

1 S.175

2 Introduced by Senators Ashe, Ayer, Lyons, Pearson, and Sirotkin

3 Referred to Committee on

4 Date:

5 Subject: Health; prescription drugs; importation; Green Mountain Care Board;

6 Attorney General; bulk purchasing; health insurance; cost

7 containment

8 Statement of purpose of bill as introduced: This bill proposes to establish a
9 program to allow wholesale importation of prescription drugs from Canada
10 into Vermont. It would create a bulk purchasing program for prescription
11 drugs through the Department of Health and require prescription drug
12 manufacturers to provide notice before introducing new, high-cost drugs to the
13 market. The bill would also require health insurers to provide information
14 about the impact of prescription drug spending on premium rates as part of the
15 Green Mountain Care Board's rate review process and direct the Board to
16 publish an annual report demonstrating the overall impact of drug costs on
17 health insurance premiums.

18 An act relating to the wholesale importation of prescription drugs into
19 Vermont, bulk purchasing, and the impact of prescription drug costs on
20 health insurance premiums

1 It is hereby enacted by the General Assembly of the State of Vermont:

2 * * * Wholesale Importation Program * * *

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

4 Subchapter 4. Wholesale Prescription Drug Importation Program

5 § 4651. WHOLESAL IMPORTATION PROGRAM FOR PRESCRIPTION

6 DRUGS; DESIGN

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

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

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

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

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

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

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

10 (7) establish a fee on each prescription or establish another financing
11 mechanism to ensure that the program is funded adequately in a manner that
12 does not jeopardize significant consumer savings; and

13 (8) include a robust audit function.

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

18 § 4652. MONITORING FOR ANTICOMPETITIVE BEHAVIOR

19 The Agency of Human Services shall consult with the Office of the
20 Attorney General to identify the potential, and to monitor, for anticompetitive

1 behavior in industries that would be affected by a wholesale prescription drug
2 importation program.

3 § 4653. REQUEST FOR FEDERAL CERTIFICATION

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

8 § 4654. IMPLEMENTATION PROVISIONS

9 Upon certification and approval by the Secretary of the U.S. Department of
10 Health and Human Services, the Agency of Human Services shall begin
11 implementation of the wholesale prescription drug importation program and
12 shall begin operating the program within six months following the date of the
13 Secretary's approval. As part of the implementation process, the Agency of
14 Human Services shall, in accordance with State procurement and contract
15 laws, rules, and procedures as appropriate:

16 (1) become licensed as a wholesaler or enter into a contract with a
17 Vermont-licensed wholesaler;

18 (2) contract with one or more Vermont-licensed distributors;

19 (3) contract with one or more licensed and regulated Canadian suppliers;

20 (4) engage with health insurance plans, employers, pharmacies, health
21 care providers, and consumers;

1 (5) develop a registration process for health insurance plans,
2 pharmacies, and prescription drug-administering health care providers who are
3 willing to participate in the program;

4 (6) create a publicly available source for listing the prices of imported
5 prescription drug products that shall be made available to all participating
6 entities and consumers;

7 (7) create an outreach and marketing plan to generate program
8 awareness;

9 (8) starting in the weeks before the program becomes operational, create
10 and staff a hotline to answer questions and address the needs of consumers,
11 employers, health insurance plans, pharmacies, health care providers, and other
12 affected sectors;

13 (9) establish the audit function and a two-year audit work-plan
14 cycle; and

15 (10) conduct any other activities that the Agency determines to be
16 important for successful implementation of the program.

17 § 4655. ANNUAL REPORTING

18 (a) Annually on or before January 15, the Agency of Human Services shall
19 report to the House Committee on Health Care and the Senate Committees on
20 Health and Welfare and on Finance regarding the operation of the wholesale

1 prescription drug importation program during the previous calendar year,

2 including:

3 (1) which prescription drugs were included in the wholesale importation
4 program;

5 (2) the number of participating pharmacies, health care providers, and
6 health insurance plans;

7 (3) the number of prescriptions dispensed through the program;

8 (4) the estimated savings to consumers, health plans, employers, and the
9 State during the previous calendar year and to date;

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

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

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

16 * * * Bulk Purchasing of Prescription Drugs * * *

17 Sec. 2. 18 V.S.A. chapter 91, subchapter 5 is added to read:

18 Subchapter 5. Bulk Purchasing

19 § 4671. DEFINITIONS

20 As used in this subchapter:

1 (1) “Pharmacy benefit manager” shall have the same meaning as in
2 section 9471 of this title.

3 (2) “Prescription drug claims processor” means a person who does one
4 or more of the following:

5 (A) processes and pays prescription drug claims;

6 (B) adjudicates pharmacy claims;

7 (C) transmits prescription drug prices and claims data between
8 pharmacies and the bulk purchasing program established in this subchapter; or

9 (D) processes payments to pharmacies related to the bulk purchasing
10 program established in this subchapter.

11 § 4672. PRESCRIPTION DRUG BULK PURCHASING PROGRAM

12 (a) Purposes. There is established a bulk purchasing program for
13 prescription drugs in the Department of Health for the purposes of:

14 (1) purchasing prescription drugs or reimbursing pharmacies for
15 prescription drugs, or both, in order to receive discounted prices and rebates;

16 (2) making prescription drugs available at the lowest possible cost to
17 participants in the program; and

18 (3) maximizing the purchasing power of prescription drug consumers in
19 this State in order to negotiate the lowest possible prices for these consumers.

20 (b) Administration. The Department of Health shall administer the
21 program by:

1 (1) negotiating price discounts and rebates on prescription drugs with
2 prescription drug manufacturers;

3 (2) purchasing prescription drugs on behalf of participants in the
4 program;

5 (3) determining program prices and reimbursing pharmacies for
6 prescription drugs;

7 (4) developing a system for allocating and distributing among program
8 participants the program's operational costs and any rebates obtained;

9 (5) cooperating with other states or regional consortia in the bulk
10 purchase of prescription drugs; and

11 (6) establishing terms and conditions for pharmacies to enroll in the
12 program.

13 (c) Contracts. The Department may enter into contracts with pharmacy
14 benefit managers or prescription drug claims processors, or both.

15 (d) Application process.

16 (1) The Department shall create and distribute an application for
17 enrollment in the program.

18 (2) The Department may charge a participant a nominal fee to:

19 (A) process the application for enrollment in the program; and

20 (B) produce and distribute identification cards for the program.

1 (e) Program prices.

2 (1) The Department shall calculate and transmit to each enrolled
3 pharmacy the program price for each prescription drug included in the
4 program.

5 (2) An enrolled pharmacy shall charge a program participant the
6 program price for a prescription drug if the participant presents a valid
7 program identification card.

8 (f) Enrollment.

9 (1) Subject to subdivision (2) of this subsection and notwithstanding any
10 other provision of law to the contrary, the Department shall automatically
11 enroll in the program all consumers receiving prescription drugs through any
12 other State agency or department.

13 (2) Notwithstanding subdivision (1) of this subsection, if another State
14 agency or department demonstrates to the Department that program enrollment
15 would result in a net increase in costs to either the State or the consumers, the
16 other agency or department shall be exempt from automatic enrollment in the
17 bulk purchasing program established in this subchapter.

18 § 4673. FEDERAL WAIVER

19 If a federal waiver is necessary to enable the participation of any Vermont
20 consumer in the bulk purchasing program established in this subchapter, the
21 Department shall take all necessary steps to obtain the waiver, and any other

1 State agency or department that provides prescription drugs to Vermont
2 consumers shall cooperate with the Department in obtaining the waiver.

3 § 4674. RULES

4 The Department shall adopt rules pursuant to 3 V.S.A. chapter 25 as needed
5 to carry out the purposes of this subchapter. At a minimum, the rules shall
6 address:

7 (1) the enrollment of pharmacies in the program; and

8 (2) the issuance of prescription drug identification cards to participants
9 in the program.

10 § 4675. REPORTING REQUIREMENTS

11 (a) Annually on or before January 15, the Department of Health shall
12 provide a report on the progress of program implementation to the House
13 Committee on Health Care and the Senate Committees on Health and Welfare
14 and on Finance.

15 (b) Each report shall include the following information:

16 (1) the number of participants in the program during the previous
17 calendar year and the number of participants the Department anticipates for the
18 upcoming calendar year;

19 (2) the number of participants for whom the program has purchased
20 prescription drugs during the previous calendar year and to date, as well as the

1 number of participants for whom the program expects to purchase prescription
2 drugs during the upcoming calendar year;

3 (3) the total and average individual savings on prescription drug prices
4 for participants for the previous calendar year and to date, as well as the
5 projected total and average individual savings on prescription drug prices for
6 participants during the upcoming calendar year;

7 (4) progress toward expanding the program; and

8 (5) any recommendations for legislation that the Department feels are
9 necessary to implement the program further and to expand program
10 participation.

11 * * * Health Insurance Plan Reporting * * *

12 Sec. 3. 8 V.S.A. § 4062 is amended to read:

13 § 4062. FILING AND APPROVAL OF POLICY FORMS AND PREMIUMS

14 * * *

15 (b)(1) In conjunction with a rate filing required by subsection (a) of this
16 section, an insurer shall file a plain language summary of the proposed rate.
17 All summaries shall include a brief justification of any rate increase requested,
18 the information that the Secretary of the U.S. Department of Health and
19 Human Services (HHS) requires for rate increases over 10 percent, and any
20 other information required by the Board. The plain language summary shall be
21 in the format required by the Secretary of HHS pursuant to the Patient

1 Protection and Affordable Care Act of 2010, Public Law 111-148, as amended
2 by the Health Care and Education Reconciliation Act of 2010, Public Law 111-
3 152, and shall include notification of the public comment period established in
4 subsection (c) of this section. In addition, the insurer shall post the summaries
5 on its website.

6 (2)(A) In conjunction with a rate filing required by subsection (a) of this
7 section, an insurer shall disclose to the Board:

8 (i) for all covered prescription drugs, including generic drugs,
9 brand-name drugs excluding specialty drugs, and specialty drugs dispensed at a
10 pharmacy, network pharmacy, or mail-order pharmacy for outpatient use:

11 (I) the percentage of the premium rate attributable to
12 prescription drug costs for the prior year for each category of prescription
13 drugs;

14 (II) the year-over-year increase or decrease, expressed as a
15 percentage, in per-member, per-month total health plan spending on each
16 category of prescription drugs; and

17 (III) the year-over-year increase or decrease in per-member,
18 per-month costs for prescription drugs compared to other components of the
19 premium rate; and

20 (ii) the specialty tier formulary list.

1 Sec. 4. 18 V.S.A. § 4636 is added to read:

2 § 4636. IMPACT OF PRESCRIPTION DRUG COSTS ON HEALTH

3 INSURANCE PREMIUMS; REPORT

4 (a) Each health insurer with more than 200 covered lives in this State shall
5 report to the Green Mountain Care Board, for all covered prescription drugs,
6 including generic drugs, brand-name drugs, and specialty drugs provided in an
7 outpatient setting or sold in a retail setting:

8 (1) the 25 most frequently prescribed drugs and the average wholesale
9 price for each drug;

10 (2) the 25 most costly drugs by total plan spending and the average
11 wholesale price for each drug; and

12 (3) the 25 drugs with the highest year-over-year price increases and the
13 average wholesale price for each drug.

14 (b) The Green Mountain Care Board shall compile the information reported
15 pursuant to subsection (a) of this section into a consumer-friendly report that
16 demonstrates the overall impact of drug costs on health insurance premiums.
17 The data in the report shall be aggregated and shall not reveal information as
18 specific to a particular health benefit plan.

19 (c) The Board shall publish the report required pursuant to subsection (b) of
20 this section on its website on or before January 1 of each year. Information
21 provided to the Board pursuant to this section is exempt from inspection and

1 copying under the Public Records Act and shall be kept confidential except to
2 the extent it is aggregated and included in the report described in subsection (b)
3 of this section.

4 * * * Notice of New High-Cost Drugs * * *

5 Sec. 5. 18 V.S.A. § 4637 is added to read:

6 § 4637. NOTICE OF INTRODUCTION OF NEW HIGH-COST

7 PRESCRIPTION DRUGS

8 (a) As used in this section:

9 (1) “Manufacturer” shall have the same meaning as “pharmaceutical
10 manufacturer” in section 4631a of this title.

11 (2) “Prescription drug” means a drug as defined in 21 U.S.C. § 321.

12 (b) A prescription drug manufacturer shall notify the Office of the Attorney
13 General in writing if it is introducing a new prescription drug to market at a
14 wholesale acquisition cost that exceeds the threshold set for a specialty drug
15 under the Medicare Part D program. The manufacturer shall provide the
16 written notice within three calendar days following the release of the drug in
17 the commercial market. A manufacturer may make the notification pending
18 approval by the U.S. Food and Drug Administration (FDA) if commercial
19 availability is expected within three calendar days following the approval.

20 (c) Not later than 30 calendar days following notification pursuant to
21 subsection (b) of this section, the manufacturer shall provide all of the

1 following information to the Office of the Attorney General in a format that the
2 Office prescribes:

3 (1) a description of the marketing and pricing plans used in the launch of
4 the new drug in the United States and internationally;

5 (2) the estimated volume of patients who may be prescribed the drug;

6 (3) whether the drug was granted breakthrough therapy designation or
7 priority review by the FDA prior to final approval; and

8 (4) the date and price of acquisition if the drug was not developed by the
9 manufacturer.

10 (d) The manufacturer may limit the information reported pursuant to
11 subsection (c) of this section to that which is otherwise in the public domain or
12 publicly available.

13 (e) The Office of the Attorney General shall publish on its website at least
14 quarterly the information reported to it pursuant to this section. The
15 information shall be published in a manner that identifies the information that
16 is disclosed on a per-drug basis and shall not be aggregated in a manner that
17 would not allow identification of the drug.

18 (f) The Attorney General may bring an action in the Civil Division of the
19 Superior Court, Washington County for injunctive relief, costs, and attorney's
20 fees and to impose on a manufacturer that fails to provide the information
21 required by subsection (c) of this section a civil penalty of not more than

