481—552.21(155A) Labeling.

552.21(1) *Ambulatory prescription labeling.* The required labeling elements for a prescription dispensed for an ambulatory patient include:

a. Patient name, except as provided by the Iowa Code.

b. Prescriber name.

c. Pharmacy name, address, and telephone number.

d. Product name, strength, dosage form, and quantity.

e. Instructions for use.

f. Dispense date.

g. Unique serial number.

h. Manufacturer name or NDC.

552.21(2) *Institutional patient-specific prescription labeling.* The required labeling elements for a patient-specific supply of prescription medication dispensed for an institutional patient include:

a. On the immediate container:

(1) Patient name.

(2) Drug name, strength, and dosage form.

b. On outer packaging, if not present on the immediate container:

(1) Instructions for use.

(2) Pharmacy name, address, and telephone number unless the pharmacy is located within the institutional facility.

(3) Dispense date.

(4) Unique serial number.

(5) Beyond-use date.

552.21(3) *Non-patient-specific drug labeling.* The required labeling elements for a non-patient-specific supply of prescription medication include:

a. Drug name, strength, and dosage form.

b. Drug manufacturer or NDC.

c. Expiration or beyond-use date.

552.21(4) *Compounded patient-specific preparation labeling.* In addition to the required labeling identified in subrule 552.21(1) or 552.21(2), as applicable, a label for a compounded preparation will also include:

a. The name and concentration of each active ingredient.

b. The date that the preparation was compounded.

c. Special storage and handling instructions, if applicable.

d. Except in institutional settings, the statement "THIS IS A COMPOUNDED DRUG" or a similar statement identifying the product as a compounded preparation, including the term "STERILE" when applicable.

e. The batch identification or control number from which the preparation was dispensed, if applicable.

f. Beyond-use date.

552.21(5) *Compounded non-patient-specific preparation labeling—batch compounding or veterinary office supply.* The required labeling elements for a non-patient-specific supply of a compounded preparation include:

a. Preparation name, strength, dosage form, and quantity.

b. Name and concentration of each active ingredient.

c. Pharmacy name, address, and telephone number, except when batch compounding.

d. Preparation date.

e. Beyond-use date.

f. Storage and handling instructions.

g. Lot or batch identification or control number, if applicable.

h. The statement "THIS IS A COMPOUNDED DRUG" or a similar statement identifying the product as a compounded preparation, including the term "STERILE" when applicable, except for use within an institutional setting.

i. The statement "NOT FOR REDISTRIBUTION" or a similar statement to ensure that use of the compounded preparation is limited to direct patient administration or dispensing pursuant to a patient-specific prescription.

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