

# 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 2220-8.020 Licensing Requirements

*PURPOSE: This rule establishes licensing requirements and procedures for drug outsourcers and third-party logistics providers.*

*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 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 3PLs and drug outsourcers operating in this state.*

*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. Absent an emergency rule, 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) No person or entity may act as a third-party logistics provider (3PL) or a drug outsourcer unless the person/entity has obtained the applicable 3PL or drug outsourcer license from the board. A separate license is required for each facility owned or operated as a 3PL or drug outsourcer.

(A) Applicants must submit a completed application to the board with the applicable fee along with the following information:

1. The name, full business address, e-mail address, and telephone number of the applicant and the facility where third-party logistics provider services or drug outsourcer activities will be provided, if different;

2. All trade or business names used by the licensee;

3. For 3PL applicants, the name, address, telephone number, and e-mail address of a manager-in-charge that meets the requirements of 20 CSR 2220-8.045 along with his/her employment history for the previous seven (7) years and a notarized manager-in-charge affidavit;

4. For drug outsourcer applicants, the name, address, telephone number, and e-mail address of a pharmacist responsible for supervising the facility who holds a current and active pharmacist license

issued by a U.S. state or territory. If the designated pharmacist does not have a current and active Missouri pharmacist license, official verification must be submitted from the board of pharmacy or equivalent pharmacist governmental licensing agency verifying that the designated pharmacist holds a current and active pharmacist license issued by such state/territory;

5. The type of ownership or legal structure; and

6. The name(s) of the owner, operator, or both, of the licensed entity, including:

A. If a sole proprietorship, the full name of the sole proprietor and the name of the business entity. The sole proprietor must sign the application;

B. If a partnership or limited liability partnerships, the name of each partner and the name of the partnership. A partner or general partner must sign the application; or

C. If a corporation, the name of the corporate president, vice president, secretary, treasurer, chief executive officer, board of directors, and senior vice presidents, or their equivalents, the corporate name(s), and the name of the state of incorporation. An officer of the corporation must sign the application.

(B) A license will not be issued to a facility located in Missouri until the board or its duly authorized agent has inspected the premises of the new location and approved it. For nonresident applicants, an inspection report must be submitted as required by 20 CSR 2220-8.030.

(C) All third-party logistics provider and drug outsourcer licenses will expire on the date specified by the director of the Division of Professional Registration by appropriate rule. Once issued, licenses must be conspicuously posted in the licensed facility where 3PL or drug outsourcer operations are conducted.

(D) A 3PL or drug outsourcer license will not be issued to any location where drugs are stored or maintained that is in a residence or that shares an address and/or physical space with a business not related to distributing prescription drugs or drug-related devices, or not licensed and regulated by the state of Missouri.

(E) An application will become null and void if the applicant fails to complete the process for licensure within six (6) months after the application is received by the board.

(F) All application fees are non-refundable.

(2) Change of Ownership. A third-party logistics provider or drug outsourcer license shall become void on the effective date of any change of ownership. The subsequent owners must obtain a new license from the board prior to operating as a third-party logistics provider or drug outsourcer in this state, provided a temporary license may be issued to the new ownership until a new license is granted as outlined in section (5). Facilities located in Missouri must be inspected by the board prior to issuing a new license.

(A) A change of ownership of a sole proprietorship is deemed to have occurred when—

1. The business is sold and the sale becomes final;

2. The proprietor enters into a partnership with another individual or business entity; or

3. The proprietor dies, provided, the proprietor's estate may continue to operate the third-party logistics provider or drug outsourcer facility for a period of no more than one (1) year if all appropriate fees are paid.

(B) If a corporation owns a third-party logistics provider or drug outsourcer, a new license is not required if the owners of the stock change. If a limited liability partnership or a limited liability company owns a third-party logistics provider or drug outsourcer, a new license is not required if the partners or members of the company change, as long as the partnership or company is not dissolved by the change. Written notice must be filed with the board within thirty (30) days after a change of twenty-five percent (25%) or more in the ownership of corporation stock, or the partners of a limited liability partnership, or the members of a limited liability company. The required

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notification must be in writing and notarized.

(C) When a sole proprietorship, corporation, limited liability partnership, or limited liability company begins or ceases ownership of a third-party logistics provider or drug outsourcer, a new license must be obtained regardless of the relationship between the previous and subsequent owners.

(3) Change of Location. A third-party logistics provider or drug outsourcer license is only valid for the address listed on the license issued by the board. If the location of a third-party logistics provider or drug outsourcer facility changes either within the existing facility or to a new facility, a change of location application must be submitted to the board with the applicable fee. A Missouri located facility may not open for business at the new location until the board or its duly authorized agent has inspected the premises of the new location and approved it. Once approved, the board will issue a license for the new location with the same license number as the previous license. A license will remain valid if the facility address changes but not the location, in such case an amended license will be issued on request without charge.

(4) Change of Name. Licensees may only conduct 3PL or drug outsourcing activities in the state of Missouri under the name(s) licensed by the board. If a name change occurs, a change of name application must be submitted to the board with the applicable fee within three (3) business days of the change. The facility's license will be reissued under the new name with the same license number. A change of ownership application is required if the licensee is changing corporate or legal structure or otherwise changing ownership.

(5) Temporary Licenses. The board may grant a temporary license to an applicant, subject to any terms or conditions the board deems necessary or appropriate, to allow the business to continue operating in Missouri until the board makes a determination on the applicant's license application. Unless otherwise authorized by the board, temporary licenses are valid for one (1) year or until final action by the board, whichever is less.

(A) The board will consider the following in determining whether to issue a temporary license:

1. Any conduct or activity that constitutes grounds for denial or discipline under section 338.055, RSMo;
2. The applicant's compliance with state and federal drug and/or distribution laws;
3. Any failure to produce records or information requested by the board or failure to provide full and truthful information;
4. Failure to cooperate with any board request or inquiry related to the application;
5. Current or pending disciplinary action by any federal, state, or local government against any license or registration currently or previously held by the applicant;
6. Compliance with licensing requirements under previously granted licenses, if any; and
7. Any other factor relevant to the applicant's ability to safely or properly operate in Missouri.

(B) A notification letter will be sent to the applicant once a decision is made on the applicant's permanent license. The temporary license will be considered void ten (10) days after board notification is sent to the applicant.

(C) Applicants issued a temporary license may conduct business in this state as a third-party logistics provider or, for drug outsourcer applicants, as a drug outsourcer as long as all state and federal laws governing provider/drug outsourcing activities are followed and no action that results in professional misconduct as outlined in section 338.055, RSMo, occurs.

(6) A nonresident third-party logistics provider or drug outsourcer licensed by the board must designate a registered agent in Missouri

for service of process. Any licensee that does not designate a registered agent shall be deemed to have designated the Missouri secretary of state to be its true and lawful attorney for service of process in any action or proceeding against the third-party logistics provider or drug outsourcer growing out of or arising from such 3PL or drug outsourcing services. Service of process shall be accomplished as authorized by law.

(7) Licensure Exemptions. A Missouri 3PL or drug outsourcer license is not required for the following activities—

(A) 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. Prior to the distribution, the unlicensed entity or proposed recipient must file a written request with the board to approve the emergency transaction. The amount sold, purchased, transferred, or traded shall not exceed one percent (1%) of the 3PL's or drug outsourcer's total gross prescription sales or, if prescriptions are not sold, one percent (1%) of the 3PL's/drug outsourcer's total drug purchases;

(B) 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; and

(C) The sale, purchase, transfer, or trade of a prescription drug by a 3PL 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 3PL's records.

*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.*