

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

PROPOSED RULE

20 CSR 2220-2.016 Pharmacy Operations During an Emergency or Declared Disaster

PURPOSE: This rule establishes guidelines for temporary pharmacy operations during an emergency or declared disaster.

(1) Definitions.

- (A) “Disaster Area”—A specified geographical area within the state that has been designated by the governor or federal authorities as an area that has been adversely affected by a natural or man-made disaster and that requires extraordinary measures to provide adequate, safe, and effective health care for the affected population.
- (B) “Emergency Situation”—An emergency caused by a natural or manmade disaster that substantially prevents a Missouri licensed pharmacy from providing pharmacy services at the pharmacy’s permitted location.
- (C) “Home Pharmacy”—A Missouri licensed pharmacy that operates or applies for an emergency temporary pharmacy permit pursuant to this rule.
- (D) “Emergency Declaration”—A state or federally declared emergency or disaster that impacts Missouri patients.

(2) Emergency Situations. A pharmacy that is substantially unable to provide pharmacy services at their permitted location due to an emergency situation may file a change of location application with the board to provide pharmacy services at a temporary site. No application fee shall apply. The location change must be approved by the board prior to changing locations and the designated location must successfully pass a board inspection.

- (A) Approval of a temporary change of location under this rule will be based on the need, type, and scope of the emergency situation, as well as the ability of the pharmacy to ensure proper security and comply with state and federal drug laws.
- (B) Unless otherwise approved by the board for good cause, temporary pharmacy permits shall be valid for up to six (6) months, if requested. A change of location application is required if the pharmacy will be operating at a temporary location for more than the allowed six (6) months or desires to permanently remain at the temporary site.
- (C) The board may waive designated facility or pharmacy operational requirements at a temporary location to prevent the interruption of pharmacy services. Waiver requests must be submitted in writing and must demonstrate how the permit holder will maintain patient safety and ensure adequate security.
- (D) A change of location application must be filed with the board when the home pharmacy is ready to return to their original permitted location. No fee will apply. The permitted location must pass a board inspection prior to resuming pharmacy services at the original location.

- (E) Records must be maintained as required by Chapter 338, RSMo, and the rules of the board.
 - (F) Approval of a temporary location change does not interfere with any rights or privileges of a pharmacy permit holder at the original pharmacy location, or prevent a permit holder from applying for a change of location as outlined in the board's rules.
- (3) Emergency Declarations/Disaster Areas. A Missouri licensed pharmacy located in Missouri may apply for an emergency temporary pharmacy permit to provide pharmacy services to Missouri patients impacted by an emergency declaration or located in a disaster area. Applications for an emergency temporary pharmacy permit must be submitted on a form provided by the board with the applicable fee, and must demonstrate that the temporary pharmacy is needed to ensure adequate pharmacy services are reasonably available for impacted patients. The following additional requirements apply, unless otherwise approved by the board:
- (A) The temporary pharmacy permit shall be considered part of the home pharmacy's permit and not a separate pharmacy permit. The home pharmacy and the temporary pharmacy must have the same pharmacist-in-charge. The home pharmacy is responsible for ensuring compliance with all applicable state and federal law at a temporary pharmacy licensed under this rule.
 - (B) Unless otherwise approved by the board, temporary pharmacy permits will only be approved for a designated location and for the pharmacy classifications authorized on the home pharmacy's permit prior to the declared disaster or emergency declaration.
 - (C) Approval of an emergency temporary pharmacy permit will be based on the need, type, and scope of emergency or disaster, as well as the pharmacy's ability to maintain proper security and comply with applicable state and federal law, including, section 338.240, RSMo.
 - (D) The temporary location must successfully pass a board inspection before a temporary pharmacy permit is issued. Additionally, temporary pharmacies must be available for inspection, as requested by the board or the board's authorized designee.
 - (E) The board may waive designated facility or pharmacy operational requirements to prevent the interruption of pharmacy services at an emergency temporary pharmacy. Waiver requests must be submitted in writing and must demonstrate how the permit holder will maintain patient safety and adequate pharmacy security, if approved. Controlled substances must be handled and dispensed in accordance with state and federal law.
 - (F) Temporary pharmacy permits issued under this section are valid for thirty- (30-) days but may be renewed at the discretion of the board. To renew, the home pharmacy must file a written request with the board and demonstrate that renewal of the temporary pharmacy permit is needed to protect the public health and ensure access to pharmacy services.
 - (G) Temporary pharmacies approved under this section must terminate services on the expiration date approved by the board or within five (5) days after the disaster area designation or emergency declaration is withdrawn or terminated, whichever is earlier.
 - (H) Records must be maintained as required by Chapter 338, RSMo, and the rules of the board. Required records must be maintained at the home pharmacy after the temporary pharmacy permit closes, and must be available for inspection or copying by the board or the board's authorized designee.

*AUTHORITY: sections 338.043 and 338.280, RSMo 2016 and sections 338.210, 338.220, and 338.333, RSMo Supp. 2020. . * This rule originally filed as 4 CSR 220-2.016. Original rule filed*

May 4, 1995, effective Dec. 30, 1995. Moved to 20 CSR 2220-2.016, effective Aug. 28, 2006. Amended: Filed May 13, 2019, effective Nov. 30, 2019. Rescinded and Readopted: Filed April 8, 2021.

PUBLIC COST: This proposed rule will result in a decrease in revenue to the State Board of Pharmacy of two-thousand dollars, six hundred and fifty dollars (\$2,650) annually for the life of the rule, as reflected in the attached public fiscal note.

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.*