required in subrule 22.5(5). In such case, the label affixed to the patient med pak shall minimally include:

- a. The name of the patient;
- b. The unique identification number for the patient med pak;
- c. The beyond-use date assigned to the patient med pak;
- d. A statement directing the patient or patient’s caregiver to the patient package insert; and
- e. The name and telephone number of the dispensing pharmacy.

22.5(7) Expiration/beyond-use dating. Beyond-use date or period of time shall be not longer than the shortest recommended beyond-use date for any dosage form included therein or not longer than 60 days from the date of preparation of the patient med pak, whichever is shorter. In no event shall the beyond-use date exceed the shortest expiration date on the original manufacturer’s bulk containers for the dosage forms included in the patient med pak. Alternatively, the package label shall state the date of the prescriptions or the date of preparation of the patient med pak, provided the package is accompanied by a record indicating the start date and the beyond-use date.

22.5(8) Record keeping.

a. The record of each patient med pak shall contain, at a minimum:

- (1) The name and address of the patient;
- (2) A unique identification number for each of the prescription drug orders for each of the drug products contained therein;
- (3) A unique identification number for the patient med pak;
- (4) Information identifying or describing the design, characteristics, or specifications of the patient med pak sufficient to allow subsequent preparation of an identical patient med pak for the patient;
- (5) The date of preparation of the patient med pak and the beyond-use date that was assigned;
- (6) Any special labeling instructions; and
- (7) The name, unique identification, or initials of the responsible pharmacist.

b. The record of the individual prescription drug orders for each of the drug products packaged in a patient med pak shall include the unique identification number for the patient med pak wherein the prescription drug is dispensed.

This rule is intended to implement Iowa Code sections 126.10, 126.11, and 155A.28.

657—22.6 Reserved.

657—22.7(124,155A) Emergency/first dose drug supply. In any facility registered with the board under Iowa Code chapter 124 that does not have an institutional pharmacy, drugs may be supplied in one or more emergency/first dose drug supply containers located at the facility, provided that the emergency/first dose drug supply meets the requirements of this rule. The use of drugs from the emergency/first dose drug supply shall be limited to authorized personnel. The pharmacy supplying the emergency/first dose drug supply is responsible for verifying the qualifications of the facility.

22.7(1) Emergency/first dose drug supplies. All contents of the emergency/first dose drug supply shall be provided by one provider pharmacy designated by the facility, and the drug supply shall be available to meet the needs of all patients of the facility, without penalty or discrimination. The provider pharmacy shall be properly registered with the federal Drug Enforcement Administration (DEA) and the board and shall be currently licensed by the board. The provider pharmacist, the consultant pharmacist, the director of nursing of the facility, and the medical director of the facility, or their respective designees, shall jointly determine and prepare a list of drugs necessary for prompt use in patient care that will be available in the emergency/first dose drug supply. Drugs shall be listed by identity and quantity, shall be limited to drugs necessary to meet the emergency needs of the patients served, and shall be periodically reviewed pursuant to policy. Careful patient planning should be a cooperative effort between the pharmacy and the facility to make drugs available, and this supply shall only be used for emergency or unanticipated needs. The intent of the emergency/first dose drug supply is not to relieve a pharmacy of the responsibility for timely provision of a patient's routine drug needs; the intent is to ensure that a supply of drugs is available to each patient in case of urgent need. The drugs in the emergency/first dose drug supply are the responsibility of the pharmacy and, therefore, shall not be used or altered in any way except as provided in this rule.

22.7(2) Storage. The emergency/first dose drug supply shall be stored in an area suitable to prevent unauthorized access and to ensure a proper environment for preservation of drugs contained therein as required in official compendia. The provider pharmacist is responsible for establishing procedures to maintain the security of the emergency/first dose drug supply.

22.7(3) Labeling—exterior. The exterior of an emergency/first dose drug supply shall be labeled clearly and shall unmistakably indicate that it is an emergency/first dose drug supply. Such label shall also contain a listing of the name, strength, and quantity of each drug contained therein and an expiration date of the supply based upon the earliest expiration date of any drug contained in the supply.

22.7(4) Labeling—interior. All drugs contained in the emergency/first dose drug supply shall be labeled in accordance with subrule 22.3(2) or 22.1(3), as appropriate.

22.7(5) Removal of drugs. A drug shall be removed from the emergency/first dose drug supply only pursuant to a valid prescription order and by authorized personnel or by the provider pharmacist. The patient's dispensing pharmacy shall be notified, prior to the administration of a second dose, that a drug was administered to a specific patient. Upon notification, the dispensing pharmacist shall perform drug use review to assess the appropriateness of the drug therapy for the patient.

22.7(6) Notifications. Whenever an emergency/first dose drug supply is opened or has expired, the provider pharmacy shall be notified and the pharmacist shall be responsible for replacing the drug within 72 hours to prevent risk of harm to patients. Policy must be developed by the provider pharmacist to address notification, record keeping, and documentation procedures for use of the supply.

22.7(7) Procedures.

a. The consultant or provider pharmacist shall, in communication with the director of nursing of the facility and the medical director of the facility, or their respective designees, develop and implement written policies and procedures to ensure compliance with this rule.

b. The provider pharmacy shall keep a record of each prescription drug stored in the emergency/first dose drug supply and the number of doses provided.

c. The facility shall keep a complete record of the use of prescription drugs from the emergency/first dose drug supply for two years following such use. The record shall include the patient's name, the date of use, the name of the drug used, the strength of the drug, the number of doses used, the name of the prescriber authorizing the administration, and the initials or unique identification of the person administering the dose.

d. The drugs maintained in the emergency/first dose drug supply shall be available for the emergency pharmaceutical care of all facility patients, without penalty or discrimination. If a service charge is assessed for the administration of a drug from the emergency/first dose drug supply, the same reasonable service charge shall be assessed to each patient to whom a drug from the emergency/first dose drug supply is administered, regardless of the patient's choice of pharmacy for pharmaceutical services.

This rule is intended to implement Iowa Code sections 124.301, 124.306, 155A.13, and 155A.15.

657—22.8 Reserved.

657—22.9(155A) Home health agency/hospice emergency drugs. Recognizing the emergency and unanticipated need for drugs to be available to qualified individuals authorized to administer drugs and employed by a home health agency or hospice, an Iowa-licensed pharmacy may provide an emergency drug supply pursuant to this rule. Such qualified individuals may carry the emergency drug supply. An inpatient hospice facility may have an emergency drug supply provided by an Iowa-licensed pharmacy pursuant to rule 22.7(124,155A), which supply may be maintained within the facility.

22.9(1) Contract. A written contract shall exist between the home health agency or hospice and the pharmacist in charge of the Iowa-licensed pharmacy. This contract shall be available for review by the board or its authorized agent upon request.

22.9(2) Ownership retained. The drugs included in this emergency supply shall remain the property of and under the responsibility of the Iowa-licensed provider pharmacy.

a. The pharmacist shall ensure that each portable container of emergency drugs is sealed in such a manner that a tamperproof seal must be broken to gain access to the drugs.

b. Each portable container of emergency drugs shall be labeled on the outside of the container with a list of the contents and the earliest expiration date.

22.9(3) Removal of drugs. All drugs shall be administered only on prior prescribers' order or by protocol approved by the agency's medical director or appropriate committee. Drugs administered from the emergency supply shall be replaced by submitting a prescription or medication order for the used item to the provider pharmacy within a reasonable time of administration.

22.9(4) Records. All records of drugs administered from the emergency supply shall be maintained as required by law. If a container of an injectable product is opened and partially used, any unused portion shall be immediately discarded and appropriately documented.

22.9(5) Drugs included. The provider pharmacist and the director of the home health agency or hospice, or their respective designees, shall jointly determine a list of drugs necessary for prompt use in the care of patients served by the home health agency or hospice and that will be available in the emergency drug supply. Drugs shall be listed by identity and quantity and shall be periodically reviewed in accordance with policy.

22.9(6) Policies and procedures. The pharmacist in charge of the provider pharmacy and the home health agency or hospice shall develop policies and procedures to address storage conditions and security for drugs and kit maintenance. Outdated, expired drugs shall be properly disposed of by the pharmacy.

22.9(7) Responsibility for compliance. The provider pharmacy is responsible to ensure compliance with this rule, and any abuse or misuse of the intent of this rule shall be immediately reported to the board.

This rule is intended to implement Iowa Code sections 155A.4, 155A.13, and 155A.15.

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