**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 board is amending subsection (5)(C).

*PURPOSE: This amendment removes the requirement that Risk Level 3 preparations must remain Risk Level 3 for the life of the preparation.*

EMERGENCY STATEMENT: *This emergency rule is being promulgated to ensure continued availability of compounded Risk Level 3 sterile preparations for Missouri patients. Current rule 20 CSR 2220-2.200 requires sterility and endotoxin testing for all Risk Level 3 preparations. To meet the rule's Risk Level 3 testing requirements, pharmacy compounders are typically required to compound three-four (3-4) times in excess medication to ensure a sufficient sample size of medication is available to perform scientifically valid testing.*

*In March 2021, the board was notified by a major pharmacy supplier that they were unable to comply with Missouri's Risk Level 3 testing requirements for intrathecal medication compounded for Missouri patients using sterile stock solution. The pharmacy indicated medication ingredients for the compounds in question (morphine and hydromorphone) are regularly in short supply and/or on the FDA shortage list, making procurement of the additional medication needed for required board testing significantly difficult, if not impossible. The pharmacy also indicated the U.S. Drug Enforcement Administration and drug manufacturers/wholesalers may not allow the pharmacy to buy additional morphine and hydromorphone supply, given these medications are Schedule II controlled substances that are highly addictive and the extra supplies are needed for testing and not patient use. The pharmacy further noted the products in question are made using Risk Level 3 sterile stock solution that has been previously tested for sterility/endotoxins, and questioned the need for additional testing of individual doses. The pharmacy communicated it would be required to immediately suspend all shipments of Risk Level 3 intrathecal medication to Missouri patients, absent an amendment of Missouri's testing requirements.*

*On March 25, 2021, a large Missouri hospital contacted the board to indicate a significant number of Missouri patients would be immediately and detrimentally impacted if the hospital is unable to procure the medication in question. Subsequent board research revealed a limited number of licensed pharmacies are engaged in compounding the medication in question. The board has discussed this issue with other pharmacy suppliers who also expressed compliance barriers and supported amending the rule as soon as possible to prevent interruptions in medication supplies.*

*The proposed rule would remove the requirement that Risk Level 3 preparations must remain Risk Level 3 for the life of the preparation. As a result of the amendment, compounded preparations made from a properly tested Risk Level 3 stock solution would not have to undergo additional sterility/endotoxin testing for each individual patient dose. Absent the emergency amendment, Missouri hospitals/physicians may be unable to procure needed medication for the treatment of Missouri patients. Significantly, the amendment does not lower the board's standard that all non-sterile to sterile compounded preparations must be tested at some point during the compounding process.*

*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. A proposed amendment, which covers the same material, is published in this issue of the* ***Missouri Register****. 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 rule is fair to all interested persons and parties under the circumstances. This emergency rule was filed April 14, 2021 effective April 28, 2021, and expires February 7, 2022.*

(5) Facilities and Equipment. The pharmacy shall establish and follow proper controls to ensure environmental quality, prevent environmental contamination, and maintain air quality in all ISO classified areas.

(C) Risk Level 3: In addition to Risk Level 1 and 2 requirements, Risk Level 3 preparations must be prepared in a PEC located in a buffer area or prepared in a RABS located within a controlled area. All non-sterile equipment that is to come in contact with the sterilized final preparation must be sterilized before introduction in the buffer area or into the RABS. *[Once compounded, Risk Level 3 preparations shall at a minimum remain Risk Level 3 for the life of the preparation.]*

*AUTHORITY: sections 338.240 and 338.280, RSMo 2016, and sections 338.010 and 338.140,, RSMo Supp. [2018]* ***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. Emergency amendment filed April 14, 2021; effective April 28, 2021, expires February 7, 2022. A proposed amendment covering this same material is published in this 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.*

*NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this emergency amendment 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.*