Rules of
Department of Economic Development
Division 220—State Board of Pharmacy
Chapter 5—Drug Distributor

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Title 4—DEPARTMENT OF ECONOMIC DEVELOPMENT
Division 220—State Board of Pharmacy
Chapter 5—Drug Distributor

4 CSR 220-5.010 Drug Distributor Advisory Committee

PURPOSE: This rule establishes operating guidelines for the drug distributor advisory committee.

(1) As authorized in section 338.140.4., RSMo, an advisory committee, composed of five (5) members, one (1) of whom shall be a representative of pharmacy, but who shall not be a member of the pharmacy board, three (3) of whom shall be representatives of wholesale drug distributors, as defined in section 338.330, RSMo, and one (1) of whom shall be a representative of drug manufacturers, shall be appointed by the State Board of Pharmacy.

(2) Appointments to the advisory committee shall be made by the president of the board.

(A) Except for the initial committee appointments, each appointment shall be for a term of five (5) years. Beginning with the first committee appointments, the terms will be staggered so that one (1) term will expire each year after that.

(B) No appointment shall become effective until approved by the board. Each candidate shall meet with the board prior to any decision by the board to confirm. This meeting will be held in order for the board to review the candidate's credentials and to familiarize him/her with board personnel and advisory committee responsibilities.

(C) Terms of new committee members shall commence on July 1, unless the appointment is to fill an unexpired term.

(3) The advisory committee shall organize by the election of a chairman and vice-chairman who shall hold their offices for one (1) year and until their successors shall have been elected and qualified. A majority of the committee shall constitute a quorum for the transaction of business.

(4) The advisory committee shall review and make any recommendations to the board on the merit of all rules dealing with pharmacy distributors, wholesale drug distributors and drug manufacturers which are proposed by the board.

(A) The advisory committee shall maintain minutes of all meetings held.

(B) Any recommendations made by the advisory committee concerning proposed regulations shall be noted and explained in the minutes which will be provided to the board at an open session meeting of the board. The advisory committee may provide other documentation, reports or correspondence to the board when necessary.

(C) Any official recommendations to be made from the committee to the board must be initiated by a motion that receives a majority vote in favor by the committee. This motion and vote shall be recorded in the minutes.

(D) The board will review any recommendations made by the advisory committee and will provide a response to the committee if any action is taken or modifications are made to a proposed regulation. In addition, the board shall note in the *Missouri Register* the dates and a summary of any recommendations made by the advisory committee on a proposed rule and report any responses that are made to those recommendations from the board.

(5) Committee members shall be reimbursed or all reasonable and necessary expenses for attending committee meetings. However, only expenses incurred within Missouri will routinely be reimbursed. No request for the compensation of expenses provided in this rule shall be processed for payment unless sufficient funds are available for that purpose within the appropriation of the State Board of Pharmacy.

AUTHORITY: section 338.390, RSMo Supp. 1989. Original rule filed Jan. 3, 1990, effective April 26, 1990.*

**Original authority: 338.390, RSMo 1989.*

4 CSR 220-5.020 Drug Distributor Licensing Requirements

PURPOSE: This rule defines terms and requirements for the lawful licensure of drug distributors.

(1) A "wholesale drug distributor" is defined in section 338.330(3), RSMo. No wholesale drug distributor 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 or pharmacy not licensed or registered by the board. Knowledge of the licensure status of a drug distributor or pharmacy includes, but is not limited to, actual or constructive knowledge. Knowledge of the license status of a drug distributor or pharmacy shall also include, but not be limited to, notification from the board by mail or electronic transmission.

(A) A wholesale drug distributor is further defined as anyone engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.

(B) A wholesale drug distributor does not include:

1. The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug for emergency medical reasons. For purposes of this section, emergency medical reasons includes transfers of prescription drugs by a licensed pharmacy to anyone other than a licensed pharmacy that constitutes five percent (5%) or less of total gross sales of the pharmacy; and

2. The sale, purchase or trade of blood and blood components intended for transfusion and any other exemptions as provided for in Chapter 338, RSMo.

(C) Wholesale drug distributors shall inform the board of their current FAX number, any change in FAX number, and/or the fact that the wholesale drug distributor does not have a working FAX. In the event a wholesale drug distributor notifies the board that the wholesale drug distributor does not have a working FAX, notification from the board will be made to the wholesale drug distributor by first class mail. For the purposes of this rule, such notification by mail shall be considered effective three (3) days after mailing and shall have the same effect as notification by FAX.

(D) Failure to receive notification from the board shall not be a defense to violations of section (1) of this rule when the wholesale drug distributor has failed to comply with the requirements of subsection (1)(C) of this rule.

(2) All licenses for the operation of a drug distributor shall expire on the date specified by the director of the Division of Professional Registration by appropriate rule.

(3) Drug distributor licenses shall be issued on the application of the owners. If the owner is a corporation or partnership, an officer of the corporation or partner must sign the application as the applicant.

(4) Drug distributor license applications and renewal applications shall be completed and submitted to the Board of Pharmacy along

with the appropriate fees before any license is issued or renewed. Information required on the application shall include:

(A) The name, full business address, electronic facsimile transmission number (FAX) and telephone number of the licensee;

(B) All trade or business names used by the licensee;

(C) The address, telephone number and the name of the manager in charge for each facility used by the licensee for the storage, handling and distribution of prescription drugs;

(D) The type of ownership or operation;

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

1. If a person, the name of the person;

2. If a partnership, the name of each partner and the name of the partnership;

3. 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; and

4. If a sole proprietorship, the full name of the sole proprietor and the name of the business entity; and

(F) The name of the manager in charge who meets the requirements as set forth in 4 CSR 220-5.030(2) and completes the manager-in-charge affidavit of the license application and has it notarized.

(5) When a drug distributor changes ownership, the original license becomes void on the effective date of the change of ownership. Before any new business entity resulting from that change opens a facility as a drug distributor, it must obtain a new license from the board. However, a grace period of thirty (30) days may be allowed after the change of ownership.

(A) A change of ownership of a drug distributor facility owned by a sole proprietor 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, however, that the proprietor's estate may continue to operate the drug distributor facility for a period of no more than one (1) year and only so long as appropriate fees are paid.

(B) A corporation is considered by law to be a separate person. If a corporation owns a drug distributor facility, it is not necessary to obtain a new license if the owners of the stock change. However, as a separate person, if the corporation begins ownership of a drug distributor facility or ceases ownership of that facility, a new license must be obtained regardless of the relationship of the previous or subsequent owner to the corporation. It is not necessary to obtain a new license when ownership of the stock in the corporation changes. It is necessary to file written notice with the Board of Pharmacy within ten (10) days after that change occurs. This notification must be in writing and certified.

(6) If an individual or business entity operating a drug distributor facility changes the location of the facility either within the existing facility (structure) or to a new facility (structure), the facility shall not open for business at the new location until the board, its duly authorized agent or the Food and Drug Administration has inspected the premises of the new location and approved it and the facility has been in compliance with all state and federal drug laws pertaining to drug distribution. Upon this approval and receipt of a change of location fee, the board shall issue a license authorizing operation of a facility at the new location and the license shall bear the same number as the previous license. However, the license remains valid if the facility address changes, but not the location, and an amended license will be issued without charge under these circumstances.

(7) Separate licenses shall be required for each drug distribution site owned or operated by a drug distributor as defined in section 338.330, RSMo.

(8) The Board of Pharmacy may grant a temporary license to a wholesale or pharmacy drug distributor to allow for the conduct of business within the state until a determination by the board is made on the issuance of a permanent license.

(A) Temporary licenses shall remain valid until a time the board shall find that the applicant meets or fails to meet the requirements for regular licensure or one (1) year, whichever is less.

1. The board will consider, at a minimum, the following factors in reviewing the qualifications of persons who apply or renew as a drug distributor:

A. Any convictions of the applicant under any federal, state or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

B. The person has been finally adjudicated and found guilty, or entered a plea of guilty or *nolo contendere*, in a criminal prosecution under the laws of any state or of the United States, for any offense reasonably related to the qualifications, functions or duties of any profession licensed or regulated under this chapter, for any offense an essential element of which is fraud, dishonesty or an act of violence, or for any offense involving moral turpitude, whether or not sentence is imposed;

C. The applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;

D. The applicant furnishing false or fraudulent material in any application made in connection with drug manufacturing or distribution;

E. Suspension, revocation or probation by federal, state or local government of any license or registration currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

F. Compliance with licensing requirements under previously granted licenses, if any; and

G. Requirements to maintain or make available, or both, to the board or the federal, state or local law enforcement officials those records required under this section are followed.

2. If an applicant for a license in any way fails to provide information as requested by the board or does not cooperate with requests and inquiries made by the board or provides false or misleading information to the board and the temporary license expires or is denied, all fees paid by the applicant shall be forfeited.

3. During the period of time that a temporary license is in effect, the applicant may conduct business in this state as a drug distributor as long as all state and federal laws governing drug distribution are followed and no action that results in professional misconduct as outlined in section 338.055, RSMo is documented.

4. If it is determined by the board that a permanent license is to be denied to an applicant, a denial notification letter shall be sent to the applicant. The temporary license will be considered invalid ten (10) days after notification is sent to the applicant by certified mail.

(B) A license must be posted in a conspicuous place in the facility to which it is issued.

AUTHORITY: sections 338.330, 338.333, 338.335, 338.337, 338.340 and 338.350, RSMo 2000. Original rule filed Feb. 4, 1991, effective June 10, 1991. Amended: Filed April 28, 1992, effective Feb. 26, 1993. Amended: Filed Jan. 27, 1995, effective Sept. 30, 1995. Amended: Filed March 15, 2000, effective Sept. 30, 2000. Amended: Filed Nov. 1, 2000, effective June 30, 2001. Amended:*

Filed April 6, 2001, effective Nov. 30, 2001. Amended: Filed June 16, 2003, effective Jan. 30, 2004.

**Original authority: 338.330, RSMo 1989, amended 1993, 1998; 338.333, RSMo 1989; 338.335, RSMo 1998; 338.337, RSMo 1989; 338.340, RSMo 1989; and 338.350, RSMo 1989, amended 1993, 1995.*

4 CSR 220-5.025 Termination of Business as a Drug Distributor

PURPOSE: This establishes guidelines for the termination of business as a drug distributor.

(1) A licensed drug distributor who plans to terminate business activities shall file a written notice with the State Board of Pharmacy. The written notice shall be submitted to the State Board of Pharmacy in person or by registered or certified mail within (15) days after the date of termination. This notice shall be made on a form provided by the board or in letter form from the license and shall 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 to which records, required to be maintained by law, have been transferred;

1. Any records that are 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;

2. Any records that are transferred to a licensed drug distributor or pharmacy must be maintained in accordance with record requirements as set forth in 4 CSR 220-5.030.

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

(A) On the date of termination, a complete inventory of all controlled substances being transferred or disposed of shall be completed according to state and federal laws. This inventory shall serve as the final inventory of the drug distributor terminatoring business and as the initial inventory of the licensed entity to which the controlled substances are being transferred. A copy of the inventory shall be included in the records of each licensee involved in the transfer;

(B) A drug distributor terminating business shall not transfer misbranded, outdated or adultered drugs, except for purposes of proper disposal; and

(C) Upon the actual termination of business, the license of the drug distributor shall be returned to the State Board of Pharmacy for cancellation either in person or by registered or certified mail.

(3) The requirements of this rule are not intended to replace or be in conflict with any other laws or regulations governing the appropriate licensure, change of ownership or change of location of a drug distributor.

(4) The termination date is the date on which the drug distributor licensee ceases to do business as a distributor as defined in section 338.330(1), (2) or (3), RSMo in the state of Missouri.

AUTHORITY: sections 338.333 and 338.350, RSMo 1994. Original rule filed May 4, 1995, effective Dec. 30, 1995.*

**Original authority: 338,333, RSMo 1989 and 338.350, RSMo 1989, amended 1993.*

4 CSR 220-5.030 Definitions and Standards for Drug Wholesale and Pharmacy Distributors

PURPOSE: This rule provides standards for the proper storage, maintenance, labeling and distribution of drugs by drug wholesale and pharmacy distributors, and further defines methods of inspections and quality assurance used by the Board of Pharmacy to ensure the public's safety in these areas. For purposes of this rule, the term drug distributor will be used to define all entities that are licensed under section 338.330, RSMo and are subject to this rule.

(1) Drug distributors must maintain standards of practice that will ensure that only drugs of appropriate quality will be distributed to practitioners for further compounding and dispensing to the public. These standards shall be subject to periodic reviews through the board's inspection process.

(A) This process will include on-site inspections for drug distributors who are located in this state and may include border states or by requesting information on licensure and inspections conducted by other states or the federal government through the board office.

(B) For purposes of this rule, the term drug distributor, when used, defines anyone engaged in any activity as defined in section 338.330, RSMo.

(2) No drug distributor license will be issued unless the facility is under the direct supervision of a manager-in-charge.

(A) The board shall consider the same factors in reviewing the qualifications of someone who is appointed as a manager-in-charge as those outlined in 4 CSR 220-5.020(8)(A)1.

(B) A person must also have appropriate education, experience, or both, before assuming the duties of manager-in-charge. Appropriate education for purposes of this section is defined as education in the areas of work environment, standards of operation and knowledge of laws concerning drug distributor compliance and requirements.

1. Minimum requirements for education/experience may be attained separately or in combination to total two (2) years.

2. Experience within a drug wholesale or pharmacy distributor facility or in any education endeavor beyond a certificate of graduation from an accredited high school or its equivalent may be utilized in meeting these minimum requirements.

(C) Any individual that is considered a manager or supervisor within a facility but is not the manager-in-charge of the facility must meet the minimum education/experience requirements as set forth in this rule for a total of one (1) year.

(D) The licensee shall require all other persons employed in any prescription drug wholesale distribution activity to have education, training and experience, or any combination, sufficient for that person to perform the assigned functions in a manner as to provide assurance that the drug product quality, safety and security at all times will be maintained as required by law.

(E) Drug distributor operations must be conducted at all times under the supervision of a properly designated manager-in-charge. When the person who is manager-in-charge resigns or is terminated from the position, the holder of the license shall immediately notify the board office of the resignation or termination of the manager-in-charge and by notarized affidavit give the name of the new manager-in-charge.

(3) Minimum standards of practice for drug distributors shall include the following:

(A) The facility must be of a suitable size and construction to facilitate cleaning, maintenance and proper operations;

(B) The temperature of the facility where drugs are stored must be maintained within temperature requirements as provided for by the manufacturer or the latest edition of the *United States Pharmacopeia* (USP). Appropriate manual, electromechanical, or elec-

tronic temperature and humidity recording equipment, devices, logs, or all of these, shall be utilized to document proper storage of prescription drugs;

(C) Appropriate housekeeping, sanitation, lighting, ventilation and humidity of all areas where drugs are stored must be maintained.

1. All aisles and walkways must be free and clear of debris, dirt or filth.

2. Dust shall be kept at low levels through adequate ventilation, cleaning procedures, or both.

3. All shelves and storage areas shall be kept free of debris, dirt, dust and filth.

4. Full cases of drug products shall be raised above floor level and placed on a pallet or similar device.

5. Upon receipt of legend drugs, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

6. Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

7. Drugs stored in a facility or being processed for distribution must be physically separated at all times from articles, supplies or other drugs that are outdated, distressed, misbranded or adulterated. An area separate from drug storage must be used to store quarantined, nonusable substances or accumulated waste/garbage. Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such and shall be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

8. Flammable articles must be stored separately and away from drug products held for later wholesale distribution.

9. Drugs which may be held for later distribution that are labeled for veterinary use must be stored separately from those drugs that are to be distributed for human use.

10. Procedures must be in place to prevent, control and alleviate infestation by insects, rodents, birds or vermin of any kind.

11. Appropriate sewage disposal and a hot and cold water supply must be available.

12. The outside perimeter of the premises shall be well-lighted.

13. All facilities shall be equipped with an alarm system to detect entry after hours.

14. All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records;

(D) The drug distributor license issued to the facility must be displayed in a public area;

(E) Adequate refrigeration must be available to ensure enough storage space for drugs requiring refrigeration or freezing and under temperatures adequate to maintain the drug products as recommended by the manufacturer, the latest edition of the USP, or both;

(F) The labeling of drug products held for wholesale distribution must conform to requirements as set forth by the manufacturer, Food and Drug Administration (FDA), the USP and section 338.059.2, RSMo;

(G) 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 shall 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. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the drug distributor shall consider, among other things, the conditions under which the drug has been held, stored or shipped before or during its return and the condition of the drug and its container, carton or labeling, as a result of storage or shipping;

(H) Drugs held for wholesale distribution must be stored in a secure area where only authorized personnel have access to them. Sufficient locking mechanisms must be in place and a list of personnel who possess keys or passes which allow them to have independent access to any part of a facility which stores drugs held for later distribution or where any controlled substances are stored must be maintained. Records on all past employees who have had access to drug storage or processing areas must be maintained for a period of three (3) years;

(I) Wholesale drug and pharmacy distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records shall include the following information:

1. The source of the drugs, including the name and principal address of the seller or transferor and the address of the location from which the drugs were shipped;

2. The identity and quantity of the drugs received and distributed or disposed of; and

3. The dates of receipt and distribution or other disposition of the drugs;

(J) Inventories and records shall be made available for inspection and photocopying by authorized federal, state or local law enforcement agency officials for a period of three (3) years following disposition of the drugs;

(K) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by an authorized official of a federal, state or local law enforcement agency;

(L) Record requirements as described in this rule shall be followed for appropriate accountability and disposition for all outdated, damaged, deteriorated, misbranded or adulterated prescription drugs;

(M) Wholesale drug and pharmacy distributors shall establish, maintain and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory and distribution of prescription drugs, including policies and procedures for identifying, recording and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Drug distributors shall include in their written policies and procedures the following:

1. A procedure where the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement if the deviation is temporary and appropriate;

2. A procedure to be followed for handling recalls and withdrawals of prescription drugs. This procedure shall be adequate to deal with recalls and withdrawals due to any—

A. Action initiated at the request of the FDA or other federal, state, or local law enforcement or other government agency, including the Board of Pharmacy;

B. Voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

C. Action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design;

3. A procedure to ensure that drug distributors prepare for, protect against and handle any crisis that affects the security or operation of any facility in the event of strike, fire, flood or other natural disaster, or other situations of local, state or national emergency; and

4. A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for three (3) years after disposition of the outdated drugs; and

(N) Drug distributors will be responsible for security procedures for the delivery of drugs from the wholesale facility to the destination site of all drug shipments.

(4) In addition to standards listed in this rule for drug distributors, drug repackagers must observe federal standards for—

(A) Packaging;
(B) Recordkeeping;
(C) Expiration dating;
(D) Plant facilities;
(E) Equipment;
(F) Personnel;
(G) Production and control procedures;
(H) Containers;
(I) Testing; and
(J) Federal registration requirements.

(5) Agents or employees of licensed or registered drug distributors 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.

(A) Storage and transport of drugs by agents or employees of drug distributors must be maintained in accordance with manufacturer or USP guidelines and must be free of contamination, deterioration or adulteration.

(B) Drug distributors shall report to the board any agents or employees that are registered pursuant to this section of this rule for any convictions for violations of state or federal drug laws.

(6) Drug distributors shall establish and maintain lists of officers, directors, managers and other persons in charge of wholesale drug distribution, storage and handling, including a description of their duties and a summary of their qualifications.

(7) Drug distributors shall be subject to the provisions of any applicable federal, state or local laws or regulations that relate to prescription drug product salvaging or reprocessing, including Parts 207, 210 and 211 of the Federal Food, Drug and Cosmetic Act.

(8) The executive director of the board, at his/her discretion, may grant exemptions to compliance with portions of section (3) of this rule when such exemptions are not contrary to federal drug distributor laws and the exemption is limited to a specific request. Any exemption requests by a licensed drug distributor must be submitted in writing. Any exemptions that are granted as outlined in this section will be provided in writing.

(9) As used in section 338.330(3), RSMo, the term "drug related device" shall be defined as 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).

(10) Brokers, their agents and employees, who act only in the capacity of an agent who arranges or negotiates agreements or contracts for the transfer of drugs or drug related devices and do not take actual possession of the drugs or drug related devices are exempt from maintaining any equipment or physical location requirements involved in the actual storage and distribution of drugs. Brokers shall be responsible for all record keeping requirements as outlined in subsections (3)(I), (J), (K) and (L).

AUTHORITY: sections 338.343 and 338.350, RSMo 2000 Original rule filed Feb. 4, 1991, effective June 10, 1991. Amended: Filed Jan. 27, 1995, effective Sept. 30, 1995. Amended: Filed March 15, 2000, effective Sept. 30, 2000. Amended: Filed Nov. 1, 2000, effective June 30, 2001.*

**Original authority: 338.343, RSMo 1989, amended 1993; and 338.350, RSMo 1989, amended 1993, 1995.*

4 CSR 220-5.040 Drug Distributor Inspection Exemptions

PURPOSE: This rule defines requirements for Board of Pharmacy inspection exemption of wholesale drug and pharmacy distributors.

(1) Inspections of drug distribution facilities shall be conducted by the board in accordance with the provisions as outlined in section 338.360, RSMo. Any drug distributor facility which has been inspected by the Food and Drug Administration (FDA) over a period of less than two (2) years and can demonstrate that all inspections resulted in a satisfactory rating shall be exempt from further inspection by the board until and upon the time that any inspection of the premises of the facility results in a less than satisfactory rating or the last full inspection by the FDA is two (2) years old or greater.

(A) For purposes of this rule, the results of federal inspections that are deemed to be less than satisfactory shall include, but not be limited to, any documentation as to deficiencies in any drug distribution, repackaging, labeling, quality control or environmental policies or procedures, or both. Deficiencies may be defined as any statement which is a part of a compliance report recorded by federal inspection with or without sanctions, penalties, fines or discipline imposed.

1. For purposes of further definition, an inspection that is conducted by the FDA that is used for exemption purposes must be a full inspection of all operations and procedures of the facility. Abbreviated inspectional options as defined in federal policy guidelines may not be considered to fulfill the exemption requirements as provided in section 338.360, RSMo and this rule.

2. Any drug distribution facility which has been granted an exemption from inspection must notify the board at any time of an inspection conducted by the FDA or the Drug Enforcement Administration that results in less than a satisfactory rating as defined in subsection (1)(A) of this rule.

AUTHORITY: section 338.350, RSMo Supp. 1989. Original rule filed Feb. 4, 1991, effective June 10, 1991.*

**Original authority: 338.350, RSMo 1989.*

4 CSR 220-5.050 Out-of-State Distributor License/Registration Requirements

PURPOSE: This rule establishes guidelines for license/registration procedures for out-of-state drug distributors.

(1) Out-of-state wholesale drug distributors or out-of-state pharmacy distributors may be licensed, as required by sections 338.210—338.370, RSMo, by reciprocity if they—

(A) Possess a valid license in good standing in the state or foreign jurisdiction in which they are located pursuant to legal standards comparable to those which must be met by a distributor of this state as prerequisites for obtaining a license under the laws of this state; and

(B) Are located in a state or foreign jurisdiction which extends reciprocal treatment under its own laws to a wholesale distributor of this state.

(2) Out-of-state wholesale drug and pharmacy distributors shall not ship, mail or deliver prescription drugs into Missouri without first obtaining a license from the Missouri Board of Pharmacy.

(A) In order for an out-of-state wholesale drug or pharmacy distributor to maintain a license, it must comply with each of the following:

1. Maintain in good standing a license from the state or foreign jurisdiction in which the nonresident distributor is located provided that a license is issued by that state or foreign jurisdiction;

2. Submit an application as provided by the board for licensure in compliance with sections 338.333 and 338.337, RSMo and with 4 CSR 220-5.020;

3. Pay all appropriate fees;

4. Submit a copy of the state or foreign jurisdiction license or its equivalent from the state or foreign jurisdiction in which the distributor is located provided that a license is issued by that state or foreign jurisdiction;

5. Submit a copy of the state or foreign jurisdiction and federal controlled substance registrations from the state or foreign jurisdiction in which they are located, if controlled substances are to be shipped into Missouri; and

6. Submit copies, when requested by the board, of any inspection reports, warning notices, notice of deficiency reports or any other related reports from the state or foreign jurisdiction in which it is located concerning the operation of an out-of-state drug or pharmacy distributor for review of compliance with state, federal or foreign jurisdiction drug laws.

(B) The Missouri Board of Pharmacy will extend reciprocal cooperation to any state or foreign jurisdiction that licenses and regulates out-of-state drug or pharmacy distributors for the purpose of investigating complaints against distributors located in Missouri or the sharing of information and investigative reports, as long as the other state or foreign jurisdiction will extend the same reciprocal cooperation to the Missouri Board of Pharmacy.

(3) An exemption to licensure is allowed when an out-of-state wholesale drug distributor supplies a drug to another drug distributor licensed in this state in an emergency situation. The amount of the distribution allowed must be confined to the emergency situation and the total amount of distribution for emergency situations must not exceed one percent (1%) of the total annual gross sales of the unlicensed distribution site.

(4) Registration in lieu of licensure may be sought by an out-of-state drug distributor when the following provisions exist:

(A) The out-of-state drug distributor is a drug manufacturer;

(B) The manufacturing facility is used for both the production (manufacture) and distribution of legend drugs;

(C) The site has been inspected with a satisfactory rating by the Food and Drug Administration within the last two (2) years. Inspections of these facilities must comply with all standards and requirements as outlined in 4 CSR 220-5.040;

(D) The state in which the manufacturing facility is located issues a license and the license is current and in good standing; and

(E) The out-of-state distributor who qualifies for registration must complete an application as provided by the board and submit it along with a filing fee of ten dollars ($10).

1. The board shall provide, on an annual basis, a registration renewal form to all registered out-of-state distributors.

2. In order for a registration to remain in good standing and in effect, the renewal must be returned to the Division of Professional Registration by an expiration date that is specified by the director of the division by appropriate rule.

3. In order for a registration to be renewed, it must comply with all the provisions for registering as a drug distributor facility as outlined in section 338.337, RSMo and this rule.

4. Each renewal application must be submitted along with a filing fee of ten dollars ($10).

AUTHORITY: sections 338.330, 338.335 and 338.350, RSMo Supp. 1999 and 338.333 and 338.337, RSMo 1994. Original rule filed Feb. 4, 1991, effective June 10, 1991. Amended: Filed March 15, 2000, effective Sept. 30, 2000.*

**Original authority: 338.330, RSMo 1989, amended 1993, 1998; 338.333, RSMo 1989; 338.335, RSMo 1998; 338.337, RSMo 1989; 338.350, RSMo 1989, amended 1993, 1995.*

4 CSR 220-5.060 Controlled Substance Reporting

PURPOSE: This rule defines requirements for reporting the distribution of controlled substances from drug and pharmacy distributors to persons and facilities that are registered with the Federal Drug Enforcement Administration.

(1) Wholesale drug and pharmacy distributors that distribute Schedule II products and Schedule III narcotics Automation of Reports and Consolidated Orders (ARCOS products) shall provide a listing of those products distributed within the state to the board on a quarterly basis when requested to do so by the board. In addition, wholesale drug and pharmacy distributors that distribute controlled substances within the state shall provide up to a twenty-four (24) month retrospective listing of all controlled substances (Schedule II through Schedule IV) distributed within the state or to a specific location to the board when requested to do so by the board. The board shall submit the request thirty (30) days in advance of the information requested. Reports must be submitted to the board either on hard copy in typewritten form or by electronic media. If electronic media is used in providing the reports, it shall be provided in one (1) of the following formats.

(A) If an electronic tape is used, it shall be an IBM 9-track, labeled or nonlabeled, 1600 or 6250 bits per inch (bpi);

(B) If a diskette is used, it shall be either a MacIntosh 400K or 800K; MS-DOS 5 1/4" 360K or 1.2 meg; MS-DOS 3 1/2" 720K or 1.44 meg; or an IBM 8" diskette; or

(C) If a cartridge is used, it shall be a 1/2" tape, 3480 Compatible.

AUTHORITY: section 338.350, RSMo Supp. 1989. Original rule filed Jan. 3, 1992, effective Aug. 6, 1992.*

**Original authority: 338.350, RSMo 1989.*

4 CSR 220-5.070 Standards of Operation for Medical Gas Distributors

PURPOSE: This rule establishes standards of operation for medical gas distributors. This proposed rule has been reviewed by the Drug Distributor Advisory Committee as required by section 338.140.4, RSMo.

(1) Medical gases are defined as compressed gases and liquid gases that a distributor or manufacturer has labeled for medical use in compliance with federal law.

(2) Medical gas distributor is defined as an entity which is licensed by the board as a drug distributor and is involved in the distribution of medical gases and related medical devices pursuant to a medical gas order to medical gas suppliers and other entities that are registered, licensed or permitted to use, administer or distribute medical gases.

(3) Medical gas distributors that are not involved in the storage or transfer of any other federal legend drugs and only store, transfer or transfill medical grade gas products other than nitrous oxide are exempt from the following regulation sections: 4 CSR 220-5.030(3)(B); (3)(C)4., 9., 11., 12., 13.; (3)(E); (3)(H) and (3)(M)4. Medical gas distributors that store, transfer or transfill

nitrous oxide are exempt from 4 CSR 220-5.030(3)(B); (3)(C)4., 9., 11.; (3)(E) and (3)(M)4. All other drug distributor requirements contained within the board's regulations shall be considered applicable to medical gas distributors.

(4) A medical gas distributor that is involved in the manufacture/transfilling of medical gases must register with the Food and Drug Administration (FDA) as a medical gas manufacturer and comply with the drug listing requirements of the federal act. In addition, all current good manufacturing practice requirements as set forth in 21 CFR 210 through 211 must be complied with.

AUTHORITY: sections 338.050, 338.333, 338.337 and 338.340, RSMo 1994 and 338.335, RSMo Supp. 1999. Original rule filed March 15, 2000, effective Sept. 30, 2000.*

**Original authority: 338.050, RSMo 1939, amended 1949, 1961, 1971, 1981; 338.333, RSMo 1989; 338.335, RSMo 1998; 338.337, RSMo 1989; 338.340, RSMo 1989.*