

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

EMERGENCY AMENDMENT

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

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

EMERGENCY STATEMENT: On January 31, 2020, the U.S. Department of Health and Human Services (HHS) declared a public health emergency in response to the nationwide COVID-19 pandemic. The Governor of Missouri declared a similar State of Emergency on March 13, 2020, finding that COVID-19 poses a serious health risk for Missouri residents and visitors. Since that time, Missouri pharmacies have played a critical role in meeting the unprecedented demand for pharmacy services, including, an increased demand for pharmacy sterile compounding services. Sterile compounding involves the process of mixing/compounding of medication in a sterile environment using aseptic procedures. Sterile compounding is used to provide specialty patient medication that is not commercially available, including medication for vulnerable and high-risk patients who may not have a commercially available alternative. Pharmacy staff must be specially trained in aseptic technique and pass an aseptic technique skills assessment and observation by a qualified observer prior to initial compounding. Under the current rule, aseptic technique skill assessments are not transferable and may take several weeks to complete depending on risk level. Instead, a new assessment must be completed at each individual pharmacy where the staff member will be compounding. During the COVID-19 pandemic, multiple pharmacies and hospitals reported the need to quickly move/re-allocate sterile compounding staff because of an unprecedented number of staff absences, increased hospitalizations/patient demand, and staffing shortages. In many instances, pharmacies/hospitals reported needing to move staff between pharmacies/compounding facilities with little or no notice and before the required aseptic technique skill assessment/observation could be completed. At the board's request, Governor Parson subsequently approved a COVID-19 waiver during the State of Emergency that allowed pharmacies/hospitals to accept aseptic technique skill assessment results from another pharmacy to meet patient needs. The COVID-19 waiver expired on December 31, 2021; Missouri pharmacies and hospitals subsequently petitioned the board to take emergency action to continue the aseptic skill assessment allowance. Pharmacies/hospitals reported the waiver was critical for meeting patient needs and ensuring pharmacy staff were available to compound an adequate supply of compounded medication during the pandemic and other emergencies. Accordingly, the board has determined this emergency amendment is needed to ensure prompt medication dispensing and the availability of critical compounded medication for Missouri patients. Absent an emergency amendment, Missouri pharmacies will likely be unable to meet patient demand for needed compounded medication and/or patients may experience a significant delay/interruption in critical medication supply, which will detrimentally impact the public safety, health, and welfare of Missouri citizens. As a result, the Missouri State 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. The scope of this emergency rule amendment is limited to the circumstances creating the emergency and complies with the protections extended in the **Missouri and United States Constitutions**. The Missouri State Board of Pharmacy believes this emergency rule is fair to all interested persons and parties under the circumstances. This emergency rule was filed February 8, 2022, effective February 24, 2022, and expires August 22, 2022.*

(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**. A proposed amendment covering this same material is published in this issue of the **Missouri Register**. . Emergency rule filed February 8,, 2022, effective February 24, 2022, expires August 22, 2022.*

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.