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. A patient med pak includes but is not limited to a strip pack prepared utilizing an automated medication distribution system (AMDS).

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 may 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 or returned to an automated medication distribution system (AMDS) component unless the drug was dispensed as a single dose and was not commingled with other patient medications in a single package or container.

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)". If a pharmacist selects an interchangeable biological product for the biological product prescribed by a practitioner, the label shall identify the interchangeable biological product dispensed and may identify the biological product prescribed by the practitioner, such as "(interchangeable biological product) for (biological 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.* The record of each patient med pak shall contain, at a minimum:

a. The name and address of the patient;

b. The unique identification number for each of the current prescription drug orders for each of the drug products contained therein;

c. A unique identification number for the patient med pak;

d. 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;

e. The date of preparation of the patient med pak and the beyond-use date that was assigned;

f. Any special labeling instructions; and

g. The name, unique identification, or initials of the responsible pharmacist.

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

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