

SENATE BILL NO. 2212

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 provide for a report; and to provide a contingent effective date.

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

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

7 **Exception - Drug importation.**

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

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

13 **Wholesale prescription drug importation program.**

14 1. The state department of health, in consultation with appropriate federal and state
15 agencies, other states, and interested parties, shall design a wholesale prescription
16 drug importation program for the importation of prescription drugs from Canada in
17 compliance with section 804 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C.
18 384], including requirements regarding safety and cost-savings.

19 2. The program must:

20 a. Designate a state agency to become a licensed drug wholesaler or to contract
21 with a licensed drug wholesaler to import safe prescription drugs and provide
22 cost-savings to consumers in the state. The designated state agency shall
23 implement and operate the program.

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

22 **Rulemaking.**

23 The health council shall adopt rules to design the program in accordance with this chapter.

24 **Implementation.**

- 25 1. The state agency designated to oversee the program shall implement the program as
26 required under this chapter.
- 27 2. The state agency designated to oversee the program shall:
 - 28 a. Become a licensed drug wholesaler or enter a contract with a licensed drug
29 wholesaler in the state.
 - 30 b. Contract with one or more wholesale drug distributors licensed in the state.

- 1 c. Contract with one or more licensed and regulated prescription drug suppliers in
- 2 Canada.
- 3 d. Consult with health insurance carriers, employers, pharmacies, pharmacists,
- 4 health care providers, and consumers.
- 5 e. Develop a registration process for health insurance carriers, pharmacies, and
- 6 health care providers authorized to prescribe and administer prescription drugs
- 7 which are willing to participate in the program.
- 8 f. Create a publicly accessible website for listing the prices of imported prescription
- 9 drugs.
- 10 g. Create an outreach and marketing plan to generate public awareness of the
- 11 program.
- 12 h. Establish a hotline to answer questions and address the needs of consumers,
- 13 employers, health insurance carriers, pharmacies, health care providers, and
- 14 others affected by the program.
- 15 i. Develop a two-year audit work plan.
- 16 j. Conduct any other activity the agency determines necessary to successfully
- 17 implement and operate the program.

18 **Reporting.**

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

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

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