

Sixty-third
Legislative Assembly
of North Dakota

ENGROSSED SENATE BILL NO. 2342

Introduced by

Senator Anderson

Representative K. Koppelman

1 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
2 North Dakota Century Code, relating to wholesale drug distribution; to amend and reenact
3 sections 43-15.3-01, 43-15.3-02, 43-15.3-03, 43-15.3-04, 43-15.3-05, 43-15.3-07, 43-15.3-08,
4 and 43-15.3-09 of the North Dakota Century Code, relating to wholesale drug distribution; and
5 to provide a penalty.

6 **BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:**

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

9 **43-15.3-01. Definitions.**

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

- 11 1. "Authentication" means to affirmatively verify before any wholesale distribution of a
12 prescription drug occurs that each transaction listed on the pedigree has occurred.
- 13 2. "Authorized distributor of record" means a wholesale distributor with whom a
14 manufacturer has established an ongoing relationship to distribute the manufacturer's
15 prescription drug. An ongoing relationship is deemed to exist between the wholesale
16 distributor and a manufacturer when the wholesale distributor, including any affiliated
17 group of the wholesale distributor as defined in section 1504 of the Internal Revenue
18 Code [26 U.S.C. 1504], complies with the following:
 - 19 a. The wholesale distributor has a written agreement currently in effect with the
20 manufacturer evidencing the ongoing relationship; and
 - 21 b. The wholesale distributor is listed on the manufacturer's current list of authorized
22 distributors of record, which is updated by the manufacturer on no less than a
23 monthly basis.
- 24 3. "Board" means the state board of pharmacy.

- 1 4. "Broker" means a party that mediates between a buyer and a seller the sale or
2 shipment of prescription drugs, medical gases, or medical equipment.
- 3 5. "Chain pharmacy warehouse" means a physical location for prescription drugs,
4 medical gases, or medical equipment which acts as a central warehouse and performs
5 intracompany sales or transfers of the drugs, gases, or equipment to a group of chain
6 pharmacies that have the same common ownership and control.
- 7 5-6. "Colicensed product" means a prescription drug, medical gas, or medical equipment in
8 which two or more parties have the right to engage in the manufacturing or marketing
9 or in the manufacturing and marketing of the drug, gas, or equipment.
- 10 7. "Device" means an instrument, apparatus, implement, machine, contrivance, implant,
11 in vitro reagent, or other similar or related article, including any component, part, or
12 accessory which:
- 13 a. Is recognized in the United States pharmacopeia or the official national formulary
14 is intended for use in the diagnosis of disease or other conditions or in the cure,
15 mitigation, treatment, or prevention of disease, in humans or other animals, or is
16 intended to affect the structure or any function of the body of humans or other
17 animals;
- 18 b. Does not achieve its primary intended purposes through chemical action within or
19 on the body of a human or other animal; and
- 20 c. Is not dependent upon being metabolized for the achievement of its primary
21 intended purposes.
- 22 6-8. "Drop shipment" means the sale of a prescription drug, medical gas, or medical
23 equipment to a wholesale distributor by the manufacturer of the prescription drug,
24 medical gas, or medical equipment or to that manufacturer's colicensed product
25 partner, that manufacturer's third-party logistics provider, or that manufacturer's
26 exclusive distributor, under the terms of which the wholesale distributor or chain
27 pharmacy warehouse takes title but not physical possession of the prescription drug,
28 medical gas, or medical equipment and the wholesale distributor invoices the
29 pharmacy or chain pharmacy warehouse, or other person authorized by law to
30 dispense or administer the drug, gas, or equipment to a patient, and the pharmacy or
31 chain pharmacy warehouse or other authorized person receives delivery of the

1 prescription drug, medical gas, or medical equipment directly from the manufacturer,
2 or that manufacturer's third-party logistics provider, or that manufacturer's exclusive
3 distributor.

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

13 ~~7-10.~~ "Facility" means a facility of a wholesale distributor where prescription drugs, medical
14 gases, or medical equipment are stored, handled, repackaged, or offered for sale.

15 ~~8-11.~~ "Manufacturer" means a person licensed or approved by the federal food and drug
16 administration to engage in the manufacture of drugs, medical gases, or devices by
17 manufacturing the drugs, gases, or devices at the person's own facility or by
18 contracting for the manufacturing by others.

19 ~~9-12.~~ "Manufacturer's exclusive distributor" means any person that contracts with a
20 manufacturer to provide or coordinate warehousing, distribution, or other services on
21 behalf of a manufacturer and which takes title to that manufacturer's prescription drug,
22 medical gases, or medical equipment but which does not have general responsibility
23 to direct the sale or disposition of the manufacturer's prescription drug, medical gas, or
24 medical equipment. The manufacturer's exclusive distributor must be licensed as a
25 wholesale distributor under this chapter, and to be considered part of the normal
26 distribution channel also must be an authorized distributor of record.

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

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

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

3 ~~10-16.~~ "Normal distribution channel" means a chain of custody for a prescription drug,
4 medical gas, or medical equipment which goes, directly or by drop shipment, from a
5 manufacturer of the prescription drug, medical gas, or medical equipment, from that
6 manufacturer to that manufacturer's colicensed partner, from that manufacturer to that
7 manufacturer's third-party logistics provider, or from that manufacturer to that
8 manufacturer's exclusive distributor to:

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

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

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

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

21 ~~44-17.~~ "Pedigree" means a document or an electronic file containing information that records
22 each distribution of any given prescription drug.

23 18. "Pharmacy distributor" means any pharmacy or hospital pharmacy licensed in this
24 state which is engaged in the delivery or distribution of prescription drugs, medical
25 gases, or medical equipment to any other pharmacy licensed in this state or to any
26 other person, including a wholesale drug distributor, engaged in the delivery or
27 distribution of prescription drugs, medical gases, or medical equipment and involved in
28 the actual, constructive, or attempted transfer of a drug, gas, or equipment in this state
29 to other than the ultimate consumer, when the financial value of the drugs, gases, or
30 equipment is equivalent to at least five percent of the total gross sales of the pharmacy
31 distributor.

- 1 ~~12-19.~~ "Prescription drug" means any drug, including any biological product, except for blood
2 and blood components intended for transfusion or biological products that are also
3 medical devices, required by federal law, including federal regulation, to be dispensed
4 only by a prescription, including finished dosage forms and bulk drug substances
5 subject to section 503(b) of the federal Food, Drug, and Cosmetic Act [21 U.S.C.
6 3539(b)].
- 7 ~~13-20.~~ "Repackage" means repackaging or otherwise changing the container, wrapper, or
8 labeling to further the distribution of a prescription drug, ~~excluding medical gas, or~~
9 medical equipment. The term does not include actions completed by the pharmacists
10 responsible for dispensing product to the patient.
- 11 ~~14-21.~~ "Repackager" means a person ~~who~~that repackages.
- 12 ~~15-22.~~ "Third-party logistics provider" means ~~anyone who~~a person that contracts with a
13 prescription drug, medical gas, or medical equipment manufacturer to provide or
14 coordinate warehousing, distribution, or other services on behalf of a manufacturer,
15 but does not take title to the prescription drug, medical gas, or medical equipment or
16 have general responsibility to direct the prescription drug's, medical gas's, or medical
17 equipment's sale or disposition. The third-party logistics provider must be licensed as
18 a wholesale distributor under this chapter and to be considered part of the normal
19 distribution channel must also be an authorized distributor of record.
- 20 23. "Trace" means the capability to identify the historical locations, the records of
21 ownership, and the packaging hierarchy for a particular traceable item. "Trace"
22 answers questions such as where has the item been, who previously owned the item,
23 and in what packaging hierarchy did the product exist at various locations.
- 24 24. "Track" means the capability to identify the current, and at the time of shipment the
25 intended future, location, ownership, and packaging hierarchy of a traceable item
26 through the supply chain as the traceable item moves between parties. "Track"
27 addresses both forward and reverse logistics operations. "Track" answers questions
28 such as where is the item currently, who is the next intended recipient, and what is the
29 current packaging hierarchy of the item.

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

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

7 ~~16-~~27. "Wholesale distribution" means distribution of prescription drugs, medical gases, or
8 medical equipment to persons other than a consumer or patient. The term does not
9 include:

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

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

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

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

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

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

- 1 d-g. Drug returns, when conducted by a hospital, health care entity, or charitable
2 institution in accordance with title 21, Code of Federal Regulations, section
3 203.23.
- 4 e-h. The sale of minimal quantities of prescription drugs, medical gases, or medical
5 equipment by retail pharmacies to licensed practitioners for office use.
- 6 f-i. The sale, purchase, or trade of a drug, gas, or equipment; an offer to sell,
7 purchase, or trade a drug, gas, or equipment; or the dispensing of a drug, gas, or
8 equipment pursuant to a prescription.
- 9 g-j. The sale, transfer, merger, or consolidation of all or part of the business of a
10 pharmacy from or with another pharmacy, whether accomplished as a purchase
11 and sale of stock or business assets.
- 12 h-k. The sale, purchase, distribution, trade, or transfer of a prescription drug, medical
13 gas, or medical equipment from one authorized distributor of record to one
14 additional authorized distributor of record when the manufacturer has stated in
15 writing to the receiving authorized distributor of record that the manufacturer is
16 unable to supply such prescription drug, medical gas, or medical equipment and
17 the supplying authorized distributor of record states in writing that the prescription
18 drug, medical gas, or medical equipment being supplied had until that time been
19 exclusively in the normal distribution channel.
- 20 i-l. The delivery of, or offer to deliver, a prescription drug, medical gas, or medical
21 equipment by a common carrier solely in the common carrier's usual course of
22 business of transporting prescription drugs, medical gases, or medical equipment
23 and the common carrier does not store, warehouse, or take legal ownership of
24 the prescription drug, medical gas, or medical equipment.
- 25 j-m. The sale or transfer from a retail pharmacy or chain pharmacy warehouse of
26 expired, damaged, returned, or recalled prescription drugs, medical gases, or
27 medical equipment to the original manufacturer or to a third-party returns
28 processor.
- 29 ~~17-28.~~ "Wholesale distributor" means anyone engaged in the wholesale distribution of
30 prescription drugs, medical gases, or medical equipment, including, manufacturers;
31 virtual manufacturers; repackagers; own-label distributors; private-label distributors;

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

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

11 **43-15.3-02. Rulemaking authority.**

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

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

19 **43-15.3-03. Wholesale drug distributor licensing requirement - Minimum**
20 **requirements for licensure.**

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

- 1 are deemed necessary and appropriate following rulemaking. The board may grant a
2 temporary license when the wholesale distributor or pharmacy distributor first applies
3 for a license to operate within this state. A temporary license is valid until the board
4 finds that the applicant meets the requirements for regular licensure.
- 5 2. A person may not engage in wholesale distributions of prescription drugs without
6 obtaining and maintaining accreditation or certification from the national association of
7 boards of pharmacy's verified accredited wholesale distributor or an accreditation body
8 approved by the board, obtaining and maintaining a license issued by the board, and
9 paying fees as may be required by the board.
- 10 3. The board shall require the following minimum information from each wholesale
11 distributor applying to get a license under subsection 1:
- 12 a. The name, full business address, and telephone number of the licensee.
13 b. All trade or business names used by the licensee.
14 c. Addresses, telephone numbers, and the names of contact persons for all facilities
15 used by the licensee for the storage, handling, and distribution of prescription
16 drugs.
17 d. The type of ownership or operation.
18 e. The name of every owner and operator of the licensee, including:
19 (1) If an individual, the name of the individual;
20 (2) If a partnership, the name of each partner, and the name of the partnership;
21 (3) If a corporation, the name and title of each corporate officer and director, the
22 corporate names, and the name of the state of incorporation; and
23 (4) If a sole proprietorship, the full name of the sole proprietor and the name of
24 the business entity.
25 f. A list of all licenses and permits issued to the applicant by any other state that
26 authorizes the applicant to purchase or possess prescription drugs, medical
27 gases, or medical equipment.
28 g. The name of the applicant's designated representative for the facility, ~~together~~
29 ~~with~~ and for a prescription drug wholesaler applicant, the personal information
30 statement and fingerprints; required pursuant to subdivision h for the individual

1 identified as the prescription drug wholesaler applicant's designated
2 representative for the facility.

3 h. Each individual identified by a prescription drug wholesaler applicant as a
4 designated representative for a facility and therefore required by subdivision g to
5 provide a personal information statement and fingerprints shall provide the
6 following information to the state:

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

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

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

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

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

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

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

29 (8) A description of any misdemeanor or felony criminal offense of which the
30 individual, as an adult, was found guilty, regardless of whether adjudication
31 of guilt was withheld or whether the individual pled guilty or nolo contendere.

1 If the individual indicates that a criminal conviction is under appeal and
2 submits a copy of the notice of appeal of that criminal offense, the applicant
3 must, within fifteen days after the disposition of the appeal, submit to the
4 state a copy of the final written order of disposition; and

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

7 ~~3.4.~~ The information required under subsection ~~23~~ must be provided under oath.

8 ~~4.5.~~ The board may not issue a wholesale distributor license to an applicant, unless the
9 board:

- 10 a. Inspects or appoints a third party recognized by the board for the purpose of
11 inspecting the wholesale distribution operations of the facility before initial
12 licensure and continues to inspect periodically thereafter in accordance with a
13 schedule to be determined by the board, but not less than every three years.
14 Manufacturing facilities are exempt from inspection by the board if the
15 manufacturing facilities are currently registered with the federal food and drug
16 administration in accordance with section 510 of the federal Food, Drug, and
17 Cosmetic Act [21 U.S.C. 301]; and
- 18 b. Determines that the designated representative meets the following qualifications:
- 19 (1) Is at least twenty-one years of age;
- 20 (2) Has been employed full time for at least three years in a pharmacy or with a
21 wholesale distributor in a capacity related to the dispensing and distribution
22 of, and recordkeeping relating to, prescription drugs, medical gases, or
23 medical equipment;
- 24 (3) Is employed by the applicant full time in a managerial level position;
- 25 (4) Is actively involved in and aware of the actual daily operation of the
26 wholesale distributor;
- 27 (5) Is physically present at the facility of the applicant during regular business
28 hours, except when the absence of the designated representative is
29 authorized, including sick leave and vacation leave;
- 30 (6) Is serving in the capacity of a designated representative for only one
31 applicant at a time, except where more than one licensed wholesale

1 distributor is colocated in the same facility and the wholesale distributors are
2 members of an affiliated group, as defined in section 1504 of the Internal
3 Revenue Code [26 U.S.C. 1504];

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

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

8 ~~5-6.~~ The board shall submit the fingerprints provided by an individual with a license
9 application for a statewide and nationwide criminal history background record check.

10 The nationwide criminal history background record check must be conducted in the
11 manner provided in section 12-60-24. All costs associated with the background check
12 are the responsibility of the applicant.

13 ~~6-7.~~ The board shall require every wholesale prescription drug distributor applying for a
14 license to submit a bond of at least one hundred thousand dollars, or other equivalent
15 means of security acceptable to the state, including an irrevocable letter of credit or a
16 deposit in a trust account or financial institution, ~~payable to a fund established by the~~
17 ~~state under subsection 7. Obtaining and maintaining accreditation or certification from~~
18 ~~the national association of boards of pharmacy's verified accredited wholesale~~
19 ~~distributor satisfies this requirement.~~ A chain pharmacy warehouse that is engaged
20 only in intracompany transfers is not subject to the bond requirement. The purpose of
21 the bond is to secure payment of any fines or penalties imposed by the state and any
22 fees and costs incurred by the state regarding that license which are authorized under
23 state law and which the licensee fails to pay thirty days after the fines, penalties, or
24 costs become final. The state may make a claim against the bond or security until one
25 year after the licensee's license ceases to be valid. A single bond may cover all
26 facilities operated by the applicant in the state. Any chain pharmacy warehouse that is
27 engaged only in intracompany transfers is exempt from the bond requirement.

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

- 1 8. If a wholesale distributor distributes prescription drugs, medical gases, or medical
2 equipment from more than one facility, the wholesale distributor shall obtain a license
3 for each facility.
- 4 9. If a manufacturer manufactures prescription drugs, medical gases, or medical
5 equipment in more than one facility but does not engage in wholesale distribution to
6 North Dakota from those facilities, the manufacturer is not required to obtain a license
7 for each facility.
- 8 10. The board shall mail or e-mail a notice for license renewal to each licensee before the
9 first day of the month in which the license expires. If application for renewal of the
10 license, along with the required fee, is not received by the board before the first day of
11 the following month, the license expires on the last day of that month. Timely renewal
12 is the responsibility of the licensee.
- 13 11. In accordance with each licensure renewal, the board shall ~~send to~~ make available on
14 the board's website for each wholesale distributor licensed under this section ~~a form~~
15 ~~setting forth~~ the information that the wholesale distributor provided pursuant to
16 subsection ~~23~~. Within thirty days of receiving the ~~form~~ notice, the wholesale distributor
17 ~~must~~ shall identify and state under oath to the state licensing authority all changes or
18 corrections to the information that was provided under subsection ~~23~~. Changes in, or
19 corrections to, any information in subsection ~~23~~ must be submitted to the board as
20 required by that authority. The board may suspend, revoke, or refuse to renew the
21 license of a wholesale distributor if the board determines that the wholesale distributor
22 no longer qualifies for the license issued under this section.
- 23 ~~10-12.~~ The designated representative identified pursuant to subdivision g of subsection ~~23~~
24 must receive and complete continuing training in applicable federal and state laws
25 governing wholesale distribution of prescription drugs, medical gases, or medical
26 equipment.
- 27 ~~11-13.~~ Information provided under subdivision h of subsection ~~23~~ may not be disclosed to any
28 person other than a government agency that needs the information for licensing or
29 monitoring purposes.

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

1 **43-15.3-04. Requirements to distribute prescription drugs, medical gases, or medical**
2 **equipment.**

- 3 1. A person may not engage in wholesale distributions of prescription drugs without, ~~after~~
4 ~~December 31, 2007,~~ obtaining and maintaining accreditation or certification from the
5 national association of boards of pharmacy's verified accredited wholesale distributor
6 or an accreditation body approved by the board under subsection 4, obtaining and
7 maintaining a license issued by the board, and paying any reasonable fee required by
8 the board. ~~By action of the board, the deadline may be extended through~~
9 ~~December 31, 2008.~~
- 10 2. The board may not issue or renew the license of a wholesale ~~drug~~ distributor that does
11 not comply with this chapter. The board shall require a separate license for each
12 facility or location where wholesale distribution operations are conducted. An agent or
13 employee of any licensed wholesale ~~drug~~ distributor does not need a license and may
14 lawfully possess pharmaceutical drugs, medical gases, or medical equipment when
15 acting in the usual course of business or employment. The issuance of a license under
16 this chapter does not affect tax liability imposed by the tax department on any
17 wholesale ~~drug~~ distributor.
- 18 3. An out-of-state wholesale distributor or pharmacy distributor or a principal or agent of
19 the distributor may not conduct business in this state unless the distributor has
20 obtained the necessary license from the board, paid the fee required by the board,
21 and registered with the secretary of state. Application for a license must be made on a
22 form furnished by the board and when submitted by the applicant to the board must
23 include a copy of the certificate of authority from the secretary of state. The issuance
24 of a license under this section does not affect tax liability imposed by the tax
25 department on any out-of-state wholesale distributor or pharmacy distributor. The
26 board may adopt rules that permit out-of-state wholesale ~~drug~~ distributors to obtain a
27 license on the basis of reciprocity if an out-of-state wholesale ~~drug~~ distributor
28 possesses a valid license granted by another state and the legal standards for
29 licensure in the other state are comparable to the standards under this chapter and the
30 other state extends reciprocity to wholesale drug distributors licensed in this state.
31 However, if the requirements for licensure under this chapter are more restrictive than

1 the standards of the other state, the out-of-state wholesale drug distributor ~~must~~shall
2 comply with the additional requirements of this chapter to obtain a license under this
3 chapter.

4 4. The board may adopt rules to approve an accreditation body to evaluate a wholesale
5 drug distributor's operations to determine compliance with professional standards, this
6 chapter, and any other applicable law, and perform inspections of each facility and
7 location where wholesale distribution operations are conducted by the wholesale drug-
8 distributor.

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

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

25 **43-15.3-05. Restrictions on transactions.**

26 1. A wholesale distributor shall receive prescription drug, medical gas, or medical
27 equipment returns or exchanges from a pharmacy or chain pharmacy warehouse
28 under the terms and conditions of the agreement between the wholesale distributor
29 and the pharmacy or between the wholesale distributor and the chain pharmacy
30 warehouse, including the returns of expired, damaged, and recalled pharmaceutical
31 product to either the original manufacturer or a third-party returns processor, and the

1 returns or exchanges are not subject to the pedigree requirement of section
2 43-15.3-06 if they are exempt from pedigree under the federal food and drug
3 administration's currently applicable guidance for the federal Prescription Drug
4 Marketing Act of 1987 [Pub. L. 100-293; 102 Stat. 95]. Wholesale distributors and
5 pharmacies ~~must~~shall ensure that the aspects of this operation are secure and do not
6 permit the entry of adulterated and counterfeit product.

7 2. A manufacturer or wholesale distributor ~~shall~~may not furnish prescription drugs ~~only,~~
8 medical gases, or medical equipment to a person unless that person is licensed by the
9 appropriate state licensing authorities. Before furnishing prescription drugs, medical
10 gases, or medical equipment to a person not known to the manufacturer or wholesale
11 distributor, the manufacturer or wholesale distributor shall affirmatively verify that the
12 person is legally authorized to receive the prescription drugs, medical gases, or
13 medical equipment by contacting the appropriate state licensing authorities.

14 3. Prescription drugs, medical gases, or medical equipment furnished by a manufacturer
15 or wholesale distributor may be delivered only to the premises listed on the license.
16 The manufacturer or wholesale distributor may furnish prescription drugs, medical
17 gases, or medical equipment to an individual or agent of that individual at the premises
18 of the manufacturer or wholesale distributor if:

- 19 a. The identity and authorization of the recipient are properly established; and
20 b. This method of receipt is employed only to meet the immediate needs of a
21 particular patient of the authorized individual.

22 4. Prescription drugs, medical gases, or medical equipment may be furnished to a
23 hospital pharmacy receiving area if a pharmacist or authorized receiving personnel
24 signs, at the time of delivery, a receipt showing the type and quantity of the
25 prescription drug, medical gas, or medical equipment so received. Any discrepancy
26 between receipt and the type and quantity of the prescription drug, medical gas, or
27 medical equipment actually received must be reported to the delivering manufacturer
28 or wholesale distributor by the next business day after the delivery to the pharmacy
29 receiving area.

30 5. A manufacturer or wholesale distributor may not accept payment for or allow the use
31 of a person's credit to establish an account for the purchase of prescription drugs,

1 medical gases, or medical equipment from any individual other than the owner of
2 record, the chief executive officer, or the chief financial officer listed on the license of
3 an individual legally authorized to receive prescription drugs, medical gases, or
4 medical equipment. Any account established for the purchase of prescription drugs,
5 medical gases, or medical equipment must bear the name of the licensee.

6 **SECTION 6. AMENDMENT.** Section 43-15.3-07 of the North Dakota Century Code is
7 amended and reenacted as follows:

8 **43-15.3-07. Order to cease distribution.**

- 9 1. The board shall issue an order requiring the appropriate person, including the
10 distributors or retailers of the drug, gas, or equipment to immediately cease distribution
11 of the drug, gas, or equipment within the state if the board finds that there is a
12 reasonable probability that:
- 13 a. A wholesale distributor, other than a manufacturer, has violated a provision in this
14 chapter or falsified a pedigree or sold, distributed, transferred, manufactured,
15 repackaged, handled, or held a counterfeit prescription drug, medical gas, or
16 medical equipment intended for human use;
- 17 b. The prescription drug, medical gas, or medical equipment at issue as a result of a
18 violation in subdivision a could cause serious, adverse health consequences or
19 death; and
- 20 c. Other procedures would result in unreasonable delay.
- 21 2. An order under subsection 1 must provide the individual subject to the order with an
22 opportunity for an informal hearing, to be held not later than ten days after the date of
23 the issuance of the order, on the actions required by the order. If, after providing an
24 opportunity for such a hearing, the board determines that inadequate grounds exist to
25 support the actions required by the order, the board shall vacate the order.

26 **SECTION 7. AMENDMENT.** Section 43-15.3-08 of the North Dakota Century Code is
27 amended and reenacted as follows:

28 **43-15.3-08. Prohibited acts - Penalty.**

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

- 1 a. Failing to obtain a license under this chapter or operating without a valid license
2 when a license is required by this chapter.
- 3 b. If the requirements of subsection 1 of section 43-15.3-05 are applicable and are
4 not met, purchasing or otherwise receiving a prescription drug, medical gas, or
5 medical equipment from a pharmacy.
- 6 c. If a state license is required under subsection 2 of section 43-15.3-05, selling,
7 distributing, or transferring a prescription drug, medical gas, or medical
8 equipment to a person that is not authorized under the law of the jurisdiction in
9 which the person receives the prescription drug, medical gas, or medical
10 equipment to receive the prescription drug, medical gas, or medical equipment.
- 11 d. Failing to deliver prescription drugs, medical gases, or medical equipment to
12 specified premises, as required by subsection 3 of section 43-15.3-05.
- 13 e. Accepting payment or credit for the sale of prescription drugs, medical gases, or
14 medical equipment in violation of subsection 5 of section 43-15.3-05.
- 15 f. Failing to maintain or provide pedigrees as required by this chapter.
- 16 g. Failing to obtain, pass, or authenticate a pedigree, as required by this chapter.
- 17 h. Providing the board or any of the board's representatives or any federal official
18 with false or fraudulent records or making false or fraudulent statements
19 regarding any matter within the provisions of this chapter.
- 20 i. Obtaining or attempting to obtain a prescription drug, medical gas, or medical
21 equipment by fraud, deceit, misrepresentation, or engaging in misrepresentation
22 or fraud in the distribution of a prescription drug, medical gas, or medical
23 equipment.
- 24 j. Except for the wholesale distribution by manufacturers of a prescription drug,
25 medical gas, or medical equipment that has been delivered into commerce
26 pursuant to an application approved under federal law by the federal food and
27 drug administration, manufacturing, repacking, selling, transferring, delivering,
28 holding, or offering for sale any prescription drug, medical gas, or medical
29 equipment that is adulterated, misbranded, counterfeit, suspected of being
30 counterfeit, or has otherwise been rendered unfit for distribution.

- 1 k. Except for the wholesale distribution by a manufacturer of a prescription drug,
2 medical gas, or medical equipment that has been delivered into commerce under
3 an application approved under federal law by the federal food and drug
4 administration, adulterating, misbranding, or counterfeiting any prescription drug,
5 medical gas, or medical equipment.
- 6 l. Receiving any prescription drug, medical gas, or medical equipment that is
7 adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or
8 suspected of being counterfeit, and the delivery or proffered delivery of such
9 drug, gas, or equipment for pay or otherwise.
- 10 m. Altering, mutilating, destroying, obliterating, or removing the whole or any part of
11 the labeling of a prescription drug, medical gas, or medical equipment or the
12 commission of any other act with respect to a prescription drug ~~that~~, medical gas,
13 or medical equipment which results in the prescription drug, medical gas, or
14 medical equipment being misbranded.
- 15 2. The prohibited acts in subsection 1 do not include a prescription drug, medical gas, or
16 medical equipment manufacturer or agent of a prescription drug, medical gas, or
17 medical equipment manufacturer obtaining or attempting to obtain a prescription drug,
18 medical gas, or medical equipment for the sole purpose of testing the prescription
19 drug, medical gas, or medical equipment for authenticity.

20 **SECTION 8. AMENDMENT.** Section 43-15.3-09 of the North Dakota Century Code is
21 amended and reenacted as follows:

22 **43-15.3-09. Penalties.**

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

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

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

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

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

22 6. A person ~~whethat~~ that knowingly or intentionally engages in the wholesale distribution of a
23 prescription drug, medical gas, or medical equipment without a license issued under
24 this chapter commits a class C felony. A person is guilty of a class C felony if that
25 person engages in the wholesale distribution of a prescription drug and with intent to
26 defraud or deceive fails to obtain or deliver to another person a complete and accurate
27 required pedigree concerning a prescription drug before obtaining the prescription
28 drug from another person or transferring the prescription drug to another person or
29 falsely swears or certifies that the person has authenticated any documents to the
30 wholesale distribution of prescription drugs.

- 1 ~~6-7.~~ A person is guilty of a class C felony if that person engages in the wholesale
2 distribution of a prescription drug, medical gas, or medical equipment and knowingly or
3 intentionally:
- 4 a. Destroys, alters, conceals, or fails to maintain a complete and accurate required
5 pedigree concerning a prescription drug in the person's possession;
- 6 b. Purchases or receives prescription drugs, medical gases, or medical equipment
7 from a person not authorized to distribute prescription drugs, medical gases, or
8 medical equipment in wholesale distribution;
- 9 c. Sells, barter, brokers, or transfers a prescription drug, medical gas, or medical
10 equipment to a person not authorized to purchase the prescription drug, medical
11 gas, or medical equipment in the jurisdiction in which the person receives the
12 prescription drug, medical gas, or medical equipment in a wholesale distribution;
- 13 d. Forges, counterfeits, or falsely creates a pedigree;
- 14 e. Falsely represents a factual matter contained in a pedigree; or
- 15 f. Fails to record material information required to be recorded in a pedigree.

16 ~~7-8.~~ A person is guilty of a class C felony if that person engages in the wholesale
17 distribution of a prescription drug and possesses a required pedigree concerning a
18 prescription drug, knowingly or intentionally fails to authenticate the matters contained
19 in the pedigree as required, and distributes or attempts to further distribute the
20 prescription drug.

21 **SECTION 9.** Section 43-15.3-10 of the North Dakota Century Code is created and enacted
22 as follows:

23 **43-15.3-10. Retail medical gas retailers - Reciprocity.**

- 24 1. A person may not sell or deliver medical gases and related medical equipment directly
25 to a consumer unless licensed by the board as a retail medical gas retailer.
- 26 a. As a term of licensure under this section, a licensee shall employ or contract with
27 an in-state licensed respiratory therapist or other health care professional
28 authorized by that professional's practice act to prescribe or administer the
29 medical gases and related medical equipment. The applicant shall furnish on the
30 application the name and license number of the individual or licensee the
31 applicant employees or with which the applicant contracts. Within thirty days of a

- 1 change, a retailer shall provide the board with notice of any change in the
2 licensee.
- 3 b. A retail medical gas retailer may sell or deliver to a patient's home medical gases
4 and related equipment in accordance with a practitioner's prescription or drug
5 order. The retail medical gas retailer shall keep the original drug order or an
6 electronic copy of each drug order at the licensed location or must have available
7 for inspection an electronic copy of the original drug order or electronic copy of
8 the drug order. A prescription or drug order is not valid after one year, except a
9 prescription or order for maintenance equipment may be perpetual. A retail
10 medical gas retailer shall maintain a prescription or drug order for five years.
- 11 2. An out-of-state retail medical gas retailer or a principal or agent of the retailer may not
12 conduct business in this state unless the retailer is licensed by the board as a retail
13 medical gas retailer, paid the fee required by the board, and is registered with the
14 secretary of state. An applicant shall submit an application for a license on a form
15 furnished by the board and the application must be accompanied by a copy of the
16 certificate of authority from the secretary of state. The issuance of a license under this
17 section does not change or affect tax liability imposed by this state on an out-of-state
18 medical gas retailer.
- 19 3. The board may adopt rules that permit an out-of-state retail medical gas retailer to
20 obtain a license on the basis of reciprocity if the retailer possesses a valid license
21 granted by another jurisdiction and the legal standards for licensure in the other
22 jurisdiction are comparable to the standards under this chapter and if the other
23 jurisdiction extends reciprocity to retail medical gas retailers licensed in this state.
24 However, if the requirements for licensure under this chapter are more restrictive than
25 the standards of the other jurisdiction, the out-of-state retail medical gas retailer shall
26 comply with the additional requirements of this chapter to obtain a license under this
27 chapter.

28 **SECTION 10.** Section 43-15.3-11 of the North Dakota Century Code is created and enacted
29 as follows:

1 **43-15.3-11. Retail durable medical equipment retailers - Reciprocity.**

2 1. A person may not sell or deliver durable medical equipment directly to a consumer
3 unless licensed by the board as a retail durable medical equipment retailer.

4 a. As a term of licensure under this section, a licensee shall employ or contract with
5 an in-state licensed health care professional authorized by that professional's
6 practice act to prescribe or administer the durable medical equipment. For
7 purposes of this section, a licensed health care professional may include a
8 respiratory therapist, physical therapist, pharmacist, registered nurse, licensed
9 practical nurse, advanced practice registered nurse, physician assistant, and
10 occupational therapist.

11 (1) The licensed health care professional must be on staff to oversee and
12 provide custom orthotics and prosthetics. The board shall establish
13 certification requirements for a qualified health care professional which may
14 include certification through the American board for certification in orthotics
15 and prosthetics or the board for certification in orthotics as a certified
16 orthotist, certified prosthetist, certified prosthetist orthotist, certified orthotic
17 fitter, certified mastectomy fitter, or certified pedorthist.

18 (2) The licensed health care professional must be on staff to oversee and
19 provide complex rehabilitation products and services for seating and
20 mobility systems. The board shall establish certification requirements for a
21 qualified health care professional which may include certification through the
22 rehabilitation engineering and assistive technology society of North America
23 as an assistive technology professional.

24 (3) The applicant shall furnish on the application the name and license number
25 of the individual the licensee employs or with which the applicant contracts.
26 Within thirty days of a change, the licensee shall provide the board with
27 notice of any change in the licensee.

28 b. A durable medical equipment retailer may sell or deliver to a patient's home
29 durable medical-related equipment in accordance with a practitioner's
30 prescription or drug order. The retail durable medical equipment retailer shall
31 keep the original prescription or order or an electronic copy at the licensed

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

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

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

23 **SECTION 11.** Section 43-15.3-12 of the North Dakota Century Code is created and enacted
24 as follows:

25 **43-15.3-12. Fees.**

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

27 <u>Chain drug warehouse</u>	<u>\$200</u>
28 <u>Chain pharmacy warehouse</u>	<u>\$200</u>
29 <u>Durable medical equipment distributor, medical gas distributor, or both</u>	<u>\$200</u>
30 <u>Durable medical equipment retailer, medical gas retailer and distributor, or both</u>	<u>\$300</u>
31 <u>Hospital offsite warehouse</u>	<u>\$200</u>

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1	<u>Jobber or broker</u>	\$400
2	<u>Manufacturer</u>	\$400
3	<u>Medical gas retailer, durable medical equipment retailer, or both</u>	\$200
4	<u>Medical gas durable medical equipment distributor and retailer</u>	\$300
5	<u>Own label distributor</u>	\$400
6	<u>Pharmacy distributor</u>	\$200
7	<u>Private label distributor</u>	\$400
8	<u>Repackager</u>	\$400
9	<u>Reverse distributor</u>	\$200
10	<u>Third-party logistic provider</u>	\$400
11	<u>Veterinary-only distributor</u>	\$200
12	<u>Virtual manufacturer</u>	\$400
13	<u>Virtual wholesaler or distributor</u>	\$400
14	<u>Wholesaler or distributor</u>	\$400