

657—20.15(124,126,155A) Compounding for office use.

20.15(1) *Human compounded preparations.* Only an FDA-registered outsourcing facility properly licensed in Iowa pursuant to 657—Chapter 41 may distribute to a practitioner for office use human compounded preparations without a patient-specific prescription.

20.15(2) *Veterinary compounded preparations.* Veterinary compounded preparations may be sold to a practitioner for office use if the preparations are compounded by an Iowa-licensed pharmacy or outsourcing facility and sold directly to the practitioner by the pharmacy or outsourcing facility. Veterinary compounded preparations sold to a practitioner for office use may be dispensed to the owner of a veterinary patient to treat an immediate medical need when timely access to a patient-specific supply of compounded medication is not available, no commercially available product can meet the need of the patient, lack of treatment will likely result in patient harm, and the supply does not exceed 14 days.

20.15(3) *Office use.* Compounded preparations distributed for office use pursuant to subrule 20.15(1) or 20.15(2) and in accordance with the labeling requirements of subrule 20.15(4) do not require a patient-specific prescription but do require that the compounded preparation be administered to a patient in the course of the practitioner's professional practice. Compounded preparations distributed for office use pursuant to this rule shall not be further distributed to other practitioners or dispensed to a patient for self-administration, except as provided in subrule 20.15(2).

20.15(4) *Labeling.* Compounded preparations for office use, in addition to the labeling requirements specified in rule 657—20.19(124,126,155A), shall include on the prescription label the practitioner's name in place of the patient's name. The label shall state "For Office Use Only—Not for Resale." If the sterility or integrity of the compounded preparation cannot be maintained after the initial opening of the container, the label shall state "Single-Dose Only."

[ARC 2194C, IAB 10/14/15, effective 11/18/15; ARC 2559C, IAB 6/8/16, effective 7/13/16; ARC 3238C, IAB 8/2/17, effective 9/6/17; ARC 6331C, IAB 6/1/22, effective 7/6/22]