

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 a wholesale prescription
18 drug importation program for the importation of prescription drugs from Canada in
19 compliance with section 804 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C.
20 384], including requirements regarding safety and cost-savings.

21 2. The program must:

22 a. Designate a state agency to become a licensed drug wholesaler or to contract
23 with a licensed drug wholesaler to import safe prescription drugs and provide

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

24 **Rulemaking.**

25 The state board of pharmacy shall adopt rules to design the program in accordance with
26 this chapter.

27 **Implementation.**

- 28 1. The state agency designated to oversee the program shall implement the program as
29 required under this chapter.
- 30 2. The state agency designated to oversee the program shall:

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

16 **Reporting.**

17 By June 1 of each year, the state agency designated to implement and operate the program

18 under this chapter shall provide a report to the legislative management regarding the

19 implementation and operation of the program during the previous calendar year. The report

20 must include:

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

1 **Transfer - Continuing appropriation.**

2 The state board of pharmacy shall transfer six hundred dollars of every wholesaler license
3 fee and every virtual wholesaler license fee collected by the board under section 43-15.3-12 to
4 the drug importation program fund. All the moneys in the fund, not otherwise appropriated, are
5 appropriated to the state agency designated to implement and operate the wholesale
6 prescription drug importation program under this chapter for the purpose of administering the
7 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 Act becomes effective six months following the date the president of the
5 state board of pharmacy certifies to the legislative council the receipt of approval and
6 certification of the state's wholesale prescription drug importation program from the United
7 States department of health and human services.