

Emergency Rules

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

EMERGENCY RULE

20 CSR 2220-2.680 Class R-Remote Dispensing Site Pharmacy

PURPOSE: This rule defines licensing requirements and compliance standards for Class-R Remote Dispensing Site pharmacies.

EMERGENCY STATEMENT: Section 338.215, RSMo, was recently enacted and became effective on August 28, 2020. Section 338.215, RSMo, establishes a Class R Remote Dispensing Site pharmacy which is authorized to prepare, dispense, and compound medication for patient dispensing without a pharmacist physically present at the Class R site to monitor and supervise pharmacy activities. Additionally, section 338.215, RSMo, authorizes dispensing of prescriptions/medication orders that have been remotely verified by a pharmacist for accuracy using compliant technology, in lieu of physical, in-person verification of the final prescription/medication order by a Missouri-licensed pharmacist. This proposed emergency rule would protect the public health and welfare by establishing safety and licensing standards to prevent medication errors and ensure safe and accurate dispensing of prescription drugs by Class R pharmacies. The proposed emergency rule also establishes supervisory requirements for Class R pharmacies operating without a pharmacist physically present to ensure pharmacy activities are safely and properly conducted. According to the national Institute of Medicine and the United States Centers for Medicare and Medicaid Services (CMS), medication errors are among the most common medical errors harming at least 1.5 million people per year. Proper supervision and oversight of Class R pharmacies by a Missouri licensed pharmacist with the training, knowledge and expertise needed to ensure safe medication dispensing is vital to protecting the lives 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 of Missouri citizens and a compelling governmental interest that requires this emergency action. Absent an emergency rule, sufficient safeguards will not be in place to ensure safe and accurate Class R pharmacy dispensing and operations. A proposed rule, which covers the same material, is published in this issue of the Missouri Register. The scope of this emergency rule 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 September 3, 2020, becomes effective September 18, 2020, and expires March 16, 2021.

(1) Definitions.

(A) “Community Mental Health Center”—A community mental health center as defined by 42 CFR § 410.2, section 205.975, RSMo, or the Missouri Department of Mental Health.

(B) “Federally qualified health center”— A federally qualified health center as defined by 42 U.S.C. § 1396d(1)(2)(B), as amended.

(C) “Intern Pharmacist”—An individual who holds a current and active Missouri intern pharmacist license and has completed employer approved training in the activities to be performed at the Class R pharmacy and has an initial and annual documented assessment of competency.

(D) “Outpatient Clinic”—A facility where healthcare services are provided by a licensed healthcare provider on the facility’s premises to patients who are not hospitalized or admitted to the outpatient clinic for greater than twenty-three (23) hours.

(E) “Qualified Pharmacy Technician”—A currently registered Missouri pharmacy technician who:

1. Holds an active pharmacy technician certification issued by a certification entity accredited by the National Commission for Certifying Agencies,

2. Has completed employer approved training in the activities to be performed at the Class R pharmacy and has an initial and annual documented assessment of competency; and

3. Has assisted in the practice of pharmacy as a registered pharmacy technician in the state of Missouri for a minimum of one (1) year.

(F) “Remote Dispensing Site Pharmacy”—Any location in this state where the practice of pharmacy occurs that is staffed by one (1) or more qualified pharmacy technicians or intern pharmacists whose activities are supervised by a pharmacist at a supervising pharmacy that is under common ownership through a continuous real-time audio and video link. A remote dispensing site pharmacy does not include a dispensing prescriber’s office or an automated device.

(G) “Retail Pharmacy”—A pharmacy licensed by the board that is open to, and offers pharmacy services to, the general public.

(H) “Rural Health Clinic”— A rural health clinic as defined by the federal Rural Health Clinic Services Act, PL. 95-210, as amended.

(I) “Supervising pharmacy”—A Missouri licensed pharmacy located in this state or approved by the board that oversees the dispensing activities of a Class R pharmacy.

(2) A Class R pharmacy permit is required for any Missouri location operating, or offering to operate, as a remote dispensing site pharmacy in Missouri. Applications for a Class R permit must be submitted on a form approved by the board with the pharmacy permit fee, in accordance with 20 CSR 2220-2.020.

(A) Class R pharmacy permits expire and must be renewed, as provided by Chapter 338, RSMo and 20 CSR 2220-2 for pharmacy permits. Renewal applications must be submitted on a form approved by the board with the applicable renewal fee.

(B) Class R pharmacies must be located at least ten (10) miles away from an existing retail pharmacy unless the Class R pharmacy is part of a community mental health center, federally qualified health center, rural health clinic, or outpatient clinic setting. Requests to waive the mileage requirement may be submitted to the board in writing along with documentation supporting the request. The board will consider the following factors when determining whether to grant a waiver request:

1. The availability of pharmacy services in the proposed pharmacy area;

2. The nature of proposed Class R pharmacy services;

3. Benefits or risks to patient care;

4. The applicant’s and supervising pharmacy’s experience and compliance history; and

5. Any other factor that may benefit or adversely impact patient safety.

(C) Class R pharmacies shall be authorized to provide Class A, Class B, and Class C pharmacy services with a Class R permit. Class R pharmacies must apply for and hold the applicable pharmacy permit classification identified in section 338.220, RSMo, for any additional pharmacy services provided by the pharmacy. A Class J Shared services permit is not required for Class R pharmacies engaged in shared pharmacy services with the supervising pharmacy. If the Class R pharmacy is engaged in Class J shared services with another pharmacy, or has an arrangement to provide or receive Class J shared services with another pharmacy, the supervising pharmacy, the remote dispensing site and all involved pharmacies must have a Class J shared services permit and comply with 20 CSR 2220-2.650.

(D) By the tenth (10th) day following each calendar quarter, Class R pharmacies must calculate the average number of prescriptions dispensed by the pharmacy per day during the previous calendar quar-

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ter, excluding immunizations given by protocol (e.g., January 10, April 10, July 10, October 10).

1. If the average number of prescriptions or medication orders dispensed by the pharmacy during the previous quarter exceeds one hundred fifty (150) prescriptions/medication orders per day, excluding immunizations given by protocol, the pharmacy must apply for a change of classification to add a Class A, B, or C permit classification within ten (10) days of discovery. Change of classification requests must be submitted on a form approved by the board with the applicable fee. Class R operations must cease once a Class A, B or C permit is issued by the board.

2. Class R operations may resume if the daily average number of prescriptions dispensed by the pharmacy does not exceed one hundred fifty (150) prescriptions/medications orders during a calendar quarter (January 1–March 31, April 1–June 30, July 1–September 30, or October 1–December 31). The pharmacy's Class A, B or C pharmacy classification must be surrendered to the board within five (5) days of resuming Class R operations.

(3) Supervising Pharmacies. Class R pharmacies must be under the supervision of a supervising pharmacy, as required by section 338.215, RSMo. The supervising pharmacy must ensure the Class R pharmacy is properly and safely operated in compliance with applicable state and federal law. Effective policies and procedures must be in place to ensure appropriate oversight of a Class R pharmacy at all times.

(A) The supervising pharmacy and Class R pharmacy must manually or electronically maintain a current and accurate written policy and procedure manual that complies with section 338.215, RSMo.

(B) The supervising pharmacy and Class R pharmacy must share a common database or have access to each other's prescription record-keeping system. The common database or shared system must allow real-time, online access to the patient's complete profile for both the supervising pharmacy and the Class R pharmacy.

(C) Supervising pharmacies must be located in Missouri and within fifty (50) miles of the supervised Class R pharmacy site, unless otherwise approved by the board. Requests to waive the location and mileage requirements must be submitted to the board in writing along with proof the Class R pharmacy will be sufficiently supported by the supervising pharmacy and that necessary personnel or supplies can be delivered to the Class R pharmacy within a reasonable period of time of an identifiable need. The board will also consider the factors identified in subsection (2)(B) of this rule when reviewing a waiver request.

(D) A Class R pharmacy must immediately cease operations if the supervising pharmacy and Class R pharmacy are no longer under common ownership, the supervising pharmacy is no longer eligible to supervise the Class R pharmacy, or the supervising pharmacy's Missouri pharmacy permit is not current and active. Class R operations may resume once the supervising pharmacy's permit returns to active or eligible status or common ownership is reestablished.

(4) Class R Standards of Operation. Except as otherwise authorized by law, Class R pharmacies must comply with all laws and regulations applicable to the pharmacy services provided by the Class R pharmacy, including, 20 CSR 2220-2.010.

(A) Class R pharmacies must be staffed by a current and active Missouri licensed pharmacist at least eight (8) hours a month. At a minimum, the pharmacist-in-charge (PIC) of the Class R pharmacy must visit the remote dispensing site weekly during the first month of operation to verify compliance and monthly thereafter. The date of the monthly PIC compliance visit must be documented in the pharmacy's records.

(B) Class R pharmacies must maintain a perpetual inventory for all controlled substances that is reconciled twice per month. The PIC must review the reconciliation for accuracy/discrepancies during the

compliance visits required by subsection (4)(A).

(C) A prominent sign must be posted at the Class R pharmacy notifying patients that the remote dispensing site is supervised by the supervising pharmacy along with the supervising pharmacy's name, address, and telephone number.

(D) Intern pharmacists and qualified pharmacy technicians activities must be supervised by a Missouri-licensed pharmacist present at the Class R pharmacy or remotely supervised by a Missouri-licensed pharmacist located at the supervising pharmacy using technology that provides a continuous real-time audio and video link. The required technology must allow the supervising pharmacist to provide the personal assistance, direction, and approval needed to verify and ensure remote tasks are safely and properly performed. The supervising pharmacist must be employed by the supervising pharmacy, as required by section 338.215, RSMo, and must be competent to perform the services being supervised. A pharmacist cannot supervise more than two (2) Class R pharmacies at the same time.

(E) A Class R pharmacy may not be operated if the required supervision technology is unavailable or not in working order unless a pharmacist is onsite. The no pharmacist on duty sign required by 20 CSR 2220-2.010 must be posted in the event of a technology or system malfunction that requires the Class R pharmacy to cease operations.

(5) Medication Dispensing. Prescriptions/Medication orders may be prepared, dispensed, or compounded at a Class R pharmacy, as authorized by section 338.215, RSMo, and the rules of the board.

(A) The final contents and label of a prescription/medication order must be verified by a Missouri licensed pharmacist at the Class R pharmacy, or remotely verified by a Missouri licensed pharmacist located at the supervising pharmacy through the use of technology that includes bar coding and visual review of the medication contents and affixed label via remote video. The verifying pharmacist must be employed by the supervising pharmacy, as required by section 338.215, RSMo.

(B) Patient counseling must be provided for all new and refill prescriptions, unless refused by the patient. The required patient counseling must be provided by a Missouri licensed pharmacist at the Class R pharmacy or remotely provided by a Missouri licensed pharmacist at the supervising pharmacy via a HIPAA-compliant continuous real-time video and audio link, as authorized by section 338.215, RSMo. Medication may not be dispensed without a pharmacist physically present at the Class R pharmacy if the required counseling technology is not available or in working order. Remote patient counseling via technology may not be delegated to an intern pharmacist.

(C) Policies and procedures must be established to ensure appropriate pharmacist review of verbal prescription orders received by an intern pharmacist or qualified pharmacy technician at a Class R pharmacy when a pharmacist is not present.

(6) Adequate security and supervision must be maintained at all times to prevent unauthorized access to a Class R pharmacy and prevent medication theft and diversion.

(A) An alarm mechanism must be maintained that alerts the supervising pharmacy or the Class R pharmacist-in-charge in the event of unauthorized access to the remote dispensing site. Unauthorized access to a Class R pharmacy must be documented and reported to the board in writing within seven (7) days of discovery.

(B) Confidential records must be securely maintained to prevent unauthorized access and ensure secure data access and storage at all times.

(7) Record-Keeping.

(A) Except as otherwise provided by law, Class R pharmacies shall comply with all applicable record-keeping and documentation

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requirements of Chapter 338, RSMo, and the board's rules.

(B) Class R pharmacies must also maintain documentation of:

The number of prescriptions dispensed by the Class R pharmacy each calendar quarter; and

Proof that qualified pharmacy technicians and intern pharmacists assisting at a Class R pharmacy have completed the experience, training and competency assessment required by this rule.

(C) Records required by this rule must be manually or electronically maintained for two (2) years at the Class R pharmacy, or at the supervising pharmacy if the Class R pharmacy is no longer operating, and must be readily retrievable on request of the board or the board's authorized designee.

AUTHORITY: section 338.280, RSMo 2016 and sections 338.140 and 338.215, RSMo Supp. 2020. Emergency rule filed Sept. 3, 2020, effective Sept. 18, 2020, expires March 16, 2021. A proposed rule covering this same material is published in this issue of the Missouri Register.

PUBLIC COST: This emergency rule 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 rule will cost private entities six thousand nine hundred forty-seven dollars and sixty cents (\$6,947.60) in the time the emergency is effective.

**FISCAL NOTE
PRIVATE COST**

I. Department Title: Department of Commerce and Insurance n
Division Title: State Board of Pharmacy
Chapter Title: General Rules

Rule Number and Title:	20 CSR 2220-2.680 Class R - Remote Dispensing Site Pharmacy
Type of Rulemaking:	Emergency Rule

II. SUMMARY OF FISCAL IMPACT

Estimate of the number of entities by class which would likely be affected by the adoption of the rule:	Classification by types of the business entities which would likely be affected:	Estimate in the aggregate as to the cost of compliance with the rule by the affected entities:
5	New Class R Pharmacy Applicants	\$ 6,947.60 <i>in the time the emergency is effective</i>

III. ASSUMPTIONS/WORKSHEETS

The following general estimations were used to calculate private fiscal costs:

1. The proposed rule/emergency rule requires an additional three (3) weekly visits to a Class R pharmacy by the designated pharmacist-in-charge during the first month of Class R operations.
2. Class R pharmacies are a newly licensed pharmacy classification, effective August 28, 2020. Accordingly, insufficient data exists to estimate the number of potential Class R pharmacy applicants per year or full fiscal impact. Based on staff research and licensee feedback, however, the Board estimates the following:
 - Approximately five (5) new Class R pharmacy applications will be submitted during the emergency rule effective period.
 - One (1) additional hour of pharmacist time would be required under the rule for each weekly compliance visit, with an estimated pharmacist-in-charge hourly salary of \$ 72.34. The estimated hourly salary is based on an average pharmacist hourly salary of \$ 60.34 as reflected in 2019 data from the United States Bureau of Labor Statistics Occupational Employment and Wages, with a 20% enhancement for a supervisory pharmacist-in-charge.
 - A remote dispensing site must be within fifty (50) miles of the supervising pharmacy, pursuant to § 338.215.10. Accordingly, the Board estimates round-trip mileage of 100 miles per compliance visit, although actual mileage may be significantly lower. The Board further estimates a mileage reimbursement rate of 57.5 cents per mile based on the 2000 standard mileage reimbursement rate recognized by the United States Internal Revenue Service.

3. Accordingly, the Board estimates an aggregate private fiscal impact for the required compliance visits of \$ 1,947.60 per year, recurring annually over the life of the rule (\$ 72.34 pharmacist hourly salary x 1 hour per compliance visit x 3 additional compliance visits x 5 new pharmacy applicants per year plus \$ 862.50 mileage reimbursement (100 miles per compliance visit x 3 compliance visits x 5 Class R pharmacies x 57.5 cents per mile)).
4. To ensure security of drugs and confidential patient records, the rule requires that Class R pharmacies have an alarm mechanism that alerts the supervising pharmacy or designated pharmacist-in-charge in the event of unauthorized access. The Board estimates the minimum required alarm equipment and notification system will cost each pharmacy approximately \$ 1,000 per year, with a total estimated annual fiscal cost of \$5,000 per year recurring annually over the life of the emergency rule (\$ 1,000 alarm costs x 5 Class R pharmacies).
5. Total estimated costs may vary with inflation and increase at the rate projected by the Legislative Oversight Committee and the Internal Revenue Service.