H.571

Introduced by Representatives Till of Jericho and Copeland-Hanzas of Bradford

Referred to Committee on

Date:

Subject: Health; prescription drugs; prescribed products; manufacturers; gift ban; disclosure

Statement of purpose: This bill proposes to make modifications and clarifying changes to laws prohibiting most gifts by manufacturers of prescribed products and requiring disclosure of allowable expenditures and permitted gifts.

An act relating to Vermont's prescribed product manufacturer gift ban and disclosure requirements

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

Sec. 1. 18 V.S.A. § 4631a is amended to read:

§ 4631a. EXPENDITURES BY MANUFACTURERS OF PRESCRIBED PRODUCTS

(a) As used in this section:

* * *

(12) "Prescribed product" means a drug or device as defined in section 201 of the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321, a compound

drug or drugs, ~~or~~ a biological product as defined in section 351 of the Public Health Service Act, 42 U.S.C. § 262, for human use, or a combination product as defined in 21 C.F.R. § 3.2(e).

* * *

(b)(1) It is unlawful for any manufacturer of a prescribed product or any wholesale distributor of medical devices, or any agent thereof, to offer or give any gift to a health care provider or to a member of the Green Mountain Care board established in chapter 220 of this title.

(2) The prohibition set forth in subdivision (1) of this subsection shall not apply to any of the following:

(A) Samples of a prescribed product or reasonable quantities of an over-the-counter drug, nonprescription medical device, ~~or~~ item of nonprescription durable medical equipment, or item of medical food as defined in the federal Orphan Drug Act, as amended, 21 U.S.C. § 360ee(b)(3), provided to a health care provider for free distribution to patients.

* * *

(H) The provision ~~of free prescription drugs or over-the-counter drugs, medical devices, biological products, medical equipment or supplies, or financial donations~~ to a free clinic of financial donations or of free:

(i) prescription drugs;

(ii) over-the-counter drugs;

(iii) medical devices;

(iv) biological products; or

(v) medical equipment or supplies.

* * *

(d) The attorney general may bring an action in Washington superior court for injunctive relief, costs, and attorney's fees and may impose on a manufacturer that violates this section a civil penalty of no more than $10,000.00 per violation. Each unlawful gift shall constitute a separate violation. In any action brought pursuant to this section, the attorney general shall have the same authority to investigate and to obtain remedies as if the action were brought under the Consumer Fraud Act, 9 V.S.A. chapter 63.

Sec. 2. 18 V.S.A. § 4632 is amended to read:

§ 4632. DISCLOSURE OF ALLOWABLE EXPENDITURES AND GIFTS BY MANUFACTURERS OF PRESCRIBED PRODUCTS

(a)(1)(A) Annually on or before April 1 of each year, every manufacturer of prescribed products shall disclose to the office of the attorney general for the preceding calendar year the value, nature, purpose, and recipient information of any allowable expenditure or gift permitted under subdivision 4631a(b)(2) of this title to any health care provider or to a member of the Green Mountain Care board established in chapter 220 of this title, except:

* * *

(B) Annually on or before April 1 of each year, every manufacturer of prescribed products shall disclose to the office of the attorney general for the preceding calendar year if the manufacturer is reporting other allowable expenditures or permitted gifts pursuant to subdivision (a)(1)(A) of this section, the product, dosage, number of units, and recipient information of over-the-counter drugs, nonprescription medical devices, and items of nonprescription durable medical equipment provided to a health care provider for free distribution to patients pursuant to subdivision 4631a(b)(2)(A) of this title; provided that any public reporting of such information shall not include information that allows for the identification of individual recipients of ~~samples~~ such products or connects individual recipients with the monetary value of the ~~samples~~ products provided.

* * *

(D) Any public reporting of the provision of free prescription or over-the-counter drugs, medical devices, biological products, medical equipment, or supplies to a free clinic shall not include information that allows for the identification of individual recipients of such products or connects individual recipients with the monetary value of the products provided.

(2)(A)(i) Subject to the provisions of subdivision (B) of this subdivision (a)(2) and to the extent allowed under federal law, annually on or before April 1 of each year beginning in 2012, each manufacturer of prescribed

products shall disclose to the office of the attorney general all samples ~~of prescribed products~~ provided to health care providers during the preceding calendar year, identifying for each sample the product, recipient, number of units, and dosage.

* * *

(5) The office of the attorney general shall report annually on the disclosures made under this section to the general assembly and the governor on or before October 1. The report shall include:

(A) Information on allowable expenditures and permitted gifts required to be disclosed under this section, which shall present information in aggregate form by selected types of health care providers or individual health care providers, as prioritized each year by the office; and showing the amounts expended on the Green Mountain Care board established in chapter 220 of this title. In accordance with subdivisions (1)(B), (1)(D), and (2)(A) of this subsection, information on samples and donations to free clinics of prescribed products and of over-the-counter drugs, nonprescription medical devices, and items of nonprescription durable medical equipment shall be presented in aggregate form.

* * *

(c) The attorney general may bring an action in Washington superior court for injunctive relief, costs, and attorney's fees, and to impose on a

manufacturer of prescribed products that fails to disclose as required by subsection (a) of this section a civil penalty of no more than $10,000.00 per violation. Each unlawful failure to disclose shall constitute a separate violation. In any action brought pursuant to this section, the attorney general shall have the same authority to investigate and to obtain remedies as if the action were brought under the Consumer Fraud Act, 9 V.S.A. chapter 63.

(d) The terms used in this section shall have the same meanings as they do in section 4631a of this title.

Sec. 3. EFFECTIVE DATE

This act shall take effect on July 1, 2012.