1	S.98
2	Introduced by Senators Ram Hinsdale, Cummings, Gulick, Hashim, Lyons,
3	MacDonald and Watson
4	Referred to Committee on Health and Welfare
5	Date: February 23, 2023
6	Subject: Health; prescription drugs; Green Mountain Care Board
7	Statement of purpose of bill as introduced: This bill proposes to authorize and
8	direct the Green Mountain Care Board to evaluate the costs of certain high-
9	cost prescription drugs and recommend methods for addressing those costs,
10	including setting limits on what Vermonters would be expected to pay for
11	some high-cost drugs. The bill would also require the Board to submit a report
12	on generic drugs and generic drug prices.
	An est relating to Green Mountain Care Poord outhority over prescription drug costs An act relating to Green Mountain Care Board authority over prescription drug costs and the Green Mountain Care Board nomination and appointment process
13	It is hereby enacted by the General Assembly of the State of Vermont:
14	Sec. 1. 18 V.S. A. chapter 01, subchapter 5 is added to read.
15	Subchapter 5 Prescription Drug Affordability
16	§ 4671. DEFINITIONS
17	As a sed in this substitution.

1	(1) "Dialogie" moone a derig that is produced or distributed in
2	accordance with a biologics license application approved under 42 C.F.R.
3	<u>§ 447.512.</u>
4	(2) "Niosimilar" means a drug that is produced or distributed in
5	accordance with a biologics license application approved under 42 U.S.C.
6	§ 262(k)(3).
7	(3) "Board" mean, the Green Mountain Care Board established pursuant
8	to chapter 220 of this title.
9	(4) "Brand-name drug" means a drug produced or distributed in
10	accordance with an original new drug application approved under 21 U.S.C.
11	§ 355(c). The term does not include an authorized generic drug as defined in
12	42 C.F.R. § 447.502.
13	(5) "Generic drug" or "generic" means:
14	(A) a retail drug that is marketed or distributed in accordance with an
15	abbreviated new drug application approved under 21 U.S.C. § 355(j);
16	(B) an authorized generic drug, as defined in 42 C.F.P. § 447.502; or
17	(C) a drug that entered the market before 1962 that was not
18	originally marketed under a new drug application.
19	(6) "Health care provider" has the same meaning as in section 4631a of
20	this chapter.

1	(7) "Health incurer" has the same meaning as in section 0102 of this
2	<u>title</u>
3	(a) "Health plan" means a health benefit plan offered, issued, or
4	administered by a health insurer doing business in Vermont.
5	(9) "Manufacturer" means an entity that:
6	(A)(i) owns the patent to a prescription drug product; or
7	(ii) enters buto a lease with another manufacturer to market and
8	distribute a prescription drux product under the entity's own name; and
9	(B) sets or changes the wholesale acquisition cost of the prescription
10	drug product it manufactures or markets.
11	(10) "Prescription drug product" means a brand-name drug, a generic
12	drug, a biologic, or a biosimilar.
13	§ 4672. GREEN MOUNTAIN CARE BOARD COST AFFORDABILITY
14	REVIEW
15	(a) Scope of review; public input. The Green Mourtain Care Board shall
16	identify high-cost prescription drug products for a potential review of their
17	affordability under this section.
18	(1) The Green Mountain Care Board shall limit its review of
19	prescription drug products to those that are:
20	(A) brand-name drugs or biologics that, as adjusted annually for
21	infration in accordance with the Consumer Price index, have.

1	(i) a wholesale acquisition cost of \$60,000,00 or more per year or
2	per course of treatment, if less than a year; or
3	(ii) a wholesale acquisition cost increase of \$3,000.00 or more in
4	any 12-month period;
5	(B) bicsimilar drugs that have a wholesale acquisition cost that is not
6	at least 20 percent lower than the brand-name biologic reference product at the
7	time the biosimilars are nunched;
8	(C) generic drugs that, as adjusted annually for inflation in
9	accordance with the Consumer Plice Index, have a wholesale acquisition cost:
10	(i) of \$100.00 or more for a 30-day supply or for a course of
11	treatment of less than 30 days; and
12	(ii) increased by 200 percent or more during the immediately
13	preceding 12-month period, as determined by the difference between the
14	resulting wholesale acquisition cost and the average of the wholesale
15	acquisition cost reported over the immediately preceding 12 months; and
16	(D) other prescription drug products that the Board, in consultation
17	with the Prescription Drug Affordability Stakeholder Advisory Council
18	established pursuant section 4674 of this subchapter, determines may cleate
19	affordability challenges for the State's health care system and for patients,
20	including drugs to address public health emergencies.

1	(2) The Roard shall solicit public input on prescription drugs thought to
2	be creating affordability challenges that meet the parameters set forth in
3	subdivition (1)(A)–(D) of this subsection.
4	(b) Selection for review. After identifying prescription drug products
5	pursuant to subjection (a) of this section, the Board shall determine whether to
6	conduct a full affordability review for the proposed prescription drugs after
7	compiling preliminary information about the cost of the product, patient cost
8	sharing for the product, health plan spending on the product, and stakeholder
9	input and other information decided by the Board.
10	(c) Information used in review.
11	(1) The information the Board uses to conduct an affordability review
12	may include any document or research related to the manufacturer's selection
13	of the introductory price or price increase of the prescription drug product,
14	patient assistance programs specific to the product, estimated or actual
15	manufacturer produce price concessions in the market, let product cost to
16	State payers, and other information as determined by the Board.
17	(2) The failure of a manufacturer to provide the Board with information
18	for an affordability review shall not affect the Board's authority to conduct
19	such a review.
20	(3) In determining whether a drug creates affordability challenges or in
21	determining an upper payment innit amount pursuant to subsection (e) of this

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effectiveness analyses that include cost per quality-adjusted life year or similar measures to identify subpopulations for which a treatment would be less costeffective du 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 is sults 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 Blard 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 ally 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.

1	(1) If the Roard finds that spending on a prescription drug product
2	reviewed pursuant to this section has led or is likely to lead to affordability
3	challenges, the Board shall establish an upper payment limit in accordance
4	with section 4673 of this chapter that takes into consideration any exceptional
5	administrative costs related to the distribution of the drug in this State.
6	(2) The upper payment limit established by the Board for a prescription
7	drug product shall apply to all purchases of and payer reimbursements for the
8	prescription drug product intended for use by individuals in Vermont in
9	person, by mail, or by any other means.
10	(f) Public comment. The Board shall provide an opportunity for the public
11	to provide written comments on pending affordability decisions.
12	(g) Rulemaking. The Green Mountain Care Board may adopt rules in
13	accordance with 3 V.S.A. chapter 25 as needed to carry out its duties under this
14	section.
15	(h) Marketing permitted. Nothing in this section shall be construed to
16	prevent a manufacturer from marketing a prescription drug product approved
17	by the U.S. Food and Drug Administration while the product is under review
18	by the Board.
19	(i) Enforcement. The Chair of the Green Mountain Care Board shall have
20	the same authority to enforce the provisions of this subchapter as are available
21	to the Chair under chapter 220 of this title.

1	(i) Appeals Any person aggricued by a decision of the Green Mountain
2	Car Board under this section may appeal the Board's decision in accordance
3	with the provisions of section 9381 of this title.
4	§ 4673. UPPER PAYMENT LIMITS; APPLICABILITY; EXEMPTIONS
5	(a)(1)(A) The upper payment limits for prescription drug products
6	established by the Green Mountain Care Board pursuant to subsection 4672(e)
7	of this chapter shall apply to all health plans and health benefit programs
8	regulated, offered, or administered by the State, including individual and
9	group health benefit plans; health plans offered to State employees, teachers,
10	and other public employees; and the Medicaid program.
11	(B) An upper payment limit shall not include either the pharmacy
12	dispensing fee or the provider administration fee.
13	(2)(A) Upper payment limits established by the Board pursuant to
14	subsection 4672(e) of this chapter shall not apply to Medicare Part D plans or
15	to employee benefit plans that the State is preempted from regulating under the
16	Employee Retirement Income Security Act, 29 U.S.C. § 1001 t seq. These
17	plans may choose to reimburse for prescription drug products in an ounts that
18	exceed Board-established upper payment limits.
19	(B) The Board shall not create an upper payment limit that differs
20	from the Medicare maximum fair price for any drug for which the Secretary of

1	the U.S. Department of Health and Human Services has negotiated a price
2	under the Medicare Drug Price Negotiation Program.
3	(1) The Board shall consider how upper payment limits would affect
4	health care providers participating in the federal 340B drug pricing program.
5	(b)(1) Health care providers who dispense or administer prescription drug
6	products to patients in this State shall bill all payers not more than the upper
7	payment limit for dispersing or administering a prescription drug product for
8	which the Board has set an upper payment limit pursuant to subsection 4672(e)
9	of this chapter, regardless of whether a payer administering a plan described in
10	subdivision (a)(2) of this section chooses to reimburse the provider in an
11	amount that exceeds the Board-established upper payment limit.
12	(2) Independent pharmacies licensed by this State pursuant to 26 V.S.A.
13	chapter 36 shall not be reimbursed less than the upper payment limit.
14	(c) An upper payment limit shall take effect not sooner than six months
15	after it is announced.
16	§ 4674. PRESCRIPTION DRUG AFFORDABILITY STAKEHOLDER
17	ADVISORY COUNCIL
18	(a) There is created the Prescription Drug Affordability Stakeholder
19	Advisory Council to assist and advise the Green Mountain Care Board In
20	making the decisions required under this subchapter.
21	(b)(1) The Council shall be composed of the following 15 members.

1	(A) five members appointed by the Speaker of the House
2	(B) five members appointed by the Senate President Pro Tempore;
3	<u>and</u>
4	(C) five members appointed by the Governor.
5	(2) The members appointed to the Council shall have knowledge in one
6	or more of the following:
7	(A) the pharmareutical business model;
8	(B) supply chain business models;
9	(C) the practice of medicine or clinical training;
10	(D) consumer or patient perspectives;
11	(E) clinical and health services research; or
12	(F) the State's health care marketplace.
13	(3) Members of the Council shall serve three-year terms and members
14	may be reappointed to additional terms.
15	(c) The Council shall have the administrative, technical and legal
16	assistance of the Green Mountain Care Board.
17	(d) The Chair of the Green Mountain Care Board shall appoint one of the
18	members of the Council to be the Council's Chair.
19	(e) Members of the Council shall not receive compensation for their
20	service on the Council but shall be entitled to reimbursement of expenses as

1	permitted under 22 VS A & 1010. These reimbursements shall be made from
2	monies appropriated to the Green Mountain Care Board.
3	Sec. 2. 18 V.S.A. § 9375 is amended to read:
4	§ 9375. DUTIES
5	(a) The Board shall execute its duties consistent with the principles
6	expressed in section 9371 of this title.
7	(b) The Board shall have the following duties:
8	* * *
9	(16)(A) Identify high-coat prescription drugs, evaluate their
10	affordability, and set upper payment limits as appropriate in accordance with
11	chapter 91, subchapter 5 of this title.
12	(B) Based on its work under chapter 91, subchapter 5 of this title, the
13	Board shall include in its annual report pursuan to subsection (d) of this
14	section:
15	(i) information on price trends for prescription drug products;
16	(ii) the number of prescription drug products that were subject to
17	Board review, including the results of the reviews and the number and
18	disposition of any appeals to the Board and to the Vermont Suprem Court;
19	<u>and</u>
20	(iii) any recommendations for further legislative action needed to
21	make prescription drug products more affordable in this State.

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2	Sec 3. PRESCRIPTION DRUG AFFORDABILITY STAKEHOLDER
3	ADVISORY COUNCIL; IMPLEMENTATION
4	(a) The Chair of the Green Mountain Care Board shall call the first
5	meeting of the Prescription Drug Affordability Stakeholder Advisory Council
6	to occur on or before February 1, 2024.
7	(b) Notwithstanding any provision of 18 V.S.A. § 4674 to the contrary, the
8	initial members of the Council shall serve staggered terms as follows:
9	(1) the terms of two members appointed by each appointing authority
10	shall expire in 2026;
11	(2) the terms of two members appointed by each appointing authority
12	shall expire in 2027; and
13	(3) the terms of one member appointed by each appointing authority
14	shall expire in 2028.
15	Sec. 4. GENERIC DRUG MARKET; GREEN MOUNTAIN CARE BOARD;
16	REPORT
17	On or before January 15, 2025, the Green Mountain Care Board shall report
18	to the House Committee on Health Care and the Senate Committee on Health
19	and Welfare regarding the operation of the generic drug market in the United
20	States and in Vermont, including generic physician-administered drugs, that
21	addresses.

1	(1) the production of game and year war year more;
2	(2) the degree to which generic drug prices affect health insurance
3	premiums based on the information provided to the Board pursuant to 18
4	<u>V.S.A. § 4636;</u>
5	(3) recent and current trends in patient cost-sharing for generic drugs;
6	(4) the causes and prevalence of generic drug shortages; and
7	(5) any other relevant information regarding generic drugs and generic
8	drug prices.
9	Sec. 5. REPEAL
10	18 V.S.A. § 4635 (prescription drug cost transparency) is repealed.
11	Sec. 6. EFFECTIVE DATE
12	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

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

prescription drug costs;

technical advisory groups;

- options; and
- (6) the impact of implementing a program is regulate the costs of
- (5) the likely return on investment of the most promising program options;
 - (6) the potential impacts on Vermonters' access to medications; and
- (7) 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; disorder; for for treatment of substance use *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.

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prescription drug cost regulation initialized shall not exceed \$1,000,000.00 in any one fixed year.

C PERCEUR DATE

This got shall take effect on July 1 2021

Sec. 4. 18 V.S.A. chapter 220 is amended to read:

CHAPTER 220. GREEN MOUNTAIN CARE BOARD

§ 9374. BOARD MEMBERSHIP; AUTHORITY

* * *

- (b)(1) The initial term of each member of the Board, including the Chair, shall be seven years, and the term of the Chair shall be six years thereafter.
- (2) The term of each member other than the Chair shall be six years, except that of the members first appointed, one each shall serve a term of three years, four years, five years, and six years Any appointment to fill a vacancy shall be for the unexpired portion of the term vacated.
- (3) Subject to the nomination and appointment process, a <u>A</u> member may serve more than one term. <u>A member may be reappointed to additional terms subject to the requirements of section 9391 of this title.</u>

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§ 9390. GREEN MOUNTAIN CARE BOARD NOMINATING COMMITTEE CREATED; COMPOSITION

* * *

(f) The Board is authorized to use the staff and services of appropriate State agencies and departments as necessary to conduct investigations of applicants The Committee shall have the administrative, technical, and legal assistance of the Department of Human Resources.

§ 9391. NOMINATION AND APPOINTMENT PROCESS

- (a) Whenever Candidate selection process.
- (1) Unless a vacancy is filled by reappointment by the Governor pursuant to subsection (c) of this section, not later than 90 days prior to a known vacancy occurs occurring on the Green Mountain Care Board, or when an incumbent does not declare that he or she will be a candidate to succeed himself or herself, the Green Mountain Care Board Nominating Committee shall commence its nomination application process. The Committee shall select for consideration by the Committee, by majority vote, and provided that a quorum is present, from the applications for membership on the Green Mountain Care Board as many candidates as it deems qualified for the position or positions to be filled. The Committee shall base its determinations on the qualifications set forth in section 9392 of this section title.
- (2) A Board member who is resigning from the Board prior to the expiration of the member's term shall notify the Committee Chair, the Governor, and the Department of Human Resources of the member's anticipated resignation date. Once notified, the Committee Chair shall commence the nomination application process as soon as is practicable in light of the anticipated resignation date.
- (b) Nomination list. The Committee shall submit to the Governor the names of the persons individuals it deems qualified to be appointed to fill the position or positions and the name of any incumbent member who was not reappointed pursuant to subsection (c) of this section and who declares notifies the Committee Chair, the Governor, and the Department of Human Resources that he or she the incumbent wishes to be a candidate to succeed himself or herself nominated. An incumbent shall not be required to submit an application for nomination and appointment to the Committee under subsection (a) of this section, but the Committee may request that the incumbent update relevant information as necessary.
 - (c) Reappointment; notification.

- (1) Not later than 120 days prior to the end of a Board member's term, the member shall notify the Governor that the member either is seeking to be reappointed by the Governor for another term or that the member does not wish to be reappointed.
- (2) If a Board member who is seeking reappointment is not reappointed by the Governor on or before 30 days after notifying the Governor, the member's term shall end on the expiration date of the member's current term, unless the member is nominated as provided in subsection (b) of this section and subsequently appointed, or as otherwise provided by law.
- (3) A Board member's reappointment shall be subject to the consent of the Senate.
- (d) The Appointment; Senate consent. Unless the Governor reappointed a Board member pursuant to subsection (c) of this section, the Governor shall make an appointment to the Green Mountain Care Board from the list of qualified candidates submitted pursuant to subsection (b) of this section not later than 45 days after receipt of the candidate list. The appointment shall be subject to the consent of the Senate. The names of candidates submitted and not selected shall remain confidential.
- (d)(e) Confidentiality. All proceedings of the Committee, including the names of candidates considered by the Committee and information about any candidate submitted by any source, shall be confidential.

Sec. 5. EFFECTIVE DATES

- (a) Sec. 4 (18 V.S.A. chapter 220; Green Mountain Care Board nomination and appointment process) and this section shall take effect on passage. Notwithstanding any provision of 18 V.S.A. chapter 220, as amended by this act, to the contrary, the Green Mountain Care Board Nominating Committee, in consultation with the Green Mountain Care Board, the Department of Human Resources, and the Governor, may establish alternative timing requirements for applications, appointments, and reappointments to the Board for Board vacancies anticipated to occur or otherwise occurring on or before December 31, 2024 if the timelines established in 18 V.S.A. chapter 220, as amended by this act, would be impractical or impossible to meet.
 - (b) The remaining sections shall take effect on July 1, 2024.