S.98

Introduced by Senators Ram Hinsdale, Cummings, Gulick, Hashim, Lyons, MacDonald and Watson

Referred to Committee on Health and Welfare

Date: February 23, 2023

Subject: Health; prescription drugs; Green Mountain Care Board

Statement of purpose of bill as introduced: This bill proposes to authorize and direct the Green Mountain Care Board to evaluate the costs of certain high-cost prescription drugs and recommend methods for addressing those costs, including setting limits on what Vermonters would be expected to pay for some high-cost drugs. The bill would also require the Board to submit a report on generic drugs and generic drug prices.

An act relating to Green Mountain Care Board authority over prescription drug costs

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

Sec. 1. 18 V.S.A. chapter 91, subchapter 5 is added to read:

Subchapter 5. Prescription Drug Affordability

§ 4671. DEFINITIONS

As used in this subchapter:

(1) "Biologic" means a drug that is produced or distributed in accordance with a biologics license application approved under 42 C.F.R. § 447.502.

(2) "Biosimilar" means a drug that is produced or distributed in accordance with a biologics license application approved under 42 U.S.C. § 262(k)(3).

(3) "Board" means the Green Mountain Care Board established pursuant to chapter 220 of this title.

(4) "Brand-name drug" means a drug produced or distributed in accordance with an original new drug application approved under 21 U.S.C. § 355(c). The term does not include an authorized generic drug as defined in 42 C.F.R. § 447.502.

(5) "Generic drug" or "generic" means:

(A) a retail drug that is marketed or distributed in accordance with an abbreviated new drug application approved under 21 U.S.C. § 355(j);

(B) an authorized generic drug, as defined in 42 C.F.R. § 447.502; or

(C) a drug that entered the market before 1962 that was not originally marketed under a new drug application.

(6) "Health care provider" has the same meaning as in section 4631a of this chapter.

(7) "Health insurer" has the same meaning as in section 9402 of this title.

(8) "Health plan" means a health benefit plan offered, issued, or administered by a health insurer doing business in Vermont.

(9) "Manufacturer" means an entity that:

(A)(i) owns the patent to a prescription drug product; or

(ii) enters into a lease with another manufacturer to market and distribute a prescription drug product under the entity's own name; and

(B) sets or changes the wholesale acquisition cost of the prescription drug product it manufactures or markets.

(10) "Prescription drug product" means a brand-name drug, a generic drug, a biologic, or a biosimilar.

§ 4672. GREEN MOUNTAIN CARE BOARD; COST AFFORDABILITY REVIEW

(a) Scope of review; public input. The Green Mountain Care Board shall identify high-cost prescription drug products for a potential review of their affordability under this section.

(1) The Green Mountain Care Board shall limit its review of prescription drug products to those that are:

(A) brand-name drugs or biologics that, as adjusted annually for inflation in accordance with the Consumer Price Index, have:

(i) a wholesale acquisition cost of $60,000.00 or more per year or per course of treatment, if less than a year; or

(ii) a wholesale acquisition cost increase of $3,000.00 or more in any 12-month period;

(B) biosimilar drugs that have a wholesale acquisition cost that is not at least 20 percent lower than the brand-name biologic reference product at the time the biosimilars are launched;

(C) generic drugs that, as adjusted annually for inflation in accordance with the Consumer Price Index, have a wholesale acquisition cost:

(i) of $100.00 or more for a 30-day supply or for a course of treatment of less than 30 days; and

(ii) increased by 200 percent or more during the immediately preceding 12-month period, as determined by the difference between the resulting wholesale acquisition cost and the average of the wholesale acquisition cost reported over the immediately preceding 12 months; and

(D) other prescription drug products that the Board, in consultation with the Prescription Drug Affordability Stakeholder Advisory Council established pursuant section 4674 of this subchapter, determines may create affordability challenges for the State's health care system and for patients, including drugs to address public health emergencies.

(2) The Board shall solicit public input on prescription drugs thought to be creating affordability challenges that meet the parameters set forth in subdivision (1)(A)–(D) of this subsection.

(b) Selection for review. After identifying prescription drug products pursuant to subsection (a) of this section, the Board shall determine whether to conduct a full affordability review for the proposed prescription drugs after compiling preliminary information about the cost of the product, patient cost sharing for the product, health plan spending on the product, and stakeholder input and other information decided by the Board.

(c) Information used in review.

(1) The information the Board uses to conduct an affordability review may include any document or research related to the manufacturer's selection of the introductory price or price increase of the prescription drug product, patient assistance programs specific to the product, estimated or actual manufacturer produce price concessions in the market, net product cost to State payers, and other information as determined by the Board.

(2) The failure of a manufacturer to provide the Board with information for an affordability review shall not affect the Board's authority to conduct such a review.

(3) In determining whether a drug creates affordability challenges or in determining an upper payment limit amount pursuant to subsection (e) of this

section and section 4673 of this chapter, the Board shall not use cost-effectiveness analyses that include cost per quality-adjusted life year or similar measures to identify subpopulations for which a treatment would be less cost-effective due to severity of illness, age, or preexisting disability. In addition, for any treatment that extends life, if the Board uses cost-effectiveness results, the Board shall use results that weight the value of all additional lifetime gained equally for all patients, regardless of their severity of illness, age, or preexisting disability.

(4) Notwithstanding any provision of 1 V.S.A. § 312 or 313 to the contrary, the Board may meet in executive session to discuss proprietary data and information or to hear from an expert witness who will discuss proprietary data and information.

(d) Affordability review criteria. When the Board conducts a review of the affordability of a prescription drug product, the review shall determine whether use of the prescription drug product in a manner fully consistent with the labeling approved by the U.S. Food and Drug Administration or standard medical practice has led or is likely to lead to affordability challenges for Vermont's health care system or to high out-of-pocket costs for patients, or both.

(e) Upper payment limit.

(1) If the Board finds that spending on a prescription drug product reviewed pursuant to this section has led or is likely to lead to affordability challenges, the Board shall establish an upper payment limit in accordance with section 4673 of this chapter that takes into consideration any exceptional administrative costs related to the distribution of the drug in this State.

(2) The upper payment limit established by the Board for a prescription drug product shall apply to all purchases of and payer reimbursements for the prescription drug product intended for use by individuals in Vermont in person, by mail, or by any other means.

(f) Public comment. The Board shall provide an opportunity for the public to provide written comments on pending affordability decisions.

(g) Rulemaking. The Green Mountain Care Board may adopt rules in accordance with 3 V.S.A. chapter 25 as needed to carry out its duties under this section.

(h) Marketing permitted. Nothing in this section shall be construed to prevent a manufacturer from marketing a prescription drug product approved by the U.S. Food and Drug Administration while the product is under review by the Board.

(i) Enforcement. The Chair of the Green Mountain Care Board shall have the same authority to enforce the provisions of this subchapter as are available to the Chair under chapter 220 of this title.

(j) Appeals. Any person aggrieved by a decision of the Green Mountain Care Board under this section may appeal the Board's decision in accordance with the provisions of section 9381 of this title.

§ 4673. UPPER PAYMENT LIMITS; APPLICABILITY; EXEMPTIONS

(a)(1)(A) The upper payment limits for prescription drug products established by the Green Mountain Care Board pursuant to subsection 4672(e) of this chapter shall apply to all health plans and health benefit programs regulated, offered, or administered by the State, including individual and group health benefit plans; health plans offered to State employees, teachers, and other public employees; and the Medicaid program.

(B) An upper payment limit shall not include either the pharmacy dispensing fee or the provider administration fee.

(2)(A) Upper payment limits established by the Board pursuant to subsection 4672(e) of this chapter shall not apply to Medicare Part D plans or to employee benefit plans that the State is preempted from regulating under the Employee Retirement Income Security Act, 29 U.S.C. § 1001 et seq. These plans may choose to reimburse for prescription drug products in amounts that exceed Board-established upper payment limits.

(B) The Board shall not create an upper payment limit that differs from the Medicare maximum fair price for any drug for which the Secretary of

the U.S. Department of Health and Human Services has negotiated a price under the Medicare Drug Price Negotiation Program.

(3) The Board shall consider how upper payment limits would affect health care providers participating in the federal 340B drug pricing program.

(b)(1) Health care providers who dispense or administer prescription drug products to patients in this State shall bill all payers not more than the upper payment limit for dispensing or administering a prescription drug product for which the Board has set an upper payment limit pursuant to subsection 4672(e) of this chapter, regardless of whether a payer administering a plan described in subdivision (a)(2) of this section chooses to reimburse the provider in an amount that exceeds the Board-established upper payment limit.

(2) Independent pharmacies licensed by this State pursuant to 26 V.S.A. chapter 36 shall not be reimbursed less than the upper payment limit.

(c) An upper payment limit shall take effect not sooner than six months after it is announced.

§ 4674. PRESCRIPTION DRUG AFFORDABILITY STAKEHOLDER ADVISORY COUNCIL

(a) There is created the Prescription Drug Affordability Stakeholder Advisory Council to assist and advise the Green Mountain Care Board in making the decisions required under this subchapter.

(b)(1) The Council shall be composed of the following 15 members:

(A) five members appointed by the Speaker of the House;

(B) five members appointed by the Senate President Pro Tempore; and

(C) five members appointed by the Governor.

(2) The members appointed to the Council shall have knowledge in one or more of the following:

(A) the pharmaceutical business model;

(B) supply chain business models;

(C) the practice of medicine or clinical training;

(D) consumer or patient perspectives;

(E) clinical and health services research; or

(F) the State's health care marketplace.

(3) Members of the Council shall serve three-year terms and members may be reappointed to additional terms.

(c) The Council shall have the administrative, technical, and legal assistance of the Green Mountain Care Board.

(d) The Chair of the Green Mountain Care Board shall appoint one of the members of the Council to be the Council's Chair.

(e) Members of the Council shall not receive compensation for their service on the Council but shall be entitled to reimbursement of expenses as

permitted under 32 V.S.A. § 1010. These reimbursements shall be made from monies appropriated to the Green Mountain Care Board.

Sec. 2. 18 V.S.A. § 9375 is amended to read:

§ 9375. DUTIES

(a) The Board shall execute its duties consistent with the principles expressed in section 9371 of this title.

(b) The Board shall have the following duties:

* * *

(16)(A) Identify high-cost prescription drugs, evaluate their affordability, and set upper payment limits as appropriate in accordance with chapter 91, subchapter 5 of this title.

(B) Based on its work under chapter 91, subchapter 5 of this title, the Board shall include in its annual report pursuant to subsection (d) of this section:

(i) information on price trends for prescription drug products;

(ii) the number of prescription drug products that were subject to Board review, including the results of the reviews and the number and disposition of any appeals to the Board and to the Vermont Supreme Court; and

(iii) any recommendations for further legislative action needed to make prescription drug products more affordable in this State.

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Sec. 3. PRESCRIPTION DRUG AFFORDABILITY STAKEHOLDER ADVISORY COUNCIL; IMPLEMENTATION

(a) The Chair of the Green Mountain Care Board shall call the first meeting of the Prescription Drug Affordability Stakeholder Advisory Council to occur on or before February 1, 2024.

(b) Notwithstanding any provision of 18 V.S.A. § 4674 to the contrary, the initial members of the Council shall serve staggered terms as follows:

(1) the terms of two members appointed by each appointing authority shall expire in 2026;

(2) the terms of two members appointed by each appointing authority shall expire in 2027; and

(3) the terms of one member appointed by each appointing authority shall expire in 2028.

Sec. 4. GENERIC DRUG MARKET; GREEN MOUNTAIN CARE BOARD; REPORT

On or before January 15, 2025, the Green Mountain Care Board shall report to the House Committee on Health Care and the Senate Committee on Health and Welfare regarding the operation of the generic drug market in the United States and in Vermont, including generic physician-administered drugs, that addresses:

~~(1) the price trend of generic drugs on a year over year basis;~~

~~(2)~~ the degree to which generic drug prices affect health insurance premiums based on the information provided to the Board pursuant to 18 V.S.A. § 4636;

(3) recent and current trends in patient cost-sharing for generic drugs;

(4) the causes and prevalence of generic drug shortages; and

(5) any other relevant information regarding generic drugs and generic drug prices.

Sec. 5. REPEAL

18 V.S.A. § 4635 (prescription drug cost transparency) is repealed.

Sec. 6. EFFECTIVE DATE

~~This act shall take effect on July 1, 2023.~~

Sec. 1. GREEN MOUNTAIN CARE BOARD; PRESCRIPTION DRUG COST REGULATION PROGRAM; IMPLEMENTATION PLAN

(a) The Green Mountain Care Board, in consultation with its own technical advisory groups and other State agencies, shall explore and create a framework and methodology for implementing a program to regulate the cost of prescription drugs for Vermont consumers and Vermont's health care system. The Board shall consider options for and likely impacts of regulating the cost of prescription drugs, including:

(1) the experiences of states that have developed prescription drug affordability boards;

(2) the Centers for Medicare and Medicaid Services' development and operation of the Medicare Drug Price Negotiation Program;

(3) other promising federal and state strategies for lowering prescription drug costs;

(4) the Board's existing authority to set rates, adopt rules, and establish technical advisory groups;

(5) the likely return on investment of the most promising program options; and

(6) the impact of implementing a program to regulate the costs of prescription drugs on other State agencies and on the private sector.

(b)(1) On or before January 15, 2025, the Board shall provide its preliminary plan for implementing a program to regulate the cost of prescription drugs in Vermont, and any proposals for legislative action needed to implement the program, to the House Committee on Health Care and the Senate Committee on Health and Welfare.

(2) On or before January 15, 2026, the Board shall provide its final plan for implementing a program to regulate the cost of prescription drugs in Vermont, along with proposals for addressing any additional identified legislative needs, to the House Committee on Health Care and the Senate Committee on Health and Welfare.

(c)(1) The following permanent classified positions are created at the Green Mountain Care Board to lead the exploration, development, and implementation of the prescription drug regulation program:

(A) one Director of Prescription Drug Pricing; and

(B) one Policy Analyst Prescription Drug Pricing.

(2) The sum of $245,000.00 is appropriated to the Green Mountain Care Board from the Evidence-Based Education and Advertising Fund in fiscal year 2025 for the positions created in this subsection.

(d)(1) The Green Mountain Care Board shall have legal assistance as needed from the Office of the Attorney General.

(2) The sum of $250,000.00 is appropriated to the Green Mountain Care Board from the Evidence-Based Education and Advertising Fund in fiscal year 2025 to contract with experts on prescription drug-related issues to assist the Board in its work under this section.

Sec. 2. 33 V.S.A. § 2004 is amended to read:

§ 2004. MANUFACTURER FEE

(a) Annually, each pharmaceutical manufacturer or labeler of prescription drugs that are paid for by the Department of Vermont Health Access for individuals participating in Medicaid, Dr. Dynasaur, or VPharm shall pay a fee to the Agency of Human Services. The fee shall be 1.75 percent of the previous calendar year's prescription drug spending by the Department and shall be assessed based on manufacturer labeler codes as used in the Medicaid rebate program.

(b) Fees collected under this section shall fund collection and analysis of information on pharmaceutical marketing activities under 18 V.S.A. §§ 4632 and 4633; analysis of prescription drug data needed by the Office of the Attorney General for enforcement activities; the Vermont Prescription Monitoring System established in 18 V.S.A. chapter 84A; the evidence-based education program established in 18 V.S.A. chapter 91, subchapter 2; the Green Mountain Care Board's prescription drug cost regulation initiatives; statewide unused prescription drug disposal initiatives; prevention of prescription drug misuse, abuse, and diversion; the Substance Misuse Prevention Oversight and Advisory Council established in 18 V.S.A. § 4803; treatment of substance use disorder; exploration of nonpharmacological approaches to pain management; a hospital antimicrobial program for the purpose of reducing hospital-acquired infections; the purchase and distribution of fentanyl testing strips; the purchase and distribution of naloxone to emergency medical services personnel; and any opioid-antagonist education, training, and distribution program operated by the Department of Health or its agents. The fees shall be collected in the Evidence-Based Education and Advertising Fund established in section 2004a of this title.

(c) The Secretary of Human Services or designee shall ~~make~~ adopt rules for the implementation of this section.

(d) The Department shall maintain on its website a list of the manufacturers who have failed to provide timely payment as required under this section.

Sec. 3. 33 V.S.A. § 2004a is amended to read:

§ 2004a. EVIDENCE-BASED EDUCATION AND ADVERTISING FUND

(a) The Evidence-Based Education and Advertising Fund is established in the State Treasury as a special fund to be a source of financing for activities relating to fund collection and analysis of information on pharmaceutical marketing activities under 18 V.S.A. §§ 4632 and 4633; for analysis of prescription drug data needed by the Office of the Attorney General for enforcement activities; for the Vermont Prescription Monitoring System established in 18 V.S.A. chapter 84A; for the evidence-based education program established in 18 V.S.A. chapter 91, subchapter 2; for the Green Mountain Care Board's prescription drug cost regulation initiatives; for statewide unused prescription drug disposal initiatives; for the prevention of prescription drug misuse, abuse, and diversion; for the Substance Misuse Prevention Oversight and Advisory Council established in 18 V.S.A. § 4803; for treatment of substance use disorder; for exploration of nonpharmacological approaches to pain management; for a hospital antimicrobial program for the purpose of reducing hospital-acquired

infections; for the purchase and distribution of fentanyl testing strips; for the purchase and distribution of naloxone to emergency medical services personnel; and for the support of any opioid-antagonist education, training, and distribution program operated by the Department of Health or its agents. Monies deposited into the Fund shall be used for the purposes described in this section.

* * *

~~*(d) Monies from the Fund to support the Green Mountain Care Board's prescription drug cost regulation initiatives shall not exceed $1,000,000.00 in any one fiscal year.*~~

Sec. 4. EFFECTIVE DATE

This act shall take effect on July 1, 2024.