



Missouri Board of Pharmacy

BOARD GUIDANCE ON NATIONAL SHORTAGE OF IODINATED CONTRAST MEDIA (6-8-22)

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. The shutdown has resulted in a national shortage of iodinated contrast media that is impacting Missouri licensees, hospitals and health care providers. In response, the Board is issuing the following guidance to address the national shortage:

Iodinated Contrast Media Distribution

The Board has been asked if a drug distributor license is required for a non-licensed entity to provide iodinated contrast media to a pharmacy, hospital, or health care entity to help alleviate the shortage. 20 CSR 2220-5.020(1)(B) provides:

(B) Licensure and/or registration as a wholesale drug distributor is not required for activities described below— 1. The sale, purchase, transfer, or trade of a drug or an offer to sell, purchase, transfer, or trade a drug for emergency administration to an individual patient if a delay in therapy would negatively affect a patient outcome. The amount sold, purchased, transferred, or traded shall not exceed five percent (5%) of the pharmacy's total gross prescription sales or, if prescriptions are not sold, five percent (5%) of the pharmacy's total drug purchases;

A drug distributor license would not be required for distribution of iodinated contrast media during the national shortage under the above exemption.

Compounding/Repackaging

To help conserve the limited supply of iodinated contrast media, licensees have asked the Board about repackaging commercially-available vials into smaller size containers for use by entities. This activity is considered sterile compounding and would normally require a patient-specific prescription.

In response to licensee requests, the Board has filed the following emergency rule amendment for 20 CSR 2220-2.200 to add the following emergency allowance:

(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.



The emergency rule is available on the Missouri Secretary of State's website at: [20 CSR 2220-2.400 Compounding Standards of Practice](#) and will be effective on June 21, 2022. However, to protect Missouri patients and ensure availability of critical medication supplies, pharmacists/licenses may now compound iodinated contrast media without a patient specific prescription in compliance with the above requirements until December 17, 2022. *(Note: Beyond-Use-Dating of repackaged product would be governed by 20 CSR 2220-2.200, for questions, please contact Inspector Katie DeBold, Katie.DeBold@pr.mo.gov)*

A Missouri [Pharmacy Change of Classification application](#) is required to add a Class H Sterile Compounding permit classification to an existing license. Applications are available on the Board's website at: <https://pr.mo.gov/boards/pharmacy/375-0475.pdf> and will be expedited by the Board office during the national shortage.

Repackaging Contract Media For Use Within a Hospital

Hospital pharmacies repackaging contrast media for use within their Missouri Department of Health and Senior Services (DHSS) licensed hospital premises must comply with DHSS requirements. For guidance, please contact the DHSS hospital section at HSRelectronic2567@health.mo.gov.

Hospital pharmacies repackaging contrast media for use outside of their DHSS licensed hospital premises or at other hospitals must comply with Board requirements.

