
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 2220-8.010 Definitions

PURPOSE: This rule adopts definitions for purposes of 20 CSR Chapter 8 governing drug outsourcers and third-party logistics providers.

EMERGENCY STATEMENT: The Missouri General Assembly 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 third-party logistics provider or 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, the board is proposing to promulgate Chapter 8 via emergency rules to provide for the immediate licensure of 3PLs and drug outsourcers operating in the state. 20 CSR 2220-8.010 would incorporate definitions applicable to proposed Chapter 8.

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 3PLs or drug outsourcers. Purchasing medication from an unlicensed 3PL or drug outsourcer is a criminal offense. Absent an emergency rule, the Missouri drug supply would be significantly and detrimentally impacted, including, the availability of medication for emergency use. 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) Definitions. The following definitions are applicable to 20 CSR 2220 Chapter 8:

(A) “Drug outsourcer” or “Drug outsourcer facility”- An entity registered with the United States Food and Drug Administration pursuant to section 503(B) of the federal Food, Drug and Cosmetic Act, as amended by the Drug Quality and Security Act (21 section USC 353b);

(B) “Drug related device”—An article that is not considered a prescription drug under federal law, but which meets the definition of a device as provided in 21 U.S.C. 321(h) and 21 U.S.C. 360j(e);

(C) “Drug” or “Prescription drug”—A legend drug as defined by section 338.330, RSMo; and

(D) “Third-party logistics provider” or “3PL”—An entity that provides or coordinates warehousing, or other logistics services of a prescription drug or drug-related device on behalf of a manufacturer, wholesale distributor, or dispenser of such a product, but does not take ownership of the product, nor has responsibility to direct the sale or disposition of the product. A third-party logistics provider license

is required for entities conducting 3PL activities that are physically located in this state or shipping drug products into Missouri.

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*.