
Emergency Rule

**Title 20—DEPARTMENT OF COMMERCE AND
INSURANCE
Division 2220—State Board of Pharmacy
Chapter 2—General Rules**

EMERGENCY AMENDMENT

20 CSR 2220-2.400 Compounding Standards of Practice. The board is adding subsection (12)(A).

PURPOSE: This emergency amendment allows compounding of iodinated contrast media prior to receiving a patient specific prescription until December 17, 2022, to address a national supply shortage.

EMERGENCY STATEMENT: On May 9, 2022, the U.S. Food and Drug Administration announced a national shortage of iohexol injection stemming from the temporary shutdown of the manufacturer's production facility in Shanghai, China, reportedly related to COVID-19. Iohexol injection is an iodinated contrast media used, in part, to provide emergency medical care to patients suffering from possible strokes, heart attacks, abdominal pain, and pulmonary embolisms. Iodinated contrast media is also used for computerized tomography (CT) scans and by oncology practices. The Missouri Hospital Association (MHA) and a large Missouri hospital system subsequently met with board staff on June 1, 2022, and asked that the board take emergency action to allow pharmacies to repackage/compound currently available iodinated contrast media in smaller quantities for use by other hospitals, ambulatory surgical centers, pharmacies, and healthcare entities. Absent emergency action, MHA indicated Missouri hospitals and healthcare providers may not have adequate supply of iodinated contrast media to treat critical Missouri patients. Significantly, multiple Missouri pharmacies and hospitals reported needed imaging contrast is unavailable from other manufacturers, with some Missouri hospitals reporting up to an eighty percent (80%) decrease in allocations/available quantities. The manufacturer has reopened production on a limited basis, however, iodinated contrast media shortages are anticipated to last through the fall, at a minimum. As a result, the Missouri Board of Pharmacy finds there is an immediate danger to the public health, safety and/or welfare and a compelling governmental interest that requires this emergency action. Specifically, the emergency amendment would allow pharmacies to repackage/compound iodinated contrast media for use by other hospitals, pharmacies, and healthcare entities until December 17, 2022. Absent an emergency rule, Missouri patients may not be able to receive critical lifesaving care/treatment. The scope of this emergency amendment is limited to the circumstances creating the emergency and complies with the protections extended in the *Missouri and United States Constitutions*. The Missouri Board of Pharmacy believe this emergency amendment is fair to all interested persons and parties under the circumstances. This emergency amendment was filed June 6, 2022, effective June 21, 2022, and expires December 17, 2022.

(12) Except as provided by law, pharmacists shall not offer or provide compounded preparations to other pharmacies, practitioners, or entities for subsequent dispensing, distribution, resale, or administration, except in the course of professional practice for a prescriber to administer to an individual patient by a prescription dispensed by the pharmacy. A pharmacist or pharmacy may advertise or otherwise provide information concerning the provision of compounding services; however, no pharmacist or pharmacy shall attempt to solicit business by making specific claims about compounded preparations.

(A) Due to a national shortage, a pharmacist may compound and provide iodinated contrast media to/for other pharmacies, practitioners, or entities without a patient specific prescription/order for dispensing or administration if the medication is compounded in a Class H Sterile Compounding

Pharmacy in compliance with 20 CSR 2220-2.200. The provisions of this subsection (12)(A) shall expire on December 17, 2022.

AUTHORITY: sections 338.010 and 338.140, RSMo Supp. [2018] 2021, and sections [338.140,] 338.240, and 338.280, RSMo 2016. This rule originally filed as 4 CSR 220-2.400. Original rule filed Aug. 25, 1995, effective April 30, 1996. For intervening history, please consult the *Code of State Regulations*. Emergency amendment filed June 6, 2022, effective June 21, 2022, expires December 17, 2022. An emergency amendment covering the same material will be published in the July 15, 2022, issue of the *Missouri Register*.

PUBLIC COST: This emergency amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the time the emergency is effective.

PRIVATE COST: This emergency amendment will not cost private entities more than five hundred dollars (\$500) in the time the emergency is effective.