

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

**PROPOSED RULE**

**20 CSR 2220-2.410 Class B Hospital Pharmacy Compounding for Drug Shortages**

*PURPOSE: This rule establishes requirements for Class B hospital pharmacies compounding medication in the event of a drug shortage.*

- (1) Class-B hospital pharmacies may compound and provide medications that are on shortage to patients without a patient specific prescription, provided:
  - (A) The pharmacy has confirmed and documented the product is not available despite due diligence;
  - (B) The medication is compounded for administration to patients in a hospital clinic or facility or in another hospital that is under common control, management, or ownership of the same hospital or hospital system, as defined by section 338.165, RSMo;
  - (C) The preparation compounded is the same dosage form and strength that is in shortage;
  - (D) The quantity distributed at one time does not exceed the amount needed to meet the anticipated healthcare practitioner need for seven (7) days based on the hospital's or hospital clinic's/facility's usage;
  - (E) The pharmacy must stop compounding and distribution once the product is available;
  - (F) The pharmacy must label the preparation container with:
    1. Pharmacy name, address, and telephone number;
    2. Date of distribution;
    3. Preparation name, strength, dosage form, and quantity;
    4. Name of each active or therapeutic ingredient included in the preparation;
    5. Preparation lot/batch number;
    6. Preparation beyond-use date; and
    7. Statement: "Pharmacy Compounded Preparation";
  - (G) The pharmacy maintains a record of the distribution that is readily available on request of the board or the board's authorized designee and can be retrieved by specific hospital or hospital clinic or facility, if requested;
  - (H) In lieu of recording an identifying prescription number or a readily retrievable unique identifier, the hospital or hospital clinic or facility name must be recorded on the compounding log;
  - (I) The pharmacy must comply with all applicable provisions of 20 CSR 2220-2.400. A Class H license and compliance with 20 CSR 2220-2.200 is required for any sterile preparation; and
  - (J) The pharmacy complies with all applicable controlled substance laws and regulations.

(2) Unless otherwise provided by law or court of competent jurisdiction, the provisions of this rule are only applicable to pharmacy services under the jurisdiction of the board and are not applicable to hospital pharmacy services under the jurisdiction of the Missouri Department of Health and Senior Services pursuant to Chapter 197, RSMo.

*AUTHORITY: sections 338.140.1 and section 338.210, RSMo Supp. 2022, and section 338.280, RSMo, 2016. Original rule filed: March 10, 2023.*

*PUBLIC COST: This proposed rule will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.*

*PRIVATE COST: This proposed rule will not cost private entities more than five hundred dollars (\$500) in the aggregate.*

*NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rule with the Missouri Board of Pharmacy, PO Box 625, 3605 Missouri Boulevard, Jefferson City, MO 65102, by facsimile at (573) 526-3464, or via email at [pharmacy@pr.mo.gov](mailto:pharmacy@pr.mo.gov). To be considered, comments must be received within thirty (30) days after publication of this rule in the **Missouri Register**. No public hearing is scheduled.*