TO THE HONORABLE SENATE:

The Committee on Finance to which was referred Senate Bill No. 216 entitled "An act relating to prescription drug formularies" respectfully reports that it has considered the same and recommends that the bill be amended by striking out all after the enacting clause and inserting in lieu thereof the following:

* * * Prescription Drug Formularies * * *

Sec. 1. PRESCRIPTION DRUG FORMULARIES; RULEMAKING

On or before January 1, 2017, the Commissioner of Financial Regulation shall adopt rules pursuant to 3 V.S.A. chapter 25 to require all health insurance and other health benefit plans, including Medicare supplemental plans, that are offered to a Vermont resident by a health insurer or by a pharmacy benefit manager on behalf of a health insurer and provide coverage of prescription drugs to provide information to enrollees, potential enrollees, and health care providers about the plan's prescription drug formulary. The rules shall ensure that the formulary is posted online in a standard format established by the Department of Financial Regulation; that the formulary is updated frequently and is searchable by enrollees, potential enrollees, and health care providers; and that it includes information about the prescription drugs covered, applicable cost-sharing amounts, drug tiers, prior authorization, step therapy, and utilization management requirements.

* * * Statewide Prescription Drug Formulary * * *

Sec. 2. 18 V.S.A. chapter 91, subchapter 4 is added to read:

Subchapter 4. Statewide Prescription Drug Formulary

§ 4651. DEFINITIONS

As used in this subchapter:

(1) "Evidence-based" shall have the same meaning as in section 4622 of this title.

(2) "Health benefit plan" means a health insurance or other health benefit plan with prescription drug coverage offered or administered by a health insurer, as defined by section 9402 of this title, and the out-of-state counterparts to such plans. The term includes:

(A) any state public assistance program with a health benefit plan that provides coverage of prescription drugs;

(B) any health benefit plan offered by or on behalf of the State of Vermont or any instrumentality of the State providing coverage for government employees and their dependents; and

(C) any insured or self-insured health benefit plan that elects to participate in the preferred drug list.

(3) "State public assistance program" includes the Medicaid program, the State Children's Health Insurance Program, VPharm, the State of Vermont AIDS medication assistance program, the General Assistance program, the

Pharmacy Discount Plan program, and the out-of-state counterparts to such programs.

§ 4652. STATEWIDE PREFERRED DRUG LIST

(a) The Drug Utilization Review Board established in connection with Vermont's Medicaid program shall develop and maintain a preferred drug list applicable to all health benefit plans covering Vermont lives.

(b)(1) The Drug Utilization Review Board's selection of drugs for inclusion on the preferred drug list shall be based upon evidence-based considerations of clinical efficacy, adverse side effects, safety, appropriate clinical trials, and cost-effectiveness. The Medical Director of the Department of Vermont Health Access shall provide the Board with evidence-based information about clinical efficacy, adverse side effects, safety, and appropriate clinical trials, and shall provide information about cost-effectiveness of available drugs in the same therapeutic class. Health benefit plans covering Vermont lives may also submit evidence-based information listed in this subdivision to the Board for its consideration.

(2) The Board may identify separate drugs within the same therapeutic class as preferred for health insurance plans and for state public assistance programs to reflect differences in available manufacturer rebates and discounts.

(3) The Board shall meet at least quarterly. The Board shall comply with the requirements of 1 V.S.A. chapter 5, subchapters 2 (Open Meetings Law) and 3 (Public Record Act), except that the Board may go into executive session:

(A) to discuss drug alternatives;

(B) to receive information on the relative price, net of any rebates, of a drug under discussion and the drug price in comparison to the prices, net of any rebates, of alternative drugs available in the same class to determine cost-effectiveness; and

(C) in compliance with 33 V.S.A. § 2002(c), to consider information relating to a pharmaceutical rebate or to supplemental rebate agreements, which is protected from disclosure by federal law or the terms and conditions required by the Centers for Medicare and Medicaid Services as a condition of rebate authorization under the Medicaid program.

(4) To the extent feasible, the Board shall review all drug classes included in the preferred drug list at least every 12 months, and may make additions to or deletions from the preferred drug list.

(5) The program shall establish Board procedures for the timely review of prescription drugs newly approved by the federal Food and Drug Administration, including procedures for the review of newly approved prescription drugs in emergency circumstances.

(6) Members of the Board shall receive per diem compensation and reimbursement of expenses in accordance with 32 V.S.A. § 1010.

Sec. 3. 1 V.S.A. § 313(a)(9) is amended to read:

(9) information relating to a pharmaceutical rebate or to supplemental rebate agreements, which is protected from disclosure by federal law or the terms and conditions required by the Centers for Medicare and Medicaid Services as a condition of rebate authorization under the Medicaid program, considered pursuant to ~~33 V.S.A. §§ 1998(f)(2) and 2002(c)~~ 18 V.S.A. § 4652(b)(3)(C) and 33 V.S.A. § 2002(c);

Sec. 4. 8 V.S.A. § 4088e is amended to read:

§ 4088e. NOTICE OF PREFERRED DRUG LIST CHANGES

On a periodic basis, no less than once per calendar year, a health insurer as defined in 18 V.S.A. § 9471(2)(A), (C), and (D) shall notify beneficiaries of changes in pharmaceutical coverage and provide access to the preferred drug list established and maintained ~~by the insurer~~ pursuant to 18 V.S.A. chapter 91, subchapter 4.

Sec. 5. 33 V.S.A. § 1901b(a) is amended to read:

(a) The Department of Vermont Health Access and the Department for Children and Families shall monitor actual caseloads, revenue, and expenditures; anticipated caseloads, revenue, and expenditures; and actual and anticipated savings from implementation of the preferred drug list established

pursuant to 18 V.S.A. chapter 91, subchapter 4, supplemental rebates, and other cost containment activities in each State pharmaceutical assistance program, including VPharm. When applicable, the Departments shall allocate supplemental rebate savings to each program proportionate to expenditures in each program.

Sec. 6. 33 V.S.A. § 1998 is amended to read:

§ 1998. PHARMACY BEST PRACTICES AND COST CONTROL PROGRAM ESTABLISHED

(a) The Commissioner of Vermont Health Access shall establish and maintain a Pharmacy Best Practices and Cost Control Program designed to reduce the cost of providing prescription drugs, while maintaining high quality in prescription drug therapies. The Program shall include:

(1) ~~use of an evidence-based preferred list of covered prescription drugs that identifies preferred choices within therapeutic classes for particular diseases and conditions, including generic alternatives and over-the-counter drugs;~~ [Repealed.]

(2) utilization review procedures, including a prior authorization review process;

(3) any strategy designed to negotiate with pharmaceutical manufacturers to lower the cost of prescription drugs for Program participants, including a supplemental rebate program;

(4) alternative pricing mechanisms, including consideration of using maximum allowable cost pricing for generic and other prescription drugs;

(5) alternative coverage terms, including consideration of providing coverage of over-the-counter drugs where cost-effective in comparison to prescription drugs, and authorizing coverage of dosages capable of permitting the consumer to split each pill if cost-effective and medically appropriate for the consumer;

(6) a simple, uniform prescription form, designed to implement the preferred drug list established pursuant to 18 V.S.A. chapter 91, subchapter 4, and to enable prescribers and consumers to request an exception to the preferred drug list choice with a minimum of cost and time to prescribers, pharmacists, and consumers;

(7) a joint pharmaceuticals purchasing consortium as provided for in subdivision (c)(1) of this section; and

(8) any other cost containment activity adopted, by rule, by the Commissioner that is designed to reduce the cost of providing prescription drugs while maintaining high quality in prescription drug therapies.

* * *

(d) A participating health benefit plan other than a State public assistance program may agree with the Commissioner to limit the plan's participation to one or more program components. The Commissioner shall supervise the

implementation and operation of the Pharmacy Best Practices and Cost Control Program~~, including developing and maintaining the preferred drug list,~~ to carry out the provisions of the subchapter. The Commissioner may include such insured or self-insured health benefit plans as agree to use the preferred drug list established pursuant to 18 V.S.A. chapter 91, subchapter 4 or otherwise participate in the provisions of this subchapter. The purpose of this subchapter is to reduce the cost of providing prescription drugs while maintaining high quality in prescription drug therapies.

* * *

(f)~~(1) The Drug Utilization Review Board shall make recommendations to the Commissioner for the adoption of the preferred drug list. The Board's recommendations shall be based upon evidence-based considerations of clinical efficacy, adverse side effects, safety, appropriate clinical trials, and cost-effectiveness. "Evidence-based" shall have the same meaning as in 18 V.S.A. § 4621. The Commissioner shall provide the Board with evidence-based information about clinical efficacy, adverse side effects, safety, and appropriate clinical trials and shall provide information about cost-effectiveness of available drugs in the same therapeutic class.~~

~~(2) The Board shall meet at least quarterly. The Board shall comply with the requirements of 1 V.S.A. chapter 5, subchapter 2 (Open Meeting Law) and 1 V.S.A. chapter 5, subchapter 3 (Public Records Act), except that the~~

~~Board may go into executive session to discuss drug alternatives and receive information on the relative price, net of any rebates, of a drug under discussion and the drug price in comparison to the prices, net of any rebates, of alternative drugs available in the same class to determine cost-effectiveness, and in order to comply with subsection 2002(c) of this title to consider information relating to a pharmaceutical rebate or to supplemental rebate agreements, which are protected from disclosure by federal law or the terms and conditions required by the Centers for Medicare and Medicaid Services as a condition of rebate authorization under the Medicaid program.~~

~~(3) To the extent feasible, the Board shall review all drug classes included in the preferred drug list at least every 12 months and may recommend that the Commissioner make additions to or deletions from the preferred drug list.~~

~~(4) The Program shall establish Board procedures for the timely review of prescription drugs newly approved by the federal Food and Drug Administration, including procedures for the review of newly approved prescription drugs in emergency circumstances.~~

~~(5) Members of the Board shall receive per diem compensation and reimbursement of expenses in accordance with 32 V.S.A. § 1010.~~

~~(6)~~ The Commissioner shall encourage participation in the joint purchasing consortium by inviting representatives of the programs and entities

specified in subdivision (c)(1) of this section to participate as observers or nonvoting members in the Drug Utilization Review Board and by inviting the representatives to use the preferred drug list established pursuant to 18 V.S.A. chapter 91, subchapter 4 in connection with the plans' prescription drug coverage.

(g) The Department shall seek assistance from entities conducting independent research into the effectiveness of prescription drugs to provide technical and clinical support in the development and the administration of the preferred drug list established pursuant to 18 V.S.A. chapter 91, subchapter 4 and the evidence-based education program established in 18 V.S.A. chapter 91, subchapter 2.

Sec. 7. 33 V.S.A. § 1999 is amended to read:

§ 1999. CONSUMER PROTECTION RULES; PRIOR AUTHORIZATION

(a)(1) The Pharmacy Best Practices and Cost Control Program shall authorize pharmacy benefit coverage when a patient's health care provider prescribes a prescription drug not on the preferred drug list established pursuant to 18 V.S.A. chapter 91, subchapter 4, or a prescription drug ~~which~~ that is not the list's preferred choice, if either of the circumstances set forth in subdivision (2) or (3) of this subsection applies.

(2)(A) The Program shall authorize coverage under the same terms as coverage for preferred choice drugs if the prescriber determines, after

consultation with the pharmacist, or with the participating health benefit plan if required by the terms of the plan, that:

(i) the preferred choice has not been effective, or with reasonable certainty is not expected to be effective, in treating the patient's condition; or

(ii) the preferred choice causes or is reasonably expected to cause adverse or harmful reactions in the patient.

(B) The prescriber's determination concerning whether the standards established in this subdivision (2) have been demonstrated shall be final if any documentation required at the direction of the Drug Utilization Review Board has been provided.

(3) The Program shall authorize coverage if the patient agrees to pay any additional cost in excess of the benefits provided by the patient's health benefit plan which is participating in the Program. The provisions of this subdivision (3) shall not apply to the extent that they may be inconsistent with any federal Medicaid laws and regulations. The provisions of this subdivision (3) shall not affect implementation by a participating health benefit plan of tiered copayments or other similar cost sharing systems.

(b) The Program or any participating health benefit plan shall provide information on how prescribers, pharmacists, beneficiaries, and other interested parties can obtain a copy of the preferred drug list established pursuant to 18 V.S.A. chapter 91, subchapter 4, whether any change has been

made to the preferred drug list since it was last issued, and the process by which exceptions to the preferred list may be made.

(c) For HIV and AIDS-related medications used by individuals with HIV or AIDS, the preferred drug list established pursuant to 18 V.S.A. chapter 91, subchapter 4 and any utilization review procedures shall not be more restrictive than the drug list and the application of the list used for the State of Vermont AIDS Medication Assistance Program.

(d) The Agency may include prescription drugs prescribed for the treatment of severe and persistent mental illness, including schizophrenia, major depression, or bipolar disorder, in the prior authorization process ~~after the Health Care Oversight Committee has reviewed the report as provided for in 2005 Acts and Resolves No. 71, Sec. 305(a)(2)(A)~~.

* * *

Sec. 8. 33 V.S.A. § 2001 is amended to read:

§ 2001. LEGISLATIVE OVERSIGHT

(a) In connection with the Pharmacy Best Practices and Cost Control Program established pursuant to this chapter and the statewide preferred drug list established pursuant to 18 V.S.A. chapter 91, subchapter 4, the Commissioner of Vermont Health Access shall report for review by the ~~Health Care Oversight Committee, prior to initial implementation, and~~ House Committees on Appropriations, on Health Care, and on Human Services and

the Senate Committees on Appropriations and on Health and Welfare prior to any subsequent modifications:

(1) the compilation that constitutes the preferred drug list or list of drugs subject to prior authorization or any other utilization review procedures;

(2) any utilization review procedures, including any prior authorization procedures; and

(3) the procedures by which drugs will be identified as preferred on the preferred drug list, and the procedures by which drugs will be selected for prior authorization or any other utilization review procedure.

(b) The ~~Health Care Oversight Committee~~ Committees shall closely monitor implementation of the preferred drug list and utilization review procedures to ensure that the consumer protection standards enacted pursuant to section 1999 of this title are not diminished as a result of implementing the preferred drug list and the utilization review procedures, including any unnecessary delay in access to appropriate medications. The ~~Committee~~ Committees shall ensure that all affected interests, including consumers, health care providers, pharmacists, and others with pharmaceutical expertise have an opportunity to comment on the preferred drug list and procedures reviewed under this subsection.

(c) The Commissioner of Vermont Health Access shall report annually on or before August 31 to the ~~Health Reform Oversight Committee~~ House

Committees on Appropriations, on Health Care, and on Human Services and the Senate Committees on Appropriations and on Health and Welfare concerning the Pharmacy Best Practices and Cost Control Program and the statewide preferred drug list. Topics covered in the report shall include issues related to drug cost and utilization; the effect of national trends on the pharmacy program; comparisons to other states; and decisions made by the Department's Drug Utilization Review Board in relation to both drug utilization review efforts and the placement of drugs on the Department's preferred drug list.

* * *

Sec. 9. 33 V.S.A. § 2002(a) is amended to read:

(a) The Commissioner of Vermont Health Access, separately or in concert with the authorized representatives of any participating health benefit plan, shall use the preferred drug list ~~authorized by the Pharmacy Best Practices and Cost Control Program~~ established pursuant to 18 V.S.A. chapter 91, subchapter 4 to negotiate with pharmaceutical companies for the payment to the Commissioner of supplemental rebates or price discounts for Medicaid and for any other State public assistance health benefit plans designated by the Commissioner, in addition to those required by Title XIX of the Social Security Act. The Commissioner may also use the preferred drug list to negotiate for the payment of rebates or price discounts in connection with

drugs covered under any other participating health benefit plan within or outside this State, provided that such negotiations and any subsequent agreement shall comply with the provisions of 42 U.S.C. § 1396r-8. The Program, or such portions of the Program as the Commissioner shall designate, shall constitute a State pharmaceutical assistance program under 42 U.S.C. § 1396r-8(c)(1)(C).

Sec. 10. 33 V.S.A. § 2076(a) is amended to read:

(a) All public pharmaceutical assistance programs shall provide coverage for those over-the-counter pharmaceuticals on the preferred drug list developed ~~under section 1998 of this title~~ pursuant to 18 V.S.A. chapter 91, subchapter 4, provided the pharmaceuticals are authorized as part of the medical treatment of a specific disease or condition, and they are a less costly, medically appropriate substitute for currently covered pharmaceuticals.

Sec. 11. 18 V.S.A. § 4635 is added to read:

§ 4635. PRESCRIPTION DRUG COST TRANSPARENCY

(a) The Green Mountain Care Board shall develop a list of critical prescription drugs for which there is a substantial public interest in understanding the development of their pricing. In developing the list, the Board shall consider the following factors:

(1) the cost of the drug to public health care programs, including Medicaid and the State employees' health plan;

(2) the current cost of the drug in Vermont;

(3) the extent to which the drug is used in Vermont; and

(4) the potential impact of the drug's cost on Vermont's efforts to contain health care costs.

(b) For each prescription drug that the Green Mountain Care Board places on the critical prescription drug list pursuant to subsection (a) of this section, the Board shall require the drug's manufacturer to report the following information:

(1) total cost of production, and approximate cost of production per dose;

(2) research and development costs for the drug, including:

(A) research and development costs paid for with public funds;

(B) after-tax research and development costs paid by the manufacturer; and

(C) research and development costs paid for by third parties;

(3) marketing and advertising costs for the drug, apportioned by marketing activities directed to consumers, marketing activities directed to prescribers, and the total cost of all marketing and advertising directed primarily to Vermont consumers and prescribers;

(4) the prices for the drug that are charged to purchasers outside the United States, by country, for a representative set of countries determined by the Board;

(5) prices charged to typical Vermont purchasers, including pharmacies, pharmacy chains, pharmacy wholesalers, and other direct purchasers; and

(6) true net typical prices charged to prescription drug manufacturers for distribution in Vermont, net of any rebates or other payments from the manufacturer to the pharmacy benefit manager and the pharmacy benefit manager to the manufacturer.

(c) The Green Mountain Care Board shall adopt rules pursuant to 3 V.S.A. chapter 25 to define further and enforce the provisions of this section, which may include monetary penalties for failure to comply with the requirements of this section.

(d) Information reported pursuant to subsection (b) of this section is exempt from public inspection and copying under the Public Records Act and shall not be released. Any public reporting of the information shall be aggregated in order to protect the financial, competitive, or proprietary nature of the information.

Sec. 12. 18 V.S.A. § 4636 is added to read:

§ 4636. DETERMINATION OF EXCESSIVE DRUG PRICES

(a) The Green Mountain Care Board shall identify, using information submitted pursuant to section 4635 of this title, those prescription drugs that due to their cost, jeopardize Vermont's efforts to contain health care costs. In reviewing the information, the Board shall consider all data reported and determine whether the price of the prescription drug is significantly high, given:

(1) the prescription drug's medical benefits;

(2) the cost to develop and manufacture the prescription drug; and

(3) the prices charged by the manufacturer in other countries.

(b) If the Board determines that the price of a prescription drug is significantly high, the Board shall forward the relevant information to the Office of the Attorney General, which may investigate for anticompetitive practices or possible violations of Vermont's consumer protection laws.

Sec. 13. EFFECTIVE DATES

(a) Secs. 1 (prescription drug formulary; rulemaking) and 11–12 (prescription drug cost transparency) and this section shall take effect on passage.

(b) Secs. 2–10 (statewide prescription drug formulary) shall take effect on July 1, 2017, except the provisions in Sec. 1 allowing the Drug Utilization

Review Board to develop the statewide preferred drug list shall take effect immediately upon passage to ensure implementation on July 1, 2017.

(Committee vote: _____)

_____

Senator _____

FOR THE COMMITTEE