657—20.19(124,126,155A) Labeling. The label, or attached auxiliary labeling if necessary, affixed to the container of any compounded preparation dispensed or distributed into or within Iowa shall contain at least the information identified in one of the following subrules, as applicable.

20.19(1) *General pharmacy or outpatient dispensing.* The label shall meet the labeling requirements of 657—subrule 6.10(1) and shall include the following additional information:

a. The name and concentration of each active ingredient.

b. The date that the preparation was compounded.

c. The beyond-use date of the compounded preparation.

d. Special storage and handling instructions, if applicable.

e. The statement "COMPOUNDED PREPARATION" or a reasonable comparable alternative statement that prominently identifies the drug as a compounded preparation.

f. If the compounded preparation is sterile, the word "STERILE."

g. If the compounded preparation was prepared from batch preparation compounding, the batch identification or control number.

20.19(2) *Hospital pharmacy or inpatient administration.* The label shall meet the labeling requirements of 657—subrule 22.1(3) and shall include the following additional information:

a. The name and concentration of each active ingredient.

b. The date that the preparation was compounded.

c. The beyond-use date of the compounded preparation.

d. If the compounded preparation was prepared from batch preparation compounding, the batch identification or control number.

e. Special storage and handling instructions, if applicable.

20.19(3) *Outsourcing facility distribution or dispensing.* The label, or auxiliary labeling if necessary, shall include the following information:

a. The statement "THIS IS A COMPOUNDED DRUG" or a reasonable comparable alternative statement that prominently identifies the drug as a compounded preparation.

b. The name, address, and telephone number of the outsourcing facility that compounded the preparation.

c. The established name of the preparation.

d. The dosage form and strength.

e. The quantity of the preparation.

f. The date that the preparation was compounded.

g. The beyond-use date of the compounded preparation.

h. Storage and handling instructions.

i. The lot or batch identification or control number.

j. The national drug code number, if available.

k. The statement "Not for resale" and, if the preparation is dispensed or distributed other than pursuant to a patient-specific prescription, the statement "OFFICE USE ONLY."

l. The following additional information, which can be included on the labeling of a container (such as a plastic bag containing individual product syringes) from which individual units of the drug are removed for dispensing or for administration if there is not space on the label for such information:

(1) Directions for use including, as appropriate, dosage and administration;

(2) A list of the active and inactive ingredients, identified by established name and quantity or proportion of each ingredient;

(3) FDA contact information (www.fda.gov/medwatch and 1-800-FDA-1088 or successor website or telephone number) to facilitate adverse event reporting.

m. If the preparation is compounded pursuant to a prescription for a specific patient, the label shall also include the label requirements in 657—subrule 6.10(1).

n. If the preparation is compounded for office use, the label shall also include the label requirements in subrule 20.15(4).

[**ARC 2194C**, IAB 10/14/15, effective 11/18/15; **ARC 3238C**, IAB 8/2/17, effective 9/6/17]