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 2220-8.045 Standards of Operation (Third-Party Logistics Providers)

PURPOSE: This rule provides standards of operation for third-party logistic providers licensed by the board.

*EMERGENCY STATEMENT: The Missouri General Assembly recently enacted HB 1719 which establishes a new license class for third-party logistics providers (3PLs), effective August 28, 2018. The Board has simultaneously filed emergency rules to license 3PLs. The proposed rule would protect Missouri patients by establishing standards of operations for 3PLs to ensure medication is properly handled and distributed in Missouri and to prevent distribution of any adulterated, illegitimate, or contaminated medication. Absent an emergency rule, no state standards of operation would be in effect for 3PLs which could endanger the lives of Missouri patients and threaten the integrity of Missouri's medical supply. 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) Third-party logistics providers (3PL) shall comply with all applicable state and federal law governing 3PL activities, controlled substances and drug distribution/handling, including, but not limited to, the federal Food, Drug and Cosmetics Act, as amended by the federal Drug Supply Chain Security Act (20 USC section 351 et seq).

(2) Manager-In-Charge. No third-party logistics provider license will be issued unless the facility is under the direct supervision of a manager-in-charge who has been designated with the board and who will be responsible for facility operations and ensuring compliance with state and federal law. The designated manager-in-charge must have appropriate education or experience to perform the duties assigned. At a minimum, the manager-in-charge must have at least two (2) years of education/experience in third-party logistics provider or drug distribution standards of operation or legal/compliance requirements. Education beyond a high school diploma or its equivalent may be used to meet these minimum requirements.

(A) 3PL activities must be conducted under the supervision of the designated manager-in-charge. The manager-in-charge must be actively involved and aware of the daily operations of the third-party logistics provider and must be physically present at the third-party logistics provider facility during normal business hours, except for absences due to illness, scheduled vacations, or other authorized absence. The manager-in-charge must ensure that policies and procedures governing the third-party logistics provider's operations are current and accurate.

(B) In the event the manager-in-charge designated with the board changes, the third-party logistics provider may not continue operations until a new manager-in-charge is named. A change of manager-in-charge application must be submitted to the board with the applicable fee within fifteen (15) calendar days after the new manager-in-charge is designated.

(C) In addition to the manager-in-charge, all individuals employed or engaged in third-party logistics operations must have sufficient education, training, or experience to perform the duties assigned. A list must be maintained of all managers or other individuals in charge of 3PL activities or drug distribution, storage and handling, and a description of the individual's duties.

(3) Facility Standards. The following requirements are applicable to all 3PL facilities:

(A) All state and federal 3PL, controlled substance and drug distribution licenses or registrations must be current and accurate. The facility's Missouri 3PL license must be conspicuously posted at the 3PL facility licensed by the board;

(B) 3PL facilities must be of suitable size and construction to allow proper cleaning, maintenance, and facility operations. Appropriate sewage disposal and a hot and cold water supply must be available. The outside perimeter of the premises must be well-lit; and

(C) 3PL facilities must be securely maintained at all times to prevent unauthorized access to the facility, drugs, or drug storage areas. Additionally, 3PL facilities must be equipped with a security system that will provide suitable protection against theft and diversion, including, electronic theft or diversion. All facilities must be equipped with an alarm system to detect entry after hours.

(4) Drug Storage and Distribution. 3PL activities must be safely and accurately performed at all times in compliance with applicable state and federal law. Only drugs of appropriate quality may be distributed. No counterfeit, outdated, misbranded, expired, or adulterated drug may be distributed, sold, or brokered by or on behalf of a 3PL.

(A) Appropriate lighting, sanitation, ventilation, and humidity must be maintained in all areas where drugs are stored or distributed. Aisles, walkways, and shelves in drug storage areas must be clear of debris, dirt, and filth. Dust must be kept at low levels through adequate ventilation or proper cleaning procedures.

(B) Waste and hazardous materials must be handled and disposed of in compliance with applicable state and federal law.

(C) Drug storage areas must be free from insects, vermin, and animals of any kind, except for service animals as defined by the Americans with Disabilities Act (ADA).

(D) Drugs must be properly stored and maintained in a thermostatically controlled area within temperature and humidity requirements as provided in the FDA approved drug product labeling or the *United States Pharmacopeia* (USP).

(E) Temperatures in drug storage areas must be recorded and reviewed at least once each day the facility is in operation. Alternatively, a continuous temperature monitoring system may be used if the system maintains ongoing documentation of temperature recordings that alerts the manager-in-charge or designated facility staff when temperatures are outside of the required range.

(F) 3PLs located in this state may only purchase or receive legend drugs and/or drug related devices from an entity licensed as a Missouri drug distributor, third-party logistics provider, or drug outsourcer.

(G) No outdated, misbranded, or adulterated drugs or devices may be dispensed or maintained within the facility's active inventory, including prescription and related nonprescription items. Outdated, misbranded, or adulterated medication must be quarantined in a clearly identified segregated area and maintained separately from drugs intended for distribution or being processed for distribution.

(H) No third-party logistics provider 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, third-party logistics provider, drug outsourcer, or pharmacy not licensed or registered by the board.

(I) Drugs held for distribution must be stored in a secure area where only authorized personnel have access to them. A list of all individuals who have independent access to drug storage areas must be maintained. The list must be maintained for three (3) years and must be readily retrievable on request of the board or the board's authorized designee.

(J) Medication may not be stored on the floor. Drug products must be raised above floor level and placed on a pallet or similar device.

(K) The outside shipping container of received medication must be visually examined for identity and for container and content integrity to prevent the acceptance or distribution of any contaminated, adulterated, or otherwise unfit medication. Any prescription drug whose immediate or sealed outer container or sealed secondary container has been opened, used, or improperly compromised must be quarantined and physically separated from the facility's active inventory.

(L) Drugs shipped for distribution or further use must be carefully inspected prior to shipping/distribution for identity and to ensure prescription drugs that have been damaged in storage or held under improper conditions are not distributed. Licensees shall maintain and follow security procedures for delivering drugs from the facility to the destination site.

(M) Drug products must be labeled as required by the manufacturer and state and federal law, including, section 338.059.2, RSMo.

(N) Third-party logistics providers must develop and implement written policies and procedures to ensure the safe and appropriate delivery of prescription drugs within the temperature requirements recommended by the manufacturer or the *United States Pharmacopeia* (USP).

(O) For returned medication, licensees must consider the conditions under which the medication has been held, stored, or shipped, the condition of the drug and its container/carton and any other relevant factor that may reflect on the drug's fitness for further use or distribution. If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug must be destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity.

(P) Licensees shall file a written or electronic report with the board within seventy-two (72) hours after discovery of:

1. Any suspected criminal activity related to or diversion of a prescription drug or device; and

2. Any real or suspected counterfeit, contraband, or illegitimate prescription drug or drug-related device. The report must include the name of the drug, quantity, and lot number(s). Recalls initiated by the Food and Drug Administration (FDA) or by a supplier licensed with the state of Missouri do not have to be reported, unless otherwise required by state and federal law.

(5) Policies and Procedures. 3PLs must maintain and follow current and accurate policies and procedures governing all aspects of the facility's 3PL activities. Policies and procedures must be physically or electronically maintained at the facility, provided the policies/procedures are immediately retrievable at the request of the board or the board's authorized designee.

(6) Agents or employees of a licensed third-party logistics provider may have legend drugs in their custody if they are acting in the usual course of business or employment and their names and addresses and the addresses of all sites where drugs are stored have been provided to the board. Drugs stored and transported by agents or employees of a third-party logistics provider must be maintained in accordance with manufacturer or USP guidelines and must be free of contamination, deterioration, or adulteration.

(7) Record-Keeping. 3PL records must be accurately maintained in compliance with state and federal law. Additionally, licensees must maintain inventories and records of all transactions regarding the receipt, distribution, or other disposition of prescription drugs or prescription drug-related devices.

(A) The following records must be maintained:

1. The date drugs or drug-related devices are received or distributed;

2. The identity and quantity of drugs or drug-related devices received, distributed, or disposed of;

3. The identity of any suppliers of prescription drugs or drug-related items, including the name and principal address of the seller/transferor and the address of the location where the drug/drug-related item was shipped from;

4. The name and address of any recipients of prescription drugs or drug-related items; and

5. Any records required by state and federal law.

(B) Unless otherwise provided by law, records required by Chapter 338 or this rule must be maintained for three (3) years. Records may be manually or electronically maintained, provided the record is readily retrievable and available for inspection, photographing, or duplication at the request of the board or the board's authorized designee or at the request of authorized federal, state, or local law enforcement officials. Records maintained offsite and not electronically retrievable at the 3PL facility must be made available for inspection within two (2) working days of a request by the board or an authorized board designee.

(8) Exemptions. At its discretion, the board may grant an exemption to the facility requirements of this rule for a time period designated by the board if such exemption is not contrary to law and the exemption will provide equal or greater protection of the public safety, health, or welfare. Exemption requests must be submitted in writing and identify the specific exemption requested, the grounds for exemption, the requested exemption length, and proposed procedures or safeguards for protecting the public safety, health, or welfare if the exemption is approved.

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****.*