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Sixty-fourth
Legislative Assembly
of North Dakota

SENATE BILL NO. 2086

Introduced by

Industry, Business and Labor Committee

(At the request of the State Board of Pharmacy)

A BILL for an Act to create and enact sections 43-15.3-13 and 43-15.3-14 of the North Dakota Century Code, relating to drugs provided by outsourcing facilities and third-party logistics providers; and to amend and reenact sections 43-15.3-01, 43-15.3-11, and 43-15.3-12 of the North Dakota Century Code, relating to the wholesale drug distribution and third-party logistic providers.

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 occurs that each transaction listed on the pedigree has occurred.
2. "Authorized distributor of record" means a wholesale distributor or a third-party logistics provider with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug. An ongoing relationship is deemed to exist between the third-party logistics provider and the manufacturer or between the wholesale distributor and a manufacturer when the third-party logistics provider or 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 or a third-party logistics provider has a written agreement currently in effect with the manufacturer evidencing the ongoing relationship; and

b. The wholesale distributor or a third-party logistics provider 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.

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.

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.

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.

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.

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.

16. "Normal distribution channel" means a chain of custody for a prescription drug which goes, directly or by drop shipment, from a manufacturer of the prescription drug, 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 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 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 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 to a patient.

17. "Outsourcing facility" means a facility at one geographic location or address which is engaged in anticipatory compounding of sterile drugs and complies with section 503(b) of the federal Food, Drug, and Cosmetic Act [21 U.S.C. 353(b)].

18. "Pedigree" means a document or an electronic file containing information that records each distribution of any given prescription drug.

~~18.~~19. "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.

~~19.~~20. "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)].

~~20.~~21. "Repackage" means repackaging or otherwise changing the container, wrapper, or labeling to further the distribution of a prescription drug. The term does not include actions completed by the pharmacists responsible for dispensing product to the patient.

~~21.~~22. "Repackager" means a person that repackages.

~~22.~~23. "Third-party logistics provider" means a person that contracts with a wholesale distributor or a prescription drug, medical gas, or medical equipment manufacturer to provide or coordinate warehousing, wholesale 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~~independently under this chapter and to be considered part of the normal distribution channel must also be an authorized distributor of record.

~~23.~~24. "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.~~25. "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.~~26. "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.~~27. "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.

~~27.~~28. "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.

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.

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

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.

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.

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.

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.

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.

~~28.~~29. "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; manufacturers' 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 43-15.3-11 of the North Dakota Century Code is amended and reenacted 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, 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 and items designated as thirteen month capped rental items by the center of medicare and medicaid services may be perpetual. A retail durable medical equipment retailer shall maintain a prescription or order for five years. A durable medical equipment retailer may only obtain medical equipment from a manufacturer or wholesaler that is duly licensed by the state.

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 3. AMENDMENT. Section 43-15.3-12 of the North Dakota Century Code is amended and reenacted 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
<u>Outsourcing facility</u>	<u>$200</u>
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

SECTION 4. Section 43-15.3-13 of the North Dakota Century Code is created and enacted as follows:

43-15.3-13. Compounding provided by an outsourcing facility.

1. A facility may provide, without a patient specific prescription, a nonpatient specific compounded drug preparation for human use only, if the following conditions apply:
   a. The entity is registered with the United States food and drug administration as an outsourcing facility pursuant to section 503(b) of the federal Food, Drug, and Cosmetic Act [21 U.S.C. 353(b)]; and
   b. The entity is licensed under this chapter with an outsourcing facility classification, has designated a licensed pharmacist in the state of residence as the responsible person on the license, and the facility meets the standards for licensure set in this chapter.
2. Within forty-eight hours of a request from the board, the facility shall make available to the board any inspection reports, federal food and drug administration reports of objectionable conditions issued against the facility, and lists of distribution of products to the state.
3. The facility shall comply with all labeling and recordkeeping requirements pursuant to section 503(b) of the federal Food, Drug, and Cosmetic Act [21 U.S.C. 353(b)].

SECTION 5. Section 43-15.3-14 of the North Dakota Century Code is created and enacted as follows:

43-15.3-14. Third-party logistics providers.

1. Each third-party logistics provider shall comply with the standards for licensure; requirements to distribute prescription drugs, medical gases, or medical equipment; restrictions on transactions; and pedigree requirements set forward in this chapter.
2. The board shall issue a separate license to each qualified third-party logistics provider applying for licensure.