
Emergency Rules

**Title 20—DEPARTMENT OF INSURANCE,
FINANCIAL INSTITUTIONS AND PROFESSIONAL
REGISTRATION
Division 2220—State Board of Pharmacy
Chapter 8—Third-Party Logistic Providers and Drug
Outsourcer Facilities**

EMERGENCY RULE

**20 CSR 2220-8.030 Nonresident Third-Party Logistics
Providers/Drug Outsourcer Facilities**

PURPOSE: This rule establishes additional guidelines for non-resident third-party logistics providers and drug outsourcer applicants.

EMERGENCY STATEMENT: The Missouri General Assembly recently enacted HB 1719 which establishes new licensure classifications for third-party logistics providers (3PL) and drug outsourcers. The new law is effective August 28, 2018, and would prohibit non-resident third-party logistics providers and drug outsourcers from operating in Missouri without the required license. These entities currently provide needed prescription medication to Missouri hospitals, pharmacies, and health care providers. In some instances, the medications may not be available from another source qualified under federal law to provide the medication. In other instances, medication may be needed for emergency use. HB 1719 does not allow a grace period for licensure. Accordingly, this rule would establish provisions for the immediate licensure of non-resident 3PLs and drug outsourcers.

The board has determined an emergency rule is needed to protect the lives and health of Missouri citizens by ensuring the continued availability and supply of prescription drugs in this state via non-resident 3PLs or drug outsourcers. Absent an emergency rule, non-resident 3PLs and drug outsourcers would be required to terminate activities which would significantly and detrimentally impact Missouri's drug supply, including, the availability of medication for emergency use. Significantly, purchasing medication from an unlicensed 3PL or drug outsourcer is a criminal offense. 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 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 November 28, 2018, becomes effective December 8, 2018, and expires June 5, 2019.

(1) Nonresident third-party logistics (3PL) providers or drug outsourcer facilities may not act as a third-party logistics provider or a drug outsourcer or ship, mail, or deliver legend drugs, or for drug outsourcers, compounded drugs into Missouri without first obtaining the applicable license from the board. Nonresident third-party logistics providers or drug outsourcers may be licensed by reciprocity if they—

(A) Possess a valid 3PL or drug outsourcer license or an equivalent license that is in good standing in the state or foreign jurisdiction in which they are located that was issued pursuant to legal standards comparable to those which must be met by a Missouri third-party logistics provider or drug outsourcer; and

(B) Are located in a state or foreign jurisdiction which extends reciprocal treatment to a third-party logistics provider of this state or, for drug outsourcer applicants, a drug outsourcer of this state.

(2) Except as otherwise provided in this rule, applicants for a non-resident third-party logistics provider or drug outsourcer license must

comply with 20 CSR 2220-8.020, including, but not limited to, all application, change of ownership, change of location, and change of name requirements. In addition to the requirements of 20 CSR 2220-8.020, non-resident applicants must also submit the following with their application:

(A) A copy of the applicant's 3PL or drug outsourcer license or its equivalent from the state or foreign jurisdiction where the nonresident third-party logistics provider or drug outsourcer facility is located;

(B) An official verification from the state or foreign jurisdiction where the third-party logistics provider or drug outsourcer facility is located verifying that the applicant holds a current and active third-party logistics provider license or its equivalent, for drug outsourcer applicants, a drug outsourcer license or its equivalent issued by such state or foreign jurisdiction;

(C) A copy of the applicant's most recent inspection report or findings from the applicant's resident board of pharmacy or its equivalent state/foreign regulatory body. For 3PL applicants, the inspection must have occurred within the last twenty-four (24) months. For drug outsourcer applicants, the inspection must have occurred within the last eighteen (18) months. If a state inspection is unavailable, an inspection by the Missouri Board of Pharmacy, the United States Food and Drug Administration (FDA) or the National Association of State Boards of Pharmacy must be submitted or a similar inspection by an entity approved by the board;

(D) If controlled substances will be shipped into Missouri, a copy of the applicant's federal controlled substance registration and, if applicable, a copy of the applicant's state controlled substance registration from the state where the applicant is located; and

(E) If requested by the board, any inspection reports, correction active responses, warning notices, deficiency notices, or any other related state, federal, or foreign jurisdiction report or notice related to the applicant's handling, distribution, manufacturing, or sale of medication.

AUTHORITY: sections 338.140, 338.150, 338.280, and 338.350, RSMo 2016, and sections 338.315, 338.330, 338.333, 338.337, and 338.340, RSMo Supp. 2018. Emergency rule filed Nov. 28, 2018, effective Dec. 8, 2018, expires June 5, 2019. An emergency rule and a proposed rule covering this same material will be published in the January 2, 2019, issue of the Missouri Register.