

1 Introduced by Committee on Health Care

2 Date:

3 Subject: Health; prescription drugs; manufacturers; costs

4 Statement of purpose of bill as introduced: This bill proposes to require the
5 manufacturers of prescription drugs identified by the Green Mountain Care
6 Board as having a significant impact on health care spending to report certain
7 information regarding the research, development, acquisition, and other costs
8 associated with the manufacture of the drug and the prices charged to
9 purchasers inside and outside the United States. It would direct the Green
10 Mountain Care Board to provide an annual report describing the information
11 received and to determine whether the data suggest the need for legislative,
12 administrative, or other policy changes.

13 An act relating to prescription drug manufacturer cost transparency

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

15 Sec. 1. 18 V.S.A. § 4635 is added to read:

16 § 4635. PHARMACEUTICAL COST TRANSPARENCY

17 (a) As used in this section:

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

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

1 (b) The Green Mountain Care Board shall develop a list of specific
2 prescription drugs on which the State spends significant health care dollars,
3 creating a substantial public interest in understanding the development of the
4 drugs' pricing.

5 (c)(1) For each prescription drug that the Green Mountain Care Board
6 places on the list developed pursuant to subsection (b) of this section, the
7 Board shall require the drug's manufacturer to report the following
8 information:

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

11 (B) the number of years remaining, if any, on the patent for each
12 formulation of the drug;

13 (C) the total research and development costs paid by the
14 manufacturer and, separately and to the extent the manufacturer has the
15 information, the total research and development costs paid by any predecessor
16 and by any third party, public or private, in the development of the drug,
17 showing both the total amounts spent on research and development by the
18 manufacturer, its predecessors, and third parties over time and the amounts
19 spent by each per year as well as any amounts from federal, State, or other
20 governmental programs and any form of subsidies, grants, or other support;

1 (D) the costs of clinical trials and other regulatory costs paid by the
2 manufacturer and, separately and to the extent the manufacturer has the
3 information, the costs of clinical trials and other regulatory costs paid by any
4 predecessor in the development of the drug, as well as the cost of any
5 postclinical studies mandated by the U.S. Food and Drug Administration;

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

9 (F) any other information the manufacturer believes to be pertinent to
10 the Board’s complete understanding of the costs related to developing and
11 manufacturing the drug;

12 (G) a cumulative annual history of increases in the average wholesale
13 price and wholesale acquisition cost of the drug over the preceding five-year
14 period, expressed as percentages, and the month each such increase took effect;

15 (H) prices for the drug charged to purchasers outside the United
16 States, by country, for a representative set of five countries to be selected
17 annually by the Green Mountain Care Board;

18 (I) prices charged to typical purchasers in Vermont during the
19 previous year, including pharmacies, pharmacy chains, pharmacy wholesalers,
20 and other direct purchasers of prescription drugs; and

1 (J) typical prices charged to pharmacy benefit managers for
2 distribution in Vermont during the previous year, net of rebates and of other
3 payments from the manufacturer to the pharmacy benefit manager and the
4 pharmacy benefit manager to the manufacturer.

5 (2) The reported information shall be audited by an independent,
6 third-party auditor prior to filing.

7 (d) The Green Mountain Care Board shall provide a report to the General
8 Assembly on or before December 1 of each year describing the information
9 received from manufacturers pursuant to this section. The Board shall review
10 and analyze the data, aggregate the data to determine trends in components of
11 drug production costs, and determine whether the data suggest the need for
12 legislative, administrative, or other policy changes. The report shall include a
13 statement of the total cost to the State of Vermont for the year for each drug
14 identified pursuant to subsection (a) of this section paid for through the State
15 Employees Health Benefit Plan, Medicaid, VPharm, and any other State
16 program for the purchase of prescription drugs. The Board shall also post the
17 report on the Board's website.

18 (e) Information and reports provided to the Green Mountain Care Board
19 pursuant to this section are exempt from public inspection and copying under
20 the Public Records Act and shall not be released. Any public reporting of the

1 information shall be aggregated in order to protect the financial, competitive,
2 or proprietary nature of the information.

3 Sec. 2. EFFECTIVE DATE

4 This act shall take effect on passage.