

S.175 - House Health Care Committee amendment (dr. 5.1) showing changes from House Ways and Means amendment (dr. 1.3)

Sec. 1. 18 V.S.A. chapter 91, subchapter 4 is added to read:

Subchapter 4. Wholesale Prescription Drug Importation Program

§ 4651. WHOLESALE IMPORTATION PROGRAM FOR PRESCRIPTION

DRUGS; DESIGN

(a) The Agency of Human Services, in consultation with interested stakeholders and appropriate federal officials, shall design a wholesale prescription drug importation program that complies with the applicable requirements of 21 U.S.C. § 384, including the requirements regarding safety and cost savings. The program design shall:

(1) designate a State agency that shall either become a licensed drug wholesaler or contract with a licensed drug wholesaler in order to seek federal certification and approval to import safe prescription drugs and provide significant prescription drug cost savings to Vermont consumers;

(2) use Canadian prescription drug suppliers regulated under the laws of Canada or of one or more Canadian provinces, or both;

(3) ensure that only prescription drugs meeting the U.S. Food and Drug Administration's safety, effectiveness, and other standards shall be imported by or on behalf of the State;

(4) import only those prescription drugs expected to generate substantial savings for Vermont consumers;

(5) ensure that the program complies with the tracking and tracing requirements of 21 U.S.C. §§ 360eee and 360eee-1 to the extent feasible and practical prior to imported drugs coming into the possession of the State wholesaler and that it complies fully after imported drugs are in the possession of the State wholesaler;

(6) prohibit the distribution, dispensing, or sale of imported products outside Vermont's borders;

(7) **establish a fee on each** **recommend a charge per** prescription or **establish** another **financing mechanism** **method of support** to ensure that the program is funded adequately in a manner that does not jeopardize significant consumer savings; and

(8) include a robust audit function.

(b) On or before January 1, 2019, the Secretary of Human Services shall submit the proposed design for a wholesale prescription drug importation program to the **House Committee on Health Care** **House Committees on Health Care and on Ways and Means** and the Senate Committees on Health and Welfare and on Finance.

§ 4652. MONITORING FOR ANTICOMPETITIVE BEHAVIOR

The Agency of Human Services shall consult with the Office of the Attorney General to identify the potential, and to monitor, for anticompetitive behavior in industries that would be affected by a wholesale prescription drug importation program.

§ 4653. FEDERAL COMPLIANCE

(a) On or before July 1, 2019, the Agency of Human Services shall submit a formal request to the Secretary of the U.S. Department of Health and Human Services for certification of the State's wholesale prescription drug importation program.

(b) The Agency of Human Services shall seek the appropriate federal approvals, waivers, exemptions, or agreements, or a combination thereof, as needed to enable all covered entities enrolled in or eligible for the federal 340B Drug Pricing Program to participate in the State's wholesale prescription drug importation program to the fullest extent possible without jeopardizing their eligibility for the 340B Program.

§ 4654. PROGRAM FINANCING

The Agency of Human Services shall not implement the wholesale prescription drug importation program until the General Assembly enacts legislation establishing a charge per prescription or another method of financial support for the program.

§ 4655. IMPLEMENTATION PROVISIONS

Upon certification and approval by the Secretary of the U.S. Department of Health and Human Services, the Agency of Human Services shall begin implementation of the wholesale prescription drug importation program and shall begin operating the program within six months following the date of the Secretary's approval. Upon the last to occur of the General Assembly enacting a method of financial support pursuant to section 4654 of this chapter and receipt of certification and approval by the Secretary of the U.S. Department of Health and Human Services, the Agency of Human Services shall begin implementation of the wholesale prescription drug importation program and shall begin operating the program within six months. As part of the implementation process, the Agency of Human Services shall, in accordance with State procurement and contract laws, rules, and procedures as appropriate:

- (1) become licensed as a wholesaler or enter into a contract with a Vermont-licensed wholesaler;
- (2) contract with one or more Vermont-licensed distributors;
- (3) contract with one or more licensed and regulated Canadian suppliers;
- (4) engage with health insurance plans, employers, pharmacies, health care providers, and consumers;

- (5) develop a registration process for health insurance plans, pharmacies, and prescription drug-administering health care providers who are willing to participate in the program;
- (6) create a publicly available source for listing the prices of imported prescription drug products that shall be made available to all participating entities and consumers;
- (7) create an outreach and marketing plan to generate program awareness;
- (8) starting in the weeks before the program becomes operational, create and staff a hotline to answer questions and address the needs of consumers, employers, health insurance plans, pharmacies, health care providers, and other affected sectors;
- (9) establish the audit function and a two-year audit work-plan cycle; and
- (10) conduct any other activities that the Agency determines to be important for successful implementation of the program.

§ 4656. ANNUAL REPORTING

- (a) Annually on or before January 15, the Agency of Human Services shall report to the ~~House Committee on Health Care~~ **House Committees on Health Care and on Ways and Means** and the Senate Committees on Health and Welfare and on Finance regarding the operation of the wholesale prescription drug importation program during the previous calendar year, including:
 - (1) which prescription drugs were included in the wholesale importation program;
 - (2) the number of participating pharmacies, health care providers, and health insurance plans;
 - (3) the number of prescriptions dispensed through the program;
 - (4) the estimated savings to consumers, health plans, employers, and the State during the previous calendar year and to date;

(5) information regarding implementation of the audit plan and audit findings; and

(6) any other information the Secretary of Human Services deems relevant.

(b) The provisions of 2 V.S.A. § 20(d) (expiration of required reports) shall not apply to the report to be made under this section.

Sec. 2. WHOLESAL IMPORTATION PROGRAM; **CONDITION FOR IMPLEMENTATION DESIGN CONTINGENT ON FUNDING**

The Agency of Human Services shall be required to design **and commence implementation** of the wholesale prescription drug importation program described in Sec. 1 of this act only to the extent that funds are appropriated for this purpose in the budget bill enacted by the General Assembly for fiscal year 2019 or are otherwise made available.