S.246

Introduced by Senators Pearson, Ingram, Lyons, Pollina and Westman

Referred to Committee on

Date:

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.

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" has the same meaning as "biological product" in section 4601 of this chapter.

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

(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 by 42 C.F.R. § 447.502.

(5) "Generic drug" or "generic" has the same meaning as in section 4601 of this chapter.

(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" has the same meaning as "pharmaceutical manufacturer" in section 4631a of this chapter.

(10) "Pharmacy benefit manager" has the same meaning as in section 9471 of this title.

(11) "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) Identification of prescription drug products. The Green Mountain Care Board shall identify prescription drug products that are:

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

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

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

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

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

(A) of $100.00 or more for:

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

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

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

(B) that 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

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

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

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

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

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

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

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

(B) accessing other available pricing information.

(3) 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.

(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. To the extent practicable, in determining whether a specific prescription drug product has led or is likely to lead to affordability challenges, the Board shall consider the following factors:

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

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

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

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

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

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

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

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

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

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

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

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

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

(e)(1) Upper payment limit. 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 for the prescription drug product after considering:

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

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

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

(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 dispensed or administered to individuals in Vermont in person, by mail, or by any other means.

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

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

(h) 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.

(i) 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.

(j) 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.

(k) 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) 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.

(2) 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) Health care providers who dispense or administer prescription drug products to patients in this State shall bill all payers no 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.

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.

* * *

Sec. 3. REPEAL

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

Sec. 4. EFFECTIVE DATE

This act shall take effect on July 1, 2020.