

1 TO THE HONORABLE SENATE:

2 The Committee on Health and Welfare to which was referred Senate Bill  
3 No. 98 entitled “An act relating to Green Mountain Care Board authority over  
4 prescription drug costs” respectfully reports that it has considered the same and  
5 recommends that the bill be amended by striking out all after the enacting  
6 clause and inserting in lieu thereof the following:

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

8 Subchapter 5. Prescription Drug Affordability

9 § 4671. DEFINITIONS

10 As used in this subchapter:

11 (1) “Biologic” means a drug that is produced or distributed in  
12 accordance with a biologics license application approved under 42 C.F.R.  
13 § 447.502.

14 (2) “Biosimilar” means a drug that is produced or distributed in  
15 accordance with a biologics license application approved under 42 U.S.C.  
16 § 262(k)(3).

17 (3) “Board” means the Green Mountain Care Board established pursuant  
18 to chapter 220 of this title.

19 (4) “Brand-name drug” means a drug produced or distributed in  
20 accordance with an original new drug application approved under 21 U.S.C.

1 § 355(c). The term does not include an authorized generic drug as defined in  
2 42 C.F.R. § 447.502.

3 (5) “Generic drug” or “generic” means:

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

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

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

9 (6) “Health care provider” has the same meaning as in section 4631a of  
10 this chapter.

11 (7) “Health insurer” has the same meaning as in section 9402 of this  
12 title.

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

15 (9) “Manufacturer” means an entity that:

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

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

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

1           (10) “Prescription drug product” means a brand-name drug, a generic  
2           drug, a biologic, or a biosimilar.

3           § 4672. GREEN MOUNTAIN CARE BOARD; COST AFFORDABILITY  
4           REVIEW

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

8           (1) The Green Mountain Care Board shall limit its review of  
9           prescription drug products to those that are: **brand-name drugs or biologics,**  
10           **biosimilar drugs, or generic drugs that the Centers for Medicare and**  
11           **Medicaid Services has selected for price negotiation under the Medicare**  
12           **Drug Price Negotiation Program established pursuant to 42 U.S.C.**  
13           **§§ 1320f et seq. or that another state’s prescription drug affordability**  
14           **board has selected for review.**

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

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

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

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

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

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

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

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

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

20 (b) Selection for review. After identifying prescription drug products  
21 pursuant to subsection (a) of this section, the Board shall determine whether to

1 conduct a full affordability review for the proposed prescription drugs after  
2 compiling preliminary information about the cost of the product, patient cost  
3 sharing for the product, health plan spending on the product, and stakeholder  
4 input and other information decided by the Board.

5 (c) Information used in review.

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

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

15 (3) In determining whether a drug creates affordability challenges or in  
16 determining an upper payment limit amount pursuant to subsection (e) of this  
17 section and section 4673 of this chapter, the Board shall not use cost-  
18 effectiveness analyses that include cost per quality-adjusted life year or similar  
19 measures to identify subpopulations for which a treatment would be less cost-  
20 effective due to severity of illness, age, or preexisting disability. In addition,  
21 for any treatment that extends life, if the Board uses cost-effectiveness results,

1 the Board shall use results that weight the value of all additional lifetime  
2 gained equally for all patients, regardless of their severity of illness, age, or  
3 preexisting disability.

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

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

15 (e) Upper payment limit.

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

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

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

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

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

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

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

1     § 4673. UPPER PAYMENT LIMITS; APPLICABILITY; EXEMPTIONS

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

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

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

16          (B) The Board shall not create an upper payment limit that differs  
17     from the Medicare maximum fair price for any drug for which the Secretary of  
18     the U.S. Department of Health and Human Services has negotiated a price  
19     under the Medicare Drug Price Negotiation Program.

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



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

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

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

12       § 4674. PRESCRIPTION DRUG AFFORDABILITY STAKEHOLDER  
13       ADVISORY COUNCIL

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

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

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

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

20       and

21               (C) five members appointed by the Governor.

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

3                   (A) the pharmaceutical business model;

4                   (B) supply chain business models;

5                   (C) the practice of medicine or clinical training;

6                   (D) consumer or patient perspectives;

7                   (E) clinical and health services research; or

8                   (F) the State’s health care marketplace.

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

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

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

15           (e) Members of the Council shall not receive compensation for their service  
16           on the Council but shall be entitled to reimbursement of expenses as permitted  
17           under 32 V.S.A. § 1010. These reimbursements shall be made from monies  
18           appropriated to the Green Mountain Care Board.

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

2 § 9375. DUTIES

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

5 (b) The Board shall have the following duties:

6 \* \* \*

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

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

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

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

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

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

3                (a) The Chair of the Green Mountain Care Board shall call the first meeting  
4                of the Prescription Drug Affordability Stakeholder Advisory Council to occur  
5                on or before February 1, 2025.

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

8                    (1) the terms of two members appointed by each appointing authority  
9                    shall expire in 2027;

10                  (2) the terms of two members appointed by each appointing authority  
11                  shall expire in 2028; and

12                  (3) the terms of one member appointed by each appointing authority  
13                  shall expire in 2029.

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

16                On or before January 15, 2026, the Green Mountain Care Board shall report  
17                to the House Committee on Health Care and the Senate Committee on Health  
18                and Welfare regarding the operation of the generic drug market in the United  
19                States and in Vermont, including generic physician-administered drugs, that  
20                addresses:

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

- 1           (2) the degree to which generic drug prices affect health insurance  
2           premiums based on the information provided to the Board pursuant to 18  
3           V.S.A. § 4636;  
4           (3) recent and current trends in patient cost-sharing for generic drugs;  
5           (4) the causes and prevalence of generic drug shortages; and  
6           (5) any other relevant information regarding generic drugs and generic  
7           drug prices.

8           Sec. 5. REPEAL

9           18 V.S.A. § 4635 (prescription drug cost transparency) is repealed.

10          Sec. 6. EFFECTIVE DATE

11          This act shall take effect on July 1, 2024.

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18          (Committee vote: \_\_\_\_\_)

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Senator \_\_\_\_\_

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FOR THE COMMITTEE