Substantive Policy

Guidance Document for Customized Patient Med-Paks

SUBSTANTIVE POLICY - CUSTOMIZED PATIENT MEDICATION PACKAGES

The Board of Pharmacy recognizes Customized Patient Medication Packages (Med Paks) as acceptable medication delivery systems for prescription drugs in proper applications and patient populations.

PROPOSAL: The Board recognizes the standards for Customized Patient Medication Packages published in the USP and paraphrased below. Compliance is based on official compendium standards (see current USP Containers-Physical Tests <661>).

In lieu of dispensing two or more prescribed drug products in separate containers, a pharmacist may, with the consent of the patient, the patient's caregiver, or a prescriber, provide a customized patient medication package (patient med pak).

A patient med pak is a package prepared by a pharmacist for a specific patient comprising a series of containers and containing two or more prescribed solid oral dosage forms. The patient med pak is so designed or each container is so labeled as to indicate the day and time, or period of time, that the contents within each container are to be taken.

A. The patient med pak shall bear a label stating:

- 1. the name of the patient;
- 2. a serial number for the patient med pak itself and a separate identifying serial number for each of the prescription orders for each of the drug products contained therein;
- 3. the name, strength, physical description or identification, and total quantity of each drug product contained therein;
- 4. the direction for use and cautionary statements, if any, contained in the prescription order for each drug product therein;
- 5. any storage instructions or cautionary statements required by the official compendia;
- 6. the name of the prescriber of each drug product;
- 7. the date of preparation of the patient med pak and the beyond-use date assigned to the patient med pak (such beyond-use date shall be not later than 60 days from the date of preparation);
- 8. the name, address, and telephone number of the dispenser and the dispenser's registration number where necessary;
- 9. any other information, statements, or warning required for any of the drug products contained therein.

B. If the patient med pak allows for the removal or separation of the intact containers therefrom, each individual container shall bear a label identifying each of the drug products contained therein.

Labeling: The patient med pak shall be accompanied by a patient package insert, in the event that any medication 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.

Packaging: In the absence of more stringent packaging requirements for any of the drug products contained therein, each container of the patient med pak shall comply with the moisture permeation requirements for a Class B single-unit or unit-dose container (see current USP, Containers-Permeation <671>). Each container shall be either not recloseable or so designed as to show evidence of having been opened.

Guidelines: It is the responsibility of the dispenser, when preparing a patient med pak, to take into account any applicable compendia requirements or guidelines and the physical and chemical compatibility of the dosage forms placed within each container as well as any therapeutic incompatibilities that may attend the simultaneous administration of the medications. In this regard, pharmacists are encouraged to report to USP headquarters any observed or reported incompatibilities.

Recordkeeping: In addition to any individual prescription filing requirements, a record of each patient med pak shall be made and filed. Each record shall contain, as a minimum:

- 1. the name and address of the patient;
- 2. the serial number of the prescription order for each drug product contained therein;
- 3. the name of the manufacturer or labeler and lot number for each drug product contained therein;
- 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 or initials of the pharmacist who prepared the patient med pak.

This substantive policy statement is advisory only. A substantive policy statement does not include internal procedural documents that only affect the internal procedures of the agency and does not impose additional requirements or penalties on regulated parties or include confidential information or rules made in accordance with the Arizona Administrative Procedure Act. If you believe that this substantive policy statement does impose additional requirements or penalties on regulated parties you may petition the agency under A.R.S. § 41-1033 for a review of the statement. **REV. 08/2002**