

1 TO THE HOUSE OF REPRESENTATIVES:

2 The Committee on Health Care to which was referred House Bill No. 866
3 entitled “An act relating to prescription drug manufacturer cost transparency”
4 respectfully reports that it has considered the same and recommends that the
5 bill be amended by striking out all after the enacting clause and inserting in
6 lieu thereof the following:

7 **Sec. 1. FINDINGS**

8 **The General Assembly finds that:**

9 **(1) The costs of prescription drugs have been increasing**
10 **dramatically without any apparent reason.**

11 **(2) Containing health care costs requires containing prescription**
12 **drug costs.**

13 **(3) In order to contain prescription drug costs, it is essential to**
14 **understand the drivers of those costs, as transparency is typically the first**
15 **step toward cost containment.**

16 Sec. 2. 18 V.S.A. § 4635 is added to read:

17 **§ 4635. PHARMACEUTICAL COST TRANSPARENCY**

18 **(a) As used in this section:**

19 **(1) “Manufacturer” shall have the same meaning as “pharmaceutical**
20 **manufacturer” in section 4631a of this title.**

21 **(2) “Prescription drug” means a drug as defined in 21 U.S.C. § 321.**

1 (b) The Green Mountain Care Board shall identify annually, in
2 collaboration with the Department of Vermont Health Access, [up to] 15
3 prescription drugs on which the State spends significant health care dollars
4 [and which have increased in cost by at least more than 50% in the prior five
5 years or at least more than 15% in the prior year], creating a substantial
6 public interest in understanding the development of the drugs' pricing. The
7 drugs identified shall represent different drug classes, with five of the drugs
8 being generic drugs, five brand-name drugs, and five specialty drugs.

9 (c)(1) For each prescription drug identified pursuant to subsection (b) of
10 this section, the [Office of the Attorney General?] Board shall require the
11 drug's manufacturer to report the following information [in a format that it
12 determines to be understandable and appropriate], by drug name:

13 (A) the number of years the drug has been available for purchase in
14 the United States;

15 (B) the year the patent for each formulation of the drug was approved
16 and the number of years remaining, if any, on the patent for each formulation
17 of the drug;

18 (C) the total research and development costs paid by the
19 manufacturer over the preceding seven years and, separately and to the extent
20 the manufacturer has the information, the total research and development costs
21 paid by any predecessor and by any third party, public or private, in the

1 development of the drug, showing both the total amounts spent on research and
2 development by the manufacturer, its predecessors, and third parties over time
3 and the amounts spent by each per year as well as any amounts from federal,
4 State, or other governmental programs and any form of subsidies, grants, tax
5 credits, or other support;

6 (D) the costs of clinical trials and other regulatory costs paid by the
7 manufacturer over the preceding seven years by year and by clinical trial phase
8 and, separately and to the extent the manufacturer has the information, the
9 costs of clinical trials and other regulatory costs paid by any predecessor in the
10 development of the drug, as well as the cost of any postclinical studies
11 mandated by the U.S. Food and Drug Administration;

12 (E) other costs to acquire the drug, including costs for the purchase of
13 patents, licensing, property rights, or acquisition of a corporate entity owning
14 rights to the drug while in development;

15 (F) amounts spent per year for the preceding seven years on direct-to-
16 consumer advertising for the drug and on physician detailing activities related
17 to the drug, both in Vermont and nationally;

18 (G) a cumulative annual history of increases in the average wholesale
19 price and wholesale acquisition cost of the drug, using the National Drug
20 Code, over the preceding five-year period, expressed as percentages, and the
21 month each such increase took effect;

1 [REMOVE THIS] (H) prices for the drug charged to the U.S.
2 Veterans Administration and to 340B covered entities, using the National Drug
3 Code;

4 (I) prices charged to typical purchasers in Vermont during the
5 previous year, including pharmacies, pharmacy chains, pharmacy wholesalers,
6 hospitals, physician practices, and other direct purchasers of prescription
7 drugs; and

8 (J) typical prices charged to mail-order pharmacies for distribution in
9 Vermont during the previous year.

10 (2) The manufacturer may provide to the Board any additional
11 information the manufacturer believes may be pertinent to the Board’s
12 complete understanding of the costs related to developing and manufacturing
13 the drug or to the drug’s price, such as costs related to acquisition of the drug.
14 [and to the understanding of the reason for the increases in the drug’s price.]

15 (3) The manufacturer shall certify, subject to the penalties of perjury,
16 that the information provided is truthful, accurate, and complete.

17 [(4) The manufacturer may indicate than a component of requested
18 information is not available in the format requested if it provides the
19 information in an alternative format acceptable to the Attorney General for
20 meeting the intent of this statute, and includes a detailed explanation of why
21 the information cannot be provided in the format requested.]

1 (d) [The Attorney General shall] The Green Mountain Care Board, in
2 consultation with the Department of Vermont Health Access, shall provide
3 a report to the General Assembly on or before December 1 of each year based
4 on the information received from manufacturers pursuant to this section.

5 (1) The report shall be based on the Board’s review and analysis of the
6 data. The Board shall aggregate the data to determine trends in components of
7 drug production costs, and shall provide recommendations for legislative,
8 administrative, or other policy changes [that could assist in containing cost
9 increases in prescription drug prices.]

10 (2) The Board shall report aggregated data by drug class in a manner
11 that maximizes the utility of the data while protecting the financial,
12 competitive, or proprietary nature of the information.

13 (3) The report shall include a statement of total State spending for the
14 year for each drug identified pursuant to subsection (a) of this section paid for
15 through the State Employees Health Benefit Plan, Medicaid, VPharm, and any
16 other State program for the purchase of prescription drugs, as well as the
17 number of prescriptions for each drug dispensed to individuals enrolled in
18 these programs.

19 (4) The Board shall also post the report on the Board’s website.

20 (e) Information provided to the Green Mountain Care Board pursuant to
21 this section is exempt from public inspection and copying under the Public

1 Records Act and shall not be released in a manner that allows for the
2 identification of an individual drug or manufacturer or that is likely to
3 compromise the financial, competitive, or proprietary nature of the
4 information.

5 Sec. 3. EFFECTIVE DATE

6 This act shall take effect on passage.

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14 (Committee vote: _____)

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Representative _____

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FOR THE COMMITTEE