657—20.12(126,155A) Compounding copies of an approved drug. A pharmacy or outsourcing facility may only compound preparations that are essentially copies of approved drugs if the compounded preparation is changed to produce for an individual patient a clinically significant difference to meet a medical need as determined and authorized by the prescriber. A pharmacy or outsourcing facility may compound a preparation that is essentially a copy of an approved drug if the approved drug is identified as currently in shortage on the FDA drug shortages database published on the FDA Web site, http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.

20.12(1) *Essentially a copy.* The board may consider the existence of the following factors as an indication that a compounded preparation is essentially a copy of an approved drug:

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

b. The active pharmaceutical ingredient(s) has the same, similar, or an easily substitutable dosage strength; and

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

20.12(2) *Clinically significant difference.* The prescription for a compounded preparation that is essentially a copy of an approved drug shall clearly indicate the relevant change and the significant clinical difference produced for the patient. A prescription that identifies only a patient name and compounded preparation formulation is insufficient documentation for a pharmacy or outsourcing facility to rely upon to conclude that the prescriber made a determination regarding a clinically significant difference.

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