

GUIDE TO VERMONT'S PHARMACEUTICAL MARKETING DISCLOSURE LAW FOR FY09 DISCLOSURES

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Introduction

Effective July 1, 2009, Vermont law bans certain gifts and requires registration and financial disclosure by manufacturers of pharmaceuticals, biological products, and medical devices. However, the disclosures required for FY09 (July 1, 2008 – June 30, 2009) remain unchanged. This is a brief guide to the law covering disclosures for FY09 only.¹

Please read this guidance carefully. Any section labeled with “*NEW*” has been added or modified since the June 2009 publication of this Guide.

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¹ Unless otherwise noted, citations are to law in effect as of July 1, 2009.

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Who must report

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. (18 V.S.A. § 4632(c)(5)[2008]; the term in the new law is “pharmaceutical manufacturer.” 18 V.S.A. § 4631a(a)(9))

How to report

What are the deadlines for disclosure?

No later than July 1, 2009, each pharmaceutical manufacturer 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. (18 V.S.A. § 4632(a)(2)) The Attorney General refers to that person as the “compliance officer.”

Any company with expenditures to report in FY09 must also pay a \$500 registration fee by July 1, 2009. (18 V.S.A. § 4632(b)(1))

If a company incorrectly files an initial Compliance Officer Form indicating no expenditures to report, and then determines that it had FY09 expenditures, the company should file a new Compliance Officer Form and send in the \$500 registration fee as soon as possible.

Pharmaceutical manufacturers with no expenditures to report and manufacturers of biological products and medical devices are encouraged to file the Compliance Officer Form so that we can readily contact you about how to comply with Vermont law. No fee is required in these instances and no further action need be taken.

No later than November 1, 2009, each pharmaceutical manufacturer subject to the law must disclose to the Vermont Office of the Attorney General certain information about marketing activities during the 12-month period ending June 30, 2009. (The effective date for 18 V.S.A. § 4632(a)(1) is November 1, 2009, based on the law in effect on June 30, 2009.)

What if the company does not know if it will have expenditures to report?

Sometimes a company will not know by July 1 whether it has been marketing to a Vermont prescriber because the prescriber holds dual licenses in Vermont and another state, such as New Hampshire. In this case, file the Compliance Officer Form by July 1 indicating “no expenditures to report” and, before you file disclosures, file a new Compliance Officer Form and send in the \$500 registration fee. We will use the latest information.

How does the company disclose the compliance officer?

A form identifying the compliance officer is at the Attorney General’s website at: www.atg.state.vt.us; under “Issues” on left, click on Disclosures of Marketing Expenditures for Prescription Drugs, Biological Products and Medical Devices, and “Compliance Officer Form.” (In an effort to streamline the process, we now discourage those making disclosures from sending a paper copy of this form to our office. Please file electronically only.)

Each company should designate a single person responsible for reporting the activities of the entire company. Reporting by each division is not necessary. The Compliance Officer Form allows you to designate a different person responsible for collecting and reporting the data.

Once your Compliance Officer Form is received by the Attorney General’s Office, we will send you an acknowledgement by email. If you do not hear from us, please email us at: prescribedproducts@atg.state.vt.us.

How does the company pay the annual \$500 registration fee?

Send a check for \$500.00, made out to “State of Vermont,” and mail to:

Vermont Office of the Attorney General
Public Protection Division
109 State Street
Montpelier, VT 05609-1001

We do not accept credit cards. To request the Vermont Attorney General’s Tax ID # or W-9 form, write us at: prescribedproducts@atg.state.vt.us with “Tax ID” in the subject line.

How does the company make disclosures?

A company can make disclosures by either entering the data through a form on the Attorney General’s website or by downloading an Access-based database from the website, entering the data, and returning the database to the Attorney General’s office. Either process will require the new username and password submitted in the Compliance Officer Form.

Data that does not comply with this guidance will be returned to the Compliance Officer for

corrections and resubmission. The Attorney General's Office will make every effort to verify compliance within five working days of receipt of the data.

*The November 1, 2009, deadline for all submissions is not met for any data that is returned to the company for corrections unless it is resubmitted with no errors by **November 1**.*

How does a company make corrections to a report?

If you find that you have submitted incorrect data after your data has been submitted to and accepted by the Office of the Attorney General, send an email identifying both the submitted data and the corrected data to: prescribedproducts@atg.state.vt.us. We will email you an acknowledgement of receipt.

What to report

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. (18 V.S.A. § 4632(a)(1)[2008])

What is required in reporting the “value, nature, and purpose” 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/check, donation, educational materials (such as books, journals or brochures), food, grant, lodging, transportation, or other. *Do not use “other” unless the expenditure does not fit into one of the supplied categories.*

Purpose - A short description of the purpose of the expenditure, such as consulting, CME grants, education (other), marketing, speaker fee/payment, or other. *Do not use “other” unless the expenditure does not fit into one of the supplied categories.*

In addition, the company must identify the drug or drugs associated with the reported expenditure. If more than five drugs were associated with the reported payment or gift, the company must list the five drugs most relevant to the expenditure.

How does a company report the recipients?

This disclosure requires the names and types of recipients, which includes all prescribers as well as hospitals, nursing homes, pharmacists, health benefit plan administrators, and any other

person authorized to dispense or purchase for distribution prescribed products in Vermont.

Prescribers and pharmacists -- In order to ensure recipients are accurately identified, reporters must include the Vermont license number of the prescriber or pharmacist. *All license numbers are in the form of three digits, dash, seven digits* (i.e. xxx-xxxxxxx). We no longer require companies to provide a prescriber's specialty or credentials.

The Access-based database includes a table of active prescribers' and pharmacists' names and license numbers as of July 1, 2008. If you do not find the name in the table, check the websites below.

License numbers for physicians, physician and anesthesiologist assistants, podiatrists, and physicians who hold limited temporary permits may be found at:

<http://www.docboard.org/vt/df/vtsearch.htm>.

State license numbers for dentists, naturopathic physicians, nurse practitioners, optometrists, osteopaths, pharmacists, veterinarians and others who may be authorized to dispense prescription drugs may be found at:

<http://www.sec.state.vt.us/seek/lrspseek.htm>.

***NEW:** You must disclose reportable expenditures even if you are unable to find a prescriber's license number.* If you are unable to find a Vermont license number for a prescriber, pharmacist, or other person authorized to dispense or recommend prescribed products, contact the recipient directly for his or her license number or for the license number(s) of the appropriate prescriber(s) to whom the expenditure should be associated.

Other Recipients -- For any recipient who is not a prescriber or pharmacist (i.e. hospitals, nursing homes, health benefit plan administrators, and others authorized to dispense or purchase for prescribed products), use a license number of "000-0000000."

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

18 V.S.A. § 4632(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.

Is non-prescribing office staff covered by the law?

All gifts must be attached to a prescriber. Please 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. Gifts are to be apportioned in this manner regardless of the number of attendees at the event.

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; and
- (E) prescription drug rebates and discounts. (18 V.S.A. § 4632(a)(4)[2008])

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. (18 V.S.A. § 4632(c)(1)[2008])

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

No. Unrestricted grants for CME are not exempt from disclosure but disclosure is limited to the value, nature, and purpose of the grant and the name of the grantee; the names of the individual participants in such a program need not be disclosed. (18 V.S.A. § 4632(d)[2008])

Penalties for failure to report

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 attorney’s 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. (18 V.S.A. § 4632(c))

Public disclosure of reported information

What happens to disclosed information?

The Vermont Office of the Attorney General must file an annual disclosure report with the Legislature and the Governor by April 1, 2010. (18 V.S.A. § 4632(a)(4)) All disclosed information that has not been designated as “trade secret,” as explained below, will posted on the Attorney General’s website after the annual report is released.

May a company designate any of this information as “trade secret”?

Yes, companies may designate one or more of the disclosed items as “trade secret” as long as the items meet the definition of “trade secret” under Vermont law. 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 Vermont Office of the Attorney General must keep confidential all trade secret information. When the attorney general receives a request for information designated as trade secret, the Attorney General will notify the pharmaceutical company of the request and the company has 30 days to respond to both the requester and the Attorney General by consenting to the release of the information or stating in writing the reasons for its claim. Any requester aggrieved by the company’s response can apply to the Washington County Superior Court for a declaration that the company’s claim of trade secret is invalid. The Attorney General shall not be made a party to that proceeding but shall keep the information confidential during the pendency of the proceeding. (18 V.S.A. § 4632(a)(3)[2008])