

# The Vermont Statutes Online

## Title 18: Health

### *Chapter 91: Prescription Drug Cost Containment*

#### **4632. Pharmaceutical marketers**

##### **§ 4632. Pharmaceutical marketers**

(a)(1) Annually on or before December 1 of each year, every pharmaceutical manufacturing company shall disclose to the office of the attorney general the value, nature, and purpose 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 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. 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.

(2) Annually on October 1, each company subject to the provisions of this section also shall disclose to the office of the attorney general, the name and address of the individual responsible for the company'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) 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.

(b) The attorney general may bring an action in Washington superior court for injunctive relief, costs, and attorneys fees, and to impose on a pharmaceutical manufacturing company 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. (Added 2001, No. 127 (Adj. Sess.), § 1, eff. June 13, 2002; amended 2003, No. 122 (Adj. Sess.), § 128b; 2005, No. 71, § 54a; 2005, No. 191 (Adj. Sess.), § 45; 2007, No. 80, §§ 3, 4.)