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Sixty-third
Legislative Assembly
of North Dakota

SENATE BILL NO. 2342

Introduced by

Senator Anderson

Representative K. Koppelman

A BILL for an Act to create and enact sections 43-15.3-10, 43-15.3-11, and 43-15.3-12 of the North Dakota Century Code, relating to wholesale drug distribution; to amend and reenact sections 43-15.3-01, 43-15.3-02, 43-15.3-03, 43-15.3-04, 43-15.3-05, 43-15.3-06, 43-15.3-07, 43-15.3-08, and 43-15.3-09 of the North Dakota Century Code, relating to wholesale drug distribution; and to provide a penalty.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. AMENDMENT. Section 43-15.3-01 of the North Dakota Century Code is amended and reenacted as follows:

43-15.3-01. Definitions.

As used in this chapter, unless the context otherwise requires:

1. "Authentication" means to affirmatively verify before any wholesale distribution of a prescription drug, medical gas, or medical equipment occurs that each transaction listed on the pedigree has occurred.
2. "Authorized distributor of record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug, medical gas, or medical equipment. An ongoing relationship is deemed to exist between the wholesale distributor and a manufacturer when the wholesale distributor, including any affiliated group of the wholesale distributor as defined in section 1504 of the Internal Revenue Code [26 U.S.C. 1504], complies with the following:
   a. The wholesale distributor has a written agreement currently in effect with the manufacturer evidencing the ongoing relationship; and

b. The wholesale distributor is listed on the manufacturer's current list of authorized distributors of record, which is updated by the manufacturer on no less than a monthly basis.

3. "Board" means the state board of pharmacy.

4. "Broker" means a party that mediates between a buyer and a seller the sale or shipment of prescription drugs, medical gases, or medical equipment.

5. "Chain pharmacy warehouse" means a physical location for prescription drugs, medical gases, or medical equipment which acts as a central warehouse and performs intracompany sales or transfers of the drugs, gases, or equipment to a group of chain pharmacies that have the same common ownership and control.

~~5.~~6. "Colicensed product" means a prescription drug, medical gas, or medical equipment in which two or more parties have the right to engage in the manufacturing or marketing or in the manufacturing and marketing of the drug, gas, or equipment.

7. "Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory which:

a. Is recognized in the United States pharmacopeia or the official national formulary is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, in humans or other animals, or is intended to affect the structure or any function of the body of humans or other animals;

b. Does not achieve its primary intended purposes through chemical action within or on the body of a human or other animal; and

c. Is not dependent upon being metabolized for the achievement of its primary intended purposes.

~~6.~~8. "Drop shipment" means the sale of a prescription drug, medical gas, or medical equipment to a wholesale distributor by the manufacturer of the prescription drug, medical gas, or medical equipment or to that manufacturer's colicensed product partner, that manufacturer's third-party logistics provider, or that manufacturer's exclusive distributor, under the terms of which the wholesale distributor or chain pharmacy warehouse takes title but not physical possession of the prescription drug,

medical gas, or medical equipment and the wholesale distributor invoices the pharmacy or chain pharmacy warehouse, or other person authorized by law to dispense or administer the drug, gas, or equipment to a patient, and the pharmacy or chain pharmacy warehouse or other authorized person receives delivery of the prescription drug, medical gas, or medical equipment directly from the manufacturer, or that manufacturer's third-party logistics provider, or that manufacturer's exclusive distributor.

9. "Durable medical equipment" means medical devices, equipment, or supplies that may be used in a residence, including oxygen and oxygen delivery systems and supplies, ventilators, respiratory disease management devices, continuous positive airway pressure (CPAP) devices, electronic and computerized wheelchairs and seating systems, apnea monitors, transcutaneous medical nerve stimulator (TENS) units, low air cutaneous pressure management devices, sequential compression devices, feeding pumps, home phototherapy devices, infusion delivery devices, distribution of medical gases to end users for human consumption, hospital beds, nebulizers, and other similar equipment as may be determined by the board by rule.

~~7.~~10. "Facility" means a facility of a wholesale distributor where prescription drugs, medical gases, or medical equipment are stored, handled, repackaged, or offered for sale.

~~8.~~11. "Manufacturer" means a person licensed or approved by the federal food and drug administration to engage in the manufacture of drugs, medical gases, or devices by manufacturing the drugs, gases, or devices at the person's own facility or by contracting for the manufacturing by others.

~~9.~~12. "Manufacturer's exclusive distributor" means any person that contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer and which takes title to that manufacturer's prescription drug, medical gases, or medical equipment but which does not have general responsibility to direct the sale or disposition of the manufacturer's prescription drug, medical gas, or medical equipment. The manufacturer's exclusive distributor must be licensed as a wholesale distributor under this chapter, and to be considered part of the normal distribution channel also must be an authorized distributor of record.

13. "Medical device" means a product or equipment used to diagnose a disease or other condition in order to cure, treat, or prevent disease.

14. "Medical equipment" means equipment prescribed or distributed by a practitioner used in the course of treatment of home care.

15. "Medical gas" means any gaseous substance that meets medical purity standards and has application in a medical environment.

~~10.~~16. "Normal distribution channel" means a chain of custody for a prescription drug, medical gas, or medical equipment which goes, directly or by drop shipment, from a manufacturer of the prescription drug, medical gas, or medical equipment, from that manufacturer to that manufacturer's colicensed partner, from that manufacturer to that manufacturer's third-party logistics provider, or from that manufacturer to that manufacturer's exclusive distributor to:

a. A pharmacy, to a patient or other designated person authorized by law to dispense or administer the drug, gas, or equipment to a patient;

b. A wholesale distributor, to a pharmacy, to a patient or other designated person authorized by law to dispense or administer the drug, gas, or equipment to a patient;

c. A wholesale distributor, to a chain pharmacy warehouse, to that chain pharmacy warehouse's intracompany pharmacy, to a patient or other designated person authorized by law to dispense or administer the drug, gas, or equipment to a patient; or

d. A chain pharmacy warehouse, to the chain pharmacy warehouse's intracompany pharmacy, to a patient or other designated person authorized by law to dispense or administer the drug, gas, or equipment to a patient.

~~11.~~17. "Pedigree" means a document or an electronic file containing information that records each distribution of any given prescription drug, medical gas, or medical equipment.

18. "Pharmacy distributor" means any pharmacy or hospital pharmacy licensed in this state which is engaged in the delivery or distribution of prescription drugs, medical gases, or medical equipment to any other pharmacy licensed in this state or to any other person, including a wholesale drug distributor, engaged in the delivery or distribution of prescription drugs, medical gases, or medical equipment and involved in

the actual, constructive, or attempted transfer of a drug, gas, or equipment in this state to other than the ultimate consumer, when the financial value of the drugs, gases, or equipment is equivalent to at least five percent of the total gross sales of the pharmacy distributor.

~~12.~~19. "Prescription drug" means any drug, including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices, required by federal law, including federal regulation, to be dispensed only by a prescription, including finished dosage forms and bulk drug substances subject to section 503(b) of the federal Food, Drug, and Cosmetic Act [21 U.S.C. 3539(b)].

~~13.~~20. "Repackage" means repackaging or otherwise changing the container, wrapper, or labeling to further the distribution of a prescription drug, ~~excluding~~medical gas, or medical equipment. The term does not include actions completed by the pharmacists responsible for dispensing product to the patient.

~~14.~~21. "Repackager" means a person ~~who~~that repackages.

~~15.~~22. "Third-party logistics provider" means ~~anyone who~~a person that contracts with a prescription drug, medical gas, or medical equipment manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer, but does not take title to the prescription drug, medical gas, or medical equipment or have general responsibility to direct the prescription drug's, medical gas's, or medical equipment's sale or disposition. The third-party logistics provider must be licensed as a wholesale distributor under this chapter and to be considered part of the normal distribution channel must also be an authorized distributor of record.

23. "Trace" means the capability to identify the historical locations, the records of ownership, and the packaging hierarchy for a particular traceable item. "Trace" answers questions such as where has the item been, who previously owned the item, and in what packaging hierarchy did the product exist at various locations.

24. "Track" means the capability to identify the current, and at the time of shipment the intended future, location, ownership, and packaging hierarchy of a traceable item through the supply chain as the traceable item moves between parties. "Track" addresses both forward and reverse logistics operations. "Track" answers questions

such as where is the item currently, who is the next intended recipient, and what is the current packaging hierarchy of the item.

25. "Virtual distributor" means a person that arranges for the distribution of a drug or device and which may or may not take actual possession of the drug or device but contracts with others for the distribution, purchase, and sale.

26. "Virtual manufacturer" means a person that owns the new drug application or abbreviated new drug application for a drug or device and which contracts with others for the actual manufacturing of the drug or device.

~~16.~~27. "Wholesale distribution" means distribution of prescription drugs, medical gases, or medical equipment to persons other than a consumer or patient. The term does not include:

a. Intracompany sales of prescription drugs, medical gases, or medical equipment, meaning any transaction or transfer between any division, subsidiary, parent or affiliated or related company under common ownership and control of a corporate entity, or any transaction or transfer between colicensees of a colicensed product.

b. The sale, purchase, distribution, trade, or transfer of a prescription drug, medical gas, or medical equipment or the offer to sell, purchase, distribute, trade, or transfer a prescription drug, medical gas, or medical equipment for emergency medical reasons.

c. The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug, gas, or equipment for the hospital's or health care entity's own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations.

d. The sale, purchase, or trade of a drug, gas, or equipment or an offer to sell, purchase, or trade a drug, gas, or equipment by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law.

e. The sale, purchase, or trade of a drug, gas, or equipment or an offer to sell, purchase, or trade a drug, gas, or equipment among hospitals or other health care entities that are under common control.

f. The distribution of prescription drug samples by manufacturers' representatives.

~~d.~~g. Drug returns, when conducted by a hospital, health care entity, or charitable institution in accordance with title 21, Code of Federal Regulations, section 203.23.

~~e.~~h. The sale of minimal quantities of prescription drugs, medical gases, or medical equipment by retail pharmacies to licensed practitioners for office use.

~~f.~~i. The sale, purchase, or trade of a drug, gas, or equipment; an offer to sell, purchase, or trade a drug, gas, or equipment; or the dispensing of a drug, gas, or equipment pursuant to a prescription.

~~g.~~j. The sale, transfer, merger, or consolidation of all or part of the business of a pharmacy from or with another pharmacy, whether accomplished as a purchase and sale of stock or business assets.

~~h.~~k. The sale, purchase, distribution, trade, or transfer of a prescription drug, medical gas, or medical equipment from one authorized distributor of record to one additional authorized distributor of record when the manufacturer has stated in writing to the receiving authorized distributor of record that the manufacturer is unable to supply such prescription drug, medical gas, or medical equipment and the supplying authorized distributor of record states in writing that the prescription drug, medical gas, or medical equipment being supplied had until that time been exclusively in the normal distribution channel.

~~i.~~l. The delivery of, or offer to deliver, a prescription drug, medical gas, or medical equipment by a common carrier solely in the common carrier's usual course of business of transporting prescription drugs, medical gases, or medical equipment and the common carrier does not store, warehouse, or take legal ownership of the prescription drug, medical gas, or medical equipment.

~~j.~~m. The sale or transfer from a retail pharmacy or chain pharmacy warehouse of expired, damaged, returned, or recalled prescription drugs, medical gases, or medical equipment to the original manufacturer or to a third-party returns processor.

~~17.~~28. "Wholesale distributor" means anyone engaged in the wholesale distribution of prescription drugs, medical gases, or medical equipment, including, manufacturers;

virtual manufacturers; repackagers; own-label distributors; private-label distributors; jobbers; brokers; virtual distributors and warehouses, including manufacturers' and distributors' warehouses; manufacturer's exclusive distributors; authorized distributors of record; drug, gas, or equipment wholesalers or distributors; independent wholesale drug, gas, or equipment traders; specialty wholesale distributors; third-party logistics providers; retail pharmacies that conduct wholesale distribution; and chain pharmacy warehouses that conduct wholesale distribution. To be considered part of the normal distribution channel such wholesale distributor must also be an authorized distributor of record.

SECTION 2. AMENDMENT. Section 43-15.3-02 of the North Dakota Century Code is amended and reenacted as follows:

43-15.3-02. Rulemaking authority.

The board shall adopt rules that conform with wholesale ~~drug~~ distributor licensing guidelines adopted by the federal food and drug administration, including rules necessary to carry out the purposes of this chapter, that incorporate and set detailed standards for meeting each of the license prerequisites set forth in this chapter, and that establish reasonable fees to carry out this chapter.

SECTION 3. AMENDMENT. Section 43-15.3-03 of the North Dakota Century Code is amended and reenacted as follows:

43-15.3-03. Wholesale ~~drug~~ distributor licensing requirement - Minimum requirements for licensure.

1. A wholesale distributor that engages in the wholesale distribution of prescription drugs, medical gases, or medical equipment shall pay the annual fee required by the board, must be licensed by the board under this chapter, and must be properly licensed in any other state in which the wholesale distributor engages in the distribution of prescription drugs, medical gases, or medical equipment before engaging in wholesale distributions of wholesale prescription drugs, medical gases, or medical equipment in this state. The licensee shall operate in a manner prescribed by law and according to rules adopted by the board. However, information and qualification requirements for licensure beyond that required by federal law or regulation do not apply to manufacturers distributing ~~their~~the manufacturers' own United States food and drug

administration-approved drugs, gases, or equipment, unless particular requirements are deemed necessary and appropriate following rulemaking. The board may grant a temporary license when the wholesale distributor or pharmacy distributor first applies for a license to operate within this state. A temporary license is valid until the board finds that the applicant meets the requirements for regular licensure.

2. A person may not engage in wholesale distributions of prescription drugs without obtaining and maintaining accreditation or certification from the national association of boards of pharmacy's verified accredited wholesale distributor or an accreditation body approved by the board, obtaining and maintaining a license issued by the board, and paying fees as may be required by the board.

3. The board shall require the following minimum information from each wholesale distributor applying to get a license under subsection 1:

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.

e. The name of every owner and operator of the licensee, including:

(1) If an individual, the name of the individual;

(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.

f. A list of all licenses and permits issued to the applicant by any other state that authorizes the applicant to purchase or possess prescription drugs, medical gases, or medical equipment.

g. The name of the applicant's designated representative for the facility~~, together with~~ and for prescription drug wholesalers the personal information statement and fingerprints~~,~~ required pursuant to subdivision h for the individual.

h. Each individual required by subdivision g to provide a personal information statement and fingerprints shall provide the following information to the state:

(1) The individual's places of residence for the past seven years;

(2) The individual's date and place of birth;

(3) The individual's occupations, positions of employment, and offices held during the past seven years;

(4) The principal business and address of any business, corporation, or other organization in which each office of the individual was held or in which each occupation or position of employment was carried on;

(5) Whether the individual has been, during the past seven years, the subject of any proceeding for the revocation of any license or any criminal violation and, if so, the nature of the proceeding and the disposition of the proceeding;

(6) Whether, during the past seven years, the individual has been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating any federal or state law regulating the possession, control, or distribution of prescription drugs or criminal violations, together with details concerning any of those events;

(7) A description of any involvement by the individual with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund, during the past seven years, which manufactured, administered, prescribed, distributed, or stored pharmaceutical products and any lawsuits in which the businesses were named as a party;

(8) A description of any misdemeanor or felony criminal offense of which the individual, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the individual pled guilty or nolo contendere. If the individual indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of that criminal offense, the applicant must, within fifteen days after the disposition of the appeal, submit to the state a copy of the final written order of disposition; and

(9) A photograph of the individual taken in the previous one hundred eighty days.

~~3.~~4. The information required under subsection ~~2~~3 must be provided under oath.

~~4.~~5. The board may not issue a wholesale distributor license to an applicant, unless the board:

a. Inspects or appoints a third party recognized by the board for the purpose of inspecting the wholesale distribution operations of the facility before initial licensure and continues to inspect periodically thereafter in accordance with a schedule to be determined by the board, but not less than every three years. Manufacturing facilities are exempt from inspection by the board if the manufacturing facilities are currently registered with the federal food and drug administration in accordance with section 510 of the federal Food, Drug, and Cosmetic Act [21 U.S.C. 301]; and

b. Determines that the designated representative meets the following qualifications:

(1) Is at least twenty-one years of age;

(2) Has been employed full time for at least three years in a pharmacy or with a wholesale distributor in a capacity related to the dispensing and distribution of, and recordkeeping relating to, prescription drugs, medical gases, or medical equipment;

(3) Is employed by the applicant full time in a managerial level position;

(4) Is actively involved in and aware of the actual daily operation of the wholesale distributor;

(5) Is physically present at the facility of the applicant during regular business hours, except when the absence of the designated representative is authorized, including sick leave and vacation leave;

(6) Is serving in the capacity of a designated representative for only one applicant at a time, except where more than one licensed wholesale distributor is colocated in the same facility and the wholesale distributors are members of an affiliated group, as defined in section 1504 of the Internal Revenue Code [26 U.S.C. 1504];

(7) Does not have any convictions under any federal, state, or local laws relating to wholesale or retail prescription drug, medical gas, or medical equipment distribution or distribution of controlled substances; and

(8) Does not have any felony conviction under federal, state, or local laws.

~~5.~~6. The board shall submit the fingerprints provided by an individual with a license application for a statewide and nationwide criminal history background record check. The nationwide criminal history background record check must be conducted in the manner provided in section 12-60-24. All costs associated with the background check are the responsibility of the applicant.

~~6.~~7. The board shall require every wholesale prescription drug distributor applying for a license to submit a bond of at least one hundred thousand dollars, or other equivalent means of security acceptable to the state, including an irrevocable letter of credit or a deposit in a trust account or financial institution~~, payable to a fund established by the state under subsection 7~~. Obtaining and maintaining accreditation or certification from the national association of boards of pharmacy's verified accredited wholesale distributor satisfies this requirement. A chain pharmacy warehouse that is engaged only in intracompany transfers is not subject to the bond requirement. The purpose of the bond is to secure payment of any fines or penalties imposed by the state and any fees and costs incurred by the state regarding that license which are authorized under state law and which the licensee fails to pay thirty days after the fines, penalties, or costs become final. The state may make a claim against the bond or security until one year after the licensee's license ceases to be valid. A single bond may cover all facilities operated by the applicant in the state. Any chain pharmacy warehouse that is engaged only in intracompany transfers is exempt from the bond requirement.

~~7. The board shall establish a fund in which to deposit the wholesale distributor bonds. Money in the fund is appropriated to the board on a continuing basis.~~

8. If a wholesale distributor distributes prescription drugs, medical gases, or medical equipment from more than one facility, the wholesale distributor shall obtain a license for each facility.

9. If a manufacturer manufactures prescription drugs, medical gases, or medical equipment in more than one facility but does not engage in wholesale distribution to

North Dakota from those facilities, the manufacturer is not required to obtain a license for each facility.

10. The board shall mail or e-mail a notice for license renewal to each licensee before the first day of the month in which the license expires. If application for renewal of the license, along with the required fee, is not received by the board before the first day of the following month, the license expires on the last day of that month. Timely renewal is the responsibility of the licensee.

11. In accordance with each licensure renewal, the board shall ~~send to~~make available on the board's website for each wholesale distributor licensed under this section ~~a form setting forth~~ the information that the wholesale distributor provided pursuant to subsection ~~2~~3. Within thirty days of receiving the ~~form~~notice, the wholesale distributor ~~must~~shall identify and state under oath to the state licensing authority all changes or corrections to the information that was provided under subsection ~~2~~3. Changes in, or corrections to, any information in subsection ~~2~~3 must be submitted to the board as required by that authority. The board may suspend, revoke, or refuse to renew the license of a wholesale distributor if the board determines that the wholesale distributor no longer qualifies for the license issued under this section.

~~10.~~12. The designated representative identified pursuant to subdivision g of subsection ~~2~~3 must receive and complete continuing training in applicable federal and state laws governing wholesale distribution of prescription drugs, medical gases, or medical equipment.

~~11.~~13. Information provided under subdivision h of subsection ~~2~~3 may not be disclosed to any person other than a government agency that needs the information for licensing or monitoring purposes.

SECTION 4. AMENDMENT. Section 43-15.3-04 of the North Dakota Century Code is amended and reenacted as follows:

43-15.3-04. Requirements to distribute prescription drugs, medical gases, or medical equipment.

1. A person may not engage in wholesale distributions of prescription drugs without~~, after December 31, 2007,~~ obtaining and maintaining accreditation or certification from the national association of boards of pharmacy's verified accredited wholesale distributor

or an accreditation body approved by the board under subsection 4, obtaining and maintaining a license issued by the board, and paying any reasonable fee required by the board. ~~By action of the board, the deadline may be extended through December 31, 2008.~~

2. The board may not issue or renew the license of a wholesale ~~drug~~ distributor that does not comply with this chapter. The board shall require a separate license for each facility or location where wholesale distribution operations are conducted. An agent or employee of any licensed wholesale ~~drug~~ distributor does not need a license and may lawfully possess pharmaceutical drugs, medical gases, or medical equipment when acting in the usual course of business or employment. The issuance of a license under this chapter does not affect tax liability imposed by the tax department on any wholesale ~~drug~~ distributor.

3. An out-of-state wholesale distributor or pharmacy distributor or a principal or agent of the distributor may not conduct business in this state unless the distributor has obtained the necessary license from the board, paid the fee required by the board, and registered with the secretary of state. Application for a license must be made on a form furnished by the board and when submitted by the applicant to the board must include a copy of the certificate of authority from the secretary of state. The issuance of a license under this section does not affect tax liability imposed by the tax department on any out-of-state wholesale distributor or pharmacy distributor. The board may adopt rules that permit out-of-state wholesale ~~drug~~ distributors to obtain a license on the basis of reciprocity if an out-of-state wholesale ~~drug~~ distributor possesses a valid license granted by another state and the legal standards for licensure in the other state are comparable to the standards under this chapter and the other state extends reciprocity to wholesale drug distributors licensed in this state. However, if the requirements for licensure under this chapter are more restrictive than the standards of the other state, the out-of-state wholesale ~~drug~~ distributor ~~must~~shall comply with the additional requirements of this chapter to obtain a license under this chapter.

4. The board may adopt rules to approve an accreditation body to evaluate a wholesale ~~drug~~ distributor's operations to determine compliance with professional standards, this

chapter, and any other applicable law, and perform inspections of each facility and location where wholesale distribution operations are conducted by the wholesale ~~drug~~ distributor.

5. The board or a designee of the board may conduct inspections during normal business hours upon all open premises purporting or appearing to be used by a wholesale distributor or pharmacy distributor in this state. A distributor that provides adequate documentation of the most recent satisfactory inspection less than three years old by the United States food and drug administration is exempt from further inspection for a period of time determined by the board. This exemption does not bar the board from initiating an investigation pursuant to a complaint regarding a wholesale distributor or pharmacy distributor. A wholesale distributor or pharmacy distributor may keep records at a central location apart from the principal office of the wholesale distributor or pharmacy distributor or the location at which the drugs are stored and from which they were shipped, provided that the records are made available for inspection within three business days of a request by the board. The records may be kept in any form permissible under federal law applicable to prescription recordkeeping.

SECTION 5. AMENDMENT. Section 43-15.3-05 of the North Dakota Century Code is amended and reenacted as follows:

43-15.3-05. Restrictions on transactions.

1. A wholesale distributor shall receive prescription drug, medical gas, or medical equipment returns or exchanges from a pharmacy or chain pharmacy warehouse under the terms and conditions of the agreement between the wholesale distributor and the pharmacy or between the wholesale distributor and the chain pharmacy warehouse, including the returns of expired, damaged, and recalled pharmaceutical product to either the original manufacturer or a third-party returns processor, and the returns or exchanges are not subject to the pedigree requirement of section 43-15.3-06 if they are exempt from pedigree under the federal food and drug administration's currently applicable guidance for the federal Prescription Drug Marketing Act of 1987 [Pub. L. 100-293; 102 Stat. 95]. Wholesale distributors and

pharmacies ~~must~~shall ensure that the aspects of this operation are secure and do not permit the entry of adulterated and counterfeit product.

2. A manufacturer or wholesale distributor ~~shall~~may not furnish prescription drugs ~~only~~, medical gases, or medical equipment to a person unless that person is licensed by the appropriate state licensing authorities. Before furnishing prescription drugs, medical gases, or medical equipment to a person not known to the manufacturer or wholesale distributor, the manufacturer or wholesale distributor shall affirmatively verify that the person is legally authorized to receive the prescription drugs, medical gases, or medical equipment by contacting the appropriate state licensing authorities.
3. Prescription drugs, medical gases, or medical equipment furnished by a manufacturer or wholesale distributor may be delivered only to the premises listed on the license. The manufacturer or wholesale distributor may furnish prescription drugs, medical gases, or medical equipment to an individual or agent of that individual at the premises of the manufacturer or wholesale distributor if:
   a. The identity and authorization of the recipient are properly established; and
   b. This method of receipt is employed only to meet the immediate needs of a particular patient of the authorized individual.
4. Prescription drugs, medical gases, or medical equipment may be furnished to a hospital pharmacy receiving area if a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the type and quantity of the prescription drug, medical gas, or medical equipment so received. Any discrepancy between receipt and the type and quantity of the prescription drug, medical gas, or medical equipment actually received must be reported to the delivering manufacturer or wholesale distributor by the next business day after the delivery to the pharmacy receiving area.
5. A manufacturer or wholesale distributor may not accept payment for or allow the use of a person's credit to establish an account for the purchase of prescription drugs, medical gases, or medical equipment from any individual other than the owner of record, the chief executive officer, or the chief financial officer listed on the license of an individual legally authorized to receive prescription drugs, medical gases, or

medical equipment. Any account established for the purchase of prescription drugs, medical gases, or medical equipment must bear the name of the licensee.

SECTION 6. AMENDMENT. Section 43-15.3-06 of the North Dakota Century Code is amended and reenacted as follows:

43-15.3-06. Pedigree.

1. Each person ~~who~~that is engaged in wholesale distribution of prescription drugs, medical gases, or medical equipment, including repackagers but excluding the original manufacturer of the finished form of the prescription drug, medical gas, or medical equipment which leave or have ever left the normal distribution channel, before each wholesale distribution of the drug, ~~must~~medical gas, or medical equipment shall provide a pedigree to the person ~~who~~that receives the drug, gas, or equipment.
   a. A retail pharmacy or chain pharmacy warehouse ~~must~~shall comply with the requirements of this section only if the pharmacy or chain pharmacy warehouse engages in wholesale distribution of prescription drugs, medical gases, or medical equipment.
   b. The ~~board shall determine by July 1, 2009, a~~ targeted implementation ~~date~~dates for electronic track and trace pedigree technology~~. The determination must be based on consultation with~~ for manufacturers, distributors, and pharmacies responsible for the sale and distribution of prescription ~~drug products~~drugs, medical gases, and medical equipment in this state are July 1, 2016, for manufacturers; July 1, 2017, for distributors; and July 1, 2018, for pharmacies. After consultation with interested stakeholders and before implementation of the electronic track and trace pedigree technology, the board ~~must~~shall determine ~~that~~whether the technology is universally available across the entire prescription pharmaceutical supply chain. The ~~implementation date for the mandated electronic track and trace pedigree technology may not be before July 1, 2010, and~~board may ~~be extended by the board~~extend the implementation dates in one-year increments if it appears the technology is not universally available across the entire prescription pharmaceutical supply chain.
2. Each person engaged in the wholesale distribution of a prescription drug, medical gas, or medical equipment, including a repackager but excluding the original manufacturer

of the finished form of the prescription drug, medical gas, or medical equipment, that is provided a pedigree for a prescription drug, medical gas, or medical equipment and attempts to further distribute that prescription drug, medical gas, or medical equipment shall verify affirmatively before any distribution of a prescription drug, medical gas, or medical equipment occurs that each transaction listed on the pedigree has occurred.

3. The pedigree must:

a. Include all necessary identifying information concerning each sale in the chain of distribution of the product from the manufacturer, or the manufacturer's third-party logistics provider, colicensed product partner, or manufacturer's exclusive distributor, through acquisition and sale by any wholesale distributor or repackager, until final sale to a pharmacy or other person dispensing or administering the drug, gas, or equipment. At minimum, the necessary chain of distribution information must include:

(1) The name, address, telephone number, and if available, the e-mail address, of each owner of the prescription drug, medical gas, or medical equipment and each wholesale distributor of the prescription drug, medical gas, or medical equipment;

(2) The name and address of each location from which the product was shipped, if different from the owner's;

(3) The transaction dates; and

(4) A certification that each recipient has authenticated the pedigree.

b. At minimum, the pedigree must also include the:

(1) Name of the prescription drug, medical gas, or medical equipment;

(2) Dosage form and strength of the prescription drug or medical gas;

(3) Size of the container;

(4) Number of containers;

(5) Lot number of the prescription drug, medical gas, or medical equipment;

(6) Name of the manufacturer of the finished dosage form; and

(7) National drug code (NDC) number for a prescription drug.

4. Each pedigree or electronic file must be:

a. Maintained by the purchaser and the wholesale distributor for three years from the date of sale or transfer; and

b. Available for inspection or use within five business days upon a request of an authorized officer of the law or the board.

5. The board shall adopt rules and a form relating to the requirements of this section.

SECTION 7. AMENDMENT. Section 43-15.3-07 of the North Dakota Century Code is amended and reenacted as follows:

43-15.3-07. Order to cease distribution.

1. The board shall issue an order requiring the appropriate person, including the distributors or retailers of the drug, gas, or equipment to immediately cease distribution of the drug, gas, or equipment within the state if the board finds ~~that~~ there is a reasonable probability ~~that~~:

   a. A wholesale distributor, other than a manufacturer, has violated a provision in this chapter or falsified a pedigree or sold, distributed, transferred, manufactured, repackaged, handled, or held a counterfeit prescription drug, medical gas, or medical equipment intended for human use;

   b. The prescription drug, medical gas, or medical equipment at issue as a result of a violation in subdivision a could cause serious, adverse health consequences or death; and

   c. Other procedures would result in unreasonable delay.

2. An order under subsection 1 must provide the individual subject to the order with an opportunity for an informal hearing, to be held not later than ten days after the date of the issuance of the order, on the actions required by the order. If, after providing an opportunity for such a hearing, the board determines that inadequate grounds exist to support the actions required by the order, the board shall vacate the order.

SECTION 8. AMENDMENT. Section 43-15.3-08 of the North Dakota Century Code is amended and reenacted as follows:

43-15.3-08. Prohibited acts - Penalty.

1. Except as otherwise provided under section 43-15.3-09, it is a class B misdemeanor for a person to perform or cause the performance of or aid and abet any of the following acts in this state:

a. Failing to obtain a license under this chapter or operating without a valid license when a license is required by this chapter.

b. If the requirements of subsection 1 of section 43-15.3-05 are applicable and are not met, purchasing or otherwise receiving a prescription drug, medical gas, or medical equipment from a pharmacy.

c. If a state license is required under subsection 2 of section 43-15.3-05, selling, distributing, or transferring a prescription drug, medical gas, or medical equipment to a person that is not authorized under the law of the jurisdiction in which the person receives the prescription drug, medical gas, or medical equipment to receive the prescription drug, medical gas, or medical equipment.

d. Failing to deliver prescription drugs, medical gases, or medical equipment to specified premises, as required by subsection 3 of section 43-15.3-05.

e. Accepting payment or credit for the sale of prescription drugs, medical gases, or medical equipment in violation of subsection 5 of section 43-15.3-05.

f. Failing to maintain or provide pedigrees as required by this chapter.

g. Failing to obtain, pass, or authenticate a pedigree, as required by this chapter.

h. Providing the board or any of the board's representatives or any federal official with false or fraudulent records or making false or fraudulent statements regarding any matter within the provisions of this chapter.

i. Obtaining or attempting to obtain a prescription drug, medical gas, or medical equipment by fraud, deceit, misrepresentation, or engaging in misrepresentation or fraud in the distribution of a prescription drug, medical gas, or medical equipment.

j. Except for the wholesale distribution by manufacturers of a prescription drug, medical gas, or medical equipment that has been delivered into commerce pursuant to an application approved under federal law by the federal food and drug administration, manufacturing, repacking, selling, transferring, delivering, holding, or offering for sale any prescription drug, medical gas, or medical equipment that is adulterated, misbranded, counterfeit, suspected of being counterfeit, or has otherwise been rendered unfit for distribution.

k. Except for the wholesale distribution by a manufacturer of a prescription drug, medical gas, or medical equipment that has been delivered into commerce under an application approved under federal law by the federal food and drug administration, adulterating, misbranding, or counterfeiting any prescription drug, medical gas, or medical equipment.

l. Receiving any prescription drug, medical gas, or medical equipment that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected of being counterfeit, and the delivery or proffered delivery of such drug, gas, or equipment for pay or otherwise.

m. Altering, mutilating, destroying, obliterating, or removing the whole or any part of the labeling of a prescription drug, medical gas, or medical equipment or the commission of any other act with respect to a prescription drug ~~that~~, medical gas, or medical equipment which results in the prescription drug, medical gas, or medical equipment being misbranded.

2. The prohibited acts in subsection 1 do not include a prescription drug, medical gas, or medical equipment manufacturer or agent of a prescription drug, medical gas, or medical equipment manufacturer obtaining or attempting to obtain a prescription drug, medical gas, or medical equipment for the sole purpose of testing the prescription drug, medical gas, or medical equipment for authenticity.

SECTION 9. AMENDMENT. Section 43-15.3-09 of the North Dakota Century Code is amended and reenacted as follows:

43-15.3-09. Penalties.

1. The board may impose the following sanctions if, after a hearing under chapter 28-32, the board finds that a person ~~has~~ violated section 43-15.3-08:
   a. Revoke, suspend, or limit the wholesale ~~drug~~ distributor's license issued under this chapter if the person is a wholesale ~~drug~~ distributor; or
   b. Assess a civil penalty against the person. A civil penalty assessed may not exceed ten thousand dollars per violation.
2. The board, upon a showing of a violation of this chapter, may revoke, suspend, or limit a license issued under this chapter after a proceeding under chapter 28-32. After a proceeding under chapter 28-32, the board may assess a civil penalty against a

licensed wholesale ~~drug~~ distributor of not more than ten thousand dollars for each occurrence. If the licensed wholesale ~~drug~~ distributor fails to pay the civil penalty within the time specified by the board, the board may suspend the license without additional proceedings.

3. Upon application by the board, a court may grant an injunction, a restraining order, or other order to enjoin a person from offering to engage or engaging in the performance of any practices for which a permit or license is required by any applicable federal or state law including this chapter, upon a showing that the practices were or are likely to be performed or offered to be performed without a permit or license. An action brought under this subsection must be commenced either in the county where the conduct occurred or is likely to occur or in the county in the state where the defendant resides. An action brought under this subsection is in addition to any other penalty provided by law and may be brought concurrently with other actions to enforce this chapter.

4. A person that knowingly purchases or receives a prescription drug, medical gas, or medical equipment through any source other than a person licensed under this chapter, including a wholesale distributor, manufacturer, pharmacy distributor, or pharmacy commits a class A misdemeanor. A subsequent unrelated violation of this subsection is a class C felony.

5. A person that knowingly fails to provide a duly authorized individual the right of entry as provided in subsection 5 of section 43-15.3-04 is guilty of a class A misdemeanor for the first conviction and a class C felony for each subsequent conviction.

6. A person ~~who~~that knowingly or intentionally engages in the wholesale distribution of a prescription drug, medical gas, or medical equipment without a license issued under this chapter commits a class C felony. A person is guilty of a class C felony if that person engages in the wholesale distribution of a prescription drug, medical gas, or medical equipment and with intent to defraud or deceive fails to obtain or deliver to another person a complete and accurate required pedigree concerning a prescription drug, medical gas, or medical equipment before obtaining the prescription drug, medical gas, or medical equipment from another person or transferring the prescription drug, medical gas, or medical equipment to another person or falsely

swears or certifies that the person has authenticated any documents to the wholesale distribution of prescription drugs, medical gases, or medical equipment.

~~6.~~7. A person is guilty of a class C felony if that person engages in the wholesale distribution of a prescription drug, medical gas, or medical equipment and knowingly or intentionally:

a. Destroys, alters, conceals, or fails to maintain a complete and accurate required pedigree concerning a prescription drug in the person's possession;

b. Purchases or receives prescription drugs, medical gases, or medical equipment from a person not authorized to distribute prescription drugs, medical gases, or medical equipment in wholesale distribution;

c. Sells, barters, brokers, or transfers a prescription drug, medical gas, or medical equipment to a person not authorized to purchase the prescription drug, medical gas, or medical equipment in the jurisdiction in which the person receives the prescription drug, medical gas, or medical equipment in a wholesale distribution;

d. Forges, counterfeits, or falsely creates a pedigree;

e. Falsely represents a factual matter contained in a pedigree; or

f. Fails to record material information required to be recorded in a pedigree.

~~7.~~8. A person is guilty of a class C felony if that person engages in the wholesale distribution of a prescription drug, medical gas, or medical equipment and possesses a required pedigree concerning a prescription drug, medical gas, or medical equipment, knowingly or intentionally fails to authenticate the matters contained in the pedigree as required, and distributes or attempts to further distribute the prescription drug, medical gas, or medical equipment.

SECTION 10. Section 43-15.3-10 of the North Dakota Century Code is created and enacted as follows:

43-15.3-10. Retail medical gas retailers - Reciprocity.

1. A person may not sell or deliver medical gases and related medical equipment directly to a consumer unless licensed by the board as a retail medical gas retailer.

a. As a term of licensure under this section, a licensee shall employ or contract with an in-state licensed respiratory therapist or other health care professional authorized by that professional's practice act to prescribe or administer the

medical gases and related medical equipment. The applicant shall furnish on the application the name and license number of the individual or licensee the applicant employees or with which the applicant contracts. Within thirty days of a change, a retailer shall provide the board with notice of any change in the licensee.

b. A retail medical gas retailer may sell or deliver to a patient's home medical gases and related equipment in accordance with a practitioner's prescription or drug order. The retail medical gas retailer shall keep the original drug order or an electronic copy of each drug order at the licensed location or must have available for inspection an electronic copy of the original drug order or electronic copy of the drug order. A prescription or drug order is not valid after one year, except a prescription or order for maintenance equipment may be perpetual. A retail medical gas retailer shall maintain a prescription or drug order for five years.

2. An out-of-state retail medical gas retailer or a principal or agent of the retailer may not conduct business in this state unless the retailer is licensed by the board as a retail medical gas retailer, paid the fee required by the board, and is registered with the secretary of state. An applicant shall submit an application for a license on a form furnished by the board and the application must be accompanied by a copy of the certificate of authority from the secretary of state. The issuance of a license under this section does not change or affect tax liability imposed by this state on an out-of-state medical gas retailer.

3. The board may adopt rules that permit an out-of-state retail medical gas retailer to obtain a license on the basis of reciprocity if the retailer possesses a valid license granted by another jurisdiction and the legal standards for licensure in the other jurisdiction are comparable to the standards under this chapter and if the other jurisdiction extends reciprocity to retail medical gas retailers licensed in this state. However, if the requirements for licensure under this chapter are more restrictive than the standards of the other jurisdiction, the out-of-state retail medical gas retailer shall comply with the additional requirements of this chapter to obtain a license under this chapter.

SECTION 11. Section 43-15.3-11 of the North Dakota Century Code is created and enacted as follows:

43-15.3-11. Retail durable medical equipment retailers - Reciprocity.

1. A person may not sell or deliver durable medical equipment directly to a consumer unless licensed by the board as a retail durable medical equipment retailer.
   a. As a term of licensure under this section, a licensee shall employ or contract with an in-state licensed health care professional authorized by that professional's practice act to prescribe or administer the durable medical equipment. For purposes of this section, a licensed health care professional may include a respiratory therapist, physical therapist, pharmacist, registered nurse, licensed practical nurse, advanced practice registered nurse, physician assistant, and occupational therapist.
      (1) The licensed health care professional must be on staff to oversee and provide custom orthotics and prosthetics. The board shall establish certification requirements for a qualified health care professional which may include certification through the American board for certification in orthotics and prosthetics or the board for certification in orthotics as a certified orthotist, certified prosthetist, certified prosthetist orthotist, certified orthotic fitter, certified mastectomy fitter, or certified pedorthist.
      (2) The licensed health care professional must be on staff to oversee and provide complex rehabilitation products and services for seating and mobility systems. The board shall establish certification requirements for a qualified health care professional which may include certification through the rehabilitation engineering and assistive technology society of North America as an assistive technology professional.
      (3) The applicant shall furnish on the application the name and license number of the individual the licensee employs or with which the applicant contracts. Within thirty days of a change, the licensee shall provide the board with notice of any change in the licensee.
   b. A durable medical equipment retailer may sell or deliver to a patient's home durable medical-related equipment in accordance with a practitioner's

prescription or drug order. The retail durable medical equipment retailer shall keep the original prescription or order or an electronic copy at the licensed location or must have available for inspection an electronic copy of the original order or electronic copy of the order. A prescription or order is not valid after one year, except a prescription or order for repair, maintenance, or replacement of equipment may be perpetual. A retail durable medical equipment retailer shall maintain a prescription or order for five years.

2. An out-of-state retail durable medical equipment retailer or a principal or agent of the retailer may not conduct business in this state unless the retailer is licensed by the board as a retail durable medical equipment retailer, paid the fee required by the board, and is registered with the secretary of state. An applicant shall submit an application for a license on a form furnished by the board and the applicant must be accompanied by a copy of the certificate of authority from the secretary of state. The issuance of a license under this section does not change or affect tax liability imposed by this state on an out-of-state retail durable medical equipment retailer.

3. The board may adopt rules that permit an out-of-state retail durable medical equipment retailer to obtain a license on the basis of reciprocity if the retailer possesses a valid license granted by another jurisdiction and the legal standards for licensure in the other jurisdiction are comparable to the standards under this chapter and if the other jurisdiction extends reciprocity to retail durable medical equipment retailers licensed in this state. However, if the requirements for licensure under this chapter are more restrictive than the standards of the other jurisdiction, the out-of-state retail durable medical equipment retailer shall comply with the additional requirements of this chapter to obtain a license under this chapter.

SECTION 12. Section 43-15.3-12 of the North Dakota Century Code is created and enacted as follows:

43-15.3-12. Fees.

The board shall charge and collect the following fees under this chapter:

Chain drug warehouse	$200
Chain pharmacy warehouse	$200
Durable medical equipment distributor, medical gas distributor, or both	$200

Durable medical equipment retailer, medical gas retailer and distributor, or both	$300
Hospital offsite warehouse	$200
Jobber or broker	$400
Manufacturer	$400
Medical gas retailer, durable medical equipment retailer, or both	$200
Medical gas durable medical equipment distributor and retailer	$300
Own label distributor	$400
Pharmacy distributor	$200
Private label distributor	$400
Repackager	$400
Reverse distributor	$200
Third-party logistic provider	$400
Veterinary-only distributor	$200
Virtual manufacturer	$400
Virtual wholesaler or distributor	$400
Wholesaler or distributor	$400