

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>.
[ARC 2194C, IAB 10/14/15, effective 11/18/15]