

# Emergency Rules

## Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION

### Division 2220—State Board of Pharmacy Chapter 2—General Rules

#### EMERGENCY AMENDMENT

**20 CSR 2220-2.650 Standards of Operation for a Class J: Shared Services Pharmacy.** The board is amending paragraph (1)(A)3. and adding new section (2).

*PURPOSE:* This rule is being amended to accommodate pharmacies dispensing medication to another pharmacy for administration by a licensed healthcare professional.

*EMERGENCY STATEMENT:* The current rule establishes mandatory requirements for pharmacies engaged in Class-J Shared Services pharmacies. The board currently issues sixteen (16) classes of pharmacy permits (Class-A to Class-P). Pharmacies are required to have a pharmacy permit for each type of pharmacy service performed. As a result, many pharmacies have multiple classes of licensure. A Class-J pharmacy permit is required for pharmacies filling, dispensing, or transferring medication/filled prescriptions to another pharmacy for dispensing to the patient.

In April 2017, the board received comments from Missouri hospitals and specialty pharmacies indicating the current Class-J requirements are detrimentally impacting patient care by effectively prohibiting the dispensing of medication to Missouri patients with complex, chronic, or rare diseases who are participating in certain patient assistance programs. Specifically, Missouri hospital and specialty pharmacies reported that an increased number of patient assistance programs and third party payors now mandate that certain high risk, high-cost medications can only be prepared/dispensed by a specialty pharmacy and shipped to another licensed pharmacy where it has to be administered to the patient on-site of the receiving pharmacy by a healthcare provider. A number of these medications are reportedly high-cost items while others require specialized pharmacist training or expertise to prepare.

To ship medication to another pharmacy, both the specialty pharmacy and the receiving pharmacy are required to have a Class-J Shared Services permit. A number of hospital/specialty pharmacies have indicated they are unable to apply for a Class-J permit primarily because of the rule's requirements that Class-J pharmacies: 1) have the same owner or have a pre-existing contract for shared services and 2) share a common electronic database that provides real-time, online access. Specifically, specialty/hospital pharmacies reported the patient may require medication before a contract can be negotiated with the corresponding pharmacy. In some instances, the receiving pharmacy may be unknown or have no business relationship with the specialty pharmacy until medication is required. In other instances, expensive software purchases would be required to render the electronic systems accessible or compliant.

Due to the Class-J licensing requirements, patients have been unable to procure medication provided by certain assistance programs from designated hospital/specialty pharmacies located throughout the state. In some instances, patients have reportedly been turned away or denied medication because the participating pharmacies could not obtain a Class-J permit. The board was informed Missouri cancer patients have been particularly impacted and denied/delayed medication services. Significantly, some of the medications discussed with the board are not dispensed by community/ambulatory pharmacies due, in part, to the required expertise, equipment, and training needed to compound these preparations and/or due to the related medication costs which can reportedly exceed one hundred thousand dollars (\$100,000) per year in some cases.

After the April 2017 meeting, the board formed a sub-committee to immediately review and draft proposed revisions to the current rule. As part of this process, the board consulted with hospital and specialty pharmacy advocates to draft language that would allow shipment of patient medication between licensed pharmacies without a Class-J pharmacy permit while maintaining appropriate safeguards to protect patient health. The board also consulted with the statutorily authorized Missouri Hospital Advisory Committee in June of 2017. The board is proposing this emergency amendment to allow continued dispensing to lower-income, uninsured Missouri patients by modifying Class-J licensing requirements for pharmacies transferring medication that will be administered on-site of the pharmacy by a health care practitioner. Significantly, the Class-J permit is an additional class of licensure. Pharmacies engaged in the affected conduct would still be required to hold a board pharmacy permit in another classification.

Absent an amendment, the board's rule would significantly and adversely affect patient health and patient access to care by prohibiting pharmacies unable to qualify for a Class-J Shared Services pharmacy permit from dispensing designated medication to lower-income/uninsured patients participating in patient assistance programs. Once again, some of these medications may be unavailable from a traditional retail pharmacy and/or otherwise unaffordable for the targeted patient population.

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 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 amendment is fair to all interested persons and parties under the circumstances. This emergency amendment was filed July 27, 2017, becomes effective August 6, 2017, and expires February 22, 2018.

(1) Class J: Shared Services: Shared Service Pharmacy is defined as the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order, or that performs or assists in the performance of functions associated with the dispensing process, drug utilization review (DUR), claims adjudication, refill authorizations, and therapeutic interventions.

(A) A pharmacy may perform or outsource centralized prescription processing services provided the parties:

1. Have the same owner, or have a written contract outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of said contract in compliance with federal and state laws and regulations;

2. Maintain separate licenses for each location involved in providing shared services; and

3. [Share a common electronic file to allow access to sufficient information necessary or required to fill or refill a prescription drug order.] Either share a common database or allow access to each pharmacy's electronic medication or prescription records. The access must provide real-time, online access to the patient's complete profile for the pharmacies involved.

(2) A Class J Shared services permit shall not be required if a completed and labeled prescription is delivered from a Missouri licensed pharmacy to another Missouri licensed pharmacy for administration by a pharmacist or other licensed health care professional to the patient on the same premises or physical location as the pharmacy.

(A) The exemption recognized in this subsection only applies if a completed and labeled prescription is delivered to the receiving pharmacy.

(B) If additional manipulation or compounding is required by

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the receiving pharmacy, receipt of a prescription or order is required and the receiving pharmacy must dispense the product as their own prescription/order. All prescription requirements, record keeping, compounding, and labeling requirements must be met.

(C) The receiving pharmacy must maintain documentation of the medication received, the name and address of the pharmacy providing the medication, the date of receipt, and the patient's name.

(D) The receiving pharmacy is responsible for ensuring compliance with all applicable patient counseling requirements.

(E) For purposes of this rule, administration is defined as applying or introducing medication to the body of a patient, whether by injection, infusion, inhalation, ingestion, or other means.

(F) Medication administered by a pharmacist must be performed in compliance with all applicable provisions of law.

(G) Notwithstanding any other provision of this rule, licensees shall comply with all applicable controlled substance laws and regulations, including, but not limited to, all applicable security and record keeping requirements.

*AUTHORITY: sections 338.140, 338.210, 338.220, 338.240, and 338.280, [RSMo 2000 and 338.210 and 338.220, RSMo Supp. 2001] RSMo 2016. This rule originally filed as 4 CSR 220-2.650. Original rule filed Nov. 30, 2001, effective June 30, 2002. Amended: Filed Dec. 3, 2002, effective June 30, 2003. Moved to 20 CSR 2220-2.650, effective Aug. 28, 2006. Emergency amendment filed July 27, 2017, effective Aug. 6, 2017, expires Feb. 22, 2018. An emergency amendment and a proposed amendment covering this same material will be published in the September 1, 2017, issue of the Missouri Register.*