Prescription drug manufacturer cost transparency

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) **Option #1:** The Green Mountain Care Board shall develop a list of specific prescription drugs for which there is a substantial public interest in understanding the development of their pricing. In developing the list, the Board shall consider the following factors:

(1) the cost of the drug to public health care programs, including Medicaid and the State employees' health plan;

(2) the current cost of the drug in Vermont;

(3) the extent to which the drug is used in Vermont;

(4) the rate at which the drug is deemed to produce successful outcomes when used to treat the condition or conditions for which it is most commonly prescribed; and

(5) the potential impact of the drug's cost on Vermont's efforts to contain health care costs.

(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:

(b) **Option #2:** Each manufacturer of a prescription drug made available in Vermont with an average wholesale price of $10,000.00 or more annually or per course of treatment shall file a report on the costs of each qualifying drug with the Green Mountain Care Board by March 1 of each year.

(1) The report shall include 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, 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, 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 post-clinical 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) 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;

(G) 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;

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

(I) 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; and

(J) the manufacturer's total profit attributed to the drug for the previous year, expressed both in dollars and as a percentage of the company's total profits.

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

(c) The Green Mountain Care Board shall provide a report to the General Assembly by December 1 of each year describing the information received from manufacturers pursuant to this section. The Board shall review and analyze the data, aggregate it to determine trends in components of drug production costs, and determine whether the data suggests 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.

(d) 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 upon the passage of legislation containing similar reporting requirements in at least five other states.