

1 H.785

2 Introduced by Representative Copeland Hanzas of Bradford

3 Referred to Committee on

4 Date:

5 Subject: Health; prescription drugs; Green Mountain Care Board

6 Statement of purpose of bill as introduced: This bill proposes to authorize and
7 direct the Green Mountain Care Board to evaluate the costs of certain high-cost
8 prescription drugs and recommend methods for addressing those costs,
9 including setting limits on what Vermonters would be expected to pay for
10 some high-cost drugs.

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

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

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

15 Subchapter 5. Prescription Drug Affordability

16 § 4671. DEFINITIONS

17 As used in this subchapter:

18 (1) “Biologic” has the same meaning as “biological product” in section
19 4601 of this chapter.

1 (2) “Biosimilar” means a biologic that is highly similar to the reference
2 product licensed pursuant to 42 U.S.C. § 262(a) against which it was evaluated
3 by the U.S. Food and Drug Administration, with no clinically meaningful
4 differences between the safety, purity, or potency of the two products, and that
5 is licensed as a biosimilar under 42 U.S.C. § 262(k)(3), regardless of whether
6 the biosimilar has been determined to be interchangeable with the reference
7 product.

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

10 (4) “Brand-name drug” means a drug produced or distributed in
11 accordance with an original new drug application approved under 21 U.S.C.
12 § 355(c). The term does not include an authorized generic drug as defined by
13 42 C.F.R. § 447.502.

14 (5) “Generic drug” or “generic” has the same meaning as in section
15 4601 of this chapter.

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

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

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

1 (9) “Manufacturer” has the same meaning as “pharmaceutical
2 manufacturer” in section 4631a of this chapter.

3 (10) “Pharmacy benefit manager” has the same meaning as in section
4 9471 of this title.

5 (11) “Prescription drug product” means a brand-name drug, a generic
6 drug, a biologic, or a biosimilar.

7 § 4672. GREEN MOUNTAIN CARE BOARD; COST AFFORDABILITY
8 REVIEW

9 (a) Identification of prescription drug products. The Green Mountain Care
10 Board shall identify prescription drug products that are:

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

13 (A) a launch wholesale acquisition cost of \$30,000.00 or more per
14 year or per course of treatment; or

15 (B) a wholesale acquisition cost increase of \$3,000.00 or more in any
16 12-month period, or in a course of treatment if less than 12 months;

17 (2) biosimilar drugs that have a launch wholesale acquisition cost that is
18 not at least 15 percent lower than the brand-name biologic reference product at
19 the time the biosimilar is launched;

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

1 (A) of \$100.00 or more for:

2 (i) a 30-day supply lasting the patient for a period of 30
3 consecutive days based on the recommended dosage approved for labeling by
4 the U.S. Food and Drug Administration;

5 (ii) a supply lasting a patient for fewer than 30 days based on the
6 recommended dosage approved for labeling by the U.S. Food and Drug
7 Administration; or

8 (iii) one unit of the drug if the labeling approved by the U.S. Food
9 and Drug Administration does not recommend a finite dosage; and

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

14 (4) other prescription drug products that the Board, in consultation with
15 the Board's prescription drug affordability stakeholder group established
16 pursuant to subsection (f) of this section, determines may create affordability
17 challenges for the State's health care system and patients.

18 (b) Selection for review. After identifying prescription drug products
19 pursuant to subsection (a) of this section, the Board shall determine whether to
20 conduct an affordability review for each identified prescription drug product
21 by:

1 (1) seeking input about the prescription drug product from the Board's
2 prescription drug affordability stakeholder group; and

3 (2) considering the average patient cost share for the prescription drug
4 product.

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 including life cycle management, net average price in this State, market
10 competition and context, projected revenue, and the estimated value or cost-
11 effectiveness of the prescription drug product.

12 (2) To the extent practicable, the Board shall access pricing information
13 for prescription drug products by:

14 (A) entering into a memorandum of understanding with another state
15 or entity to which manufacturers already report pricing information; and

16 (B) accessing other available pricing information.

17 (3) 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 (4) Notwithstanding any provision of 1 V.S.A. § 312 or 313 to the
21 contrary, the Board may meet in executive session to discuss proprietary data

1 and information or to hear from an expert witness who will discuss proprietary
2 data and information.

3 (d) Affordability review criteria. When the Board conducts a review of the
4 affordability of a prescription drug product, the review shall determine whether
5 use of the prescription drug product in a manner fully consistent with the
6 labeling approved by the U.S. Food and Drug Administration or standard
7 medical practice has led or is likely to lead to affordability challenges for
8 Vermont's health care system or to high out-of-pocket costs for patients, or
9 both. To the extent practicable, in determining whether a specific prescription
10 drug product has led or is likely to lead to affordability challenges, the Board
11 shall consider the following factors:

12 (1) the wholesale acquisition cost of the prescription drug product when
13 sold in Vermont;

14 (2) the average monetary price concession, discount, or rebate the
15 manufacturer provides or is expected to provide to health plans in this State for
16 the prescription drug product, as reported by manufacturers and health plans,
17 expressed as a percentage of the wholesale acquisition cost;

18 (3) the total amount of the price concession, discount, or rebate the
19 manufacturer provides to each pharmacy benefit manager operating in this
20 State for the prescription drug product, as reported by manufacturers and

1 pharmacy benefit managers, expressed as a percentage of the wholesale
2 acquisition cost;

3 (4) the price at which therapeutic alternatives are sold in Vermont;

4 (5) the average monetary concession, discount, or rebate the
5 manufacturer provides or is expected to provide to health plans and pharmacy
6 benefit managers for therapeutic alternatives;

7 (6) the costs to health plans based on patient access consistent with U.S.
8 Food and Drug Administration-labeled indications and recognized standard
9 medical practice;

10 (7) the impact on patient access resulting from the cost of the
11 prescription drug product relative to insurance benefit design;

12 (8) the current or expected dollar value of drug-specific patient access
13 programs that the manufacturer supports;

14 (9) the relative financial impacts on health, medical, or social services
15 costs that can be quantified and compared to baseline effects of existing
16 therapeutic alternatives;

17 (10) the average patient co-payment or other cost-sharing required for
18 the prescription drug product in Vermont;

19 (11) any additional information the manufacturer chooses to provide;

20 and

21 (12) any other factors established by the Board by rule.

1 (e)(1) Upper payment limit. If the Board finds that spending on a
2 prescription drug product reviewed pursuant to this section has led or is likely
3 to lead to affordability challenges, the Board shall establish an upper payment
4 limit for the prescription drug product after considering:

5 (A) the cost of administering the prescription drug product;

6 (B) the cost of delivering the prescription drug product to consumers;

7 and

8 (C) other relevant administrative costs related to the prescription drug
9 product.

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

14 (f) Prescription drug affordability stakeholder group. The Board shall
15 establish a prescription drug affordability stakeholder group to advise the
16 Board in making the decisions required by this section. The stakeholder group
17 shall comprise representatives of health care professionals, of health plans, of
18 patients, of health care facilities, of pharmacists, and of prescription drug
19 manufacturers; health care researchers, including researchers specializing in
20 prescription drugs; and other interested stakeholders with applicable subject
21 matter expertise.

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

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

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

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

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

16 § 4673. UPPER PAYMENT LIMITS; APPLICABILITY; EXEMPTIONS

17 (a)(1) The upper payment limits for prescription drug products established
18 by the Green Mountain Care Board pursuant to subsection 4672(e) of this
19 chapter shall apply to all health plans and health benefit programs regulated,
20 offered, or administered by the State, including individual and group health

1 benefit plans; health plans offered to State employees, teachers, and other
2 public employees; and the Medicaid program.

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

9 (b) Health care providers who dispense or administer prescription drug
10 products to patients in this State shall bill all payers no more than the upper
11 payment limit for dispensing or administering a prescription drug product for
12 which the Board has set an upper payment limit pursuant to subsection 4672(e)
13 of this chapter, regardless of whether a payer administering a plan described in
14 subdivision (a)(2) of this section chooses to reimburse the provider in an
15 amount that exceeds the Board-established upper payment limit.

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

17 § 9375. DUTIES

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

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

21 * * *

