



Rules of
Department of Insurance,
Financial Institutions and
Professional Registration
Division 2220—State Board of Pharmacy
Chapter 8—Third-Party Logistic Providers and Drug
Outsourcer Facilities

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**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**

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.

(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, expired June 5, 2019. Original rule filed Nov. 28, 2018, effective May 30, 2019.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; 338.150, RSMo 1939, amended 1951, 1961, 1980, 1981, 2011, 2013; 338.280, RSMo 1951, amended 1971, 1981; 338.315, RSMo 1989, amended 2011, 2012, 2014, 2018; 338.330, RSMo 1989, amended 1993, 1998, 2011, 2018; 338.333, RSMo 1989, amended 2010, 2012, 2018; 338.337, RSMo 1989, amended 2009, 2010, 2018; 338.340, RSMo 1989, amended 2018; and 338.350, RSMo 1989, amended 1993, 1995.*

20 CSR 2220-8.020 Licensing Requirements

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

(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 2220-8.030 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 non-resident 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 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, expired June 5, 2019. Original rule filed Nov. 28, 2018, effective May 30, 2019.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; 338.150, RSMo 1939, amended 1951, 1961, 1980, 1981, 2011, 2013; 338.280, RSMo 1951, amended 1971, 1981; 338.315, RSMo 1989, amended 2011, 2012, 2014, 2018; 338.330, RSMo 1989, amended 1993, 1998, 2011, 2018; 338.333, RSMo 1989, amended 2010, 2012, 2018; 338.337, RSMo 1989, amended 2009, 2010, 2018; 338.340, RSMo 1989, amended 2018; and 338.350, RSMo 1989, amended 1993, 1995.*

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.

(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 nonresident 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, nonresident 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, expired June 5, 2019. Original rule filed Nov. 28, 2018, effective May 30, 2019.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; 338.150, RSMo 1939, amended 1951, 1961, 1980, 1981, 2011, 2013; 338.280, RSMo 1951, amended 1971, 1981; 338.315, RSMo 1989, amended 2011, 2012, 2014, 2018; 338.330, RSMo 1989, amended 1993, 1998, 2011, 2018; 338.333, RSMo 1989, amended 2010, 2012, 2018; 338.337, RSMo 1989, amended 2009, 2010, 2018; 338.340, RSMo 1989, amended 2018; and 338.350, RSMo 1989, amended 1993, 1995.*

20 CSR 2220-8.040 Standards of Operation (Drug Outsourcers)

PURPOSE: This rule provides standards of operation for drug outsourcers licensed by the board.

(1) Drug outsourcers shall comply with all applicable state and federal laws governing drug outsourcing activities, including, but not limited to, controlled substance laws and the federal Food, Drug and Cosmetics Act, as amended by the Drug Quality and Security Act.

(A) Except as otherwise required by federal law, drug outsourcers must comply with all applicable current good manufacturing practices (cGMPs) required by federal law and the United States Food and Drug Administration.

(B) A separate Missouri drug distributor license is required if a drug outsourcer is engaged in any additional drug distribution activities as defined by Chapter 338, RSMo, other than drug outsourcing. A pharmacy license is required if medication will be dispensed pursuant to a patient-specific prescription.

(2) No drug outsourcer license will be issued unless the facility is under the direct supervision of a licensed pharmacist who has been

designated with the board and who will be responsible for facility operations and ensuring compliance with state and federal law. For drug outsourcers located in Missouri, the pharmacist must hold a current and active Missouri pharmacist license. For non-resident drug outsourcers, the pharmacist must hold a current and active pharmacist license issued by Missouri or another U.S. state/territory.

(A) Drug outsourcing activities must be conducted at all times under the supervision of the designated pharmacist. The pharmacist must be actively involved in and aware of the daily operations of the outsourcing facility and must ensure that policies and procedures governing drug outsourcing operations are current and accurate.

(B) In the event the pharmacist designated with the board to supervise the facility changes, the drug outsourcer may not continue operations until a new pharmacist is named to supervise the facility. A change of pharmacist application must be submitted to the board with the applicable fee within fifteen (15) calendar days after a new pharmacist is designated to supervise.

(3) Sterile compounding and drug outsourcing activities must be safely and accurately performed at all times to ensure that only drugs of appropriate quality are distributed. No counterfeit, misbranded, expired, or adulterated drug may be compounded, distributed, sold, or brokered by or on behalf of a drug outsourcer.

(A) All individuals employed or engaged in sterile compounding or drug outsourcer activities must have sufficient education, training, or experience to perform the duties assigned. A list must be maintained of all individuals engaged in sterile compounding or in drug outsourcer activities with a description of the individual's duties.

(B) Drug outsourcers 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, drug outsourcer, or pharmacy.

(C) Medication 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.

(D) The outside shipping container of received medication and product ingredients 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 or drug ingredient 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.

(E) Medication shipped for distribution or further use must be carefully inspected prior to shipping/distribution for identity and to ensure no contaminated, adulterated, or misbranded drug or compounded preparation is distributed. Licensees shall maintain and follow security procedures for delivering drugs and compounded preparations from the facility to the destination site.

(F) Drug outsourcers 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).

(G) For returned medication, licensees must consider the conditions under which the drug 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 medication 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.

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

(4) Facility Standards. The following standards are applicable to all drug outsourcing facilities:

(A) Drug outsourcing facilities must be securely maintained at all times to prevent unauthorized access to the facility, drugs, or drug storage areas. Additionally, the facility 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 unauthorized entry after hours.

(B) Appropriate sewage disposal and a hot and cold water supply must be available.

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

(D) Drug outsourcing facilities must be

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

(E) Medication 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).

(F) 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 pharmacist designated with the board for supervising the facility or alerts designated facility staff when temperatures are outside of the required range.

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

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

(I) Drug outsourcers must report any recall of medication or a sterile preparation that is, or suspected to be, misbranded, adulterated, or non-sterile. Recalls must be reported to the board in writing within seven (7) days of a recall.

(5) Policies and Procedures. Drug outsourcers must maintain and follow current and accurate policies and procedures governing all aspects of the facility's drug outsourcing activities. Policies and procedures may 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) Record-Keeping. Drug outsourcer 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, compounding, or other disposition of prescription drugs or sterile preparations. Unless otherwise provided by law, records required by Chapter 338 of 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 authorized designee, or at the request of authorized federal, state, or local law enforcement officials. Records maintained offsite and not electronically retrievable at the drug outsourcer facility must be made available for inspection within two (2) working days of a request by the board or an authorized board designee.

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, expired June 5, 2019. Original rule filed Nov. 28, 2018, effective June 30, 2019.*

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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.

(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 non-prescription 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, expired June 5, 2019. Original rule filed Nov. 28, 2018, effective May 30, 2019.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; 338.150, RSMo 1939, amended 1951, 1961, 1980, 1981, 2011, 2013; 338.280, RSMo 1951, amended 1971, 1981; 338.315, RSMo 1989, amended 2011, 2012, 2014, 2018; 338.330, RSMo 1989, amended 1993, 1998, 2011, 2018; 338.333, RSMo 1989, amended 2010, 2012, 2018; 338.337, RSMo 1989, amended 2009, 2010, 2018; 338.340, RSMo 1989, amended 2018; and 338.350, RSMo 1989, amended 1993, 1995.*

20 CSR 2220-8.050 Inspection Exemptions

PURPOSE: This rule defines requirements for inspection standards for drug outsourcers and third-party logistics providers and standards for inspection exemptions for third-party logistic providers.

(1) Board inspections of third-party logistics providers and drug outsourcers will be conducted in accordance with Chapter 338, RSMo. At the discretion of the board, a third-party logistics provider facility that has been inspected by the United States Food and Drug Administration (FDA) within the previous two (2) years may be exempt from inspection by the board if the FDA inspection(s) resulted in a satisfactory rating. The FDA inspection must be a full inspection of all facility operations and procedures.

(2) The board may terminate an exemption under this section if deemed necessary or appropriate, if the last full FDA inspection is two (2) years old or greater or if any subse-

quent facility inspection by a state or federal entity results in less than a satisfactory rating.

(A) For purposes of this rule, a less than satisfactory rating includes, but is not limited to, any documented deficiency related to third-party logistic provider operations, drug distribution, repackaging, labeling, quality control, environmental policies/procedures, or controlled substances. Deficiencies include any statement that is a part of a federal compliance, inspection or observational report with or without sanctions, penalties, fines, or discipline imposed.

(B) Licensees granted an inspection exemption under this section shall notify the board if any inspection conducted by the FDA or the Drug Enforcement Administration results in less than a satisfactory rating as defined in subsection (2)(A).

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. Original rule filed Nov. 28, 2018, effective May 30, 2019.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; 338.150, RSMo 1939, amended 1951, 1961, 1980, 1981, 2011, 2013; 338.280, RSMo 1951, amended 1971, 1981; 338.315, RSMo 1989, amended 2011, 2012, 2014, 2018; 338.330, RSMo 1989, amended 1993, 1998, 2011, 2018; 338.333, RSMo 1989, amended 2010, 2012, 2018; 338.337, RSMo 1989, amended 2009, 2010, 2018; 338.340, RSMo 1989, amended 2018; and 338.350, RSMo 1989, amended 1993, 1995.*

20 CSR 2220-8.060 Termination of Business

PURPOSE: This rule establishes guidelines for terminating business as a third-party logistics provider or drug outsourcer.

(1) A licensed third-party logistics provider or drug outsourcer must notify the board within fifteen (15) days after terminating business in Missouri. Notification must be in writing or on a form provided by the board and include the following information:

- (A) The name, address, license number, and effective date of closure;
- (B) The name, address, and license number of the entity to which any of the stock/inventory will be transferred; and
- (C) The name and address of the location where records required to be maintained by law will be transferred.

(2) Licensees terminating business may transfer all drugs and records in accordance with the following:

- (A) Misbranded, outdated, or adulterated



drugs may not be transferred, except for purposes of proper disposal;

(B) The entity's Missouri license must be returned to the board either in person or by registered or certified mail; and

(C) Any records transferred to an unlicensed location must be retrievable for board review within seven (7) working days of a request made by an authorized official of the board.

(3) This rule does not preempt any other laws or regulations governing third-party logistic (3PL) or drug outsourcer licensure, change of ownership, change of location, or change of name.

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. Original rule filed Nov. 28, 2018, effective May 30, 2019.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; 338.150, RSMo 1939, amended 1951, 1961, 1980, 1981, 2011, 2013; 338.280, RSMo 1951, amended 1971, 1981; 338.315, RSMo 1989, amended 2011, 2012, 2014, 2018; 338.330, RSMo 1989, amended 1993, 1998, 2011, 2018; 338.333, RSMo 1989, amended 2010, 2012, 2018; 338.337, RSMo 1989, amended 2009, 2010, 2018; 338.340, RSMo 1989, amended 2018; and 338.350, RSMo 1989, amended 1993, 1995.*