

1 TO THE HONORABLE SENATE:

2 The Committee on Health and Welfare to which was referred Senate Bill
3 No. 175 entitled “An act relating to the wholesale importation of prescription
4 drugs into Vermont, bulk purchasing, and the impact of prescription drug costs
5 on health insurance premiums” respectfully reports that it has considered the
6 same and recommends that the bill be amended by striking out all after the
7 enacting clause and inserting in lieu thereof the following:

8 * * * Wholesale Importation Program * * *

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

10 Subchapter 4. Wholesale Prescription Drug Importation Program

11 § 4651. WHOLESALE IMPORTATION PROGRAM FOR PRESCRIPTION

12 DRUGS; DESIGN

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

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

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

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

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

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

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

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

18 (8) include a robust audit function.

19 (b) On or before January 1, 2019, the Secretary of Human Services shall
20 submit the proposed design for a wholesale prescription drug importation

1 program to the House Committee on Health Care and the Senate Committees
2 on Health and Welfare and on Finance.

3 § 4652. MONITORING FOR ANTICOMPETITIVE BEHAVIOR

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

8 § 4653. FEDERAL COMPLIANCE

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

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

19 § 4654. IMPLEMENTATION PROVISIONS

20 Upon certification and approval by the Secretary of the U.S. Department of
21 Health and Human Services, the Agency of Human Services shall begin

1 implementation of the wholesale prescription drug importation program and
2 shall begin operating the program within six months following the date of the
3 Secretary's approval. As part of the implementation process, the Agency of
4 Human Services shall, in accordance with State procurement and contract
5 laws, rules, and procedures as appropriate:

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

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

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

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

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

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

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

20 (8) starting in the weeks before the program becomes operational, create
21 and staff a hotline to answer questions and address the needs of consumers,

1 employers, health insurance plans, pharmacies, health care providers, and other
2 affected sectors;

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

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

7 § 4655. ANNUAL REPORTING

8 (a) Annually on or before January 15, the Agency of Human Services shall
9 report to the House Committee on Health Care and the Senate Committees on
10 Health and Welfare and on Finance regarding the operation of the wholesale
11 prescription drug importation program during the previous calendar year,
12 including:

13 (1) which prescription drugs were included in the wholesale importation
14 program;

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

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

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

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

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

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

5 * * * Bulk Purchasing of Prescription Drugs * * *

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

7 Subchapter 5. Bulk Purchasing

8 § 4671. DEFINITIONS

9 As used in this subchapter:

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

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

14 (A) processes and pays prescription drug claims;

15 (B) adjudicates pharmacy claims;

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

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

20 (3) “Wholesale drug distributor” shall have the same meaning as in 26
21 V.S.A. § 2022.

1 § 4672. PRESCRIPTION DRUG BULK PURCHASING PROGRAM

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

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

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

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

10 (b) Administration. The Department of Health shall administer the
11 program, with the assistance of a wholesale drug distributor if the Department
12 deems it appropriate, by:

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

15 (2) purchasing prescription drugs on behalf of participants in the
16 program;

17 (3) determining program prices and reimbursing pharmacies for
18 prescription drugs;

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

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

3 (6) establishing terms and conditions for pharmacies to enroll in the
4 program.

5 (c) Contracts. The Department may enter into contracts with one or more
6 of the following:

7 (1) pharmacy benefit managers;

8 (2) prescription drug claims processors; or

9 (3) wholesale drug distributors.

10 (d) Application process.

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

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

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

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

16 (e) Program prices.

17 (1) The Department shall calculate and transmit to each enrolled
18 pharmacy the program price for each prescription drug included in the
19 program.

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

4 (f) Enrollment.

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

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

14 § 4673. FEDERAL WAIVER

15 If a federal waiver is necessary to enable the participation of any Vermont
16 consumer in the bulk purchasing program established in this subchapter, the
17 Department shall take all necessary steps to obtain the waiver, and any other
18 State agency or department that provides prescription drugs to Vermont
19 consumers shall cooperate with the Department in obtaining the waiver.

1 § 4674. RULES

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

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

6 (2) the issuance of prescription drug identification cards to participants
7 in the program.

8 § 4675. REPORTING REQUIREMENTS

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

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

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

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

1 152, and shall include notification of the public comment period established in
2 subsection (c) of this section. In addition, the insurer shall post the summaries
3 on its website.

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

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

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

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

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

18 (ii) the specialty tier formulary list.

19 (B) The insurer shall provide, if available, the percentage of the
20 premium rate attributable to prescription drugs administered by a health care

1 provider in an outpatient setting that are part of the medical benefit as separate
2 from the pharmacy benefit.

3 (C) The insurer shall include information on its use of a pharmacy
4 benefit manager, if any, including which components of the prescription drug
5 coverage described in subdivisions (A) and (B) of this subdivision (2) are
6 managed by the pharmacy benefit manager, as well as the name of the
7 pharmacy benefit manager or managers used.

8 (c)(1) The Board shall provide information to the public on the Board's
9 website about the public availability of the filings and summaries required
10 under this section.

11 (2)(A) ~~Beginning no later than January 1, 2014, the~~ The Board shall post
12 the rate filings pursuant to subsection (a) of this section and summaries
13 pursuant to subsection (b) of this section on the Board's website within five
14 calendar days ~~of~~ following filing. The Board shall also establish a mechanism
15 by which members of the public may request to be notified automatically each
16 time a proposed rate is filed with the Board.

17 * * *

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

1 \$1,000.00 per day for every day after the notification period described in
2 subsection (b) of this section that the required information is not reported. In
3 any action brought pursuant to this section, the Attorney General shall have the
4 same authority to investigate and to obtain remedies as if the action were
5 brought under the Consumer Protection Act, 9 V.S.A. chapter 63.

6 * * * Disclosures by Pharmacists * * *

7 Sec. 6. 18 V.S.A. § 9473(b) is amended to read:

8 (b) A pharmacy benefit manager or other entity paying pharmacy claims
9 shall not:

10 (1) impose a higher co-payment for a prescription drug than the co-
11 payment applicable to the type of drug purchased under the insured's health
12 plan;

13 (2) impose a higher co-payment for a prescription drug than the
14 maximum allowable cost for the drug; ~~or~~

15 (3) require a pharmacy to pass through any portion of the insured's co-
16 payment to the pharmacy benefit manager or other payer;

17 (4) prohibit or penalize a pharmacy or pharmacist for providing
18 information to an insured regarding the insured's cost-sharing amount for a
19 prescription drug; or

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FOR THE COMMITTEE