USP CUSTOMIZED PATIENT MEDICATION PACKAGES

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 care giver, or a prescriber, provide a customized patient medication package (patient med pack).6

A patient med pack 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 pack 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.

Label- (A) The patient med pack shall bear a label stating:

(1) the name of the patient;
(2) a serial number for the patient med pack itself and 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 directions 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 the preparation of the patient med pack and the beyond-use date assigned to the patient med pack (such beyond-use date shall be no 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 and
(9) any other information, statements, or warnings required for any of the drug products contained therein.

(B) If the patient med pack 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 pack shall be accompanied by the 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 pack.

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

Guidelines- It is the responsibility of the dispenser, when preparing a patient med pack, to take into account any applicable compendial 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 the USP headquarters any observed or reported incompatibilities.

Record keeping- In addition to any individual prescription filling requirements, a record of each patient med pack 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 product contained therein;
(4) information identifying or describing the design, characteristics or specifications of the patient med

pack sufficient to allow subsequent preparation of an identical patient med pack for the patient;

(5) the date of the preparation of the patient med pack 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 pack