6800.3450 LABELING OF OUTPATIENT INTRAVENOUS ADMIXTURE DRUGS.

Subpart 1. **Labeling requirements.** Intravenous admixture drugs dispensed to or for a patient, other than a hospitalized patient, shall be labeled according to the requirements of part 6800.3400, subpart 1, items A to J, and in addition shall contain the following:

A. date of compounding;

B. beyond-use date;

C. storage requirements if other than room temperature;

D. infusion or administration rate;

E. administration times, administration frequency, or both; and

F. other accessory cautionary information which in the professional judgment of the pharmacist is necessary or desirable for proper use by and safety of the patient.

Subp. 2. **Additions to admixtures.** When an additional drug is added to intravenous admixtures, the admixtures shall be labeled on the original label or with a distinctive supplementary label indicating the name and the amount of the drug added, date and time of addition and expiration, and the unique identifier of the person adding the drug.

Subp. 3. **Audit trail.** A pharmacy engaged in the dispensing of outpatient intravenous admixtures shall develop a five-year audit trail system that will identify the dispensing pharmacist for each unit dispensed.

Statutory Authority: *MS s 151.06; 152.02*

History: *18 SR 1145; 31 SR 1673; 36 SR 237*

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