6800.3750 UNIT DOSE DISPENSING.

Subpart 1. **Control.** A unit dose system shall be under the control of the pharmacist-in-charge. The act of drug dispensing is reserved for licensed pharmacists and registered pharmacist-interns acting under the supervision of licensed pharmacists, as set forth in part 6800.3100. A unit dose system may be used as an alternative to part 6800.3100, subpart 1, items D, F, and G, according to the following subparts.

Subp. 2. **Unit dose packaging.** Unit dose packaging is the packaging of individual doses of medication in containers which will preserve the identity and integrity of the drug from the point of packaging to the point of administration to the patient. Packaging may be accomplished by a manufacturer or by a pharmacy in accordance with part 6800.3200.

Individual doses of medication shall be properly labeled from the manufacturer with the name of the drug, dosage form and strength, manufacturer's name and lot number, and expiration date of all time dated drugs, or labeled in accordance with part 6800.3200 if prepackaged by the pharmacy.

Unit dose packaging may provide individual doses of medication attached to each other by placement in a card or other container. Such packaging shall be labeled in accordance with part 6800.3200 in such a manner as to provide continuous identification of the contents and, when dispensed, the name and location of the patient, name of the prescribing practitioner, prescription number, date, the directions for use, and identification of the pharmacy.

Subp. 3. **Unit dose system.** The unit dose system is that drug distribution system which is pharmacy based and which uses unit dose packaging in a manner which removes traditional drug stocks from patient care areas and enables the selection and distribution of unit dose packaging to be pharmacy based and controlled.

The system must provide and the pharmacist must utilize:

A. a means of separating medications by patient name and bed number;

B. a means of separating medications by day of administration;

C. a means of identifying individual doses dispensed, doses administered, and doses returned;

D. a means of identifying the dosage regimen of each drug, including the date of the original prescription drug order and the date of changes, if any, made to the prescription drug order;

E. a means of identifying the total dosage regimen of each patient;

F. a means of identifying the time of administration of each drug;

G. a means for the pharmacist to verify the original prescription drug order; and

H. a means for the pharmacist to certify the accuracy of the selected medication before the dose is delivered for administration to the patient.

Subp. 4. **Written policies.** Each pharmacy utilizing a unit dose dispensing system shall establish written policies specifying the categories of drugs which will or which will not be dispensed under the unit dose distribution system. Such policies shall be available in the pharmacy for inspection by the board.

Subp. 5. **Unit dose preferred.** Proper utilization of the unit dose system requires that in as far as is practicable all medications be in unit dose packaging when dispensed.

Subp. 6. **Controlled substances.** Schedule II, III, and IV controlled substances may be included in the unit dose system if the methods of including such drugs in the system are in compliance with applicable federal and state laws and rules.

Subp. 7. **Legend drugs.** Legend drugs not dispensed under the unit dose dispensing system must be dispensed in accordance with part 6800.3100 and labeled in accordance with parts 6800.3400 and 6800.4150.

Subp. 8. **Who may perform non-dispensing functions.** Selection of individual unit dose packaging for placement in individual patient containers, bins, compartments, or drawers is not dispensing under part 6800.3100, and may be performed by supportive personnel. Dispensing occurs upon the certification of the accuracy of the selected unit dose packages, which shall be done by the pharmacist before the dose is delivered for administration to the patient.

Subp. 9. **Storage of medications.**

A. All controlled substances must be stored in a locked area or locked cart at all times.

B. All noncontrolled substances must be stored in a locked area or locked cart when a patient care area is not staffed. An area in which staff is actively providing patient care or preparing to receive patients is considered a secure area and locked storage of noncontrolled substances is not required.

Subp. 10. **Compliance.** Unit dose system shall comply with existing law with respect to provisions of pharmaceutical services to hospitals and nursing homes and as set forth in parts 6800.6100 to 6800.7950.

Statutory Authority: *MS s 151.06*

History: *9 SR 1656; 36 SR 237*

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