

657—20.16(124,126,155A) Compounding for hospital use. Compounded preparations distributed or dispensed to a hospital or hospital pharmacy pursuant to this rule shall be administered to an individual patient in the hospital.

20.16(1) *By an FDA-registered outsourcing facility.* Only an FDA-registered outsourcing facility properly licensed in Iowa pursuant to 657—Chapter 41 may distribute human compounded preparations to a hospital or hospital pharmacy in the absence of a patient-specific prescription. The compounded preparation shall be labeled in compliance with subrule 20.19(3).

20.16(2) *By a pharmacy that is not an FDA-registered outsourcing facility.* Human compounded preparations that are not compounded at an FDA-registered outsourcing facility may be dispensed to a hospital or hospital pharmacy by an Iowa-licensed pharmacy pursuant to a prescriber's authorization for administration to a specific patient. The compounded preparation shall be labeled in compliance with subrule 20.19(2).

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