481—552.22(155A) Compounding.

552.22(1) *USP standards—pharmacies.* Preparations compounded pursuant to 21 U.S.C. §353a (Food, Drug, and Cosmetic Act §503A) as amended November 27, 2013, will be prepared in accordance with the standards of USP General Chapter 795 (2023) for nonsterile compounds and USP General Chapter 797 (2023) for sterile compounds.

552.22(2) *Compounding copies of an approved drug.*

a. The compounding of a preparation that is essentially a copy of an FDA-approved drug is prohibited unless:

(1) The compounded preparation is changed to produce for an individual patient a clinically significant difference to meet a medical need as documented by the prescriber, or

(2) The FDA-approved product is identified as currently in shortage on the FDA drug shortages database.

b. The factors that indicate that a compounded preparation is essentially a copy of an approved drug include:

(1) The compounded preparation has the same active pharmaceutical ingredient(s) as the commercially available drug product;

(2) The active pharmaceutical ingredients have the same, a similar, or an easily substitutable dosage strength; and

(3) The commercially available drug product can be used by the same route of administration as prescribed for the compounded preparation.

c. A prescription issued for a compounded preparation that is essentially a copy of an approved drug will clearly document the relevant change and the significant clinical difference produced for the patient.

552.22(3) *Compounding for veterinary office use.* A pharmacy may compound preparations for distribution to a veterinarian for office use, which may include direct patient administration or dispensing pursuant to a patient-specific prescription.

552.22(4) *Reporting.* Annually, prior to April 1, each licensed pharmacy located in Iowa that dispensed compounded preparations for human use interstate in the previous calendar year will report compounding data to the NABP information-sharing network.

552.22(5) *Exemptions.* The combining of commercially manufactured, ready-to-use products is exempt from USP General Chapter 795 (2023) compounding standards under the following conditions:

a. No more than four commercially manufactured, ready-to-use products (that have not been manipulated) are used.

b. Compounding is not done in anticipation of medication orders.

c. Preparations are assigned beyond-use dates in accordance with USP General Chapter 795 (2023).

d. The use of commercially manufactured, ready-to-use flavoring agents does not exceed 5 percent of the total volume of the drug to which the flavoring agents are added.

e. The prescription label will comply with USP General Chapter 795 (2023) and subrule 552.21(4).

552.22(6) *Records.* A record for each compounded preparation will be prepared and maintained and will include:

a. All ingredients used in the preparation, including manufacturer or NDC, lot number, and expiration date.

b. The compounding steps involved in the preparation.

c. All personnel involved in compounding and reviewing the preparation.

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