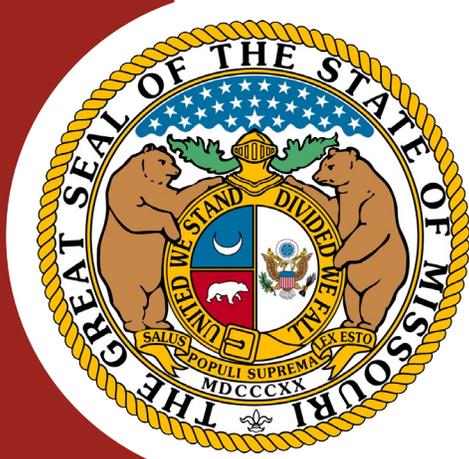




# Drug Distributor Compliance Guide

February | 2012



## MESSAGE FROM THE BOARD

The Missouri Board of Pharmacy is pleased to provide the *Missouri Drug Distributor Compliance Guide*. The *Compliance Guide* is designed to increase licensee compliance by providing guidance on basic provisions of Missouri's law governing drug distributors.

The Missouri Board of Pharmacy is an autonomous Board within the Division of Professional Registration, an agency of the Missouri Department of Insurance, Financial Institutions and Professional Registration. The Board consists of seven (7) members, including, one (1) public member and six (6) licensed pharmacists actively engaged in the practice of pharmacy in Missouri. Since 1909, the Missouri Board of Pharmacy has served Missouri citizens through the regulation and licensing of the pharmacy profession and drug distributors in the state of Missouri.

Additional compliance resources and materials are available on the Board's website at <http://pr.mo.gov/pharmacists>. License and regulatory updates are also provided via e-alerts and the Board's electronic newsletter. To sign up for the Board's newsletter and e-alerts, visit [www.nabp.net/indexmobop.asp](http://www.nabp.net/indexmobop.asp) or e-mail [MissouriBOPNewsletter@nabp.net](mailto:MissouriBOPNewsletter@nabp.net).

*The Missouri Drug Distributor Compliance Guide is provided for informational purposes only. The Compliance Guide does not constitute a comprehensive review of all governing law or controlled substance requirements. To ensure compliance, licensees should thoroughly review Chapter 338, RSMo, 20 CSR 2220 and all other applicable state and federal laws. The Compliance Guide does not constitute a rule statement of general applicability or binding law. In the event of a conflict or inconsistency, duly promulgated or enacted state or federal law shall control. The Board of Pharmacy expressly reserves the right to revise the contents as deemed appropriate or necessary. Questions regarding this document may be addressed to the Board office.*

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## Section 1. Missouri Licensing Requirements

- 1.1 GENERAL REQUIREMENTS.** Pursuant to [§ 338.330](#), RSMo, all “wholesale drug distributors” must be licensed or registered by the Board. A separate drug distributor license/registration is required for each distribution site. [\[20 CSR 2220-5.020\(7\)\]](#).

A “wholesale drug distributor” is defined as any person/entity engaged in delivering or distributing legend drugs and who is involved in the actual, constructive or attempted transfer of a drug in this state to any person/entity other than the ultimate consumer. [\[20 CSR 2220-5.020\(1\)\]](#). This definition includes, but is not limited to,:

- Brokers
- Independent wholesale drug traders
- Jobbers
- Manufacturers (Missouri doesn’t issue a separate manufacturer license.)
- Own-label distributors
- Private label distributors
- Retail pharmacies conducting wholesale distributions
- Warehouses (i.e.- chain, manufacturer and wholesale warehouses)

A distributor license is not required if drugs are being delivered, distributed or transferred directly to the ultimate consumer (i.e.- the patient). [\[§ 338.330\(4\)\]](#). The ultimate consumer does not include practitioner offices (physician, dentist, veterinarian, etc.), hospitals, nursing home facilities, ambulance/fire districts, other distributors, or intra-company transfers. **Note: A Missouri pharmacy license is required to fill/dispense a patient specific prescription.**

For purposes of drug distributor licensing, a “legend drug” or “prescription drug” is defined as any drug or biological product:

- a. Subject to Section 503(b) of the Federal Food, Drug and Cosmetic Act, including finished dosage forms and active ingredients subject to such Section 503(b); or
- b. Required by any applicable federal or state law or regulation to be dispensed by prescription only or that is restricted to use or dispensed by practitioners only, or;
- c. Required under federal law to be labeled with one of the following statements prior to being dispensed or delivered:
  - i. “Caution: Federal law prohibits dispensing without prescription”;
  - ii. “Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian”;
  - iii. “Rx Only”. [\[§ 338.330\(1\)\(a\)\]](#).

The term "drug", "prescription drug", or "legend drug" does not include:

- a. An investigational new drug, as defined by 21 CFR 312.3(b), that is being utilized for the purposes of conducting a clinical trial or investigation of such drug or product that is governed by, and being conducted under and pursuant to, 21 CFR 312, et. seq.;
- b. Any drug product being utilized for the purposes of conducting a clinical trial or investigation that is governed by, and being conducted under and pursuant to, 21 CFR 312, et. seq.; or

- c. Any drug product being utilized for the purposes of conducting a clinical trial or investigation that is governed or approved by an institutional review board subject to 21 CFR Part 56 or 45 CFR Part 46. [\[§ 338.330\(1\)\(b\)\]](#).

*In addition to Missouri law, distributors must comply with all applicable state and federal controlled substance laws. Distributors handling controlled substances should contact the Missouri Bureau of Narcotics and Dangerous Drugs (BNDD) or the DEA for controlled substance guidance and questions.*

**1.2 EXEMPTIONS.** By law, “wholesale drug distribution” does not include, and a license is not required for,:

- 1) Common carriers or individuals hired solely to transport legend drugs (i.e.- delivery services, FedEx or UPS) [\[§ 338.330\(4\)\]](#);
- 2) The sale, purchase or trade of blood and blood components intended for transfusion [\[20 CSR 2220-5.020\(1\)\(B\)\]](#);
- 3) Emergency shipments from out-of-state pharmacies, as authorized by Missouri law (*See Section 5.1*), or;
- 4) Shipments of investigational drugs. Investigational drugs are defined as:
  - An investigational new drug, as defined by 21 CFR 312.3(b), that is being utilized for the purposes of conducting a clinical trial or investigation of such drug or product that is governed by, and being conducted under and pursuant to, 21 CFR 312, et. seq.;
  - Any drug product being utilized for the purposes of conducting a clinical trial or investigation that is governed by, and being conducted under and pursuant to, 21 CFR 312, et. seq.; or
  - Any drug product being utilized for the purposes of conducting a clinical trial or investigation that is governed or approved by an institutional review board subject to 21 CFR Part 56 or 45 CFR Part 46. [\[§ 338.330\(1\)\(b\)\]](#)

**1.3 GENERAL LICENSE REQUIREMENTS (MISSOURI FACILITIES).** Applicants for drug distributor licensure must:

- Submit a completed application and pay the appropriate fee;
- Designate a manager-in-charge who is responsible for direct supervision of the distributor’s operations, and;
- Pass a Board inspection.

To apply for licensure, the designated manager-in-charge must submit fingerprints and undergo a criminal background check. For non-publicly traded companies, owners with a 10% or more ownership interest must also be fingerprinted and complete a criminal background check. [\[20 CSR 2220-5.020\(4\)\]](#)

If the facility passes inspection, a temporary distributor license number will be issued at the close of the inspection. [\[20 CSR 2220-5.020\(8\)\]](#). Applicants may begin operating once the temporary license number has been issued. No receipt or distribution of legend products may occur until the facility has passed inspection and a temporary license number or a permanent license has

been issued by the Board. If the license expires, all distribution of legend drug products must immediately cease.

Temporary licenses expire automatically in 12 months from the date issued and cannot be renewed. [\[20 CSR 2220-5.020\(8\)\(A\)\]](#). The temporary license will become null and void if the application is denied by the Board. ***Note: Receipt of a temporary license does not guarantee permanent licensure. The Board reserves the right to deny, probate or otherwise restrict a license, as authorized by Missouri law.***

**1.4 DISTRIBUTOR LICENSING FOR PHARMACIES.** A Missouri licensed pharmacy may deliver or distribute legend drugs to authorized persons without a drug distributor license, provided the amount delivered/distributed does not exceed five percent (5%) of the pharmacy's total gross sales. [\[§ 338.330\(3\)\]](#). If the amount delivered/distributed exceeds five percent, the pharmacy must be licensed as a distributor. ***Note: Missouri pharmacies cannot sell or transfer drugs to other entities or healthcare practitioners by prescription. Drug sales/transfers must be documented by invoice or via a DEA-222 form, if applicable. Pharmacies may not distribute compounded preparations for office stock.*** [\[§ 338.095\]](#).

**1.5 DRUG DISTRIBUTOR REGISTRANTS.** In lieu of drug distributor licensure, an out-of-state drug manufacturer may apply for a Missouri drug distributor registration by filing an abbreviated drug registrant application. [\[§ 338.337\]](#). Applicants for registration must meet the following requirements:

- The applicant must be currently registered as an FDA drug manufacturer;
- The manufacturing facility must be used for both the production (manufacture) and distribution of legend drugs;
- The manufacturing facility must have been successfully inspected and approved by the Food and Drug Administration. A copy of the applicant's most recent Food and Drug Administration Establishment Inspection Report (EIR) must be submitted with the registration application. The application may be denied, probated or further reviewed by the Board if an FDA 483 Form has been issued.
- The manufacturing facility must hold a drug distributor/manufacturer license that is current and in good standing in the state or jurisdiction where the facility is located. Inspection reports or statements of Good Manufacturing Practice (GMP) compliance/certification are insufficient. [\[20 CSR 2220-5.050\]](#)

Registrants may conduct wholesale drug distribution in the state of Missouri, provided the registrant complies with all drug distribution standards applicable to licensed distributors. ***Note: Manufacturing facilities located in Missouri are only eligible for drug distributor licensure and are not eligible to apply for a drug distributor registration.***

**1.6 OUT-OF-STATE DISTRIBUTORS.** Missouri law prohibits any out-of-state wholesale drug/pharmacy distributor from shipping, mailing or delivering prescription drugs into this state without a Missouri drug distributor license/registration. [\[§ 338.333\]](#). A separate distributor license must be obtained for each site/address shipping products into Missouri. [\[§ 338.335\]](#). *[See Section 1.8 for intra-company device shipments.]*

To be eligible for licensure, applicants must be located in a state/foreign jurisdiction that extends reciprocal treatment to Missouri distributors and that has comparable legal standards for drug distributor licensure. [\[§ 338.333\]](#). Out-of-state applicants must:

- Submit a completed application with the applicable fee;
- Designate a manager-in-charge responsible for daily supervision of the distributor's operations;
- Hold a valid license in good standing in the state or foreign jurisdiction where the applicant is located, and;
- Hold a valid controlled substance registration/authorization, if controlled substances will be shipped into Missouri. [\[20 CSR 2220-5.050\(2\)\]](#).

If the applicant's home state/jurisdiction does not issue a separate controlled substance registration, a notarized letter must be submitted with the application attesting that the applicant's home state does not issue a separate controlled substance license/registration.

The Board does not routinely inspect out-of-state facilities. However, a copy of the out-of-state facility's most recent inspection report must be submitted with the application. [\[20 CSR 2220-5.050\(2\)\(A\)6.\]](#). Inspection findings/deficiencies may result in further review by the Board.

A temporary drug distributor license number will be issued once a completed application has been received. [\[20 CSR 2220-5.020\(8\)\]](#). To be complete, the designated manager-in-charge and all owners with more than a 10% interest must submit proof of fingerprinting and undergo a criminal background check. [\[20 CSR 2220-2.450\]](#). Applicants may begin operating once the temporary license number has been issued.

Temporary licenses expire automatically in 12 months from the date issued and cannot be renewed. [\[20 CSR 2220-5.020\(8\)\(A\)\]](#). The temporary license will become null and void if the application is denied by the Board. ***Note: Receipt of a temporary license does not guarantee permanent licensure. The Board reserves the right to deny, probate or otherwise restrict a license, as authorized by Missouri law.***

***Out-Of-State Third-Party Logistics Distributors:*** Any out of state facility that ships legend drugs or drug-related devices into Missouri must be licensed as a Missouri drug distributor. If a manufacturer uses a third-party logistics distributor to perform their distribution activity then a Missouri drug distributor license is required for the third party logistics distributor. A Missouri drug distributor license is not required if the manufacturer's facility does not ship legend products into Missouri.

- 1.7 DRUG SALES REPRESENTATIVES.** Drug sales representatives and other agents or employees of a licensed/registered distributor may have legend drugs in their custody if the representative, agent or employee is acting in the usual course of his/her business or employment. [\[20 CSR 2220-5.030\(5\)\]](#). A separate drug distributor license is not required for sites used to store drugs in the custody of a drug sales representative or other agent/employee. However, the name and address of the drug sales representative or agent/employee must be reported to the Board along with the

address of all sites where drugs are stored. Licensees must ensure that prescription drugs in the custody of a drug sales representative or other agent/employee are stored and transported in accordance with manufacturer or USP guidelines. [\[20 CSR 2220-5.030\(5\)\]](#).

**1.8 DEVICE DISTRIBUTORS.** Missouri law requires a drug distributor license for facilities distributing, providing, or offering legend drug-related medical devices to any person other than the ultimate consumer/patient. [\[§ 338.330\(4\)\]](#). Legend items bear one of the following statements on their label:

- “Rx only”
- “Caution: Federal (U.S.A.) law prohibits dispensing without a prescription.”
- “Caution: Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.”
- “Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician”.

A “drug-related medical device” refers to those devices that contain a legend drug as part of the device. [\[20 CSR 2220-5.030\(9\)\]](#). Examples may include, but are not limited to, pre-filled heparin/saline syringes and sterile water/saline for irrigation or inhalation.

A Missouri drug distributor license is not required for facilities solely distributing legend devices that do not contain a legend drug as part of the device. Additionally, a license is not required if devices are only being distributed to the ultimate consumer/patient. [\[§ 338.330\(4\)\]](#). ***Note: The ultimate consumer does not include practitioners offices (physician, dentist, veterinarian, etc.), hospitals, nursing home facilities, ambulance/fire districts, home medical equipment providers, other distributors, or intra-company transfers.***

***Over-The-Counter Devices:*** Distribution of over-the counter devices such as blood glucose testing supplies and insulin syringes/needles does not require a distributor license. The sale of such products to the patient does not require a license unless your facility chooses to dispense them as a prescription in which case, a Missouri pharmacy license is required.

***Exemptions:*** A drug distributor licensure exemption exists for out-of-state intra-company transfers of drug-related devices. Specifically, [§ 338.335.2](#) provides the following exemption requirements:

*2. A wholesale drug distributor distributing drug-related devices in Missouri is not required to obtain a license from the board for out-of-state distribution sites owned by the wholesale drug distributor if:*

*(1) The wholesale drug distributor has one or more distribution sites located in Missouri, and all such in-state distribution sites receiving shipments of drug-related devices are licensed by the board as a distributor;*

*(2) The wholesale drug distributor's out-of-state distribution sites shipping to the in-state distribution site are in compliance with their respective state's licensing laws;*

(3) *The wholesale drug distributor's out-of-state distribution sites that deliver drug-related devices regulated by the board into Missouri for patient use deliver such devices only to the licensed wholesale drug distributor's in-state distribution site.*

- 1.9 MEDICAL GAS DISTRIBUTORS.** Pursuant to [20 CSR 2220-5.070](#), a Missouri drug distributor license is required for any person or entity engaged in the distribution of medical gas pursuant to a medical gas order to medical gas suppliers or any other entity authorized to use, administer or distribute medical gasses. For purposes of drug distributor licensing, “medical gases” are defined as compressed and liquid gases that a distributor or manufacturer has labeled for medical use in compliance with federal law. [\[20 CSR 2220-5.070\(2\)\]](#). ***Note: A Missouri drug distributor license is not required if medical gases are being dispensed solely to individual consumers (i.e.- the patient). The ultimate consumer does not include practitioner offices (physician, dentist, veterinarian, etc.), hospitals, nursing home facilities, ambulance/fire districts, other distributors, or intra-company transfers.***

Medical gas distributors are required to comply with all Missouri drug distributor requirements, including, all security, drug storage, recordkeeping and facility requirements. However, medical gas distributors engaged in storing, transferring or transfilling medical gases other than nitrous oxide are exempt from, and do not have to comply with, the following distributor requirements:

- Thermostatically maintaining distributor facilities and taking/recording daily temperature logs;
- Maintaining temperature and humidity recording equipment;
- Ensuring drug products are raised above floor level and placed on a pallet;
- Ensuring the facility’s outside premises are well-lit;
- Separating medical gases labeled for veterinary use from medical gases distributed for human use;
- Maintaining an alarm system to detect entry after hours, and
- Maintaining refrigeration/freezer units. [\[20 CSR 2220-5.070\(3\)\]](#).

Medical gas distributors that store, transfer or transfill nitrous oxide are exempt from, and do not have to comply with, the following requirements:

- Thermostatically maintaining distributor facilities and taking/recording daily temperature logs;
- Maintaining temperature and humidity recording equipment;
- Ensuring drug products are raised above floor level and placed on a pallet;
- Separating medical gases labeled for veterinary use from medical gases distributed for human use, and;
- Maintaining refrigeration/freezer units. [\[20 CSR 2220-5.070\(3\)\]](#).

In addition to Missouri’s requirements, entities engaged in manufacturing/transfilling medical gases must be registered with the Food and Drug Administration (FDA) as a medical gas manufacturer and comply with all federal drug listing and current good manufacturing practice requirements. [\[20 CSR 2220-5.070\(4\)\]](#). ***Note: Medical gas cylinders and containers must bear a complete, intact, and legible drug label that includes the lot number.***

## Section 2. Facility Requirements

**2.1 GENERAL REQUIREMENTS.** Distributors must comply with all applicable state/federal laws governing plant facilities and equipment. Additionally, facilities must comply with the following minimum requirements [\[20 CSR 2220-5.030\(3\)\]](#):

- Facilities must be suitably sized and constructed to allow proper operation, cleaning and maintenance of the distributorship [\[20 CSR 2220-5.030\(3\)\(A\)\]](#);
- The facility's drug distributor license must be posted/displayed in a public area. [\[20 CSR 2220-5.030\(3\)\(D\)\]](#). Licenses posted/displayed in private areas with restricted access are non-compliant (i.e.- a locked office);
- The outside perimeter of the facility must be well lit at all times. [\[20 CSR 2220-5.030\(3\)\(C\)12.\]](#). Motion sensitive lighting may be used, however, equipment should be routinely tested to ensure adequate functioning and movement detection;
- All aisles, walkways and shelves must be clear of debris, dirt or other filth [\[20 CSR 2220-5.030\(3\)\(C\)1.\]](#);
- Refrigeration must be available with sufficient storage space for storing all drug products that require refrigeration/freezing. [\[20 CSR 2220-5.030\(3\)\(E\)\]](#). **Note: Refrigeration is not required if the facility does not store or distribute drugs that require refrigeration/freezing.** [See also Section 2.4- Refrigeration], and;
- Appropriate sewage disposal and a hot and cold water supply must be available. [\[20 CSR 2220-5.030\(3\)\(C\)11.\]](#). Water supplies may be located in a separate part of the facility, however, the area must be accessible to staff/employees.

The Board has statutory authority to enter and inspect facilities to ensure compliance with Missouri law. [\[§ 338.150\]](#).

**2.2 SECURITY.** Adequate security policies and procedures must be established and maintained to prevent theft or diversion. [\[20 CSR 2220-5.030\(3\)\(C\)14.\]](#). At a minimum, facilities must comply with the following security requirements:

- Facilities must be equipped with an adequate security system that includes an alarm system capable of detecting entry after hours. [\[20 CSR 2220-5.030\(3\)\(C\)13.\]](#). Security cameras alone are insufficient. While cameras may record unauthorized entry, they generally do not protect against theft and diversion as required by law. The Board recommends security systems that are able to promptly detect unauthorized entry and provide timely alerts.
- The facility's security systems must protect against theft or diversion facilitated by tampering with computers or electronic records. [\[20 CSR 2220-5.030\(3\)\(C\)14.\]](#).
- Facilities must be equipped with sufficient locking mechanisms to prevent theft or diversion. [\[20 CSR 2220-5.030\(3\)\(C\)14.\]](#). Manual, biometric or electronic equipment may be used.

Additionally, drugs held for distribution must be stored in a secure area that can only be accessed by authorized personnel. [\[20 CSR 2220-5.030\(3\)\(H\)\]](#). Distributors must maintain a list of all current staff with keys, passes or codes that will allow them to independently access any part of a

facility where controlled substances are stored or where drugs are stored for later distribution. [\[20 CSR 2220-5.030\(3\)\(H\)\]](#). Additionally, licensees must maintain a record of all former employees who have had access to drug storage or processing areas. [\[20 CSR 2220-5.030\(3\)\(H\)\]](#). Records must be maintained for three (3) years and must be available or retrievable during inspection. [\[20 CSR 2220-5.030\(3\)\(H\)\]](#).

- 2.3 TEMPERATURE/HUMIDITY CONTROLS.** Distributor facilities must be thermostatically maintained and equipped with appropriate temperature and humidity recording devices/equipment. [\[20 CSR 2220-5.030\(3\)\(B\)\]](#). A drug storage area is non-compliant if the area is not heated or air conditioned.

Temperature and humidity readings should be taken and recorded daily. Manual, electronic or electromechanical equipment may be used for readings, however, equipment should be regularly tested to ensure proper functioning. [\[20 CSR 2220-5.030\(3\)\(B\)\]](#). Proof of temperature/humidity documentation will be requested during an inspection. ***Note: The Board continues to cite violations because of broken or malfunctioning temperature/humidity equipment. Devices should be regularly checked to ensure proper functioning.***

- 2.4 REFRIGERATION.** Drugs must be maintained within the manufacturer's temperature recommendations and/or as recommended by USP at all times. [\[20 CSR 2220-5.030\(3\)\(B\)\]](#). Adequate refrigeration storage space must be available to store all drug products requiring refrigeration/freezing. [\[20 CSR 2220-5.030\(3\)\(E\)\]](#). Refrigeration units must be equipped with appropriate temperature reading devices or equipment. [\[20 CSR 2220-5.030\(3\)\(B\)\]](#). ***Note: Refrigeration units are not required if the facility does not store or distribute drugs that require refrigeration/freezing.***

Temperature readings for refrigeration/freezer units should be taken and recorded daily. [\[20 CSR 2220-5.030\(3\)\(B\)\]](#). Mobile, temporary or portable units may be used as long as drugs are stored within recommended temperature limits and temperature readings are appropriately documented. Proof of compliance will be requested during an inspection.

### Section 3. Policies & Procedures

- 3.1 Distributors must establish and maintain written policies and procedures for receiving, storing, securing, inventorying and distributing prescription drugs. [\[20 CSR 2220-5.030\(3\)\(M\)\]](#). At a minimum, the facility's policies and procedures must include policies/procedures for:
- 1) Identifying, recording and reporting losses or thefts;
  - 2) Product receipt, storage and distribution;
  - 3) Product security;
  - 4) Stock rotation;
  - 5) Correcting inventory errors and inaccuracies;
  - 6) Handling prescription drug recalls/withdrawals;

- 7) Preparing for, protecting against and handling the security or operation of a facility in the event of a strike, fire, flood or other natural disaster, or any other local, state or national emergency;
- 8) Reporting counterfeit or suspected counterfeit drugs, devices or other activities to the Board;
- 9) Reporting any prescription drug shortage to the Board and any other appropriate federal/state agency where it is known or suspected that diversion or theft is occurring;
- 10) Investigating discrepancies involving counterfeit, suspected counterfeit or contraband drugs in the facility's inventory and reporting such discrepancies to the appropriate federal or state agencies within seven (7) business days;
- 11) Reporting criminal or suspected criminal activities involving drug inventory to the Board within seven (7) business days;
- 12) Segregating outdated prescription drugs;
- 13) Security procedures for delivering drugs from the facility to the destination site, and;
- 14) Destroying outdated prescription drugs or returning outdated prescription drugs to the manufacturer. Written documentation of the disposition of outdated drugs is required. [\[20 CSR 2220-5.030\(3\)\(M\)\]](#)

Failure to adhere to required policies/procedures could result in disciplinary action. **Note:** *Failure to maintain a complete policy and procedure manual is a common violation. Licensees should regularly review 20 CSR 2220-5.030 to ensure compliance. Distributor staff should know the location of the policy and procedure manual so it may be located during an inspection. Failure to produce the policy and procedure manual may result in an inspection violation.*

## Section 4. Staff/Personnel

- 4.1 **Manager-In-Charge.** Distributor operations must be conducted under the direct supervision of a manager-in-charge (MIC) that has been properly designated with the Board for the facility. [\[20 CSR 2220-5.030\(2\)\(E\)\]](#). To be designated, the MIC must have two (2) years of experience/education in:
- A wholesale/pharmacy distributor facility;
  - Drug distributor law, standards of operation or compliance, or;
  - Any educational endeavor beyond graduation from an accredited high school or its equivalent. [\[20 CSR 2220-5.030\(2\)\(B\)\]](#).

Experience and education may be combined to meet the two (2) year requirement. [\[20 CSR 2220-5.030\(2\)\(B\)\]](#).

The designated MIC is responsible for supervising distributor activities and must be actively involved in, and aware of, the facility's daily operations. [\[20 CSR 2220-5.030\(2\)\(E\)\]](#). To ensure supervision, the MIC must be **physically present** on-site during the facility's normal business hours except when absent for illness, scheduled vacations or other authorized absences. Distribution activities may be conducted during an authorized absence, however, the authorized absence should be documented in the distributor's records. [\[20 CSR 2220-5.030\(2\)\(B\)\]](#). **Note:**

*The Board recognizes that a MIC may be briefly and momentarily absent from a facility during business hours for legitimate reasons. The Board has determined distributorship operations may continue during these brief absences, provided the MIC must be otherwise actively involved in, and aware of, the facility's operations in the interim. The MIC should also ensure adequate policies and procedures are in place to ensure compliance with applicable state/federal law.*

Licensees must immediately notify the Board if the designated MIC changes, resigns or is terminated. [\[20 CSR 2220-5.030\(2\)\(E\)\]](#). The distributorship may not continue operations until a new MIC has been properly designated with the Board by submitting a completed [Manager-In-Charge Change application](#). Newly designated MICs must satisfy all education/experience requirements and undergo a criminal background check.

The newly designated MIC may begin serving once the completed [Manager-In-Charge Change application](#) has been mailed or submitted to the Board. To be complete, the application must include the applicable fee and proof of fingerprinting (i.e.- a receipt). A copy of the application should be retained in the distributor's files.

- 4.2 **MANAGERS/SUPERVISORS.** Any person considered to be a manager or supervisor of drug distributor activities must have at least one (1) year of experience/education in:
- A wholesale/pharmacy distributor facility;
  - Drug distributor law, standards of operation or compliance, or;
  - Any educational endeavor beyond graduation from an accredited high school or its equivalent. [\[20 CSR 2220-5.030\(2\)\(C\)\]](#).

Experience and education may be combined to satisfy the one (1) year requirement. [\[20 CSR 2220-5.030\(2\)\(C\)\]](#).

The 1-year experience/education requirement applies to any person "considered" to be a manager or supervisor regardless of job title. [\[20 CSR 2220-5.030\(2\)\(C\)\]](#). The Board may consider a variety of factors when determining if an employee is considered a manager or supervisor, including, the employee's actual job duties and ability to direct, manage or supervise facility operations/staff. A list of all officers, directors, managers and other persons in charge of wholesale drug distribution, storage and handling must be maintained at the facility, along with a description of each individual's job duties and their qualifications. [\[20 CSR 2220-5.030\(2\)\(C\)\]](#).

- 4.3 **STAFF/PERSONNEL TRAINING.** All staff performing drug distribution activities must have sufficient education, training or experience to perform the duties assigned. [\[20 CSR 2220-5.030\(2\)\(D\)\]](#). At a minimum, staff should be sufficiently trained to ensure awareness of drug safety requirements as well as distribution standards, policies and procedures. The Board recommends ongoing training/education of all staff to ensure continued competency/compliance.

## Section 5. Drug Handling/Storage

- 5.1 RECEIPT OF LEGEND DRUGS.** Pursuant to [20 CSR 2220-5.020\(1\)](#), a drug distributor can only receive legend drugs or drug-related devices from Missouri licensed drug distributors or Missouri licensed pharmacies. Licensees are responsible for ensuring proper licensure prior to receiving a shipment. License status may be verified on the [Board's website](#). *Note: The Board periodically faxes a list of known unlicensed distributors to licensees. Licensees are deemed to have knowledge of the unlicensed status of any person/entity on the Board's unlicensed distributor listing.*

Missouri law recognizes a limited exemption for emergency drug shipments from out-of-state distributors. [\[20 CSR 2220-5.050\(3\)\]](#). Specifically, an out-of-state drug distributor may supply legend drugs without a Missouri drug distributor license to a Missouri-licensed distributor in the event of an emergency if:

- The total amount distributed does not exceed one percent (1%) of the total annual gross sales of the unlicensed distribution site, and;
- The amount of the distribution is confined to the emergency. Shipments that exceed the amount needed to address the identified emergency will be considered unauthorized and unlicensed activity. [\[20 CSR 2220-5.050\(3\)\]](#).

The nature of the emergency should be documented in the records of both the shipping and receiving distributor. *Note: This exemption only applies to shipments received from out-of-state wholesale distributors.*

Once received, the outside shipping container of any legend drug must be visually examined to verify identity and to prevent acceptance of any contaminated, misbranded, adulterated or unfit drug product. [\[20 CSR 2220-5.030\(3\)\(C\)5.\]](#). The examination must be adequate to reveal container damage or any other damage that may suggest possible contamination. [\[20 CSR 2220-5.030\(3\)\(C\)5.\]](#).

Any prescription drug whose immediate or sealed outer/secondary container has been opened or used must be identified and physically separated from other prescription drugs until the drug product is either destroyed or returned to the supplier. [\[20 CSR 2220-5.030\(3\)\(C\)5.\]](#)

- 5.2 LABELING.** Prescription drugs held for wholesale distribution must be labeled with the manufacturer's name, expiration date, if applicable, batch or lot number and national drug code. [\[20 CSR 2220-5.030\(3\)\(F\)\]](#). Additionally, distributors must comply with all manufacturer, FDA and USP labeling requirements. [\[20 CSR 2220-5.030\(3\)\(F\)\]](#). *Note: Medical gas cylinders and containers must bear a complete, intact, and legible drug label that includes the lot number.*
- 5.3 SANITATION.** Distributors must establish adequate policies/procedures to ensure drugs are stored in a clean and sanitary manner. [\[20 CSR 2220-5.030\(3\)\(C\)\]](#). Distribution of any adulterated or misbranded drug violates state and federal law and may result in disciplinary action.

At a minimum, distributors must comply with the following sanitation requirements:

- Drug storage areas must be maintained in a clean and sanitary manner at all times with appropriate housekeeping, lighting, sanitation, ventilation and humidity [\[20 CSR 2220-5.030\(3\)\(C\)\]](#);
- All aisles, walkways and shelves must be clear of debris, dirt or other filth [\[20 CSR 2220-5.030\(3\)\(C\)1.\]](#);
- Procedures must be in place to prevent, control and alleviate infestation by insects, rodents, birds or other vermin. [\[20 CSR 2220-5.030\(3\)\(C\)10.\]](#). If an infestation is suspected, distributors should immediately take steps to protect the drug supply and prevent contamination (i.e.- moving/segregating drug inventory);
- All legend drug products must be raised above floor level and placed on a pallet or similar device [\[20 CSR 2220-5.030\(3\)\(C\)4.\]](#);
- Accumulated waste/garbage must be separated and cannot be stored in the same area as drug products [\[20 CSR 2220-5.030\(3\)\(C\)7.\]](#);
- Appropriate sewage disposal must be available [\[20 CSR 2220-5.030\(3\)\(C\)11.\]](#), and;
- Animals are not allowed in drug storage areas, except for service animals as defined by the Americans with Disabilities Act (ADA). [\[20 CSR 2220-5.030\(3\)\(C\)10.\]](#)

The Board recognizes that dust cannot be entirely prevented. However, adequate ventilation and/or cleaning procedures must be used to keep dust collection at a low level. [\[20 CSR 2220-5.030\(3\)\(C\)1.\]](#). Excessive dust is unsanitary and may result in an inspection violation.

Distributors are encouraged to establish a regular scheduled time for physically checking shelves and other drug storage areas. Regular monitoring will prevent compliance issues and ensure proper maintenance.

- 5.4 DRUG SHIPMENTS.** Distributors must establish and maintain standards of practice to ensure drugs of appropriate quality are distributed. [\[20 CSR 2220-5.030\(3\)\(M\)\]](#). Prior to shipment/distribution, all outgoing shipments of prescription drugs must be carefully inspected to verify identity and to ensure that no drug is dispensed that has been damaged in storage or held under improper conditions. [\[20 CSR 2220-5.030\(3\)\(C\)6.\]](#)

The oldest approved stock of a prescription drug must be distributed first. [\[20 CSR 2220-5.030\(3\)\(M\)1.\]](#). Distributors may temporarily deviate from this requirement if deemed appropriate. [\[20 CSR 2220-5.030\(3\)\(M\)1.\]](#). Licensees may be asked to substantiate cause for distributing newer stock during an inspection.

Distributors must also comply with all applicable with all state/federal law governing:

- 1) Packaging;
- 2) Record keeping;
- 3) Expiration dating;
- 4) Production and control procedures;
- 5) Containers;
- 6) Testing, and;
- 7) Federal registration. [\[20 CSR 2220-5.030\(4\)\]](#).

- 5.5 INVENTORY SEGREGATION.** Drugs products stored in the facility or held for distribution must be physically separated and stored away from:
- Any article, supply or drug that is outdated, distressed, misbranded or adulterated [\[20 CSR 2220-5.030\(3\)\(C\)7.\]](#);
  - Any quarantined or nonusable substance [\[20 CSR 2220-5.030\(3\)\(C\)7.\]](#);
  - Drugs labeled for veterinary use (human drugs must be stored separately), and; [\[20 CSR 2220-5.030\(3\)\(C\)9.\]](#)
  - Any flammable article (including flammable non-drug products). [\[20 CSR 2220-5.030\(3\)\(C\)8.\]](#)
- 5.6 RETURNS.** Prescription drugs may only be returned to the distributorship as allowed by state/federal law. If the conditions under which a prescription drug has been returned casts doubt on the drug's safety, identity, strength, quality or purity, the drug must be destroyed or returned to the supplier, unless examination, testing or other investigation proves the drug meets appropriate standards of safety, identity, strength, quality and purity. [\[20 CSR 2220-5.030\(3\)\(G\)\]](#). At a minimum, distributors must consider:
- The conditions under which the drug was held, stored or shipped before or during its return;
  - The condition of the drug as a result of storage or shipping, and;
  - The condition of the drug's container, carton or labeling. [\[20 CSR 2220-5.030\(3\)\(G\)\]](#).
- Note: Drugs not properly labeled as required by the manufacturer or the FDA are misbranded and may not be redistributed (i.e.- labels missing, removed or substantially altered/torn).*
- 5.7 DRUG DISPOSAL/DISPOSITION.** Prescription drugs must be destroyed/disposed of in compliance with applicable state/federal law. Written documentation of the disposition of outdated drugs must be maintained for three (3) years after disposition. [\[20 CSR 2220-5.030\(3\)\(I\)\]](#).
- 5.8 SALVAGING/REPROCESSING.** Distributors must comply with all applicable federal, state or local laws or regulations related to prescription drug product salvaging or reprocessing, including, Parts 207, 210 and 211 of the Federal Food, Drug and Cosmetic Act. [\[20 CSR 2220-5.030\(7\)\]](#).
- 5.9 COUNTERFEIT/CONTRABAND DRUGS.** Distributors must investigate any discrepancy involving real or suspected counterfeit or contraband drugs in the distributor's inventory. [\[20 CSR 2220-5.030\(3\)\(M\)6.\]](#). Discrepancies must be reported within seven (7) business days to the Board and any applicable federal/state agency. [\[20 CSR 2220-5.030\(3\)\(M\)6.\]](#).

Distributors must also report any drug received or distributed that is found to be counterfeit in whole or in part. [\[20 CSR 2220-5.030\(3\)\(C\)7.\]](#). Reports must be filed with the Board within seven (7) days after gaining knowledge of the transaction. [\[20 CSR 2220-5.030\(3\)\(C\)7.\]](#). Reporting is not required if a recall is initiated by the Food and Drug Administration (FDA) or a Missouri licensed vendor. [\[20 CSR 2220-5.030\(3\)\(C\)7.\]](#). *Note: Reporting is required for drugs received directly or indirectly (i.e.- through a secondary broker (paper) transaction).*

## SECTION 6. Records

6.1 **GENERAL REQUIREMENTS.** Distributors must accurately maintain all records required by state and federal law, including, all records required by the Drug Enforcement Agency (DEA), FDA or Missouri’s Bureau of Narcotics and Dangerous Drugs (BNDD). The following chart summarizes selected Missouri recordkeeping requirements and is not a comprehensive listing. Licensees should thoroughly review Chapter 338, RSMo, and 20 CSR 2220-5 to ensure compliance with Missouri requirements.

Record	Retention Period	Cite
Disposition of outdated drugs	Three (3) years after disposition	<a href="#">20 CSR 2220-5.030(3)(M)8.</a>
Transaction records	Three (3) years after distribution/disposition	<a href="#">20 CSR 2220-5.030(3)(J)</a>
Records of current/former employees with access to drug storage or processing areas	Three (3) years	<a href="#">20 CSR 2220-5.030(3)(I)</a>
Authorized personnel listings	Three (3) years	<a href="#">20 CSR 2220-5.030(3)(H)</a>
Temperature/humidity records	Three (3) years	<a href="#">20 CSR 2220-5.030(3)(B)</a>
MIC and other supervisors job descriptions	Three (3) years	<a href="#">20 CSR 2220-5.030(6)</a>
Controlled substance records (annual inventories, loss reports, C-II order forms, CSOS records, power of attorney forms)	Two (2) years	<a href="#">BNDD/DEA regulations</a>

6.2 **TRANSACTION RECORDS.** Licensees must maintain inventories and records of all transactions regarding the receipt, distribution or other disposition of prescription drugs. [\[20 CSR 2220-5.030\(3\)\(I\)\]](#). The facility’s transaction records must document:

- 1) The date(s) drugs were received, disposed of or distributed;
- 2) The identity and quantity of drugs received, distributed or disposed of;
- 3) The source of the drugs, including, the name and principal address of the seller or transferor, and;
- 4) If drugs are received, the address of the location shipping the drug product. [\[20 CSR 2220-5.030\(3\)\(I\)\]](#).

**Note:** *Records must be maintained for all drugs, including, outdated, damaged, deteriorated, misbranded or adulterated drugs.*

6.3 **PRODUCTION/INSPECTION OF RECORDS.** Required records may be manually or electronically maintained.

- *Manual Records:* Records manually stored at the facility must be made available for inspection and photocopying during inspection. Manual records may be stored offsite provided records must be produced for inspection within two (2) working days of a

request from the Board or its representative. [\[20 CSR 2220-5.030\(3\)\(K\)\]](#). **Note: *Manual records include records stored on microfilm.***

- **Electronic Records:** Licensees/registrants must be able to immediately retrieve electronically stored records during an inspection. [\[20 CSR 2220-5.030\(3\)\(K\)\]](#). Alternatively, distributors may provide a computer terminal that will allow the inspector to immediately access the system. To allow review, the inspector may ask for code information. **Note: *Licensees should review DEA requirements to determine which controlled substance records may legally be maintained offsite.***

## Section 7. License/Registration Changes

**7.1 CHANGE OF NAME.** Distributors may only conduct business under the name licensed/registered with the Board. [\[§ 338.333\]](#). A drug distributor [Name Change application](#) must be submitted if the entity conducts distribution operations under any name not reflected on the license/registration.

**7.2 CHANGE OF LOCATION.** A [Location Change application](#) must be filed with the Board if:

- The facility's address changes, or;
- The facility moves to another location within the existing structure that has not been inspected by the Board. **Note: *This includes a change of location to another floor or other area at the same address that has not been inspected by the Board.*** [\[20 CSR 2220-5.020\(6\)\]](#).

Distributor operations may not begin at a new location or address until the [Location Change application](#) has been approved and a new license has been issued. For in-state facilities, the new location must pass a Board inspection. [\[20 CSR 2220-5.020\(6\)\]](#). For out-of-state (non-Missouri) distributors, a copy of the updated license from the applicant's home state or jurisdiction must be attached to the application along with an updated copy of the applicant's state/federal controlled substance registrations, if applicable. [\[20 CSR 2220-5.050\(2\)\(A\)\]](#).

Once approved by the Board, a license will be used for the new location under the same license number. **Note: *A Location Change application is not required if the facility's postal address changes but not the location. In such case and on request, an amended license will be issued reflecting the new address without charge.***

**7.3 CHANGE OF OWNERSHIP.** A distributor license/registration is only valid for the entity/owners reflected in the facility's original application. [\[20 CSR 2220-5.020\(5\)\]](#). If a change of ownership occurs, the original distributor license will become void on the effective date of the change and cannot be transferred. The new owners must obtain a new distributor license/registration from the Board prior to assuming operations. [\[20 CSR 2220-5.020\(5\)\]](#). The new owners may not receive or distribute legend products until a temporary or permanent license has been issued for the facility under the new ownership.

Rule [20 CSR 2220-5.020\(5\)](#) contains detailed guidelines for determining when a change of ownership has occurred. Licensees should thoroughly review the rule's requirements to ensure compliance. **Note: A change-of-ownership application will likely be required if an entity changes corporate structure (i.e.- from an LLC to an LLP/corporation/sole proprietorship).**

Prior to approval, facilities located in Missouri must pass another Board inspection. Once the facility passes inspection, a temporary license will be issued at the close of the inspection with a new license number. [\[20 CSR 2220-5.020\(8\)\]](#). The new ownership may begin operating once the temporary license number has been issued.

For facilities located **outside** of Missouri, a temporary license will be issued to the new owners once a completed [Change of Ownership application](#) has been received by the Board. [\[20 CSR 2220-5.020\(8\)\]](#). To be complete, the application must include the required fee and proof of fingerprinting for the manager-in-charge and all owners with more than a 10% interest. [\[20 CSR 2220-2.450\]](#). Once again, the new owners may not receive or distribute legend products until a temporary or permanent license has been issued under the new ownership.

Temporary licenses expire automatically in 12 months from the date issued and cannot be renewed. [\[20 CSR 2220-5.020\(8\)\(A\)\]](#). The temporary license will become null and void if the application is denied by the Board. **Note: Receipt of a temporary license does not guarantee permanent licensure. The Board reserves the right to deny, probate or otherwise restrict a license, as authorized by Missouri law.**

**7.4 TERMINATION OF BUSINESS.** Prior to terminating drug distribution activities, licensees should ensure proper arrangements have been made for all prescription drugs and records. Additionally, an [official Out-of-Business Notification Form](#) must be filed with the Board within fifteen (15) days after termination and the facility's distributor license must be returned to the Board. [\[20 CSR 2220-5.025\]](#).

Any remaining drug inventory may be transferred/disposed of as authorized by state and federal law. [\[20 CSR 2220-5.025\(2\)\(A\)\]](#). A complete inventory of all controlled substances being transferred or disposed of must be taken on the date of termination, as required by state/federal law. [\[20 CSR 2220-5.025\(2\)\(A\)\]](#). The inventory will serve as the final inventory of the distributor terminating business and the initial inventory of the entity receiving the transfer(s). No misbranded, outdated or adulterated drug may be transferred, except for purposes of disposal.

Distributors must identify a location where distribution records will be maintained after the facility terminates business on the facility's [Out-Of-Business Notification form](#). [\[20 CSR 2220-5.025\(1\)\(C\)\]](#). Distributor records must be retrievable within seven (7) working days of a request from the Board or an official designee. [\[20 CSR 2220-5.025\(C\)1.\]](#). **Note: Entities changing location or ownership must file an official Location Change/Change of Ownership application with the Board.**

## Section 8. Common Inspection Violations

*The following is a list of the most common deficiencies found during drug distributor inspections. Please pay special attention to each item on this list and check for compliance.*

### **FACILITY:**

1. Insufficient outside lighting.
2. Lack of equipment to measure temperature in drug storage refrigerators/freezers.
3. Lack of equipment to measure temperature/humidity in other drug storage areas.
4. No alarm system on facility.
5. No separate area for distressed/outdated products.
6. No separate area for flammable products.
7. Veterinary products not stored separately from human products.
8. Drug products not kept off floor or on pallets.
9. No daily temperature recordings for refrigerators/freezers used for drug storage.
10. No daily temperature/humidity recordings for other drug storage areas.
11. Insufficient security (i.e.- drop ceilings, doors/locks insufficient to prevent access).

### **RECORDS:**

1. No current written list of personnel authorized to be in facility.
2. Non-existent or incomplete policies and procedures. ***See Section 3.1 for Policy & Procedure requirements.***
3. No written job description of Manager-in-Charge or other supervisors of distribution and control.

### **MISCELLANEOUS:**

1. Purchasing from unlicensed vendors. ***Rule 20 CSR 2220-5.020 generally provides legend drugs and drug-related devices may only be received from Missouri-licensed distributors or pharmacies.***
2. Distributing to customer not appropriately licensed to receive legend drugs.