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Source:
Vermont Statutes/TITLE 33 Human Services /PART 2 Economic Assistance /CHAPTER 19. MEDICAL ASSISTANCE /Subchapter 5. Prescription Drug Cost Containment / § 2005. Pharmaceutical marketers.

§ 2005. Pharmaceutical marketers.

(a) (1) Annually on or before January 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 March 1.

(2) Annually in the month of October, 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.

(3) The office of the attorney general shall keep confidential all trade secret information, as defined by subdivision 317(b)(9) of Title 1. The disclosure form shall permit the company to identify any information that is a trade secret.

(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;

(E) unrestricted grants for continuing medical education programs; and

(F) 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.

Added 2001, No. 127 (Adj. Sess.), § 1, eff. June 13, 2002; amended 2003, No. 122 (Adj. Sess.), § 128b.

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Source:
Vermont Statutes/TITLE 33 Human Services /PART 2 Economic Assistance /CHAPTER 19. MEDICAL ASSISTANCE /Subchapter 5. Prescription Drug Cost Containment / § 2005a. Pharmaceutical marketer price disclosure.

§ 2005a. Pharmaceutical marketer price disclosure.

(a) When a pharmaceutical marketer engages in any form of prescription drug marketing directly to a physician or other person authorized to prescribe prescription drugs, the marketer shall disclose to the physician or other prescriber the average wholesale price (AWP) of the drugs being marketed. Disclosure shall include the AWP per pill and the price relationship between the drug being marketed and other drugs within the same therapeutic class.

(b) The disclosures required under this section shall be on a form and in a manner prescribed by the office of the attorney general. The attorney general may adopt rules to implement the provisions of this section.

(c) In addition to any other remedy provided by law, the attorney general after consultation with the commissioner of banking, insurance, securities, and health care administration may file an action in superior court for a violation of this section or of rules adopted under this section. In any such action, 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, chapter 63 of Title 9. Each violation of this section or of rules adopted under this section constitutes a separate civil violation for which the attorney general may obtain relief.

(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 and listed in a nationally recognized drug pricing file.

(2) "Pharmaceutical manufacturing company" is defined by subdivision 2005(c)(5) of this title.

(3) "Pharmaceutical marketer" is defined by subdivision 2005(c)(4) of this title.

Added 2003, No. 122 (Adj. Sess.), § 128c.