H.866

Introduced by Committee on Health Care

Date:

Subject: Health; prescription drugs; manufacturers; costs

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

An act relating to prescription drug manufacturer cost transparency

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

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

§ 4635. PHARMACEUTICAL COST TRANSPARENCY

(a) As used in this section:

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

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

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

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

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

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

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

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

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

(F) any other information the manufacturer believes to be pertinent to the Board's complete understanding of the costs related to developing and manufacturing the drug or to the drug's price;

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

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

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

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

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

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

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

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

Sec. 2. EFFECTIVE DATE

This act shall take effect on passage.