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

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 for 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.

Auth: section 338.390, RSMo (Cum. Supp. 1989). Original rule filed Jan. 3, 1990, effective April 26, 1990.*

**Original authority 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) As defined in section 338.315, RSMo, pharmacies and all individuals employed by pharmacies shall purchase or receive legend drugs only from a licensed or registered drug distributor or licensed pharmacy. For purposes of this rule, the term drug distributor is used to define anyone engaged in an activity as defined in section 338.330, RSMo.

(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 distrubutions.

(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 one percent (1%) 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.

(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 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. Any felony convictions of the applicant under federal, state or local laws;

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 conspicious place in the facility to which it is issued.

Auth: section 338.350, RSMo (1994). 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.*

**Original authority 1989.*

STATE OF MISSOURI
BOARD OF PHARMACY
DRUG DISTRIBUTOR LICENSE APPLICATION

Send completed application to: MISSOURI BOARD OF PHARMACY
P.O. BOX 625
JEFFERSON CITY, MO 65102

INSTRUCTIONS

1. This form must be typewritten.
2. All fees are **non-refundable.**
3. Fee $200.00.

FOR OFFICE USE ONLY	
LICENSE NUMBER	
DATE TEMPORARY	DATE PERMANENT

APPLICATION

APPLICANT NAME (CORPORATION, PARTNERSHIP, INDIVIDUAL OWNERSHIP)

APPLICANT ADDRESS (STREET, CITY, STATE, ZIP CODE)

D/B/A NAME OF FACILITY (IF SAME AS ABOVE PLEASE INDICATE) | TELEPHONE NUMBER ( )

FACILITY ADDRESS (STREET, CITY, STATE, ZIP CODE)

MISSOURI TAX I.D. INFORMATION | APPROXIMATE DATE FACILITY WILL BE READY FOR INSPECTION

FOR THE PURPOSE OF SECURING SUCH LICENSE, THE APPLICANT STATES AND REPRESENTS:

1. APPLICANT IS
☐ INDIVIDUAL ☐ PARTNERSHIP ☐ CORPORATION ☐ OTHER

IF A CORPORATION, PROVIDE NAME OF STATE OF INCORPORATION

2. APPLICANT WILL PLACE THE FOLLOWING INDIVIDUAL AS MANAGER IN CHARGE OF SUCH FACILITY (FULL NAME)

3. FACILITY IS
☐ WHOLESALE DRUG DISTRIBUTOR ☐ PHARMACY DISTRIBUTOR

4. ACTIVITIES
☐ WHOLESALER ☐ MANUFACTURER ☐ REPACKAGER ☐ OTHER ▶

5. TYPE OF FACILITIES SERVICED
☐ PHYSICIAN ☐ DENTIST ☐ PODIATRIST ☐ VETERINARIAN ☐ PHARMACIST ☐ WHOLESALER

6. THE ABOVE NAMED FACILITY IS
☐ NEW ☐ CHANGE OF OWNERSHIP (IF CHANGE OF OWNERSHIP, COMPLETE INFORMATION BELOW)

PREVIOUS NAME OF FACILITY | ADDRESS | LICENSE NUMBER

7. To the best of your knowledge, have any of the applicant(s) and/or the manager-in-charge associated with this license ever:

(A) Been denied, refused, convicted, fined, disciplined or had a drug distributor/ wholesale license revoked for violation of pharmacy, liquor or drug laws, or presently charged with any such violations, in Missouri or any other state? ☐ Yes ☐ No

(B) Been convicted of any felony, or presently charged with the commission of a felony, in Missouri or any other state? ☐ Yes ☐ No

If you are presently charged with or have been previously convicted of any such violations, explain in detail. If your license has been disciplined, explain in detail. Use separate sheet.

"338.185 RSMo. After the effective date of this act, notwithstanding any other provisions of law, the Board of Pharmacy shall have access to the records involving an applicant for a license or permit or renewal of a license or permit as provided within this chapter, where the applicant has been adjudicated and found guilty or entered a plea of guilty or nolo contendere in a 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."

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8. Applicant promises and swears that if a license is issued as requested, such business shall maintain a manager-in-charge and such business will be conducted and operated in full compliance with the pharmacy laws, professional ethics and all other laws of Missouri as long as continued under such license.

I do solemnly swear or affirm that I am the aforementioned applicant and that the statements and representations made in the foregoing application are true and correct. All this I affirm under penalties of perjury.

MUST BE SIGNED IN PRESENCE OF NOTARY	SIGNATURE OF APPLICANT ▶	
NOTARY PUBLIC EMBOSSER SEAL	STATE OF	COUNTY (OR CITY OF ST. LOUIS)
	SUBSCRIBED AND SWORN BEFORE ME, THIS DAY OF 19	**USE RUBBER STAMP IN CLEAR AREA BELOW.**
	NOTARY PUBLIC SIGNATURE / MY COMMISSION EXPIRES	
	NOTARY PUBLIC NAME (TYPED OR PRINTED)	

9. TO BE COMPLETED BY THE MANAGER-IN-CHARGE:

I, do solemnly swear or affirm that I serve as the manager-in-charge of the business described in the foregoing application, that I meet the requirement of six (6) years education and/or experience to qualify for this position and that I understand the license will be issued with my name appearing thereon as manager-in-charge. All this I affirm under penalties of perjury.

MUST BE SIGNED IN PRESENCE OF NOTARY	SIGNATURE OF MANAGER-IN-CHARGE ▶	
NOTARY PUBLIC EMBOSSER SEAL	STATE OF	COUNTY (OR CITY OF ST. LOUIS)
	SUBSCRIBED AND SWORN BEFORE ME, THIS DAY OF 19	**USE RUBBER STAMP IN CLEAR AREA BELOW.**
	NOTARY PUBLIC SIGNATURE / MY COMMISSION EXPIRES	
	NOTARY PUBLIC NAME (TYPED OR PRINTED)	

List below the names and addresses of any other out-of-state facilities owned by the applicant. If the facility is licensed to do business in Missouri, include license number.

NAME OF FACILITY	ADDRESS (STREET, CITY, STATE, ZIP CODE)	LICENSE NO.

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PARTNERSHIP

PARTNER NAME	DATE OF BIRTH	SOCIAL SECURITY NUMBER
ADDRESS (STREET, CITY, STATE, ZIP CODE)		PERCENTAGE OF OWNERSHIP
PARTNER NAME	DATE OF BIRTH	SOCIAL SECURITY NUMBER
ADDRESS (STREET, CITY, STATE, ZIP CODE)		PERCENTAGE OF OWNERSHIP
PARTNER NAME	DATE OF BIRTH	SOCIAL SECURITY NUMBER
ADDRESS (STREET, CITY, STATE, ZIP CODE)		PERCENTAGE OF OWNERSHIP

CORPORATION

PRESIDENT NAME	DATE OF BIRTH	SOCIAL SECURITY NUMBER
ADDRESS (STREET, CITY, STATE, ZIP CODE)		
VICE-PRESIDENT NAME	DATE OF BIRTH	SOCIAL SECURITY NUMBER
ADDRESS (STREET, CITY, STATE, ZIP CODE)		
SECRETARY NAME	DATE OF BIRTH	SOCIAL SECURITY NUMBER
ADDRESS (STREET, CITY, STATE, ZIP CODE)		
TREASURER NAME	DATE OF BIRTH	SOCIAL SECURITY NUMBER
ADDRESS (STREET, CITY, STATE, ZIP CODE)		
CEO NAME	DATE OF BIRTH	SOCIAL SECURITY NUMBER
ADDRESS (STREET, CITY, STATE, ZIP CODE)		
BOARD OF DIRECTORS NAME	DATE OF BIRTH	SOCIAL SECURITY NUMBER
ADDRESS (STREET, CITY, STATE, ZIP CODE)		
BOARD OF DIRECTORS NAME	DATE OF BIRTH	SOCIAL SECURITY NUMBER
ADDRESS (STREET, CITY, STATE, ZIP CODE)		
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BOARD OF DIRECTORS NAME	DATE OF BIRTH	SOCIAL SECURITY NUMBER
ADDRESS (STREET, CITY, STATE, ZIP CODE)		
BOARD OF DIRECTORS NAME	DATE OF BIRTH	SOCIAL SECURITY NUMBER
ADDRESS (STREET, CITY, STATE, ZIP CODE)		

CONTINUE ON PAGE 4

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SENIOR VICE-PRESIDENT NAME	DATE OF BIRTH	SOCIAL SECURITY NUMBER
ADDRESS (STREET, CITY, STATE, ZIP CODE)		
SENIOR VICE-PRESIDENT NAME	DATE OF BIRTH	SOCIAL SECURITY NUMBER
ADDRESS (STREET, CITY, STATE, ZIP CODE)		
SENIOR VICE-PRESIDENT NAME	DATE OF BIRTH	SOCIAL SECURITY NUMBER
ADDRESS (STREET, CITY, STATE, ZIP CODE)		
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SENIOR VICE-PRESIDENT NAME	DATE OF BIRTH	SOCIAL SECURITY NUMBER
ADDRESS (STREET, CITY, STATE, ZIP CODE)		
SENIOR VICE-PRESIDENT NAME	DATE OF BIRTH	SOCIAL SECURITY NUMBER
ADDRESS (STREET, CITY, STATE, ZIP CODE)		
COMMENTS:		

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STATE OF MISSOURI
DEPARTMENT OF ECONOMIC DEVELOPMENT
DIVISION OF PROFESSIONAL REGISTRATION

MISSOURI BOARD OF PHARMACY
P.O. Box 7003, Jefferson City, MO 65102
(314) 751-0091

APPLICATION TO RENEW LICENSE
INSTATE - DRUG DISTRIBUTOR

July 1, 1992 - June 30, 1993

FEE: $150.00

LICENSE NO. **DD**

Manager in Charge:

Indicate Change of Manager in Charge _____
Type or Print in black ink

***IF CHANGE IS INDICATED, NOTARY SECTION AT TOP OF PAGE 2 MUST BE COMPLETED**

INSTRUCTIONS

1. YOUR CURRENT LICENSE EXPIRES JUNE 30, 1992. This is the application to renew your Drug Distributor license. You may apply for your license renewal upon receipt of this notice.
2. IN ORDER TO PROVIDE SUFFICIENT TIME FOR PROCESSING, PLEASE RETURN THIS RENEWAL APPLICATION WITH THE CORRECT RENEWAL FEE BY MAY 1, 1992.
3. Use the enclosed envelope to return the renewal notice and renewal fee of $150.00, payable to MISSOURI STATE BOARD OF PHARMACY.
4. If the business name and/or address has changed from that printed above, DO NOT RETURN this renewal. CONTACT THE BOARD OF PHARMACY.
5. You may not do business in Missouri after June 30, 1992 unless you renew by the renewal date.
6. All fees are non-refundable.

Please carefully read the instructions on each page of this application and when completed, sign the forms where needed.

A LICENSE WILL NOT BE ISSUED WITHOUT CORRECT FEE STATED
ABOVE AND SUBMISSION OF THIS PROPERLY COMPLETED FORM
PLEASE ALLOW THE DIVISION 60 DAYS TO PROCESS YOUR RENEWAL LICENSE

DD

* FOR CHANGE OF MANAGER IN CHARGE ONLY

NOTARY SECTION*

State of Missouri County of _____

Subscribed and sworn to me before this ____ day of _____, 1991.

My Commission expires : _____

_____
Notary Public, Commissioned in _____ Co.,MO

Signature _____ Date _____
(MUST BE SIGNED BY THE MANAGER IN CHARGE)

INSTRUCTIONS

A. FAILURE TO RENEW THE DRUG DISTRIBUTOR LICENSE BY JUNE 30, WILL VOID THE LICENSE AND REQUIRE THAT A NEW APPLICATION BE FILED WITH THE BOARD. A FEE OF $200 IS REQUIRED ON ALL NEW APPLICATIONS.

THE FOLLOWING QUESTIONS MUST BE ANSWERED. FAILURE TO DO SO WILL RESULT IN REJECTION OF RENEWAL NOTICE AND FEE.

1. Has the facility had a change of ownership or change of location within the last 12 months which had not been reported to the Board office? If yes, DO NOT COMPLETE this renewal notice, but request the proper forms from this office.YES___ NO___

2. During the last year, has this business experienced any noticeable shortage of controlled substances? If yes, please attach a copy of loss report. YES___ NO___

Signature _____ Date _____
MANAGER IN CHARGE

Drug Dist page 2 of 2

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

PURPOSE: This rule 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 licensee 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 terminating 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 adulterated 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.

Auth: 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.

Editor's Note: The secretary of state has determined that the publication of this rule in its entirety would be unduly cumbersome or expensive. The entire text of the material referenced has been filed with the secretary of state. This material may be found at the Office of the Secretary of State or at the headquarters of the agency and is available to any interested person at a cost established by state law.

(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.

1. Minimum requirements for education/experience may be attained separately or in combination to total six (6) 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 three (3) years.

(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) 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 electronic 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 two (2) 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 two (2) 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 two (2) 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.