House Proposal of Amendment

S. 104

An act relating to modifications to the ban on gifts by manufacturers of prescribed products.

The House proposes to the Senate to amend the bill by striking all after the enacting clause and inserting in lieu thereof the following:

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

§ 4631a. EXPENDITURES BY MANUFACTURERS OF PRESCRIBED PRODUCTS

(a) As used in this section:

(1) "Allowable expenditures" means:

(A) Payment to the sponsor of a significant educational, medical, scientific, or policy-making conference or seminar, provided:

(i) the payment is not made directly to a health care professional or pharmacist;

(ii) funding is used solely for bona fide educational purposes, except that the sponsor may, in the sponsor's discretion, apply some or all of the funding to provide meals and other food for all conference participants; and

(iii) all program content is objective, free from industry control, and does not promote specific products.

(B) Honoraria and payment of the expenses of a health care professional who serves on the faculty at a bona fide significant educational, medical, scientific, or policy-making conference or seminar, provided:

(i) there is an explicit contract with specific deliverables which are restricted to medical issues, not marketing activities; and

(ii) consistent with federal law, the content of the presentation, including slides and written materials, is determined by the health care professional.

(C) For a bona fide clinical trial:

(i) gross compensation for the Vermont location or locations involved;

(ii) direct salary support per principal investigator and other health care professionals per year; and

(iii) expenses paid on behalf of investigators or other health care professionals paid to review the clinical trial.

(D) For a research project that constitutes a systematic investigation, is designed to develop or contribute to general knowledge, and reasonably can be considered to be of significant interest or value to scientists or health care professionals working in the particular field of inquiry:

(i) gross compensation;

(ii) direct salary support per health care professional; and

(iii) expenses paid on behalf of each health care professional.

(E) Payment or reimbursement for the reasonable expenses, including travel and lodging-related expenses, necessary for technical training of individual health care professionals on the use of a medical device if the commitment to provide such expenses and the amounts or categories of reasonable expenses to be paid are described in a written agreement between the health care provider and the manufacturer.

(F) Royalties and licensing fees paid to health care providers in return for contractual rights to use or purchase a patented or otherwise legally recognized discovery for which the health care provider holds an ownership right.

(G) The payment of the reasonable expenses of an individual related to the interview of the individual by a manufacturer of prescribed products in connection with a bona fide employment opportunity <u>or for health care services on behalf of an employee of the manufacturer</u>.

(H) Other reasonable fees, payments, subsidies, or other economic benefits provided by a manufacturer of prescribed products at fair market value.

(2) "Bona fide clinical trial" means an FDA-reviewed clinical trial that constitutes "research" as that term is defined in 45 C.F.R. § 46.102 and reasonably can be considered to be of interest to scientists or health care professionals working in the particular field of inquiry.

(3) "Clinical trial" means any study assessing the safety or efficacy of prescribed products administered alone or in combination with other prescribed products or other therapies, or assessing the relative safety or efficacy of prescribed products in comparison with other prescribed products or other therapies.

(4) "Free clinic" means a health care facility operated by a nonprofit private entity that:

(A) in providing health care, does not accept reimbursement from any third-party payor, including reimbursement from any insurance policy, health plan, or federal or state health benefits program that is individually determined;

(B) in providing health care, either:

(i) does not impose charges on patients to whom service is provided; or

(ii) imposes charges on patients according to their ability to pay;

(C) may accept patients' voluntary donations for health care service provision; and

(D) is licensed or certified to provide health services in accordance with Vermont law.

(5) "Gift" means:

(A) Anything of value provided for free to a health care provider ~~for free~~ or to a member of the Green Mountain Care 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 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 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, and who either is licensed by this state to provide or is otherwise lawfully providing health care in this 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. The term does not include a hospital foundation that is organized as a nonprofit entity separate from a hospital.

(9) "Manufacturer" means a pharmaceutical, biological product, or medical device manufacturer or any other person who is engaged in the production, preparation, propagation, compounding, processing, marketing, packaging, repacking, distributing, or labeling of prescribed products. The term does not include a wholesale distributor of biological products, a retailer, or a pharmacist licensed under chapter 36 of Title 26. The term also does not include a manufacturer whose only prescribed products are classified as Class I by the U.S. Food and Drug Administration, are exempt from pre-market notification under Section 510(k) of the federal Food, Drug and Cosmetic Act, and are sold over-the-counter without a prescription.

(10) "Marketing" shall include promotion, detailing, or any activity that is intended to be used or is used to influence sales or market share or to evaluate the effectiveness of a professional sales force.

(11) "Pharmaceutical manufacturer" means any entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drugs, whether directly or indirectly by extraction from substances of natural origin, independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or any entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of prescription drugs. The term does not include a wholesale distributor of prescription drugs, a retailer, or a pharmacist licensed under chapter 36 of Title 26.

(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.

(13) "Sample" means a unit of a prescription drug, biological product, or medical device that is not intended to be sold and is intended to promote the sale of the drug, product, or device. The term includes starter packs and coupons or other vouchers that enable an individual to receive a prescribed product free of charge or at a discounted price. The term does not include prescribed products distributed free of charge or at a discounted price pursuant to a manufacturer-sponsored or manufacturer-funded patient assistance program.

(14) "Significant educational, scientific, or policy-making conference or seminar" means an educational, scientific, or policy-making conference or seminar that:

(A) is accredited by the Accreditation Council for Continuing Medical Education or a comparable organization or is presented by an approved sponsor of continuing education, provided that the sponsor is not a manufacturer of prescribed products; and

(B) offers continuing education credit, features multiple presenters on scientific research, or is authorized by the sponsor to recommend or make policy.

(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, provided to a health care provider for free distribution to patients.

(B) The loan of a medical device for a short-term trial period, not to exceed ~~90~~ 120 days, to permit evaluation of a medical device by a health care provider or patient.

(C) The provision of reasonable quantities of medical device demonstration or evaluation units to a health care provider to assess the appropriate use and function of the product and determine whether and when to use or recommend the product in the future.

(D) The provision, distribution, dissemination, or receipt of peer-reviewed academic, scientific, or clinical articles or journals and other items that serve a genuine educational function provided to a health care provider for the benefit of patients.

(E) Scholarship or other support for medical students, residents, and fellows to attend a significant educational, scientific, or policy-making conference or seminar of a national, regional, or specialty medical or other professional association if the recipient of the scholarship or other support is selected by the association.

(F) Rebates and discounts for prescribed products provided in the normal course of business.

(G) Labels approved by the federal Food and Drug Administration for prescribed products.

(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.

(I) ~~The provision of free prescription drugs to or on behalf of an individual through a prescription drug manufacturer's patient assistance program.~~ Prescribed products distributed free of charge or at a discounted price pursuant to a manufacturer-sponsored or manufacturer-funded patient assistance program.

(J) Fellowship salary support provided to fellows through grants from manufacturers of prescribed products, provided:

(i) such grants are applied for by an academic institution or hospital;

(ii) the institution or hospital selects the recipient fellows;

(iii) the manufacturer imposes no further demands or limits on the institution's, hospital's, or fellow's use of the funds; and

(iv) fellowships are not named for a manufacturer and no individual recipient's fellowship is attributed to a particular manufacturer of prescribed products.

(K) The provision of coffee or other snacks or refreshments at a booth at a conference or seminar.

(c) Except as described in subdivisions (a)(1)(B) and (C) of this section, no manufacturer or other entity on behalf of a manufacturer shall provide any fee, payment, subsidy, or other economic benefit to a health care provider in connection with the provider's participation in research.

(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.

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 ~~October~~ April 1 of each year, every manufacturer of prescribed products shall disclose to the office of the attorney general for the ~~fiscal~~ preceding calendar year ~~ending the previous June 30th~~ the value, nature, purpose, and recipient information of~~:~~

~~(A)~~ 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:

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

(ii) 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 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 ~~two~~ 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 the clinical trial, the start date, and the web link to the clinical trial registration on the national clinical trials registry;

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

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

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

(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 or connects individual recipients with the monetary value of the samples 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 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:

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

(ii) 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 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 ~~two~~ 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 the clinical trial, the start date, and the web link to the clinical trial registration on the national clinical trials registry.

(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 ~~free~~ 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.

(ii) The office of the attorney general may contract with academic researchers to release to such researchers data relating to manufacturer distribution of ~~free~~ samples, subject to confidentiality provisions and without including the names or license numbers of individual recipients, for analysis and aggregated public reporting.

(iii) Any public reporting of manufacturer distribution of ~~free~~ samples shall not include information that allows for the identification of individual recipients of samples or connects individual recipients with the monetary value of the samples provided.

(B) Subdivision (A) of this subdivision (a)(2) shall not apply to samples of prescription drugs required to be reported under Sec. 6004 of the Patient Protection and Affordable Care Act of 2010, Public Law 111-148, as amended by the Health Care and Education Reconciliation Act of 2010, Public Law 111-152, if ~~as of January 1, 2011,~~ the office of the attorney general ~~has~~

~~determined~~ determines that the U.S. Department of Health and Human Services will collect and report state- and recipient-specific information regarding manufacturer distribution of ~~free~~ samples of such prescription drugs.

(3) Annually on ~~July~~ January 1, each manufacturer of prescribed products also shall disclose to the office of the attorney general the name and address of the individual responsible for the manufacturer's compliance with the provisions of this section.

(4) Disclosure shall be made on a form and in a manner prescribed by the office of the attorney general and shall require manufacturers of prescribed products to report each allowable expenditure or gift permitted under subdivision 4631a(b)(2) of this title including:

(A) except as otherwise provided in ~~subdivision~~ subdivisions (a)(1)(B) and (a)(2) of this section, the value, nature, and purpose of each allowable expenditure, and gift permitted under subdivision 4631a(b)(2) of this title according to specific categories identified by the office of the attorney general;

(B) the name of the recipient;

(C) the recipient's address;

(D) the recipient's institutional affiliation;

(E) prescribed product or products being marketed, if any; and

(F) the recipient's state board number or, in the case of an institution, foundation, or organization, the federal tax identification number or the identification number assigned by the attorney general.

(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 ~~April 1~~ October 1. The report shall include:

(A) Information on allowable expenditures and permitted gifts required to be disclosed under this section, which shall ~~be presented in both~~ present information in aggregate form ~~and~~ 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) and (2)(A) of this subsection, information on samples 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.

(B) Information on violations and enforcement actions brought pursuant to this section and section 4631a of this title.

(6) After issuance of the report required by subdivision (5) of this subsection and except as otherwise provided in ~~subdivision~~ subdivisions (1)(B) and (2)(A)~~(i)~~ of this subsection, the office of the attorney general shall make all disclosed data used for the report publicly available and searchable through an Internet website.

(7) The department of Vermont health access shall examine the data available from the office of the attorney general for relevant expenditures and determine whether and to what extent prescribing patterns by health care providers of prescribed products reimbursed by Medicaid, VHAP, Dr. Dynasaur, VermontRx, and VPharm may reflect manufacturer influence. The department may select the data most relevant to its analysis. The department shall report its analysis annually to the general assembly and the governor on or before ~~October 1~~ March 1.

(b)(1) ~~Annually on July 1~~ Beginning January 1, 2013 and annually thereafter, the office of the attorney general shall collect a $500.00 fee from each manufacturer of prescribed products filing annual disclosures of expenditures greater than zero described in subsection (a) of this section.

(2) Fees collected under this section shall fund collection and analysis of information on activities related to the marketing of prescribed products under section 4631a of this title and under this section. The fees shall be collected in a special fund assigned to the office.

(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.

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

Sec. 3. REPORTING FEES

(a) Notwithstanding the provisions of 18 V.S.A. § 4632(b)(1), on July 1, 2011, the office of the attorney general shall collect a $500.00 fee from each manufacturer of prescribed products filing annual disclosures of expenditures greater than zero described in 18 V.S.A. § 4632(a) for the fiscal year ending June 30, 2011.

(b) Notwithstanding the provisions of 18 V.S.A. § 4632(b)(1), on January 1, 2012, the office of the attorney general shall collect a $250.00 fee from each manufacturer of prescribed products filing disclosures of expenditures greater than zero described in 18 V.S.A. § 4632(a) for the six-month period from July 1, 2011 through December 31, 2011.

Sec. 4. ELECTRONIC PRIOR AUTHORIZATION

The commissioner of Vermont health access and the Vermont information technology leaders (VITL), in collaboration with health insurers, prescribers, representatives of the independent pharmacy community, and other interested parties, shall evaluate the use of electronic means for requesting and granting prior authorization for prescription drugs. No later than January 15, 2012, the commissioner and VITL shall report their findings to the senate committee on health and welfare and the house committee on health care and make recommendations for processes to develop standards for electronic prior authorizations.

Sec. 5. SPECIALTY TIER DRUGS

(a) Prior to July 1, 2012, no health insurer or pharmacy benefit manager shall utilize a cost-sharing structure for prescription drugs that imposes on a consumer for any drug a greater co-payment, deductible, coinsurance, or other cost-sharing requirement than that which applies for a nonpreferred brand-name drug.

(b) The commissioner of banking, insurance, securities, and health care administration shall not approve any form for a health insurance policy prior to July 1, 2012 that imposes on a consumer for any prescription drug a greater co-payment, deductible, coinsurance, or other cost-sharing requirement than that which applies for a nonpreferred brand-name drug.

Sec. 6. EFFECTIVE DATES

(a) Secs. 1, 2, and 3 of this act shall take effect on July 1, 2011, except that, in Sec. 2, the amendments to 18 V.S.A. § 4632(a)(1)(B) shall take effect on January 1, 2012.

(b) Sec. 4 of this act and this section shall take effect on passage.

(c) Sec. 5 of this act shall take effect on passage and shall apply to all forms that have previously been approved by the department of banking, insurance, securities, and health care administration or that may be approved by the department after passage of this act.