

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

PROPOSED AMENDMENT

20 CSR 2220-2.200 Sterile Compounding. The Missouri Board of Pharmacy is adding subsection (10)(E).

PURPOSE: This amendment allows pharmacies to accept aseptic technique skill assessment results for compounding staff from another pharmacy during an emergency.

(10) Aseptic Technique Skill Assessment. Individuals engaged in sterile compounding must take and successfully pass an aseptic technique skill assessment to verify aseptic competency. The assessment must include a direct visual observation of the individual's aseptic competency during a process simulation that represents the most challenging or stressful conditions encountered or performed by the person being evaluated. The assessment must include media-fill testing for all risk levels performed. Self-observation is not allowed.

(E) If needed to prevent interruptions in patient care during an emergency, a pharmacy may accept aseptic technique skill assessment results from another pharmacy or hospital in lieu of the required initial aseptic technique skill assessment, provided:

- 1. A pharmacist verifies the aseptic technique skill assessment to be accepted complies with the requirements under subsections (10)(A)–(C) of this rule for an ongoing aseptic technique skill assessment, at a minimum;**
- 2. The pharmacy maintains documentation of the other pharmacy or hospital's completed aseptic technique skill assessment, including the dates and results of the required training, visual observation, and media-fill testing. Additionally, the receiving pharmacy must maintain a manual or electronic copy of the other pharmacy's or hospital's policies and procedures on aseptic technique skill assessment and media fill testing for board licensees or registrants;**
- 3. The board licensee or registrant has received training on applicable pharmacy operational procedures as needed to ensure proper compounding. The licensee or registrant must be skilled and trained to accurately and competently perform the duties; and**
- 4. Individuals may not assist with compounding under the emergency allowance authorized by this subsection for more than forty-five (45) days without an initial aseptic technique skill assessment for the pharmacy.**

*AUTHORITY: sections 338.240 and 338.280, RSMo 2016, and sections 338.010 and 338.140, RSMo Supp. 2020. * This rule originally filed as 4 CSR 220-2.200. Original rule filed May 4, 1992, effective Feb. 26, 1993. For intervening history, please consult the **Code of State Regulations**. Amended: filed February 8, 2022*

PUBLIC COST: This proposed amendment 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. 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.*