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Sixty-seventh
Legislative Assembly
of North Dakota

SENATE BILL NO. 2209

Introduced by

Senator Anderson

Representatives M. Nelson, Satrom

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

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

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

Exception - Drug importation.

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

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

Wholesale prescription drug importation program.

1. The state board of pharmacy, in consultation with appropriate federal and state agencies, other states, and interested parties, shall design a wholesale prescription drug importation program for the importation of prescription drugs from Canada in compliance with section 804 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 384], including requirements regarding safety and cost-savings.
2. The program must:
   a. Designate a state agency to become a licensed drug wholesaler or to contract with a licensed drug wholesaler to import safe prescription drugs and provide

cost-savings to consumers in the state. The designated state agency shall implement and operate the program.

b. Use prescription drug suppliers in Canada which are regulated under the laws of Canada, one or more Canadian provinces, or both.

c. Ensure compliance with title II of the federal Drug Quality and Security Act of 2013 [Pub. L. 113-54; 21 U.S.C. 301 et seq.] for the safety and effectiveness of imported prescription drugs.

d. Limit importation to prescription drugs expected to generate substantial cost-savings for consumers in the state.

e. Ensure the program complies with the transaction and tracing requirements of sections 360eee and 360eee-1 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 384] to the extent feasible and practical before the imported prescription drugs come into the possession of the licensed drug wholesaler and ensure the program complies fully after the imported drugs are in the possession of the state wholesaler.

f. Consider whether the program may be developed on a multistate basis through collaboration with other states.

g. Except as provided under subdivision f, prohibit the distribution, dispensing, or sale of imported prescription drugs outside the state.

h. Recommend a charge per prescription or another method of financing to ensure the program is adequately funded in a manner that does not jeopardize significant consumer savings.

i. Include an audit function.

Rulemaking.

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

Implementation.

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

2. The state agency designated to oversee the program shall:

a. Become a licensed drug wholesaler or enter a contract with a drug wholesaler licensed by the state.

b. Contract with one or more wholesale drug distributors licensed by the state.

c. Contract with one or more licensed and regulated prescription drug suppliers in Canada.

d. Consult with health insurance carriers, employers, pharmacies, pharmacists, health care providers, and consumers.

e. Develop a registration process for health insurance carriers, pharmacies, and health care providers authorized to prescribe and administer prescription drugs which are willing to participate in the program.

f. Create a publicly accessible website for listing the prices of imported prescription drugs.

g. Develop a two-year audit work plan.

h. Conduct any other activity the agency determines necessary to successfully implement and operate the program.

Reporting.

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

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

Transfer - Continuing appropriation.

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

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 as follows:

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~~Not to exceed $1,000
Manufacturer	~~$400~~Not to exceed $1,000
Medical gas retailer, durable medical equipment retailer, or both	$200
Medical gas durable medical equipment distributor and retailer	$300
Outsourcing facility	$200
Own label distributor	~~$400~~Not to exceed $1,000
Pharmacy distributor	$200
Private label distributor	~~$400~~Not to exceed $1,000
Repackager	~~$400~~Not to exceed $1,000
Reverse distributor	$200
Third-party logistic provider	~~$400~~Not to exceed $1,000
Veterinary-only distributor	$200
Virtual manufacturer	$400
Virtual wholesaler or distributor	~~$400~~Not to exceed $1,000
Wholesaler or distributor	~~$400~~Not to exceed $1,000

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