TO THE HOUSE OF REPRESENTATIVES:

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

indicates changes from Senate passed; indicates changes from Draft 1.1

* * * Wholesale Importation Program * * *

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 prescription or establish another financing mechanism 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 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. 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. 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.

§ 4655. ANNUAL REPORTING

(a) Annually on or before January 15, the Agency of Human Services shall report to the House Committee on Health Care 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.

* * * Bulk Purchasing of Prescription Drugs * * *

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

Subchapter 5. Bulk Purchasing

§ 4671. DEFINITIONS

As used in this subchapter:

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

(2) "Prescription drug claims processor" means a person who does one or more of the following:

(A) processes and pays prescription drug claims;

(B) adjudicates pharmacy claims;

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

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

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

§ 4672. PRESCRIPTION DRUG BULK PURCHASING PROGRAM

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

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

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

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

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

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

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

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

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

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

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

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

(1) pharmacy benefit managers;

(2) prescription drug claims processors; or

(3) wholesale drug distributors.

(d) Application process.

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

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

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

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

(e) Program prices.

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

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

(f) Enrollment.

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

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

§ 4673. FEDERAL WAIVER

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

§ 4674. RULES

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

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

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

§ 4675. REPORTING REQUIREMENTS

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

(b) Each report shall include the following information:

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

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

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

(4) progress toward expanding the program; and

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

* * * Condition for Implementation of Secs. 1 and 2 * * *

Sec. 2a. WHOLESALE IMPORTATION AND BULK PURCHASING PROGRAMS; CONDITION FOR IMPLEMENTATION

The Agency of Human Services and the Department of Health shall be required to design and commence implementation of the wholesale prescription drug importation program described in Sec. 1 of this act and the bulk purchasing program described in Sec. 2 of this act only to the extent that funds are appropriated for either or both of these purposes in the budget bill enacted by the General Assembly for fiscal year 2019.

* * * Health Insurance Plan Reporting * * *

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

§ 4062. FILING AND APPROVAL OF POLICY FORMS AND PREMIUMS

* * *

(b)(1) In conjunction with a rate filing required by subsection (a) of this section, an insurer shall file a plain language summary of the proposed rate. All summaries shall include a brief justification of any rate increase requested, the information that the Secretary of the U.S. Department of Health and Human Services (HHS) requires for rate increases over 10 percent, and any other information required by the Board. The plain language summary shall be in the format required by the Secretary of HHS pursuant to the Patient Protection and Affordable Care Act of 2010, Public Law 111-148, as amended by the Health Care and Education Reconciliation Act of 2010, Public Law 111-152, and shall include notification of the public comment period established in subsection (c) of this section. In addition, the insurer shall post the summaries on its website.

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

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

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

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

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

(ii) the specialty tier formulary list.

(B) The insurer shall provide, if available, the percentage of the premium rate attributable to prescription drugs administered by a health care provider in an outpatient setting that are part of the medical benefit as separate from the pharmacy benefit.

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

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

(2)(A) ~~Beginning no later than January 1, 2014, the~~ The Board shall post the rate filings pursuant to subsection (a) of this section and summaries

pursuant to subsection (b) of this section on the Board's website within five calendar days ~~of~~ following filing. The Board shall also establish a mechanism by which members of the public may request to be notified automatically each time a proposed rate is filed with the Board.

* * *

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

§ 4636. IMPACT OF PRESCRIPTION DRUG COSTS ON HEALTH INSURANCE PREMIUMS; REPORT

(a)**(1)** Each health insurer with more than ~~**200**~~ **1,000** covered lives in this State shall report to the Green Mountain Care Board, for all covered prescription drugs, including generic drugs, brand-name drugs, and specialty drugs provided in an outpatient setting or sold in a retail setting:

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

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

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

(2) A health insurer shall not be required to provide to the Green Mountain Care Board the actual price paid, net of rebates, for any prescription drug.

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

(c) The Board shall publish the report required pursuant to subsection (b) of this section on its website on or before January 1 of each year. ~~**Information provided to the Board pursuant to this section is exempt from inspection and copying under the Public Records Act and shall be kept confidential except to the extent it is aggregated and included in the report described in subsection (b) of this section.**~~

* * * Prescription Drug Price Transparency and Notice of New High-Cost Drugs * * *

Sec. 5. 18 V.S.A. § 4635 is amended to read:

§ 4635. ~~**PHARMACEUTICAL**~~ **PRESCRIPTION DRUG** COST TRANSPARENCY

(a) As used in this section:

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

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

(b)(1)(A) The Green Mountain Care Board, in collaboration with the Department of Vermont Health Access, shall identify annually ~~up to 15~~ **10** prescription drugs**, representing different drug classes,** on which the State spends significant health care dollars and for which the wholesale acquisition cost has increased by 50 percent or more over the past five years or by 15 percent or more over the past 12 months, creating a substantial public interest in understanding the development of the drugs' pricing. ~~The drugs identified shall represent different drug classes.~~ **The Department of Vermont Health Access shall rank the drugs from those with the largest increase in their wholesale acquisition cost to those with the smallest increase; indicate whether each drug was included based on its cost increase over the past five years or over the past 12 months, or both; and provide the Department's total expenditure for each drug during the most recent fiscal year.**

(B) The Department of Vermont Health Access shall provide to the Green Mountain Care Board annually a list of 15 prescription drugs, representing different drug classes, on which the State spends significant health care dollars and for which the cost to the Department of Vermont Health Access, net of rebates, has increased by 50 percent or more over the past five years or by 15 percent or more over the past 12 months, creating a substantial public interest in understanding the development of

the drugs' pricing. The Department of Vermont Health Access shall rank the drugs from those with the greatest increase in their wholesale acquisition cost to those with the smallest increase; indicate whether each drug was included based on its cost increase over the past five years or over the past 12 months, or both; and provide the Department's total expenditure for each drug during the most recent fiscal year.

(C)(i) Each health insurer with more than 1,000 covered lives in this State shall provide to the Green Mountain Care Board annually a list of 15 prescription drugs, representing different drug classes, on which its health insurance plans spend significant amounts of their premium dollars and for which the cost to the plans, net of rebates, has increased by 50 percent or more over the past five years or by 15 percent or more over the past 12 months, creating a substantial public interest in understanding the development of the drugs' pricing.

(ii) A health insurer shall not be required to identify the exact percentage by which the cost to its plans for any prescription drug, net of rebates, increased over any specific period of time, but shall rank the drugs on its list in order from the largest to the smallest cost increase and shall provide the insurer's total expenditure for each drug during the most recent plan year.

~~(iii) Each health insurer shall have its list and the methodology underlying the development of the list reviewed by an actuary prior to providing the list to the Board in order to verify that cost to the insurer's plans for each prescription drug identified, net of rebates, increased by 50 percent or more over the past five years or by 15 percent or more over the past 12 months.~~

(2) The Board shall provide to the Office of the Attorney General the ~~list~~ **lists** of prescription drugs developed pursuant to this subsection and**, for the list in subdivision (1)(A) of this subsection,** the percentage of the wholesale acquisition cost increase for each drug**,** and shall make **all of** the information available to the public on the Board's website.

(c)(1) For each prescription drug identified pursuant to ~~subsection (b)~~ **subdivisions (b)(1)(B) and (C)** of this section, the Office of the Attorney General shall require the drug's manufacturer to provide ~~a justification~~ **all of the following:**

(A) Justification for the increase in the ~~wholesale acquisition~~ cost of the drug**, which shall be provided to the Office of the Attorney General** in a format that the Attorney General determines to be understandable and appropriate. The manufacturer shall submit to the Office of the Attorney General all relevant information and supporting documentation necessary to

justify the manufacturer's ~~wholesale acquisition~~ cost increase **over the identified period of time**, ~~which may include~~ **including**:

~~(A)~~**(i)** ~~all factors that have contributed to the wholesale acquisition created the~~ **each factor that specifically caused the** cost increase **over the specified period of time**;

~~(B)~~**(ii)** the percentage of the total ~~wholesale acquisition~~ cost increase attributable to each factor; and

~~(C)~~**(iii)** an explanation of the role of each factor in contributing to the ~~wholesale acquisition~~ cost increase.

(B) A version of the information submitted pursuant to subdivision (A) of this subdivision (1) that is in a format that can be easily understood by the public and in which any proprietary or confidential information has been redacted. The information, format, and redactions shall be subject to approval by the Office of the Attorney General.

(C) Additional information in response to all ~~reasonable~~ requests for such information by the Office of the Attorney General.

(2) Nothing in this section shall be construed to restrict the legal ability of a prescription drug manufacturer to change prices to the extent permitted under federal law.

(d) The Attorney General, in consultation with the Department of Vermont Health Access, shall provide a report to the General Assembly on or before

~~December 1~~ **February 1** of each year based on the information received from manufacturers pursuant to this section. The Attorney General shall also post the report on the Office of the Attorney General's website.

(e) ~~Information~~ **Except for the version of the information prepared for release to the public pursuant to subdivision (c)(1)(B) of this section, all information** provided to the Office of the Attorney General pursuant to this section is exempt from public inspection and copying under the Public Records Act and shall not be released in a manner that allows for the identification of an individual drug or manufacturer or that is likely to compromise the financial, competitive, or proprietary nature of the information.

(f) The Attorney General may bring an action in the Civil Division of the Superior Court, Washington County for injunctive relief, costs, and attorney's fees, and to impose on a manufacturer that fails to provide **any of** the information required by subsection (c) of this section **in the format requested by the Office of the Attorney General** a civil penalty of no more than $10,000.00 per violation. Each unlawful failure to provide information shall constitute a separate violation. In any action brought pursuant to this section, the Attorney General shall have the same authority to investigate and to obtain remedies as if the action were brought under the Consumer Protection Act, 9 V.S.A. chapter 63.

Sec. 7. 18 V.S.A. § 4637 is added to read:

§ 4637. NOTICE OF INTRODUCTION OF NEW HIGH-COST PRESCRIPTION DRUGS

(a) As used in this section:

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

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

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

(c) Not later than 30 calendar days following notification pursuant to subsection (b) of this section, the manufacturer shall provide all of the following information to the Office of the Attorney General in a format that the Office prescribes:

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

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

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

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

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

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

(f) The Attorney General may bring an action in the Civil Division of the Superior Court, Washington County for injunctive relief, costs, and attorney's fees and to impose on a manufacturer that fails to provide the information required by subsection (c) of this section a civil penalty of not more than $1,000.00 per day for every day after the notification period described in subsection (b) of this section that the required information is not reported. In any action brought pursuant to this section, the Attorney General shall have the

same authority to investigate and to obtain remedies as if the action were brought under the Consumer Protection Act, 9 V.S.A. chapter 63.

Sec. 7. IDENTIFICATION OF POTENTIAL PRICE GOUGING; FEASIBILITY ANALYSIS

The Department of Vermont Health Access shall determine the feasibility of identifying all or a subset of those prescription drugs for which the cost to the Department on behalf of Medicaid beneficiaries has increased by 30 percent or more over the past 12 months or by 50 percent or more over the past 24 months. On or before January 15, 2019, the Department shall provide the results of its feasibility analysis to the House Committee on Health Care and the Senate Committee on Health and Welfare.

* * * Disclosures by Pharmacists * * *

Sec. 8. 18 V.S.A. § 9473(b) is amended to read:

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

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

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

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

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

(5) prohibit or penalize a pharmacy or pharmacist for the pharmacist or other pharmacy employee disclosing to an insured the cash price for a prescription drug or selling a lower cost drug to the insured if one is available.

* * * Effective Dates * * *

Sec. 9. EFFECTIVE DATES

(a) Sec. 8 (18 V.S.A. § 9473; disclosures by pharmacists) shall take effect on July 1, 2018 and shall apply to all contracts taking effect on or after that date.

(b) The remaining sections shall take effect on passage.

(Committee vote: _____)

_____

Representative _____

FOR THE COMMITTEE