

# GUIDE TO VERMONT'S PHARMACEUTICAL MARKETING DISCLOSURE LAW

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## **Introduction**

Vermont law 33 V.S.A. § 2005 requires registration and financial disclosure by pharmaceutical manufacturing companies and pharmaceutical marketers. This is a brief guide to the law, including some frequently asked questions, followed by the text of the law.

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## **Who must disclose?**

Pharmaceutical manufacturing companies must disclose the required information to the Vermont Office of the Attorney General.

What is a pharmaceutical manufacturing company?

“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. 33 V.S.A. § 2005(c)(5))

Who is a pharmaceutical marketer?

“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. (33 V.S.A. § 2005(c)(4))

What are the deadlines for disclosure?

**No later than October 31, 2005** - Each pharmaceutical manufacturing company subject to the law must disclose to the Vermont Office of the Attorney General the name and address of the person responsible for the company’s compliance with the law. This disclosure deadline is the same every year. (33 V.S.A. § 2005(a)(2))

**No later than January 1, 2006** - Each pharmaceutical manufacturing company subject to the law must disclose to the Vermont Office of the Attorney General certain information about marketing activities. This disclosure looks back and covers the 12-month period ending June 30, 2005. The January 1 disclosure deadline will be the same every year after the January 1, 2005 deadline. On January 1, disclosure must be made for activities occurring during the preceding fiscal year (July 1 – June 30). This provides a six-month time period after the end of the fiscal year, in which companies may collect and file the required information. (33 V.S.A. § 2005(a)(1))

Can a company designate one person to be responsible for reporting or must each division of a company report?

Each company should designate a single person to report for the activities of the entire company. Reporting by each division is not necessary.

What is the format for disclosure?

Each disclosure must be made by filing an electronic form within the appropriate deadline. These forms are available at <http://www.atg.state.vt.us/display.php?smod=177>. After input of the disclosures online, companies are required to forward a hard copy of the “Signature of Individual Responsible” to the Attorney General’s Office.

What must be disclosed?

The following information must be disclosed to the Vermont 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.” (33 V.S.A. § 2005(a)(1))

What is required in reporting the “value, nature and purpose and recipient” of an economic benefit?

**Value** - The fair market value of the economic benefit, rounded to the nearest dollar.

**Nature** - A description of the economic benefit given, whether it is cash, dinner, plane tickets, etc.

**Purpose** - A short description of the detailing, promotional or other marketing activities, such as advertising, charity function, seminar, etc.

**Recipient** – This disclosure requires the names and type of recipients, which includes institutions, physicians, hospitals, pharmacists, etc. The disclosure law was amended in 2004 to require the disclosure of the names of the recipients.

Does disclosure of gifts, etc. to “a person authorized to purchase prescription drugs” include the general public?

33 V.S.A. § 2005(a)(1) requires disclosure of gifts to various health care professionals and institutions and “...any other person in Vermont authorized to prescribe, dispense or purchase prescription drugs in this state.” This does not include consumers. This means persons authorized to purchase for resale or distribution. The Legislature could not have intended disclosure of gifts or other economic benefits to every member of the general public.

What is exempt from disclosure?

The following are 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. (33 V.S.A. § 2005(a)(4))

Are continuing medical education (CME) programs supported by pharmaceutical marketing companies exempt from disclosure?

Unrestricted grants for CME are exempt because they are not considered “marketing” or “promotional” under the statute. An unrestricted grant is “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.” This exemption would apply to any unrestricted grant made by a pharmaceutical marketing company for any purpose other than those provided in connection with detailing, promotional or other marketing activities by the company. (33 V.S.A. § 2005(c)(6))

What is an “approved” clinical trial?

An “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. (33 V.S.A. § 2005(c)(1))

### What happens to disclosed information?

The Vermont Office of the Attorney General collects and stores the information on the disclosure forms in electronic format and requires the companies to send in a hard copy of the responsible individual's signature. Disclosed information is public, except for trade secrets, as explained below. The Vermont Office of the Attorney General must file an annual disclosure report with the Legislature and the Governor by March 1, 2006. (33 V.S.A. § 2005(a)(1))

### What happens to trade secrets?

The Vermont Office of the Attorney General must keep all trade secret information Confidential. Trade secrets are defined in 1 V.S.A. § 317(b)(9) as “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.” The disclosure forms provided permit a company to identify any information that is a trade secret. (33 V.S.A. § 2005(a)(3))

### What are the penalties for failing to comply with the law?

The Vermont Attorney General may bring a civil suit in Washington Superior Court for an injunction, costs, and attorneys fees. In addition, a company that fails to disclose under the law may be assessed a civil penalty of not more than \$10,000 per violation. Each unlawful failure to disclose constitutes a separate violation. (33 V.S.A. § 2005(b))

### Are non-prescribing office staff covered by the law?

The Attorney General will treat gifts to an office or office staff as gifts to the prescriber. Example: If the gift is a \$60 luncheon for an office of two physicians and three non-prescribing office staff, the gift amount is to be divided per prescriber, or \$30 each and is reportable. The gift may not be divided by five and considered as five separate and unreportable \$12 gifts.