

TITLE 172 PROFESSIONAL AND OCCUPATIONAL LICENSURE

CHAPTER 131 WHOLESALE DRUG DISTRIBUTORS

131-001 SCOPE AND AUTHORITY: These regulations apply to licensure of wholesale drug distributors pursuant to Neb. Rev. Stat. §§ 71-7427 to 71-7463 which is cited as the Wholesale Drug Distributor Licensing Act.

131-002 DEFINITIONS

Act means the Wholesale Drug Distributor Licensing Act.

Attest/Attestation means that the individual declares that all statements on the application/petition are true and complete.

Authenticate means to affirmatively verify that each transaction listed on the pedigree and any other accompanying documentation has occurred, in accordance with 172 NAC 131.

Blood means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

Blood component means that part of blood separated by physical or mechanical means.

Board means the Board of Pharmacy.

Bond means a "surety" bond of not less than \$100,000, or other equivalent means of security acceptable to the Department, including insurance, an irrevocable letter of credit, or funds deposited in a trust account or financial institution, to secure payment of any administrative penalties imposed by the Department and any fees or costs incurred by the Department regarding that licensee when those penalties, fees, or costs are authorized under state law and the licensee fails to pay 30 days after the penalty, fee, or costs becomes final. A separate surety bond or other equivalent means of security is not required for each company's separate locations or for affiliated companies/groups when such separate locations or affiliated companies/groups are required to apply for or renew their wholesale drug distributor license with the Department. The Department may make a claim against such bond or other equivalent means of security until one year after the expiration of the wholesale drug distributor's license.

Chain pharmacy warehouse means a facility utilized as a central warehouse for intracompany sales or transfers of prescription drugs or devices by two or more pharmacies operating under common ownership or common control.

Co-licensed products means prescription drugs that have been approved by the federal Food and Drug Administration (FDA) and are the subject of an arrangement by which two or more parties have the right to engage in a business activity or occupation concerning such drugs.

Co-licensee means a pharmaceutical manufacturer that has entered into an agreement with another pharmaceutical manufacturer to engage in a business activity or occupation related to the manufacture or distribution of a prescription drug.

Common carrier means an entity that provides transportation or delivery of prescription drugs without storing, warehousing, or taking legal ownership of such drugs.

Common control means that the power to direct or cause the direction of the management and policies of a person or an organization by ownership of stock or voting rights, by contract, or otherwise is held by the same person or persons.

Department means the Division of Public Health of the Department of Health and Human Services.

Designated representative means an individual designated by the wholesale drug distributor who will serve as the responsible individual of the wholesale drug distributor who is actively involved in and aware of the actual daily operation of the wholesale drug distributor.

Director means the Director of Public Health of the Division of Public Health or the Chief Medical Officer if one has been appointed.

Drop shipment means the sale, by a manufacturer, that manufacturer's co-licensee, that manufacturer's third party logistics provider, or that manufacturer's exclusive distributor of the manufacturer's prescription drug, to a wholesale drug distributor whereby the wholesale drug distributor takes title to but not possession of such prescription drug and the wholesale drug distributor invoices the pharmacy, the chain pharmacy warehouse, or other designated persons authorized by law to dispense, administer or distribute such drug and the pharmacy, chain pharmacy warehouse, or other designated persons authorized by law to dispense, administer or distribute such drug receives delivery of the prescription drug directly from the manufacturer, that manufacturer's co-licensee, that manufacturer's third party logistics provider, or that manufacturer's exclusive distributor, of such prescription drug. Drop shipments must be part of the "normal distribution chain".

Drug Sample means a unit of a prescription drug intended to promote the sale of the drug and not intended to be sold.

Emergency Medical Reasons means the alleviation of a temporary shortage by transfers of prescription drugs between any of the following: (1) Holders of pharmacy licenses, (2) health care practitioner facilities as defined in section 71-414, (3) hospitals as defined in section 71-419, and (4) practitioners as defined in section 71-1,142. Emergency medical reasons also means a natural disaster or other situations of local, state or national emergency.

Exclusive distributor means an entity that:

1. Contracts with a manufacturer to provide or coordinate warehousing, wholesale drug distribution, or other services on behalf of a manufacturer and who takes title to that

- manufacturer's prescription drug, but who does not have general responsibility to direct the sale or disposition of the manufacturer's prescription drug; and
2. Is licensed as a wholesale drug distributor under 172 NAC 131.

Facility means a physical structure utilized by a wholesale drug distributor for the storage, handling, or repackaging of prescription drugs or the offering of prescription drugs for sale.

FDA means the federal Food and Drug Administration.

Licensee means wholesale drug distributor as defined in 172 NAC 131-002.

Manufacturer means any entity engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repacking, or labeling a prescription drug.

NAC means the Nebraska Administrative Code, the system for classifying State agency rules and regulations. These regulations are 172 NAC 131.

Nationally recognized accreditation program means an accreditation program that conforms to the standards required for accreditation by the Verified-Accredited Wholesale Distributors (VAWD) program, established and operated by the National Association of Boards of Pharmacy (NABP), and is approved by the Board.

Normal distribution chain means the transfer of a prescription drug or the co-licensed product of the original manufacturer of the finished form of a prescription drug along a chain of custody directly from the manufacturer or co-licensee of such drug to a patient or ultimate consumer of such drug. Normal distribution chain includes reverse distribution and transfers of a prescription drug or co-licensed product:

1. From a manufacturer or co-licensee to a wholesale drug distributor, to a pharmacy, and then to a patient or a patient's agent;
2. From a manufacturer or co-licensee to a wholesale drug distributor, to a pharmacy, to a health care practitioner, health care practitioner facility, or hospital, and then to a patient or a patient's agent;
3. From a manufacturer or co-licensee to a wholesale drug distributor, to a chain pharmacy warehouse, to a pharmacy affiliated with the chain pharmacy warehouse, and then to a patient or a patient's agent;
4. From a manufacturer or co-licensee to a chain pharmacy warehouse, to a pharmacy affiliated with the chain pharmacy warehouse, and then to a patient or a patient's agent;
5. From a manufacturer or co-licensee to a wholesale drug distributor, to a pharmacy buying cooperative warehouse, to a pharmacy that is a member or member owner of such pharmacy buying cooperative warehouse, and then to a patient or a patient's agent;

6. From a manufacturer or co-licensee to a pharmacy buying cooperative warehouse, to a pharmacy that is a member or member owner of such pharmacy buying cooperative warehouse, and then to a patient or a patient's agent;
7. From a manufacturer or co-licensee, to a third party logistics provider or an exclusive distributor, to a wholesale drug distributor, to a pharmacy, and then to a patient or a patient's agent;
8. From a manufacturer or co-licensee to a third party logistics provider or an exclusive distributor, to a wholesale drug distributor, to a pharmacy, to a health care practitioner, health care practitioner facility, or hospital, and then to a patient or a patient's agent;
9. From a manufacturer or co-licensee to a third party logistics provider or an exclusive distributor, to a pharmacy, to a health care practitioner, health care practitioner facility, or hospital, and then to a patient or a patient's agent;
10. From a manufacturer or co-licensee to a third party logistics provider or an exclusive distributor, to a wholesale drug distributor, to a chain pharmacy warehouse, to a pharmacy affiliated with the chain pharmacy warehouse, and then to a patient or a patient's agent;
11. From a manufacturer or co-licensee to a third party logistics provider or an exclusive distributor, to a chain pharmacy warehouse, to a pharmacy affiliated with the chain pharmacy warehouse, and then to a patient or a patient's agent; or
12. From a manufacturer or co-licensee either through drop shipment or directly to a pharmacy, health care practitioner, health care practitioner facility, hospital, chain pharmacy warehouse, or other designated persons authorized by law to dispense, administer or distribute such drug, and then to a patient or a patient's agent.

Owner or ownership means a person who has control over the operations of an entity pursuant to 172 NAC 131-002.

Pedigree means a written or electronic documentation of every transfer of a prescription drug as provided in Neb. Rev. Stat. §§71-7455 and 71-7456.

Pharmacy Buying Cooperative Warehouse means a permanent physical location that acts as a central warehouse for prescription drugs and from which sales of such drugs are made to an exclusive group of pharmacies that are members or member owners of the buying cooperative operating the warehouse and shall be licensed as a wholesaler.

Prescription drug means any human drug required by federal law or regulation to be dispensed only by prescription, including finished dosage forms and active ingredients subject to section 503 (b) of the Federal Food, Drug, and Cosmetic Act, as such section existed on August 1, 2006.

Repackage means repackaging or otherwise changing the container, wrapper, or labeling of a prescription drug to facilitate the wholesale distribution of such drug.

Repackager means a person who repackages.

Reverse distributor means a person whose primary function is to act as an agent for a pharmacy, wholesaler, manufacturer, or other entity by receiving, inventorying, and managing the disposition of outdated, expired, or otherwise non-saleable medications.

Third party logistics provider means an entity that:

1. Provides or coordinates warehousing, drug distribution, or other services on behalf of a manufacturer, but does not take title to the prescription drug or have general responsibility to direct the prescription drug's sale or disposition; and
2. Is licensed as a wholesale drug distributor under 172 NAC 131.

Wholesale drug distribution means distribution of prescription drugs to a person other than a consumer or patient. Wholesale drug distribution does not include:

1. Intracompany sales of prescription drugs, including any transaction or transfer between any division, subsidiary, or parent company and an affiliated or related company under common ownership or common control;
2. The sale, purchase, or trade of or an offer to sell, purchase, or trade a prescription drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code, a state, a political subdivision, or any other governmental agency to a nonprofit affiliate of the organization, to the extent otherwise permitted by law;
3. The sale, purchase, or trade of or an offer to sell, purchase, or trade a prescription drug among hospitals or other health care entities operating under common ownership or common control;
4. The sale, purchase, or trade of or an offer to sell, purchase, or trade a prescription drug for emergency medical reasons;
5. The sale, purchase, or trade of, an offer to sell, purchase, or trade, or the dispensing of a prescription drug pursuant to a prescription;
6. The distribution of drug samples by representatives of a manufacturer or of a wholesale drug distributor;
7. The sale, purchase, or trade of blood and blood components intended for transfusion;
8. The delivery of or the offer to deliver a prescription drug by a common carrier solely in the usual course of business of transporting such drugs as a common carrier if the common carrier does not store, warehouse, or take legal ownership of such drugs; or
9. The sale, transfer, merger, or consolidation of all or part of the business of a retail pharmacy or pharmacies from or with another retail pharmacy or pharmacies, whether accomplished as a purchase and sale of stock or business assets, in accordance with these regulations.

Wholesale drug distributor means any person or entity engaged in wholesale drug distribution in this state, including manufacturers, repackagers, own-label distributors, jobbers, private-label distributors, brokers, warehouses including manufacturer and distributor warehouses, chain pharmacy warehouses, and wholesale drug warehouses, wholesale medical gas distributors, independent wholesale drug traders, and retail pharmacies that engage in wholesale drug distribution in this state. Wholesale drug distributor also includes reverse distributors. Wholesale drug distributor does not include a common carrier or other person or entity hired solely to transport prescription drugs if the common carrier, person, or entity does not store, warehouse, or take legal ownership of such drugs.

Wholesale medical gas distributor means any person engaged in the wholesale drug distribution of medical gases provided to suppliers or other entities licensed or otherwise authorized to use, administer, or distribute such gases.

131-003 REQUIREMENTS FOR ISSUANCE OF LICENSE: Any person, partnership, corporation, or business firm, or other entity that engages in wholesale drug distribution pursuant to Neb. Rev. Stat. § 71-7447 of the Act and 172 NAC 131-002 must obtain a wholesale drug distributor license from the Department. A separate license must be obtained for each facility engaged in wholesale drug distribution. The criteria for issuance of a license and the documentation required by the Department are set forth below.

131-003.01 Requirements for Issuance of a Wholesale Drug Distributor License

131-003.01A The Department, upon the recommendation of the Board, will issue a wholesale drug distributor license to an applicant who:

1. Makes application to the Department for a wholesale drug distributor license; and
2. Passes an inspection conducted pursuant to 172 NAC 131-005. Inspections will be accepted by the Department if they have been conducted within the six months preceding the date of application or if accreditation status by either a nationally recognized accreditation program or another state or federal regulatory agency inspection approved by the Board remains current.

131-003.02 Procedures for Issuance of a Wholesale Drug Distributor License

131-003.02A An applicant for a wholesale drug distributor license must:

1. Submit an application for a wholesale drug distributor license on a form provided by the Department or on an alternate format. Only applications that are complete will be considered. The application must be completed by the designated representative and must include the following information, except that for wholesale medical gas distributors, 172 NAC 131-003.02A items 1.a. through 1.h. are required; and for manufacturers of FDA-approved drugs, the application may be completed by a corporate officer or other designated managerial employee, only 172 NAC 131-003.02A items 1.a. through 1.h. and 6 are required, and inspection, bonding and

appointment of a designated representative are not a condition of licensure:

- a. Applicant's name;
- b. Business address;
- c. Telephone number;
- d. Type of business entity:
 - (1) If the applicant is a partnership:
 - (a) the name of each partner; and
 - (b) the name of the partnership;
 - (2) If the applicant is a corporation:
 - (a) the name of each corporate officer and director;
 - (b) the title of each corporate officer and director;
 - (c) all corporate names of the applicant; and
 - (d) the applicant's state of incorporation;
 - (3) If the applicant is a sole proprietorship:
 - (a) the name of the sole proprietor;
 - (b) the name of the proprietorship; and
 - (c) Social Security Number of the sole proprietor;
- e. All trade or business names used by the applicant;
- f. Addresses of all facilities used by the applicant for the storage, handling, and wholesale distribution of prescription drugs;
- g. Telephone numbers of all facilities used by the applicant for the storage, handling, and wholesale distribution of prescription drugs;
- h. Name(s) of the person(s) in charge of such facilities;
- i. List of all licenses, permits, or other similar documentation issued to the applicant in any other state authorizing the applicant to purchase or possess prescription drugs;
- j. Name(s) and address(es) of the following:
 - (1) Owner(s);
 - (2) Manager(s);
 - (3) Designated representative;
- k. Name(s) of all managerial employees for the facility;
- l. Entity conducting the initial inspection:
 - (1) Department;
 - (2) Nationally recognized accreditation program;
 - (3) Another state regulatory agency; or
 - (4) A federal regulatory agency;
- m. Signature of the designated representative, attesting that s/he has completed the application; and
- n. Required signature(s)
 - (1) If applicant is an individual or partnership, signature of owner;
 - (2) If applicant is a limited liability company with two members or less, signature of one member;

- (3) If applicant is a limited liability company with more than two members, signature of two or more members;
 - (4) If the applicant is a corporation, signature of two officers.
2. Obtain a criminal background check pursuant to 172 NAC 131-004 for the following personnel:
 - a. The designated representative;
 - b. The supervisor of the designated representative; and
 - c. If the company is non-publicly held, each owner with greater than ten percent interest in the wholesale drug distributor;
3. Provide the following information regarding the designated representative:
 - a. Place of residence for the immediately preceding seven years;
 - b. Date of birth;
 - c. Place of birth;
 - d. List of all occupations, positions of employment, and offices held during the immediately preceding seven years;
 - e. The principal businesses, including addresses of any business, corporation, or other organization in which such occupations, positions, or offices were held;
 - f. Whether s/he has been, at any time during the immediately preceding seven years, the subject of any proceeding for the revocation of any license, and if so, the nature of the proceeding and its disposition;
 - g. Whether s/he has been, at any time during the immediately preceding seven years, either temporarily or permanently enjoined by a court of competent jurisdiction from violations of any federal or state law regulating the possession, control, or distribution of prescription drugs, and, if so, the details of such order;
 - h. A description of any involvement by the designated representative during the immediately preceding seven years, other than the ownership of stock in a publicly traded company or mutual fund, with any business which manufactured, administered, distributed, or stored prescription drugs and any lawsuits in which such businesses were named as a party;
 - i. Whether s/he has ever been convicted of any felony and details relating to such conviction; and
 - j. A photograph of the designated representative taken within the immediately preceding 30 days.
4. Provide proof of a bond;
5. Submit documentation of passing an initial inspection pursuant to 172 NAC 131-005.01; and
6. Submit the required fee pursuant to 172 NAC 131-012.

131-003.02B The Department will act within 150 days of receipt of a completed application.

131-004 CRIMINAL BACKGROUND CHECKS: The following individuals are subject to a criminal background check:

1. The designated representative of a wholesale drug distributor;
2. The supervisor of the designated representative of a wholesale drug distributor; and
3. Each owner with greater than a ten percent interest in the wholesale drug distributor, if the wholesale drug distributor is a non-publicly held company.

131-004.01 Procedures for Providing Background Checks: The individuals specified above must:

1. Obtain two fingerprint cards from the Department or from any State Patrol office or law enforcement agency;
2. Print the following information on the fingerprint cards:
 - a. Name;
 - b. Address;
 - c. Social Security Number;
 - d. Date of birth;
 - e. Place of birth;
 - f. Any physical identifiers; and
 - g. In the space on the fingerprint cards marked "Reason Fingerprinted", print "Credential";
3. Report to any State Patrol office, law enforcement agency, or other entity that offers the service of fingerprinting to provide their fingerprints on the fingerprint cards;
4. Forward the completed fingerprint cards and payment for the criminal background check as specified in 172 NAC 131-004.02 to the Nebraska State Patrol, CID Division, P.O. Box 94907, Lincoln, NE 68509.

131-004.02 Payment for criminal background checks is the responsibility of the individual and can be made by personal check, money order or cashier's check, payable to the Nebraska State Patrol. The fee for criminal background checks is established by the Nebraska State Patrol and can be found on the web site of the Department at www.hhss.ne.gov/crl/crlindex.htm.

131-004.03 Submission by the individual of completed fingerprint cards and the appropriate payment to the Nebraska State Patrol authorizes the release of the results of the criminal background check to the Department. The results will be forwarded by the Nebraska State Patrol directly to the Department for consideration with the application for licensure.

131-005 INSPECTION REQUIREMENTS: Each wholesale drug distributor doing business in Nebraska must be inspected onsite by the Department, by a nationally recognized accreditation program approved by the Board, or by another state or federal regulatory agency approved by the Board. Such inspections will occur as a condition of receiving and retaining a wholesale drug distributor license.

131-005.01 Procedures for Initial Inspection: Prior to the issuance of a wholesale drug distributor license, the Department, a nationally recognized accreditation program approved by the Board, or another state or federal regulatory agency approved by the Board will conduct an inspection of the applicant's facility within which wholesale drug distribution is to occur.

131-005.01A Applicant Responsibilities:

1. If inspected by the Department, the applicant must:
 - a. Contact the Department to schedule an inspection; and
 - b. Pay to the Department all fees for conducting the inspection, including but not limited to transportation costs, lodging, meals, and an inspection fee pursuant to 172 NAC 131-012.
2. If inspected by a nationally recognized accreditation program approved by the Board, the applicant must:
 - a. Submit documentation of current accreditation; or
 - b. Contact the nationally recognized accreditation program to schedule an inspection; and
 - c. Pay to the nationally recognized accreditation program all fees necessary for conducting the inspection.
3. If inspected by another state or federal regulatory agency approved by the Board, the applicant must:
 - a. Submit documentation of current state or federal inspection; or
 - b. Make arrangements with a state or federal regulatory agency to schedule an inspection; and
 - c. Pay any fees required by the state or federal regulatory agency for conducting the inspection.

131-005.01B Department Responsibilities: The Department will:

1. Respond to requests for inspections to be conducted by the Department;
2. Conduct an inspection within 90 days after the request for inspection; or
3. Determine, upon the recommendation of the Board, whether an inspection conducted by a nationally recognized accreditation program or another state or federal regulatory agency meets the inspection criteria pursuant to 172 NAC 131-005.04; and
4. Review the application for completeness and inform the applicant in writing if the application is incomplete and warrants the submission of additional information; or
5. Issue a wholesale drug distributor license to each applicant who meets the criteria pursuant to 172 NAC 131-003.

131-005.02 Procedures for Triennial Inspection: A pharmacy inspector of the Department, a nationally recognized accreditation program approved by the Board, or another state or federal regulatory agency approved by the Board must conduct a triennial inspection of each facility engaging in wholesale drug distribution to determine if the licensee remains in compliance with the standards pursuant to 172 NAC 131-006. A wholesale drug distributor must be inspected every three years. Inspections may occur more frequently if the Department considers it necessary.

131-005.02A Licensee Responsibilities:

1. The designated representative is present at the facility at the time of inspection;
2. All records which describe the wholesale drug distribution activities for the triennium are accessible pursuant to 172 NAC 131-006, during the inspection; and
3. Pay any required fees for conducting the inspection.

131-005.02B Department Responsibilities:

1. If the inspection is performed by the Department, the inspection will be:
 - a. Conducted by a pharmacy inspector of the Department, using a Wholesale Drug Distributor Inspection Report pursuant to 172 NAC 131-005.04; and
 - b. Conducted during normal business hours in which wholesale drug distribution occurs.
2. If the inspection is performed by a nationally recognized accreditation program approved by the Board or another state or federal regulatory agency approved by the Board, the inspection must meet the inspection criteria pursuant to 172 NAC 131-005.04, as determined by the Department, upon the recommendation of the Board.

131-005.03 Inspection for Cause: The Department may inspect a wholesale drug distributor to determine violations when any one or more of the following conditions or circumstances occur:

1. An accident or natural disaster resulting in damage to the facility or interruption of utility services which could result in adverse effects to the potency, efficacy, safety or security of the prescription drugs;
2. A complaint alleging violation of the Wholesale Drug Distributor Licensing Act or these regulations;
3. A complaint that raises concern about the maintenance, operation, or management of the facility;
4. Change of scope or type of services offered, management or location;
5. Change in the designated representative;
6. Any other event that raises concerns about the maintenance, operation, or management of the facility.

131-005.04 Wholesale Drug Distributor Inspection Report: A pharmacy inspector will conduct a Department inspection using the Wholesale Drug Distributor Inspection Report. The report will include the following:

1. Business name;
2. Street address;
3. City, state, Zip Code;
4. Name of designated representative of the facility;
5. Telephone number;
6. Wholesale drug distributor license number;
7. DEA Controlled Substances Registration number (if applicable);
8. Business hours;
9. Type of business entity:
 - a. Partnership;
 - b. Corporation; or
 - c. Sole proprietor; and
10. Standards for:
 - a. Personnel;
 - b. Facility;
 - c. Pedigrees;
 - d. Policies and procedures; and
 - e. Records.

131-005.04A Upon completion of an inspection using the Wholesale Drug Distributor Inspection Report, the pharmacy inspector will assess the compliance of the wholesale drug distributor with the standards for engaging in wholesale drug distribution pursuant to 172 NAC 131-006.

131-005.05 CRITERIA FOR SUCCESSFUL COMPLETION OF WHOLESALE DRUG DISTRIBUTOR INSPECTION: Each applicant for a wholesale drug distributor license pursuant to 172 NAC 131-003.01 must successfully complete an inspection to receive a wholesale drug distributor license and to retain such license. The criteria for successful completion of inspections conducted by the Department are set forth below.

131-005.05A Criteria for Successful Completion of Initial Inspection

1. The Department will issue a rating of "Pass/Fail" on an initial inspection.
2. The Department will issue a rating of "Fail," on the initial inspection when an applicant of a wholesale drug distributor license does not meet all the applicable requirements.
 - a. When an applicant receives a rating of "Fail" the applicant must not open the wholesale drug distribution facility;
 - b. The applicant must pay the re-inspection fee pursuant to 172 NAC 131-012.
 - c. The Department will conduct a re-inspection within 90 days

- after the applicant has failed the initial inspection to determine if the applicant meets the requirements.
- d. When the applicant receives a "Fail" rating, at the time of the re-inspection, the Department will deny the issuance of a license to engage in wholesale drug distribution.
3. The Department will issue a rating of "Pass" when the applicant meets all the applicable requirements.

131-005.05B Criteria for Successful Completion of a Triennial Inspection

1. The Department will issue a rating of "Pass" on a triennial inspection when the licensee meets all the standards for engaging in wholesale drug distribution pursuant to 172 NAC 131-006.
2. The Department will issue a rating of "Fail" on the triennial inspection when the licensee does not meet all the standards for engaging in wholesale drug distribution pursuant to 172 NAC 131-006.
 - a. When a licensee receives a rating of "Fail," it will be granted up to 90 days from the date of the triennial inspection to meet the requirements.
 - b. The licensee must pay the re-inspection fee pursuant to 172 NAC 131-012.
 - c. The Department will conduct a re-inspection within 90 days after the wholesale drug distributor has failed the inspection to determine if the wholesale drug distributor meets the requirements necessary to pass the inspection.
 - (1) If the wholesale drug distributor meets the requirements at the time of re-inspection, the Department will change the "Fail" rating and enter a "Pass" rating.
 - (2) If the wholesale drug distributor fails to meet the requirements at the time of re-inspection, the Department will, within ten days of the completion of the re-inspection, give notice to the wholesale drug distributor that the wholesale drug distributor license is revoked. Such notice will be in written form and will:
 - (a) State that the wholesale drug distributor license is revoked;
 - (b) State the reasons for the license revocation;
 - (c) State that the license revocation will become

- final 30 days after the mailing of the notice of revocation unless the licensee submits a written request for a hearing within such 30 day period; and
- (d) Be sent to the licensee by certified mail.
- (3) Upon receipt of a written request for a hearing the licensee must be given a hearing before the Department.
- (4) The Department's decision regarding the revocation of the wholesale drug distributor license will become final 30 days after a copy of the decision is mailed to the licensee unless the licensee appeals the decision pursuant to the Administrative Procedure Act and regulations adopted thereto as 184 NAC 1.
- d. When a wholesale drug distributor license is revoked for failure of a triennial inspection the wholesale drug distributor must reapply to the Department for a license to engage in wholesale drug distribution pursuant to 172 NAC 131-003.02.

131-006 STANDARDS FOR ENGAGING IN WHOLESALE DRUG DISTRIBUTION

131-006.01 Personnel: A wholesale drug distributor must employ staff to operate the wholesale drug distribution facility pursuant to 172 NAC 131. To this end, the wholesale drug distributor must designate a representative to be in charge of wholesale drug distribution and the storage and handling of all drugs. Such designated representative must:

1. Have knowledge of federal and state statutes applicable to wholesale drug distribution;
2. Have had no convictions under any federal, state, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;
3. Have a minimum of two years of verifiable full-time managerial or supervisory experience in a pharmacy or wholesale drug distributor licensed in this state or another state, where the designated representative's responsibilities included but were not limited to recordkeeping, storage, and shipment of prescription drugs;
4. Be actively involved in and aware of the actual daily operations of the wholesale drug distributor:
 - a. Employed full-time in a managerial position by the wholesale drug distributor;
 - b. Physically present at the wholesale drug distributor during normal business hours, except for time periods when absent due to illness,

family illness or death, scheduled vacation, or other authorized absence; and

- c. Aware of, and knowledgeable about, all policies and procedures pertaining to the operations of the wholesale drug distributor.

131-006.02 Facility: All facilities at which prescription drugs are received, stored, warehoused, handled, held, offered, marketed, displayed, or transported from must:

1. Be of suitable construction to ensure that all prescription drugs in the facilities are maintained in accordance with the product labeling of such prescription drugs, or in compliance with official compendium standards such as the United States Pharmacopeia–USP/NF;
2. Be of suitable size and construction to facilitate cleaning, maintenance, and proper wholesale drug distribution operations;
3. Have adequate storage areas to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
4. Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, counterfeit, or suspected of being counterfeit, otherwise unfit for distribution or wholesale drug distribution, or that are in immediate or sealed secondary containers that have been opened;
5. Be maintained in a clean and orderly condition;
6. Be free from infestation of any kind;
7. Be a commercial location and not a personal dwelling or residence;
8. Provide for the secure and confidential storage of information with restricted access and policies and procedures to protect the integrity and confidentiality of the information;
9. Provide and maintain appropriate inventory controls in order to detect and document any theft, counterfeiting, or diversion of prescription drugs;
10. Provide to another wholesale drug distributor or pharmacy pedigrees for prescription drugs that leave the normal distribution chain before wholesale drug distribution to such other wholesale drug distributor or pharmacy in accordance with 172 NAC 131-006.03;
11. Maintain records of pedigrees for three years; and
12. Be duly registered with Drug Enforcement Administration (DEA) and appropriate state controlled substance agency and in compliance with all applicable laws and rules for the storage, handling, transport, shipment, and

wholesale drug distribution of controlled substances, if the wholesale drug distributor is involved in the distribution of controlled substances.

131-006.03 Pedigrees

131-006.03A Pedigree Requirements: All prescription drugs that leave the normal distribution chain must be accompanied by a paper or electronic pedigree. A pedigree must include all necessary identifying information concerning each sale or other transfer in the chain of distribution of the prescription drug from the manufacturer, through acquisition and sale by any wholesale drug distributor, until final sale to a pharmacy or other person dispensing or administering such drug, including:

1. Name of the prescription drug;
2. Dosage form and strength of the prescription drug;
3. Size of the container;
4. Number of containers;
5. Lot number of the prescription drug;
6. Name of the original manufacturer of the finished dosage form of the prescription drug;
7. Name, address, telephone number, and if available, the e-mail address of each owner of the prescription drug and each wholesale drug distributor who does not take title to the prescription drug;
8. Name and address of each location from which the prescription drug was shipped if different from the owner's;
9. Transaction dates;
10. Certification that each recipient has authenticated the pedigree;
11. Name of any repackager, if applicable; and
 - a. Name and address of person certifying the delivery.
 - b. Each paper or electronic pedigree must be maintained by the purchaser and the wholesale drug distributor for three years from the date of sale or transfer and available for inspection or use upon request of law enforcement or an authorized agent of the Department.

131-006.03B Authentication of Pedigrees

1. Wholesale drug distributors and manufacturers from whom wholesale drug distributors have acquired prescription drugs must cooperate with pedigree authentication efforts and provide the requested information within 48 hours.

2. If the wholesale drug distributor attempting to authenticate the pedigree of the prescription drug is unable to authenticate the pedigree, the wholesale drug distributor must quarantine the prescription drug and file a report with the Department within five business days after completing the attempted authentication; and
3. If the wholesale drug distributor attempting to authenticate the pedigree of the prescription drug is able to authenticate the pedigree, the wholesale drug distributor must maintain records of the authentication for three years, and must produce them to the Department upon request.

131-006.04 Policies and Procedures: Wholesale drug distributors must include in their written policies and procedures the following:

1. A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure must be adequate to deal with recalls and withdrawals due to:
 - a. Any action initiated at the request of FDA or any other federal, state, or local law enforcement or other government agency, including the Board; or
 - b. Any volunteer action by the manufacturer to remove defective or potentially defective prescription drugs from the market.
2. A procedure for guarding against losses and/or employee theft.
3. A procedure for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories.
4. A procedure for reporting criminal or suspected criminal activities involving the inventory of prescription drug(s) to the Department within the five business days.
5. A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of a strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.
6. A procedure that provides for inspection of all incoming and outgoing prescription drug shipments.
7. A procedure to ensure that any outdated prescription drugs must be segregated from other prescription drugs and are then either returned to the manufacturer or a reverse distributor or destroyed in accordance with federal and state laws, including all necessary documentation and the appropriate witnessing. This procedure must provide for written documentation of the

disposition of outdated prescription drugs. This documentation must be maintained for two years after disposition of the outdated prescription drugs.

8. A procedure for the destruction of outdated prescription drugs in accordance with federal and state laws, including all necessary documentation, maintained for a minimum of three years, and the appropriate witnessing of the destruction of outdated prescription drugs in accordance with all applicable federal and state requirements.
9. A procedure for the disposing and destruction of containers, labels, and packaging to ensure that the containers, labels, and packaging cannot be used in counterfeiting activities, including all necessary documentation, maintained for a minimum of three years, and the appropriate witnessing of the destruction of any labels, packaging, immediate containers, or containers in accordance with all applicable federal and state requirements.
10. A procedure for identifying, investigating and reporting significant prescription drug inventory discrepancies involving counterfeit, suspect of being counterfeit, contraband, or suspect of being contraband, in the inventory and reporting of such discrepancies within five business days to the Department and/or appropriate federal or state agency upon discovery of such discrepancies.
11. A procedure for conducting authentication of pedigrees pursuant to 172 NAC 131-006.03B.

131-006.05 Records: A wholesale drug distributor must have records to document all drug purchases and sales.

131-006.05A Wholesale drug distributors must establish and maintain inventories and records of all transactions regarding the receipt and wholesale drug distribution or other disposition of prescription drugs. These records must include:

1. Dates of receipt and wholesale drug distribution or other disposition of the prescription drugs; and
2. Pedigrees for all prescription drugs that are wholesale distributed outside the normal distribution chain.

131-006.05B Such records must include the inventories and records must be made available for inspection and photocopying by any authorized official of any state, federal, or local governmental agency for a period of three years following their creation date.

131-006.05C Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means must 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 must be made available for inspection within two working days of a request by an

authorized official of any state or federal governmental agency charged with enforcement of these rules.

131-006.05D Wholesale drug distributors and manufacturers must maintain an ongoing list of persons with whom they do business to sell or purchase prescription drugs.

131-006.05E All facilities must establish and maintain procedures for reporting counterfeit and contraband or suspected counterfeit and contraband drugs or counterfeiting and contraband or suspected counterfeiting and contraband activities to the Department and FDA.

131-006.05F Wholesale drug distributors must maintain a system for the mandatory reporting of significant shortages or losses of prescription drugs where it is known or suspected that diversion is occurring to the Department and FDA, and, where applicable, to DEA.

131-006.05G Records must be maintained by the wholesale drug distributor to document all purchases, sales, destruction, transfer, loss, and return of drugs.

131-006.05H Records may be kept manually or by electronic or automated means. When an automated recordkeeping system is used, there must be a complete back-up system every seven days that is verifiable to prevent loss of records.

131-007 AMENDING A WHOLESALE DRUG DISTRIBUTOR APPLICATION OR LICENSE: A license is issued only for the premises and person(s) named in the application and is not transferable or assignable. Change of ownership or change of premises terminates the license. The owner(s) must apply for a new wholesale drug distributor license.

131-007.01 Amendment: An applicant or licensee must notify the Department when there is a change in the designated representative. The applicant or licensee is responsible for meeting the requirements pursuant to 172 NAC 131-003.02A item 3 and may amend the wholesale drug distributor application or license by submitting the required information regarding the new designated representative to the Department.

131-008 PROCEDURES FOR RENEWAL OF A LICENSE: All licenses issued by the Department pursuant to the Act and 172 NAC 131 expire on July 1 of each year.

131-008.01 Renewal process: Any licensee who wishes to renew his/her license must:

1. Pay the renewal fee pursuant to 172 NAC 131-012;
2. Provide proof of a bond;
3. Respond to the following questions:
 - a. Has any license of the facility in another state been revoked, suspended, limited or disciplined in any manner?

This question relates to the time period since the last renewal of the license

or during the time period since initial licensure in Nebraska if such license was issued within the last year.

- b. Since the last renewal of the license or since initial licensure in Nebraska if such license was issued within the last year, has the designated representative of the facility been:
 - (1) The subject of any proceeding for the revocation of any license, and if so, the nature of the proceeding and its disposition;
 - (2) Either temporarily or permanently enjoined by a court of competent jurisdiction from violations of any federal or state law regulating the possession, control, or distribution of prescription drugs, and if so, the details of such order;
 - (3) Involved in any lawsuits regarding the manufacture, administration, distribution or storage of prescription drugs; or
 - (4) Convicted of any felony, and if so, the details relating to such conviction.
5. Attest that the information provided is true and correct to the best of their knowledge;
6. Be inspected pursuant to 172 NAC 131-005.02 prior to the renewal of the license; and
7. Submit to the Department:
 - a. The completed renewal notice;
 - b. Proof of a bond;
 - c. Proof of an acceptable inspection completed with the previous three years;
 - d. If any misdemeanor or felony conviction(s) of the designated representative of the licensee or any disciplinary action was taken against the licensee by another state, an official copy of the disciplinary action or court records, including charges and disposition;
 - e. Attestation that the completed renewal notice is true and correct to the best of their knowledge; and
 - f. The renewal fee;

131-008.02 First Notice: At least 30 days before July 1 of each year, the Department will send a renewal notice by means of regular mail to each licensee at the licensee's current mailing address as noted in the records of the Department. It is the responsibility of the licensee prior to the renewal period to notify the Department of any name and/or address changes.

131-008.02A The renewal notice must specify:

1. The name of the licensee;
2. The licensee's last known address of record;
3. The license number;
4. The expiration date of the license;

5. The renewal fee pursuant to 172 NAC 131-012;

131-008.02B The licensee must apply for renewal by submitting to the Department:

1. The completed renewal notice;
2. Proof of a bond;
3. Proof of an acceptable inspection completed within the previous three years;
4. Documentation relating to misdemeanor or felony conviction(s) of the designated representative of the licensee or licensure revocation, suspension, limitation or disciplinary action of the licensee since the last renewal (if applicable); and
5. The renewal fee.

131-008.03 Second Notice: The Department will send to each licensee who fails to renew his/her license in response to the first notice, a second notice of renewal pursuant to 172 NAC 131-005.01 that specifies:

1. The licensee failed to pay the renewal fee;
2. The license has expired;
3. Upon receipt of the renewal fee, together with an additional late fee of \$100, no order of revocation will be entered; and
4. Upon failure to receive \$100 in addition to the regular renewal fee, the license will be revoked pursuant to 172 NAC 131-009.

131-008.03A The licensee must apply for renewal by submitting to the Department:

1. The renewal notice; and
2. The renewal fee and the additional late fee of \$100;

131-008.04 When any licensee fails, within 30 days of expiration of a license, to pay the renewal fee and/or to pay an additional late fee of \$100, the Department will automatically revoke the license without further notice or hearing and make proper record of the revocation.

131-008.05 The Department may refuse to renew a license for falsification of any information submitted for renewal of a license. The refusal must be made pursuant to Neb. Rev. Stat. §§ 71-149 to 71-155 and 184 NAC 1, Rules of Practice and Procedure of the Department.

131-009 CREDENTIAL REVOCATION FOR FAILURE TO MEET RENEWAL REQUIREMENTS:
The Department will revoke a wholesale drug distributor license when the licensee fails to meet the renewal requirements.

131-009.01 Revocation for Non-Renewal within 30 Days of Expiration of the License.

131-009.01A When a licensee fails to meet the renewal requirements, pay the required renewal fee, and/or to pay a late fee of \$100 within 30 days of its expiration,

the Department automatically revokes the credential without further notice or hearing.

131-009.01A1 A revocation notice will be sent which will specify that:

1. The licensee was given a first and final notice of renewal requirements and the respective dates for these notices;
2. Department has revoked the license; and
3. The licensee has a right to request reinstatement of the license.

131-010 PROCEDURES FOR REINSTATEMENT OF WHOLESALE DRUG DISTRIBUTOR LICENSE

131-010.01 Reinstatement After Revocation for Non-Renewal: A wholesale drug distributor whose license has been revoked for not meeting the renewal requirements may have such license reinstated by the Department, upon recommendation of the Board, and meeting the renewal requirements, payment of renewal fee and penalty fee when the application for reinstatement is made within one year of revocation.

131-010.01A The licensee must submit:

1. A verified completed application for reinstatement on a form provided by the Department, which includes the following information:
 - a. The name of the licensee;
 - b. The licensee's last known address of record;
 - c. The license number;
 - d. The expiration date of the license;
 - e. Provide proof of a bond;
 - f. Respond to the following questions:
 - (1) Has designated representative of the licensee been convicted of a misdemeanor or felony?
 - (2) Has any license of the entity in any profession in another state been revoked, suspended, limited or disciplined in any manner?

These questions relate to the time period since the last renewal of the license or during the time period since initial licensure in Nebraska if such occurred within the two years prior to the license expiration date.
 - g. Be inspected pursuant to 172 NAC 131-005.02 prior to the renewal of the license: and
2. Cause to be submitted to the Department:
 - a. The renewal notice;
 - b. Proof of a bond;

- c. Proof of an acceptable inspection completed with the previous three years;
- d. If any misdemeanor or felony conviction(s) of the designated representative of the licensee or any disciplinary action was taken against the licensee by another state, an official copy of the disciplinary action or court records, including charges and disposition; and
- e. The renewal fee and the reinstatement fee pursuant to 172 NAC 131-012.

131-010.02 Reapplication After One Year of Revocation for Non-Payment of Renewal Fee:

A wholesale drug distributor whose license has been revoked for more than one year for not meeting renewal requirements, may reapply to the Department for a license. Such reapplication must be made in the same manner as an application for an initial license. The procedures for such are pursuant to 172 NAC 131-003.02.

131-010.03 Reinstatement After Disciplinary Action: A wholesale drug distributor license which has been suspended or revoked for disciplinary action, may be reinstated by the Department upon the recommendation of the Board.

131-010.03A A wholesale drug distributor license, when suspended for disciplinary action, will be suspended for a definite period of time to be fixed by the Director and may be reinstated upon the expiration of such period, payment of the current renewal fee and reinstatement fee after discipline pursuant to 172 NAC 131.012, and meeting the requirements of 172 NAC 131-003.02.

131-010.03B A wholesale drug distributor license, when revoked for disciplinary action, will be revoked permanently, except that at any time after the expiration of two years, a petition for reinstatement may be made.

131-010.03B1 The petitioner must submit an application in the same manner as an application for an initial license. The procedures for such are pursuant to 172 NAC 131-003.02.

131-011 GROUND ON WHICH THE DEPARTMENT MAY DENY, REFUSE RENEWAL OF, OR DISCIPLINE A WHOLESALE DRUG DISTRIBUTOR LICENSE

131-011.01 The Department will deny an application for a wholesale drug distributor license when an applicant fails to meet the requirements pursuant to 172 NAC 131-003.

131-011.02 The Department will refuse renewal of a wholesale drug distributor license if the licensee fails to meet the renewal requirements pursuant to 172 NAC 131-008, or is found to be in violation of any of the provisions pursuant to 172 NAC 131-011.03.

131-011.03 The Department may deny, suspend, limit, or revoke a wholesale drug distributor license when the Director finds that the licensee has violated any provisions of the Wholesale Drug Distributor Licensing Act or of these regulations; or any of the following acts:

1. Conviction of any crime that has rational connection with the licensee's fitness to hold a license as a wholesale drug distributor;
2. Obtaining a wholesale drug distributor license by false representation and/or fraud;
3. Operating a wholesale drug distribution facility without a currently valid license;
4. Any conviction under Federal, State, or local laws or regulations relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;
5. Unprofessional conduct which is hereby defined to include:
 - a. Misrepresentation or fraud in the conduct of a wholesale drug distribution facility;
 - b. Aiding or abetting an unlicensed facility to engage in wholesale drug distribution; and
 - c. Knowingly purchasing or receiving prescription drugs from any source other than a person or entity licensed or exempt from licensure pursuant to the Wholesale Drug Distributor Licensing Act, except transfers for emergency medical reasons. This will not apply to returns or recalls, misshipments, misorders, or damaged goods, etc.
6. Failure of the licensee to maintain and make available to the Department or to Federal, State, or local law enforcement officials records required by these regulations;
7. Falsification of a pedigree;
8. Selling, distributing, transferring, manufacturing, repackaging, handling, or holding a counterfeit prescription drug intended for human use;
9. Commission of any acts pursuant to Neb. Rev. Stat. §§ 71-147 and 71-148 of the Uniform Licensing Law;
10. The adulteration, misbranding, or counterfeiting of any prescription drug;
11. The receipt of any prescription drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected of being counterfeit, or the delivery or proffered delivery of such prescription drug for pay or otherwise;
12. The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the product labeling of a prescription drug or the commission of any other act with respect to a prescription drug that results in the prescription drug being misbranded;

13. The purchase or receipt of a prescription drug from a person that is not licensed to wholesale distribute prescription drugs to that purchaser or recipient;
14. The sale or transfer of a prescription drug to a person who is not legally authorized to receive a prescription drug;
15. Providing the Department or any of its representatives or any state or federal official with false or fraudulent records or making false or fraudulent statements regarding any matter within the provisions of this Act and rules;
16. The obtaining of or attempting to obtain a prescription drug by fraud, deceit, misrepresentation or engaging in misrepresentation or fraud in the distribution or wholesale distribution of a prescription drug;
17. The failure to obtain, authenticate, or pass on a pedigree when required under these rules;
18. The receipt of a prescription drug pursuant to a wholesale drug distribution without first receiving a pedigree, when required, that was attested to as accurate and complete by the wholesale drug distributor;
19. The distributing or wholesale drug distributing of a prescription drug that was previously dispensed by a pharmacy or distributed by a practitioner; and
20. The failure to report any prohibited act as listed in these rules.

131-011.04 If the Department determines to deny, suspend, limit, revoke, or refuse renewal of a wholesale drug distributor license for any of the grounds specified in 172 NAC 131-011, it will give the applicant or licensee an opportunity for a hearing before the Department; and the applicant or licensee must have a right to present evidence on his/her own behalf.

131-011.05 Hearings before the Department will be conducted pursuant to the Administrative Procedure Act and 184 NAC 1, Rules of Practice and Procedure of the Department.

131-011.06 The Department, upon issuance of a final disciplinary action against a person who violates any provision of these regulations, will assess a fine of \$1,000 against such person. For each subsequent final disciplinary action for such violation issued by the Department against such person, the Department will assess a fine of \$1,000 plus \$1,000 for each final disciplinary action for such violation previously issued against such person, not to exceed \$10,000.

131-011.07 The Department, upon issuance of a final disciplinary action against a person who fails to provide authorized personnel the right of entry pursuant to 172 NAC 131-005 will assess a fine of \$500 against such person. For each subsequent final disciplinary action for such failure issued against such person, the Department will assess a fine equal to \$1,000 times the number of such disciplinary actions, not to exceed \$10,000.

131-011.08 All fines collected under 172 NAC 131-011 will be remitted to the State Treasurer for credit to the Permanent School Fund.

131-012 SCHEDULE OF FEES: The following fees have been set by the Department:

131-012.01 Initial License Fee: By an applicant for a wholesale drug distributor license, the fee of \$550;

131-012.02 License Renewal Fee: By an applicant for a renewal on a wholesale drug distributor license, the fee of \$550;

131.012.03 Inspection Fee: By an applicant for issuance or renewal of a wholesale drug distributor license who requests an inspection to be conducted by a pharmacy inspector of the Department, the fee of \$3,000 in addition to actual costs for transportation, lodging and meals of the pharmacy inspector who conducts the inspection.

131-012.04 Re-inspection Fee: By an applicant for issuance or renewal of a wholesale drug distributor license who requests a re-inspection to be conducted by a pharmacy inspector of the Department, the fee of \$750 in addition to actual costs for transportation, lodging and meals of the pharmacy inspector who conducts the re-inspection.

131-012.05 Renewal Late Fee: By an applicant for renewal on an annual basis of a credential, who fails to pay the renewal fee on or before the expiration date of the credential, the fee of \$100 as a late fee in addition to the renewal fee.

131-012.06 Reinstatement Fee: For a reinstatement of a credential for failure to meet renewal requirements, the fee of \$50.

131-012.07 Reinstatement Fee After Discipline: For reinstatement of a wholesale drug distributor credential following suspension, limitation, or revocation for disciplinary reasons, the fee of \$100.

131-012.08 Duplicate License Fee: By an applicant for a duplicate original license or a reissued license, the fee of \$10.

131-011.08 Administrative Fee: For a denied credential or a withdrawn application, the administrative fee of \$25 will be retained by the Department, except if onsite inspection has been completed prior to such denial, the Department may retain the entire license fee.

Approved by the Attorney General on June 6, 2007

Approved by the Governor on June 26, 2007

Filed by the Secretary of State on June 26, 2007

Effective Date: July 1, 2007