

Emergency Rule

Title 20—DEPARTMENT OF COMMERCE AND INSURANCE

Division 2220—State Board of Pharmacy Chapter 5—Drug Distributor

EMERGENCY AMENDMENT

20 CSR 2220-5.020 Drug Distributor Licensing Requirements. The Board of Pharmacy is amending subsection (1)(B).

PURPOSE: This emergency amendment would waive Missouri drug distributor licensure requirements for entities shipping drugs or vaccines to treat or immunize patients during a state or federally declared disaster or emergency, or pursuant to an emergency use authorization issued by the United States Food and Drug Administration for a public health emergency.

EMERGENCY STATEMENT: On January 31, 2020, the U.S. Department of Health and Human Services (HHS) declared a public health emergency in response to the nationwide COVID-19 pandemic. The Governor of Missouri declared a similar State of Emergency on March 13, 2020, finding that COVID-19 poses a serious health risk for Missouri residents and visitors. HHS is currently collaborating with U.S. drug manufacturers to develop a COVID-19 vaccine/treatment, with anticipated availability as early as November 2020. In response, the Missouri Department of Health and Senior Services (DHSS) has developed a statewide vaccine and drug distribution plan to coordinate shipment of federally authorized drug supplies into Missouri. The statewide distribution/shipment plan includes procedures for intrastate shipments of emergency medication between state/federally authorized first responders/healthcare entities (e.g., hospitals, local public health agencies, physician clinics, mobile/temporary vaccination sites). Under the current rule, a Missouri drug distributor license is required for entities shipping medication pursuant to the emergency plan and declaration. HHS and the United States Centers for Disease Control and Prevention (CDC) have asked all states to remove licensing related barriers that would impede nationwide coordination of medication shipments during the federal emergency. DHSS has made a similar request to the board. Significantly, state/federal authorities have advised drug shipments may need to be coordinated between entities with little or no advance notification. Board processing of a Missouri drug distributor application could delay drug shipments by 4-6 weeks due to current application requirements (e.g., notarization, state inspection, and non-resident independent license verification from other states). In line with the HHS, CDC and DHSS requests, the proposed emergency amendment would exempt entities distributing medication and drug supplies to treat Missouri patients during a state/federal emergency from Missouri's drug distributor licensure requirements. The board has determined this emergency amendment is needed to ensure the availability and prompt distribution of medication to treat/prevent COVID-19 and other medical needs/illnesses during a federal or state emergency. Absent an emergency amendment, Missouri citizens will experience a significant delay in receiving COVID-19 vaccines/medication and related emergency supplies, which will detrimentally impact the public safety, health, and welfare 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 and a compelling governmental interest that requires this emergency action. The scope of this emergency rule 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 rule is fair to all interested persons and parties under the circumstances. This emergency amendment was filed October 29, 2020, becomes effective November 13, 2020, and expires May 11, 2021.

(1) A "wholesale drug distributor" is defined in section 338.330(3), RSMo. No wholesale drug distributor with physical facilities located in the state of Missouri shall knowingly purchase or receive legend drugs and/or drug related devices from a wholesale drug distributor or pharmacy not licensed or registered by the board. Knowledge of the licensure status of a drug distributor or pharmacy includes, but is not limited to, actual or constructive knowledge. Knowledge of the license status of a drug distributor or pharmacy shall also include, but not be limited to, notification from the board by mail or electronic transmission.

(B) Licensure and/or registration as a wholesale drug distributor is not required for activities described below—

1. The sale, purchase, transfer, or trade of a drug or an offer to sell, purchase, transfer, or trade a drug for emergency administration to an individual patient if a delay in therapy would negatively affect a patient outcome. The amount sold, purchased, transferred, or traded shall not exceed five percent (5%) of the pharmacy's total gross prescription sales or, if prescriptions are not sold, five percent (5%) of the pharmacy's total drug purchases;

2. The sale, purchase, or trade of blood and blood components intended for transfusion and any other exemptions as provided for in Chapter 338, RSMo;

3. The sale, purchase, transfer, or trade of a drug or an offer to sell, purchase, or trade a drug by a Missouri licensed pharmacy that does not exceed five percent (5%) of the pharmacy's total gross sales. For purposes of this section, total gross sales shall be calculated based on the pharmacy's total annual prescription drug sales or, if prescriptions are not sold, five percent (5%) of the pharmacy's total drug purchases;

4. The sale, purchase, transfer, or trade of a drug or offer to sell, purchase, transfer, or trade a drug among hospitals or by a hospital to a healthcare entity under the same common control or ownership as the hospital. "Common control or ownership" means the power to direct or cause the direction of the management and policies of a person or an organization whether by ownership, stock, voting rights, contract, or otherwise. For purposes of this rule, a "hospital" shall be limited to a hospital as defined by Chapter 197, RSMo, or a hospital operated by the state;

5. The storage or distribution of drugs by a local, state, or federal facility that are received from the Strategic National Stockpile or the state stockpile for the purpose of providing those drugs in an emergency situation as authorized by a state or federal agency;

6. **The sale, purchase, or transfer of a drug or vaccine received from or on behalf of a federal, state, or municipal entity for the purpose of treating or immunizing patients during a state or federally declared disaster or emergency;**

7. **The sale, purchase, or transfer of a drug or vaccine subject to an emergency use authorization issued by the United States Food and Drug Administration for a public health emergency;**

[6.]8. The sale, purchase, transfer, or trade of a prescription drug to alleviate a temporary shortage of a prescription drug that is in limited supply or unavailable due to delays in or interruption of supply. Drugs sold, purchased, transferred, or traded pursuant to this section shall only be sold, purchased, transferred, or traded directly from an importer or manufacturer authorized by or registered with the United States Food and Drug Administration (FDA) to import or manufacture the drug that is unavailable or in short supply. In addition, sales, purchases, transfers, or trades shall be limited to the period of shortage and to the drug that is unavailable or in limited supply. Documentation of FDA authorization or registration shall be maintained in the licensee's or recipient's records; and

[7.]9. The sale, purchase, transfer, or trade of a drug between a Missouri licensed pharmacy and a non-resident pharmacy that is located in and licensed by another state or United States territory. The total amount of drug sold, purchased, transferred, or traded by the Missouri-licensed pharmacy pursuant to this subsection shall not

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exceed five percent (5%) of the pharmacy's total annual prescription drug sales. Missouri pharmacies receiving drugs pursuant to this section from a non-resident pharmacy shall maintain the following records for two (2) years from the date of sale, purchase, transfer, or trade:

A. Proof the non-resident pharmacy holds a current pharmacy license in the state or territory from which the drug is shipped or distributed; and

B. An invoice record which documents the name and address of the non-resident pharmacy, the date of sale, purchase, transfer, or trade, and the name, strength, and quantity of the drug received. The pharmacies shall also comply with all applicable controlled substance requirements.

*AUTHORITY: sections [338.340] 338.335 and 338.350, RSMo [2000] 2016, and sections 338.140.1, 338.315, 338.330, 338.333, [338.335] 338.337, and 338.340 , RSMo [Supp. 2014] Supp. 2020. This rule originally filed as 4 CSR 220-5.020. Original rule filed Feb. 4, 1991, effective June 10, 1991. For intervening history, please consult the **Code of State Regulations**. Emergency amendment filed Oct. 29, 2020, effective Nov. 13, 2020, expires May 11, 2021. An emergency amendment and a proposed amendment covering this same material will be published in the Dec. 1, 2020 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.