6800.3400 PRESCRIPTION LABELING.

Subpart 1. **Requirements applicable to all drugs.** Except for radiopharmaceuticals, all drugs dispensed to or for a patient, other than an inpatient of a hospital must be labeled with the following information:

A. name, address, and telephone number of the pharmacy filling the prescription drug order, except that central service pharmacies shall use the name, address, and telephone number of the pharmacy dispensing the medication to the patient;

B. patient's name;

C. prescription number;

D. name of prescribing practitioner;

E. directions for use;

F. name of manufacturer or distributor of the finished dosage form of the drug;

G. auxiliary labels as needed;

H. date of original issue or renewal;

I. generic or trade name of drug and strength, except when specified by prescriber to the contrary. In the case of combining premanufactured drug products, the names of the products, or a category of use name shall suffice. In the case of compounding basic pharmaceutical ingredients, the common pharmaceutical name, if such exists, the names and strengths of the principal active ingredients or a category of use name shall suffice;

J. prescription drug orders filled as part of a central service operation must bear an identifier that indicates the central service pharmacy at which they were filled; and

K. after July 1, 2008, any dispensed legend drug, or nonlegend drug not dispensed in the manufacturer's original container, must be labeled with its physical description, including any identification code that may appear on tablets and capsules. This requirement does not apply to drugs dispensed as part of an investigational drug study.

Subp. 2. **Small container labeling.** In cases where the physical characteristics of the immediate container of the medication do not permit full labeling, a partial label containing, at a minimum, the patient name and the prescription number may be placed on the container and the complete labeling applied to an appropriate outer container.

Subp. 3. **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 caregiver, or the prescriber, provide a customized patient medication package as defined in the United States Pharmacopeia (USP), chapter 661, standards.

Subp. 4. **Veterinary prescription drug label.** The label for a filled veterinary prescription that is dispensed by a licensed pharmacy must include:

A. in the case of non-food-producing animals, the name of the client or animal. In the case of food-producing animals, the name of the owner and the specific name and address of the facility at which the filled prescription will be used;

B. identification of the species for which the drug is prescribed or ordered;

C. the name, strength, and quantity of the drug, except when specified by the prescriber to the contrary. In the case of combining premanufactured drug products, the names of the products, or category of use may suffice;

D. the name of the manufacturer or distributor of the finished dosage form of the drug;

E. the date of issue;

F. directions for use;

G. withdrawal time, excluding non-food-producing animals;

H. cautionary statements if appropriate for the drug;

I. the name, address, and telephone number of the pharmacy, except that central service pharmacies must use the name, address, and telephone number of the pharmacy dispensing the medication to the client;

J. the name and address of the prescribing veterinarian, except that the address of the prescribing veterinarian is not required if the prescription is for a non-food-producing animal; and

K. the prescription number.

When the veterinary drug is in the manufacturer's original package and the information that is required on the label includes the drug or drugs, strength of the drug or drugs, directions for use, withdrawal time for food-producing animals, and cautionary statements, a label will be required on each individual bottle or package.

Subp. 5. **Radiopharmaceutical labeling.** Radiopharmaceutical labeling shall comply with the requirements in part 6800.8550.

Statutory Authority: *MS s 151.06; 151.212; 152.02*

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

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