

ARTICLE 61-10 WHOLESALE DRUG DISTRIBUTORS

Chapter
61-10-01 Wholesale Drug Distributors

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61-10-01-01. Scope.

This article applies to any person, partnership, corporation, or business firm engaging in the wholesale distribution of any prescription drugs in the state of North Dakota.

History: Effective June 1, 1992.

General Authority: NDCC 43-15.1-07

Law Implemented: NDCC 43-15.1

61-10-01-02. Purpose.

The purpose of this article is to implement the Prescription Drug Marketing Act of 1987 by providing minimum standards, terms, and conditions for the licensing by the North Dakota state board of pharmacy of persons who engage in wholesale distribution in the state of North Dakota of any prescription drugs.

History: Effective June 1, 1992.

General Authority: NDCC 43-15.1-07

Law Implemented: NDCC 43-15.1; 21 USC 353(e)

61-10-01-03. Definitions.

As used in this article:

1. "Article" or "this article" means all of the terms and provisions contained in article 61-10, including sections 61-10-01-01 through 61-10-01-09, inclusive, and any amendments or additions to said article or any of said sections.
2. "Board of pharmacy" means the North Dakota state board of pharmacy.
3. "Blood" means whole blood collected from a single donor processed either for transfusion or further manufacturing.
4. "Blood component" means that part of blood separated by physical or mechanical means.

5. "Drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.
6. "Manufacturer" is defined as provided in subsection 2 of North Dakota Century Code section 43-15.1-01.
7. "Prescription drug" is defined as provided in subsection 4 of North Dakota Century Code section 43-15.1-01.
8. "Wholesale drug distribution" is defined as provided in subsection 5 of North Dakota Century Code section 43-15.1-01, provided that:
 - a. Concerning the exclusion from the definition of "wholesale drug distribution" for "intracompany sale" set forth in subdivision a of subsection 5 of North Dakota Century Code section 43-15.1-01, such "sale" includes any transaction or transfer between any division, subsidiary, parent, and/or affiliated or related company under common ownership and control of a corporate entity.
 - b. For purposes of subdivision a of this subsection and subdivision d of subsection 5 of North Dakota Century Code section 43-15.1-01, "common control" means the power to direct or cause the direction of the management and policies of a person or organization, whether by ownership by stock, voting rights, by contract, or otherwise.
 - c. For purposes of subdivision e of subsection 5 of North Dakota Century Code section 43-15.1-01, "emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage, except that the gross dollar value of such transfers may not exceed five percent of the total prescription drug sales revenue of either the transferor or transferee retail pharmacy during any twelve-consecutive-month period.
 - d. "Wholesale drug distribution" does not include the sale, purchase, or trade of blood and blood components intended for transfusion.
9. "Wholesale drug distributor" is defined as provided in subsection 6 of North Dakota Century Code section 43-15.1-01.

History: Effective June 1, 1992.

General Authority: NDCC 43-15.1-07

Law Implemented: NDCC 43-15.1

61-10-01-04. Wholesale drug distributor licensing requirement.

Every wholesale drug distributor whether located in this state or any other state or foreign territory who engages in wholesale drug distribution of any prescription drugs in the state of North Dakota must be licensed by the board of pharmacy in accordance with this article and North Dakota Century Code chapter 43-15.1 before engaging in wholesale distribution of any prescription drugs in the state of North Dakota.

History: Effective June 1, 1992.

General Authority: NDCC 43-15.1-07

Law Implemented: NDCC 43-15.1-04, 43-15.1-05

61-10-01-05. Minimum required information for licensure.

1. Each wholesale drug distributor shall provide to the board of pharmacy the following minimum information as part of the application for the license described in this article or North Dakota Century Code chapter 43-15.1 and as part of any application for renewal of such license:

- a. The name, full business address, and telephone number of the licensee;
 - b. All trade or business names used by the licensee;
 - c. Addresses, telephone numbers, and the names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of prescription drugs;
 - d. The type of ownership or operation, i.e., partnership, corporation, or sole proprietorship; and
 - e. The names of the owner or operator, or both, of the licensee, 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 and title of each corporate officer and director, the corporate names, 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.
2. The board of pharmacy may provide for a single license for a business entity operating more than one facility within the state, or for a parent entity with divisions, subsidiaries, and/or affiliate companies within the state when operations are conducted at more than one location and there exists joint ownership and control among all the entities.
 3. Changes in any information in subsection 1 must be submitted to the board of pharmacy by the licensee within thirty days of any change.

History: Effective June 1, 1992.

General Authority: NDCC 43-15.1-07

Law Implemented: NDCC 43-15.1-04, 43-15.1-05, 43-15.1-06

61-10-01-06. Minimum qualifications.

1. The board of pharmacy shall consider, at a minimum, the following factors in reviewing the qualifications for licensure of persons who engage in wholesale distribution of prescription drugs within the state of North Dakota:
 - 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 furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;
 - e. Suspension or revocation by federal, state, or local government of any license 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;

- g. Compliance with requirements to maintain or make available to the board of pharmacy or to federal, state, or local law enforcement officials, or both, those records required under this section;
 - h. Any other factors or qualifications the board of pharmacy considers relevant to and consistent with the public health and safety; and
 - i. Other factors or requirements contained in subsection 5 of North Dakota Century Code section 43-15.1-04.
2. The board of pharmacy has the right to deny a license to an applicant if it determines that the granting of such a license would not be in the public interest. Public interest considerations must be based on factors and qualifications that are directly related to the protection of the public health and safety.

History: Effective June 1, 1992.

General Authority: NDCC 43-15.1-07

Law Implemented: NDCC 43-15.1-04, 43-15.1-05

61-10-01-07. Personnel.

As a condition for receiving and retaining a wholesale drug distributor license, the licensee shall require each person employed in any prescription drug wholesale distribution activity to have education, training, and experience, or any combination thereof, sufficient for that person to perform the assigned functions in such a manner as to provide assurance that the drug product quality, safety, and security will at all times be maintained as required by law.

History: Effective June 1, 1992.

General Authority: NDCC 43-15.1-07

Law Implemented: NDCC 43-15.1-04, 43-15.1-05

61-10-01-08. Violations and penalties.

- 1. The board of pharmacy has the authority to restrict or suspend any licenses granted under this article or pursuant to North Dakota Century Code chapter 43-15.1 upon conviction of any violation of federal, state, or local drug laws or regulations which constitutes a clear and present danger to the public health and safety in the state of North Dakota. Before any license may be restricted or suspended, a wholesale distributor has a right to prior notice and a hearing pursuant to North Dakota Century Code chapter 28-32.
- 2. The board of pharmacy may restrict or suspend any license granted under this article and North Dakota Century Code chapter 43-15.1 for willful and serious violations of this article which constitute a clear and present danger to the public health and safety in the state of North Dakota in the manner provided in subsection 1.

History: Effective June 1, 1992.

General Authority: NDCC 43-15.1-07

Law Implemented: NDCC 43-15.1-08

61-10-01-09. Minimum requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

The following constitutes minimum requirements for the storage and handling of prescription drugs, and for the establishment and maintenance of prescription drug distribution records by wholesale drug distributors and their officers, agents, representatives, and employees:

1. **Facilities.** All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:
 - a. Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
 - b. Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
 - c. Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;
 - d. Be maintained in a clean and orderly condition; and
 - e. Be free from infestation by insects, rodents, birds, or vermin of any kind.
2. **Security.**
 - a. All facilities used for wholesale drug distribution must be secure from unauthorized entry.
 - (1) Access from outside the premises must be kept to a minimum and be well-controlled.
 - (2) The outside perimeter of the premises must be well-lighted.
 - (3) Entry into areas where prescription drugs are held must be limited to authorized personnel.
 - b. All facilities must be equipped with an alarm system to detect entry after hours.
 - c. All facilities must be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system must provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
3. **Storage.** All prescription drugs must be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary.
 - a. If no storage requirements are established for a prescription drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.
 - b. Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs, or combination thereof, must be utilized to document proper storage of prescription drugs.
 - c. The recordkeeping requirements in subsection 6 must be followed for all stored drugs.
4. **Examination of materials.**
 - a. Upon receipt, each outside shipping container must 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 must be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

- b. Each outgoing shipment must 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.
- c. The recordkeeping requirements in subsection 6 must be followed for all incoming and outgoing prescription drugs.

5. Returned, damaged, and outdated prescription drugs.

- a. Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated must be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier.
- b. Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used must be identified as such, and must be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.
- c. If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug must be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. 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 wholesale 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.
- d. The recordkeeping requirements in subsection 6 must be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.

6. Recordkeeping.

- a. Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records must 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.
- b. Inventories and records must be made available for inspection and photocopying by authorized federal, state, or local law enforcement agency officials for a period of two years following disposition of the drugs.
- c. 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 three business days of a request by an authorized official of a federal, state, or local law enforcement agency.

7. Written policies and procedures. Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which must 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. Wholesale drug distributors must include in their written policies and procedures the following:

- a. A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.
 - b. 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:
 - (1) Any action initiated at the request of the food and drug administration or other federal, state, or local law enforcement or other government agency, including the board of pharmacy;
 - (2) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or
 - (3) Any action undertaken to promote public health and safety by replacement of existing merchandise with an improved product or new package design.
 - c. 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 strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.
 - d. A procedure to ensure that any outdated prescription drugs must be segregated from other drugs and either returned to the manufacturer or destroyed. 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 drugs.
8. **Responsible persons.** Wholesale drug distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.
9. **Compliance with federal, state, and local law.** Wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations.
- a. Wholesale drug distributors shall permit the board of pharmacy's authorized personnel and authorized federal, state, and local law enforcement officials, to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law. Such officials are required to show appropriate identification prior to being permitted access to wholesale drug distributors' premises and delivery vehicles.
 - b. Wholesale drug distributors that deal in controlled substances shall register with the North Dakota controlled substances board and with the drug enforcement administration, and shall comply with all applicable state, local, and drug enforcement administration regulations.
10. **Salvaging and reprocessing.** Wholesale drug distributors are subject to the provisions of any applicable federal, state, or local laws or regulations that relate to prescription drug product salvaging or reprocessing, including all applicable provisions of this article.

History: Effective June 1, 1992.

General Authority: NDCC 43-15.1-07

Law Implemented: NDCC 43-15.1-04, 43-15.1-05