

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.

[ARC 9338C, IAB 6/11/25, effective 7/16/25; see Delay note at end of chapter]