

S.48

An act relating to marketing of prescription drugs

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

Sec. 1. 18 V.S.A. § 4631(b) is amended to read:

(b) As used in this section:

* * *

(3) "Health care professional" shall have the same meaning as health care provider in section 9402 of this title.

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Sec. 2. 18 V.S.A. § 4631a is added to read:

§ 4631a. GIFTS BY PHARMACEUTICAL MANUFACTURERS

(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;

(ii) funding is used solely for bona fide educational purposes; and

(iii) all program content is objective, free from industry influence, 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) the content of the presentation, including slides and written materials, is determined by the health care professional.

(C) Gross compensation for a bona fide clinical trial per principal investigator per year and the Vermont location or locations of the clinical trial.

(D) Gross compensation 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.

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

(F) Other reasonable fees, payments, subsidies, or other economic benefits provided by a pharmaceutical manufacturer 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 prescription drugs administered alone or in combination with other prescription drugs or other therapies or assessing the relative safety or efficacy of prescription drugs in comparison with other prescription drugs or other therapies.

(4) “Gift” means a payment, food, entertainment, travel, subscription, advance, service, or anything else of value provided to a health care professional for less than fair market value.

(5)(A) “Health care professional” means:

(i) a person who is authorized to prescribe prescription drugs and who 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 (5)(A); or

(iii) an officer, employee, agent, or contractor of a person described in subdivision (i) of this subdivision (5)(A) who is acting in the course and scope of employment, agency, or 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 (5) who is employed solely by a pharmaceutical manufacturer.

(6) "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.

(7) "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 or a pharmacist licensed under chapter 36 of Title 26.

(8) "Prescription drug" means a drug as defined in section 201 of the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321.

(9) "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; and

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

(b)(1) It is unlawful for any pharmaceutical manufacturer, or any agent thereof, to offer or give any gift to a health care professional.

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

(A) Samples of a prescription drug provided to a health care professional for free distribution to patients.

(B) The provision, distribution, dissemination, or receipt of peer-reviewed academic, scientific, or clinical articles or journals.

(C) 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.

(D) Rebates and discounts for prescription drugs provided in the normal course of business.

(c) The attorney general may bring an action in Washington superior court for injunctive relief, costs, and attorney's fees and may impose on a pharmaceutical 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. 3. 18 V.S.A. § 4632 is amended to read:

§ 4632. PHARMACEUTICAL MARKETERS DISCLOSURE OF ALLOWABLE EXPENDITURES AND GIFTS BY PHARMACEUTICAL MANUFACTURERS

(a)(1) Annually on or before ~~December~~ September 1 of each year, every pharmaceutical ~~manufacturing company~~ manufacturer shall disclose to the office of the attorney general the value, nature, ~~and purpose, and recipient information of any gift, fee, payment, subsidy, or other economic benefit provided in connection with detailing, promotional, or other marketing activities by the company, directly or through its pharmaceutical marketers, to:~~

(A) any allowable expenditure to any physician, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person in Vermont authorized to prescribe, dispense, or purchase prescription drugs in this state health care professional, except for royalties and licensing fees as described in subdivision 4631(a)(1)(E) of this title;

~~Disclosure shall include the name of the recipient. Disclosure shall be made on a form and in a manner prescribed by the office of the attorney general and shall require pharmaceutical manufacturing companies to report the value, nature, and purpose of all gift expenditures according to specific categories. 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.~~

(B) any allowable expenditure or gift, except as provided for in subdivision (2) of this subsection, to:

(i) a hospital, nursing home, pharmacist, health benefit plan administrator, or any other person authorized to dispense or purchase for distribution prescription drugs in this state;

(ii) an academic institution in this state; and

(iii) a nonprofit professional, educational, or patient organization representing health care professionals or consumers.

(2) The disclosure requirement in subdivision (1)(B) of this subsection shall not apply to any of the following:

(A) Samples of a prescription drug provided to a health care professional for free distribution to patients.

(B) The provision, distribution, dissemination, or receipt of peer-reviewed academic, scientific, or clinical articles or journals.

(C) 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.

(D) Royalties and licensing fees as described in subdivision 4631a(a)(1)(E) of this title.

(E) Rebates and discounts for prescription drugs provided in the normal course of business.

~~(2)(3)~~ Annually on ~~October~~ July 1, each ~~company~~ pharmaceutical manufacturer subject to the ~~provisions of this section~~ pharmaceutical manufacturer also shall disclose to the office of the attorney general, the name and address of the individual responsible for the ~~company's~~ pharmaceutical manufacturer's compliance with the provisions of this section, ~~or if this information has been previously reported, any changes to the name or address of the individual responsible for the company's compliance with the provisions of this section.~~

~~(3)(4)~~ The office of the attorney general shall keep confidential all trade secret information, as defined by subdivision 317(b)(9) of Title 1, except that ~~the office may disclose the information to the department of health and the office of Vermont health access for the purpose of informing and prioritizing the activities of the evidence-based education program in subchapter 2 of~~

~~chapter 91 of Title 18. The department of health and the office of Vermont health access shall keep the information confidential. The disclosure form shall permit the company to identify any information that it claims is a trade secret as defined in subdivision 317(c)(9) of Title 1. In the event that the attorney general receives a request for any information designated as a trade secret, the attorney general shall promptly notify the company of such request. Within 30 days after such notification, the company shall respond to the requester and the attorney general by either consenting to the release of the requested information or by certifying in writing the reasons for its claim that the information is a trade secret. Any requester aggrieved by the company's response may apply to the superior court of Washington County for a declaration that the company's claim of trade secret is invalid. The attorney general shall not be made a party to the superior court proceeding. Prior to and during the pendency of the superior court proceeding, the attorney general shall keep confidential the information that has been claimed as trade secret information, except that the attorney general may provide the requested information to the court under seal.~~

~~(4) The following shall be exempt from disclosure:~~

~~(A) free samples of prescription drugs intended to be distributed to patients;~~

~~(B) the payment of reasonable compensation and reimbursement of expenses in connection with bona fide clinical trials;~~

~~(C) any gift, fee, payment, subsidy or other economic benefit the value of which is less than \$25.00;~~

~~(D) scholarship or other support for medical students, residents, and fellows to attend a significant educational, scientific, or policy making conference 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; and~~

~~(E) prescription drug rebates and discounts.~~

Disclosure shall be made on a form and in a manner prescribed by the office of the attorney general and shall require pharmaceutical manufacturers to report each allowable expenditure or gift, including:

(A) the value, nature, and purpose of each allowable expenditure, 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 area or areas of specialty;

(E) the recipient's institutional affiliation;

(F) the prescription drug or drugs being marketed, if any; and

(G) the recipient's state board number.

(5) The office of the attorney general shall make all disclosed data publicly available and searchable on its website.

(6) 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. The report shall include:

(A) Information on allowable expenditures and gifts required to be disclosed under this section, which shall be presented in both aggregate form and by selected types of health care professionals or individual health care professionals, as prioritized each year by the office.

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

(7) The office of Vermont health access shall analyze the data in the report from the office of the attorney general and report annually to the general assembly and the governor on or before October 1 on whether and to what extent prescribing patterns by health care professionals of prescription drugs reimbursed by Medicaid or other state health programs may reflect pharmaceutical manufacturer influence.

(b) Annually on July 1, the office of the attorney general shall collect a \$500.00 fee from each pharmaceutical manufacturer filing annual disclosures described in subsection (a) of this section as long as the pharmaceutical manufacturer has actual expenditures to disclose.

(c) The attorney general may bring an action in Washington superior court for injunctive relief, costs, and ~~attorneys~~ attorney's fees, and to impose on a pharmaceutical ~~manufacturing company~~ manufacturer 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.

~~(c) As used in this section:~~

~~(1) "Approved clinical trial" means a clinical trial that has been approved by the U.S. Food and Drug Administration (FDA) or has been approved by a duly constituted Institutional Review Board (IRB) after reviewing and evaluating it in accordance with the human subject protection standards set forth at 21 C.F.R. Part 50, 45 C.F.R. Part 46, or an equivalent set of standards of another federal agency.~~

~~(2) "Bona fide clinical trial" means an approved clinical trial that constitutes "research" as that term is defined in 45 C.F.R. § 46.102 when the results of the research can be published freely by the investigator and reasonably can be considered to be of interest to scientists or medical practitioners working in the particular field of inquiry.~~

~~(3) "Clinical trial" means any study assessing the safety or efficacy of drugs administered alone or in combination with other drugs or other therapies,~~

~~or assessing the relative safety or efficacy of drugs in comparison with other drugs or other therapies.~~

~~(4) "Pharmaceutical marketer" means a person who, while employed by or under contract to represent a pharmaceutical manufacturing company, engages in pharmaceutical detailing, promotional activities, or other marketing of prescription drugs in this state to any physician, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person authorized to prescribe, dispense, or purchase prescription drugs. The term does not include a wholesale drug distributor or the distributor's representative who promotes or otherwise markets the services of the wholesale drug distributor in connection with a prescription drug.~~

~~(5) "Pharmaceutical manufacturing company" means any entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drugs, either directly or indirectly by extraction from substances of natural origin, or 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 drug distributor or pharmacist licensed under chapter 36 of Title 26.~~

~~(6) "Unrestricted grant" means any gift, payment, subsidy, or other economic benefit to an educational institution, professional association, health~~

~~care facility, or governmental entity which does not impose any restrictions on the use of the grant, such as favorable treatment of a certain product or an ability of the marketer to control or influence the planning, content, or execution of the education activity.~~

~~(d) Disclosures of unrestricted grants for continuing medical education programs shall be limited to the value, nature, and purpose of the grant and the name of the grantee. It shall not include disclosure of the individual participants in such a program~~ The terms used in this section shall have the same meanings as they do in section 4631a of this title.

Sec. 4. 1 V.S.A. § 317(c) is amended to read:

(c) The following public records are exempt from public inspection and copying:

* * *

(9) trade secrets, including, ~~but not limited to,~~ any formulae, plan, pattern, process, tool, mechanism, compound, procedure, production data, or compilation of information which is not patented, which is known only to certain individuals within a commercial concern, and which gives its user or owner an opportunity to obtain business advantage over competitors who do not know it or use it, except that the disclosures required by section 4632 of Title 18 shall not be included in this subdivision;

Sec. 5. 18 V.S.A. § 4633(d) is amended to read:

(d) As used in this section:

(1) “Average wholesale price” or “AWP” means the wholesale price charged on a specific commodity that is assigned by the ~~drug manufacturer~~ pharmaceutical manufacturing company and listed in a nationally recognized drug pricing file.

(2) “Pharmaceutical manufacturing company” ~~is defined by subdivision 4632(e)(5) of this title~~ shall have the same meaning as “pharmaceutical manufacturer” in section 4631a of this title.

(3) “Pharmaceutical marketer” ~~is defined by subdivision 4632(e)(4) of this title~~ means a person who, while employed by or under contract to represent a pharmaceutical manufacturing company, engages in marketing, as that term is defined in section 4631a of this title.

Sec. 6. 2 V.S.A. chapter 26 is amended to read:

CHAPTER 26. ~~NORTHEAST~~ NATIONAL LEGISLATIVE ASSOCIATION

ON PRESCRIPTION ~~DRUGS PRICING~~ DRUG PRICES

§ 951. ~~NORTHEAST~~ NATIONAL LEGISLATIVE ASSOCIATION ON

PRESCRIPTION ~~DRUGS PRICING~~ DRUG PRICES

(a) The general assembly finds that the ~~Northeast~~ National Legislative Association on Prescription ~~Drugs Pricing~~ Drug Prices is a nonprofit organization of legislators formed for the purpose of making prescription drugs

more affordable and accessible to citizens of the member states. The general assembly further finds that the activities of the Association provide a public benefit to the people of the state of Vermont.

(b) On or before January 15, upon the convening of each biennial session of the general assembly, three directors shall be appointed by the speaker, which may include the speaker, and three directors shall be appointed by the committee on committees, which may include a member of the committee on committees, to serve as the Vermont directors of the ~~Northeast~~ National Legislative Association on Prescription ~~Drugs Pricing~~ Drug Prices. Directors so appointed from each body shall not all be from the same party. Directors so appointed shall serve until new members are appointed.

(c) For meetings of the Association, directors who are legislators shall be entitled to per diem compensation and reimbursement of expenses in accordance with section 406 of Title 2. If the lieutenant governor is appointed as a director pursuant to subsection (b) of this section, his or her compensation and expenses shall be paid from the appropriation made to the office of the lieutenant governor.

(d) The Vermont directors of the Association shall report to the general assembly on or before January 1 of each year with a summary of the activities of the Association, and any findings and recommendations for making prescription drugs more affordable and accessible to Vermonters.

Sec. 7. 33 V.S.A. § 1998(c)(4)(A) is amended to read:

(4) The actions of the commissioners, the director, and the secretary shall include:

(A) active collaboration with the ~~Northeast~~ National Legislative Association on Prescription Drugs in the Association's efforts to establish a ~~Prescription Drug Fair Price Coalition~~ Drug Prices;