

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

PROPOSED RULE

20 CSR 2220-2.685 Standards of Operation for a Class Q: Charitable Pharmacy

PURPOSE: This rule establishes licensing requirements and standards of operation for a Class Q Charitable Pharmacy.

(1) Definitions.

- (A) "Charitable organization"—An organization qualified as a charitable organization pursuant to section 501(c)(3) of the Internal Revenue Code.
- (B) "Charitable pharmacy"—A site in Missouri that is owned or operated by a charitable organization for purposes of providing pharmacy services to appropriately screened and qualified indigent patients. Class Q pharmacies may only provide services to or for qualified indigent patients.
- (C) "Health care entity"—A hospital owned by the State of Missouri or any entity or organization that is licensed or certified by the state or federal government as a hospital, hospice facility, ambulatory surgical center, nursing home, long-term care facility, residential care facility, skilled nursing facility, mental/behavioral health care facility, or a habilitation center as defined by Chapter 630, RSMo, and that is required to maintain patient records by state or federal law.
- (D) "Qualified indigent patient"—A patient of a charitable pharmacy that has been screened and approved by a charitable organization and deemed not to have sufficient funds to obtain needed medication based on the charitable organization's pre-established criteria.
- (E) "Qualified intern pharmacist"—A currently licensed Missouri intern pharmacist who has completed employer approved training in the activities to be performed at a Class Q pharmacy and has an initial and, if applicable, annual documented assessment of competency.
- (F) "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 a Class Q pharmacy and has an initial and, if applicable, 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.

(2) Applications for a Class Q pharmacy must be submitted on a form approved by the board and must be renewed as provided by Chapter 338, RSMo, and 20 CSR 2220-2. No application fee is required (initial or renewal).

- (3) Except as otherwise authorized by the board, Class Q pharmacies must comply with all laws and regulations applicable to the pharmacy services provided, including but not limited to 20 CSR 2220-2.010. Class Q pharmacies/applicants may petition the board to waive designated facility or pharmacy operational requirements not applicable to the Class Q pharmacy's operations. Waiver requests must be submitted in writing and must demonstrate how the permit holder will maintain patient safety and ensure appropriate patient care and pharmacy security, if approved. Controlled substances must be handled and dispensed in accordance with state and federal law.
- (4) Class Q pharmacy services must be safely and accurately provided at all times, in compliance with state and federal law. If authorized by the pharmacist-in-charge, a qualified pharmacy technician or qualified intern pharmacist may assist in the practice of pharmacy at a Class Q pharmacy when a pharmacist is absent, with the exception of sterile compounding activities.
- (A) Non-controlled medication may be dispensed or provided by a Class Q pharmacy when a pharmacist is absent if:
1. A pharmacist has previously verified the prescription/medication order contents and affixed label; or
 2. Medication is provided to a healthcare provider for administration or delivery to the ultimate user as authorized by the healthcare provider's scope of practice, and bar code technology is used to verify the correct medication has been provided for the applicable patient. The healthcare provider must be notified that the medication has not been verified by a pharmacist prior to or on delivery.
- (B) Patients or the patient's designee must be offered an opportunity to consult with a pharmacist as required by 20 CSR 2220-2.190. If the pharmacist is not present on site or unavailable to provide remote patient counseling, a written offer to counsel with a contact telephone number for a pharmacist must be supplied with the medication.
- (C) If medication is dispensed or provided without a pharmacist present, a Missouri-licensed pharmacist designated by the pharmacist-in-charge must visit the Class Q pharmacy on a weekly basis to review the pharmacy's activities and records to ensure proper dispensing and compliance with this rule. The name of the reviewing pharmacist and review date must be documented and maintained in the pharmacy's records.
- (D) The pharmacy's prescription records must identify any prescription/medication order dispensed without a pharmacist present.
- (5) If authorized by the pharmacist-in-charge, a Missouri-licensed physician, dentist, physician assistant, or registered nurse may remove non-controlled medication from the pharmacy when a pharmacist is not at the Class Q location in an amount or volume needed to provide or administer to patients on the premises. Medication may only be removed pursuant to a valid order from a healthcare provider authorized to prescribe. The Class Q pharmacy must maintain a record of the distribution that includes the identity of the person removing the medication, the date removed, and the medication's identity, quantity, strength and dosage form. A Missouri-licensed pharmacist must review the required documentation on a weekly

basis to ensure compliance with this rule. Controlled substances may not be removed or dispensed by a Class Q pharmacy unless a Missouri-licensed pharmacist is present and supervising.

- (6) Donated Medication. A Class Q pharmacy may accept and dispense donated medication if:
 - (A) The medication is a non-controlled substance and is donated by a pharmacy, drug distributor, healthcare entity or a healthcare provider who is licensed to prescribe. Donated medication cannot be accepted from a patient or a member of the public;
 - (B) The medication has not been previously dispensed to a patient and is donated in the original, sealed, and unopened manufacturer or unit of use packaging/container;
 - (C) The medication is not adulterated, misbranded, expired, outdated, subject to a recall, or otherwise not appropriate for patient use. A pharmacist must visually inspect all donated medication prior to placing the medication in active inventory to ensure the medication complies with the requirements of this rule;
 - (D) The donating entity/healthcare provider attests in writing that the medication has been stored in accordance with manufacturer or United States Pharmacopeia requirements/guidelines and all applicable state and federal law;
 - (E) The Class Q pharmacy maintains a record of donated medication that identifies the medication received, the donating entity/healthcare provider, the date received, and the medication's quantity, strength, lot number, dosage form and expiration date; and
 - (F) The parties comply with all applicable state and federal laws.

- (7) Policies and Procedures. Class Q pharmacies must maintain current and accurate policies and procedures governing pharmacy operations, including, but not limited to, policies/procedures for the following, if applicable:
 - (A) Accepting, dispensing, or filling prescriptions;
 - (B) Training pharmacy staff;
 - (C) Drug storage and security;
 - (D) Offering patient counseling;
 - (E) Contacting a pharmacist for consultation during the pharmacy's business operations or in the event of an emergency;
 - (F) If applicable, procedures for dispensing or providing medication in a pharmacist's absence pursuant to section (4) of this rule, including, documenting medication dispensed in the pharmacist's absence, reconciling medication inventory, notifying healthcare providers as required by section (4)(A), and documenting required healthcare provider notifications;
 - (G) Receiving, storing, dispensing and disposal of donated medication;
 - (H) Granting, terminating and monitoring authorized pharmacy access when a pharmacist is not present; and
 - (I) Reporting and handling of dispensing errors. The pharmacist-in-charge must be notified of a dispensing error within twenty-four (24) hours after the error is learned by pharmacy staff. Policies/procedures must include the manner of notification.

(8) Records. Records required by this rule must be maintained at the pharmacy for a minimum of two (2) years and must be readily retrievable and made available to the board or the board's authorized designee upon request.

AUTHORITY: sections 338.140, 338.210, and 338.280 and sections 338.220, 338.333, RSMo Supp. 2020 and sections 338.280 and 338.350, RSMo 2016. Original rule filed: January 25, 2021.

PUBLIC COST: This proposed rule will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

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.*