

SENATE BILL NO. 2209

Introduced by

Senator Anderson

Representatives M. Nelson, Satrom

1 A BILL for an Act to create and enact a new section to chapter 19-02.1 and a new chapter to
2 title 19 of the North Dakota Century Code, relating to increased access to low-cost prescription
3 drugs; to amend section 43-15.3-12 of the North Dakota Century Code, relating to drug
4 wholesaler fees; to provide for a report; to provide a continuing appropriation; to provide for a
5 transfer; and to provide a contingent effective date.

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

7 **SECTION 1.** A new section to chapter 19-02.1 of the North Dakota Century Code is created
8 and enacted as follows:

9 **Exception - Drug importation.**

10 This chapter does not prohibit a manufacturer of a drug approved by the federal drug
11 administration from importing a version of the approved drug sold in foreign countries pursuant
12 to section 801 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 384].

13 **SECTION 2.** A new chapter to title 19 of the North Dakota Century Code is created and
14 enacted as follows:

15 **Wholesale prescription drug importation program.**

16 1. ~~The state board of pharmacy, in consultation with appropriate federal and state~~
17 ~~agencies, other states, and interested parties, shall design~~ If another state creates a
18 wholesale prescription drug importation program for the importation of prescription
19 drugs from Canada in compliance with section 804 of the Federal Food, Drug, and
20 Cosmetic Act [21 U.S.C. 384] and this chapter, including requirements regarding
21 safety and cost-savings, the state department of health may contract with the other
22 state for the importation of prescription drugs from Canada.

23 2. The program must:

- 1 a. Designate a state agency to become a licensed drug wholesaler or to contract
- 2 with a licensed drug wholesaler to import safe prescription drugs and provide
- 3 cost-savings to consumers in the state. The designated state agency shall
- 4 implement and operate the program.
- 5 b. Use prescription drug suppliers in Canada which are regulated under the laws of
- 6 Canada, one or more Canadian provinces, or both.
- 7 c. Ensure compliance with title II of the federal Drug Quality and Security Act of
- 8 2013 [Pub. L. 113-54; 21 U.S.C. 301 et seq.] for the safety and effectiveness of
- 9 imported prescription drugs.
- 10 d. Limit importation to prescription drugs expected to generate substantial cost-
- 11 savings for consumers in the state.
- 12 e. Ensure the program complies with the transaction and tracing requirements of
- 13 sections 360eee and 360eee-1 of the Federal Food, Drug, and Cosmetic Act
- 14 [21 U.S.C. 384] to the extent feasible and practical before the imported
- 15 prescription drugs come into the possession of the licensed drug wholesaler and
- 16 ensure the program complies fully after the imported drugs are in the possession
- 17 of the state wholesaler.
- 18 f. Consider whether the program may be developed on a multistate basis through
- 19 collaboration with other states.
- 20 g. Except as provided under subdivision f, prohibit the distribution, dispensing, or
- 21 sale of imported prescription drugs outside the state.
- 22 h. Recommend a charge per prescription or another method of financing to ensure
- 23 the program is adequately funded in a manner that does not jeopardize
- 24 significant consumer savings.
- 25 i. Include an audit function.

26 **Rulemaking.**

27 The ~~state board of pharmacy~~health council shall adopt rules to design the program in
28 accordance with this chapter.

29 **Implementation.**

- 30 1. The state agency designated to oversee the program shall implement the program as
31 required under this chapter.

- 1 2. The state agency designated to oversee the program shall:
- 2 a. Become a licensed drug wholesaler or enter a contract with a drug wholesaler
- 3 licensed by the state.
- 4 b. Contract with one or more wholesale drug distributors licensed by the state.
- 5 c. Contract with one or more licensed and regulated prescription drug suppliers in
- 6 Canada.
- 7 d. Consult with health insurance carriers, employers, pharmacies, pharmacists,
- 8 health care providers, and consumers.
- 9 e. Develop a registration process for health insurance carriers, pharmacies, and
- 10 health care providers authorized to prescribe and administer prescription drugs
- 11 which are willing to participate in the program.
- 12 f. Create a publicly accessible website for listing the prices of imported prescription
- 13 drugs.
- 14 g. Develop a two-year audit work plan.
- 15 h. Conduct any other activity the agency determines necessary to successfully
- 16 implement and operate the program.

17 **Reporting.**

18 By June 1 of each year, the state agency designated to implement and operate the program
19 under this chapter shall provide a report to the legislative management regarding the
20 implementation and operation of the program during the previous calendar year. The report
21 must include:

- 22 1. The prescription drugs included in the program.
- 23 2. The number of participating pharmacies, health care providers, and health insurance
- 24 carriers.
- 25 3. The number of prescription drugs dispensed through the program.
- 26 4. The estimated cost-savings to consumers, health insurance carriers, employers, and
- 27 the state during the previous calendar year and over the course of the program.
- 28 5. Information regarding the implementation of the audit work plan and audit findings.
- 29 6. Any other information the state agency designated to oversee the program considers
- 30 relevant.

1 **Drug importation fund - Transfer - Continuing appropriation.**

2 The state board of pharmacy shall ~~transfer~~ deposit six hundred dollars of every wholesaler
3 license fee and every virtual wholesaler license fee collected by the board under section
4 43-15.3-12 to the drug importation program fund. All the moneys in the fund, not otherwise
5 appropriated, are appropriated to the state ~~agency designated~~ department of health to
6 implement and operate the wholesale prescription drug importation program under this chapter
7 for the purpose of administering the program.

8 **SECTION 3. AMENDMENT.** Section 43-15.3-12 of the North Dakota Century Code is
9 amended and reenacted as follows:

10 **43-15.3-12. Fees.**

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

12	Chain drug warehouse	\$200
13	Chain pharmacy warehouse	\$200
14	Durable medical equipment distributor, medical gas distributor, or both	\$200
15	Durable medical equipment retailer, medical gas retailer and distributor, or both	\$300
16	Hospital offsite warehouse	\$200
17	Jobber or broker	\$400 <u>Not to exceed \$1,000</u>
18	Manufacturer	\$400 <u>Not to exceed \$1,000</u>
19	Medical gas retailer, durable medical equipment retailer, or both	\$200
20	Medical gas durable medical equipment distributor and retailer	\$300
21	Outsourcing facility	\$200
22	Own label distributor	\$400 <u>Not to exceed \$1,000</u>
23	Pharmacy distributor	\$200
24	Private label distributor	\$400 <u>Not to exceed \$1,000</u>
25	Repackager	\$400 <u>Not to exceed \$1,000</u>
26	Reverse distributor	\$200
27	Third-party logistic provider	\$400 <u>Not to exceed \$1,000</u>
28	Veterinary-only distributor	\$200
29	Virtual manufacturer	\$400
30	Virtual wholesaler or distributor	\$400 <u>Not to exceed \$1,000</u>
31	Wholesaler or distributor	\$400 <u>Not to exceed \$1,000</u>

1 **SECTION 4. CONTINGENT EFFECTIVE DATE.** ~~The state board of pharmacy shall submit~~
2 ~~a request to the United States department of health and human services for approval and~~
3 ~~certification of a wholesale prescription drug importation program created under section 2 of this~~
4 ~~Act. Section 2 of this~~ This Act becomes effective six months following the date the ~~president of~~
5 ~~the state board of pharmacy~~ department of health certifies to the legislative council the receipt of
6 ~~approval and certification of the state's~~ a contract with another state for the implementation of a
7 wholesale prescription drug importation program ~~from the United States department of health~~
8 ~~and human services.~~