H.278

Introduced by Representatives Dickinson of St. Albans Town and Savage of Swanton

Referred to Committee on

Date:

Subject: Health; prescription drugs; prescribed product manufacturers; gift ban

Statement of purpose of bill as introduced: This bill proposes to exempt items of nominal value and certain employees of health care practitioners from Vermont's prescribed product manufacturer gift ban.

An act relating to exemptions to Vermont's prescribed product manufacturer gift ban

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:

* * *

(5) "Gift" means:

(A) Anything of value provided for free to a health care provider or to a member of the Green Mountain Care ~~board~~ Board established in chapter 220 of this title; or

(B) Except as otherwise provided in subdivision (a)(1)(A)(ii) of this section, any payment, food, entertainment, travel, subscription, advance, service, or anything else of value provided to a health care provider or to a member of the Green Mountain Care ~~board~~ Board established in chapter 220 of this title, unless:

(i) it is an allowable expenditure as defined in subdivision (a)(1) of this section; or

(ii) the health care provider or ~~board~~ Board member reimburses the cost at fair market value.

(6) "Health benefit plan administrator" means the person or entity who sets formularies on behalf of an employer or health insurer.

(7)(A) "Health care professional" means:

(i) a person who is authorized by law to prescribe or to recommend prescribed products, who regularly practices in this ~~state~~ State, and who either is licensed by this ~~state~~ State to provide or is otherwise lawfully providing health care in this ~~state~~ State; or

(ii) a partnership or corporation made up of the persons described in subdivision (i) of this subdivision (7)(A)~~; or~~

~~(iii) an officer, employee, agent, or contractor of a person described in subdivision (i) of this subdivision (7)(A) who is acting in the course and scope of employment, of an agency, or of a contract related to or supportive of the provision of health care to individuals~~.

(B) The term shall not include a person described in subdivision (A) of this subdivision (7) who is employed solely by a manufacturer.

(8) "Health care provider" means a health care professional, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person authorized to dispense or purchase for distribution prescribed products in this ~~state~~ State. The term does not include a hospital employee, other than a purchasing agent, without the authority to prescribe or recommend prescribed products or a hospital foundation that is organized as a nonprofit entity separate from a hospital.

* * *

(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~~ 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:

* * *

(L) Items of nominal value, as defined by the Attorney General by rule.

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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~~ 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~~ Board established in chapter 220 of this title, except for the following:

(i) ~~royalties~~ Royalties and licensing fees as described in subdivision 4631a(a)(1)(F) of this title~~;~~.

(ii) ~~rebates~~ Rebates and discounts for prescribed products provided to health care providers in the normal course of business as described in subdivision 4631a(b)(2)(F) of this title~~;~~.

(iii) ~~payments~~ Payments for clinical trials as described in subdivision 4631a(a)(1)(C) of this title, which shall be disclosed after the earlier of the date of the approval or clearance of the prescribed product by the Food and Drug Administration for the use for which the clinical trial is being conducted or four calendar years after the date the payment was made. For a clinical trial for which disclosure is delayed under this subdivision (iii), the manufacturer shall identify to the ~~attorney general~~ Attorney General the clinical trial, the start date, and the web link to the clinical trial registration on the national clinical trials registry~~;~~.

(iv) ~~interview~~ Interview or health care expenses as described in subdivision 4631a(a)(1)(G) of this title~~;~~.

(v) ~~coffee~~ Coffee or other snacks or refreshments at a booth at a conference or seminar~~;~~.

(vi) ~~loans~~ Loans of medical devices for short-term trial periods pursuant to subdivision 4631a(b)(2)(B) of this title, provided the loan results in the purchase, lease, or other comparable arrangement of the medical device after issuance of a certificate of need pursuant to chapter 221, subchapter 5 of this title~~; and~~.

(vii) ~~prescribed~~ Prescribed products distributed free of charge or at a discounted price pursuant to a manufacturer-sponsored or manufacturer-funded patient assistance program.

(viii) Items of nominal value, as defined by the Attorney General by rule.

(B) Annually on or before April 1 of each year, every manufacturer of prescribed products shall disclose to the ~~office of the attorney general~~ 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, items of nonprescription durable medical equipment, medical food, and infant formula 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 such products or connects individual recipients with the monetary value of the products provided.

(C) Annually on or before April 1 of each year, every manufacturer of prescribed products shall disclose to the ~~office of the attorney general~~ Office of the Attorney General for the preceding calendar year the value, nature, purpose, and recipient information of any allowable expenditure or gift to an academic institution, to a nonprofit hospital foundation, or to a professional, educational, or patient organization representing or serving health care

providers or consumers located in or providing services in Vermont, except for the following :

(i) ~~royalties~~ Royalties and licensing fees as described in subdivision 4631a(a)(1)(F) of this title~~;~~.

(ii) ~~rebates~~ Rebates and discounts for prescribed products provided in the normal course of business as described in subdivision 4631a(b)(2)(F) of this title~~; and~~.

(iii) ~~payments~~ Payments for clinical trials as described in subdivision 4631a(a)(1)(C) of this title, which shall be disclosed after the earlier of the date of the approval or clearance of the prescribed product by the Food and Drug Administration for the use for which the clinical trial is being conducted or four calendar years after the date the payment was made. For a clinical trial for which disclosure is delayed under this subdivision (iii), the manufacturer shall identify to the ~~attorney general~~ Attorney General the clinical trial, the start date, and the web link to the clinical trial registration on the national clinical trials registry.

(iv) Items of nominal value, as defined by the Attorney General by rule.

(D) Any public reporting of the provision of free prescription or over-the-counter drugs, medical devices, biological products, medical equipment, combination products, medical food, infant formula, or supplies to

a free clinic shall not include information that allows for the identification of individual recipients of such products or that connects individual recipients with the monetary value of the products provided.

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Sec. 3. EFFECTIVE DATE

This act shall take effect on July 1, 2013.