

GUIDE TO VERMONT'S PRESCRIBED PRODUCTS LAW FOR FY10 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. The registration deadline is July 1, and the reporting deadline October 1.

Please read this guidance carefully. If you have additional questions after having read the guidance, please email us at: prescribedproducts@atg.state.vt.us.

Manufacturers Affected

- What companies must comply with the new law?
- What is a prescribed product?

Gift Ban

- What gifts are banned?
- What is a “health care provider”?
- What is not banned?

How to report

- What are the deadlines for disclosure?
- What if the company does not know if it will have expenditures to report?
- How does the company disclose the compliance officer?
- How does the company pay the annual \$500 registration fee?
- How does the company make disclosures?
- How does a company make corrections to a submitted report?

What to report

- What must be disclosed?
- What is exempt from disclosure?
- What is required in reporting the “value, nature, and purpose” of permitted gifts and allowable expenditures?
- Do the prescribed products being marketed have to be identified?
- What is “recipient information”?
- Must all expenditures to prescribers with Vermont licenses be reported?
- What are the special rules for clinical trials?
- Are continuing medical education (CME) programs supported by pharmaceutical marketing companies exempt from disclosure?

Public disclosure of reported information

- What happens to disclosed information?
- May a company designate any of this information as “trade secret”?

Penalties for failure to comply with gift ban or to report

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

Manufacturers Affected

What companies must comply with the new law?

Manufacturers of prescribed products, i.e. manufacturers of pharmaceuticals, biological products, and medical devices, or any other person or company engaged in the production, preparation, propagation, compounding, processing, packaging, repacking, distributing, or labeling of prescribed products for humans must comply with the gift ban and must report expenditures to the Attorney General.

Wholesale distributors of prescription drugs and biological products (but *not* wholesale distributors of medical devices), as well as pharmacists licensed under chapter 36 of Title 26, Vermont Statutes Annotated, are not “manufacturers” under the law.

If a company has multiple divisions, some of which market prescribed products to Vermont prescribers and institutions, and some of which do not, the entire company is bound by the gift ban and must report allowable expenditures.

What is a prescribed product?

A “prescribed product” is “a drug or device as defined in section 201 of the federal Food, Drug and Cosmetic Act 21 U.S.C. § 321, or a biological product as defined in section 351 of the Public Health Service Act, 42 U.S.C. § 262.” Although the federal statutory sections cover products that are not prescribed, the Vermont law applies only to manufacturers of products that are prescribed to humans.

A company that manufactures *only* products that do not fit within the definition above do not need to report.

Examples of Products: Medical oxygen, medical food products, and CT scanner.

Gift Ban—Effective July 1, 2009

What gifts are banned?

The ban covers anything of value given to a health care provider for free, as well as any payment, food, entertainment, travel, subscription, advance, service or anything else of value provided to a health care provider unless it is explicitly allowed or the health care provider reimburses the cost at fair market value. The Vermont gift ban encompasses more than just those items prohibited by the PhRMA and AdvaMed Codes.

- *Examples of banned gifts:* Monetary donations from a manufacturer of prescribed products to a doctor or clinic; charitable donations to a hospital; fellowship for a residency program even if the company does not select the recipient; lunch provided in a doctor’s office at which information on a drug is discussed, unless the office reimburses the pharmaceutical representative for the lunch; coffee and donuts for the non-prescribing staff in a

physician's office; dinner provided in New Hampshire to a physician whose primary office is in Vermont; driving a Vermont physician to an event in New York, unless the physician reimburses the reasonable expenses of the trip.

What is a "health care provider"?

A health care provider is a health care professional, a hospital, nursing home, pharmacist, health benefit plan administrator, or any other person authorized to dispense or purchase for distribution prescribed products in Vermont.

A "health care professional" is either (1) a person who is licensed to prescribe products, or is authorized to recommend prescribed products (such as a licensed clinical social worker or a licensed psychologist), or is lawfully providing health care in Vermont, or (2) a partnership or corporation made up of the persons described in subdivision (1), or (3) an officer, employee, agent, or contractor of a person described in subdivision (1) who is acting in the course and scope of employment providing health care to individuals, including nursing and front office staff.

Neither term includes a person employed solely by a manufacturer of prescribed products.

What is not banned?

The following gifts are not banned as long as the requirements are met (*items with asterisks must be reported*):

- **Free samples** of prescribed products for distribution to patients and the **labels** and package inserts approved by the federal Food and Drug Administration for them. This exemption applies to free samples provided to a Vermont prescriber for humanitarian needs to be distributed outside the United States.
- **Rebates and discounts** for prescribed products provided in the normal course of business.
- **Articles or journals and other educational items**** provided to a health care provider as long as they are peer-reviewed academic, scientific, or clinical articles or journals, or serve a genuine educational function and are for the benefit of patients.

Examples: Brochures for patients including a corporate logo, medical books or product information for physicians, models of human anatomy, other visual aids to be used with patients.

- **Loan of a medical device ****for a short-term trial period, not to exceed 90 days, to permit evaluation of a medical device by a health care provider or patient. These devices will be returned to the device manufacturer.

Examples: a medical imaging instrument loaned for evaluation purposes, such as an X-ray; the loan of an ultrasound machine to an office to replace a broken machine until the office receives a replacement.

- **Medical device demonstration or evaluation units**** to a health care provider to assess the appropriate use and function of the product and determine whether and when to use or recommend the product in the future, as long as only reasonable quantities are provided. These devices may not be returned to the manufacturer, because they are provided for patient education purposes or because the device is a single-use instrument.

Example of a Demonstration Unit: a model of a prosthetic device to be used in a knee replacement for the purpose of illustrating information to the patient

Example of an Evaluation Unit: single-use instruments that will not be returned to the device manufacturer, such as disposable devices for endometrial ablation or urodynamic testing.

- **Scholarships**** 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 as long as the recipient of the scholarship or other support is selected by the association.
- **Gifts to academic institutions and professional, educational, or patient organizations**** representing or serving health care providers or consumers are not banned, but must be reported.

The following are “allowable expenditures” -- not “gifts” -- under the law, and are not banned as long as the requirements are met (*items with asterisks must be reported*):

- **Royalties and licensing fees** paid to health care providers in return for contractual rights to use or purchase a patented or otherwise legally recognized discovery for which the health care provider holds an ownership right.
- **Conference sponsorship**** as long as (1) the event is a significant educational, medical, scientific, or policy-making conference or seminar, (2) the payment is not made directly to a health care provider, (3) the funding is used solely for bona fide educational purposes, and (4) all program content is objective, free from industry control, and does not promote specific products.

Example of allowed expenditure: Monies given to an academic institution for a conference meeting the above criteria must be reported and may be used by the academic institution for any expenses of the educational program, including meals.

Example of prohibited expenditure: Support provided to a hospital for a manufacturer-run conference.

- **Honoraria and payment of the expenses**** of a health care professional as long as (1) the individual serves on the faculty at a bona fide significant educational, medical, scientific, or policy-making conference or seminar, (2) there is an explicit contract with specific deliverables which are restricted to medical issues, not marketing activities, and (3) the content of the presentation, including slides and written materials, is determined by the health care professional.

- **Technical training on medical devices** ** expenses for individual health care professionals as long as the expenses are reasonable, including food, travel and lodging-related expenses, and the commitment to provide such expenses and the amounts or categories of reasonable expenses to be paid are described in a written agreement between the health care provider and the manufacturer. Costs of setting up and providing a training on a medical device where the prescribers are not paid by the manufacturer for their time or expenses in taking the training need not be reported.

Examples: The cost of a cadaver used in the training need not be reported. The cost of a hotel room for an individual health care professional does need to be reported.

- **Bona fide clinical trial**** expenses of gross compensation for the Vermont location or locations involved, direct salary support per principal investigator and other health care professionals per year, and expenses paid on behalf of investigators or other health care professionals paid to review the clinical trial.
- **Research project**** expenses as long as the project 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, and the expense are limited to (1) gross compensation, (2) direct salary support per health care professional, and (3) expenses paid on behalf of each health care professional.
- **Other**** reasonable fees, payments, subsidies, or other economic benefits provided by a manufacturer of prescribed products **at fair market value**.

Examples:

- Expenses for advisory meetings or product development meetings, even those including food, as long as the payment for the work is at fair market value.
- Payment to a physician to present information to other physicians, even without CME accreditation, if no food is provided.
- A “clinical trial” which is not FDA-approved is an allowable expense if it meets the requirements of a “research project,” or may be an allowable expense if it is a payment for fair market value.

How to report

What are the deadlines for disclosure?

No later than July 1, 2010, each manufacturer of prescribed products (including wholesale distributors of medical devices) 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. The Attorney General refers to that person as the “compliance officer.”

All manufacturers of prescribed products are encouraged to file the Compliance Officer Form as soon as possible so that we can readily contact you about how to comply with Vermont law.

Any company with expenditures to report in FY10 must also pay a \$500 registration fee by July 1, 2010.

Manufacturers of prescribed products with no expenditures to report who file the Compliance Officer Form need not file a fee and need not take further action prior to the October 1 deadline.

No later than October 1, 2010, each manufacturer of prescribed products (including wholesale distributors of medical devices) with expenditures to report must disclose to the Vermont Office of the Attorney General certain information described below about marketing expenditures during the 12-month period ending June 30, 2010 for pharmaceuticals, or during the 6-month period ending June 30, 2010 for biological products or medical devices.

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, the company should file the Compliance Officer Form by July 1 indicating “no expenditures to report” and, before filing disclosures, file a new Compliance Officer Form and send in the \$500 registration fee. We will use the most recent compliance officer 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 may designate a single person responsible for reporting the activities of the entire company, or may designate a single person responsible for reporting each of pharmaceutical products, biological products, or medical devices.

The Compliance Officer Form allows a company 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 number 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 either (1) by entering the data through a form on the Attorney General's website or (2) 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 October 1, 2010, 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 October 1.***

How does a company make corrections to a submitted 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 "value, nature, and purpose, and recipient information" of most permitted gifts or allowable expenditures to any health care provider must be disclosed to the Vermont Office of the Attorney General, as well as the prescribed product or products being marketed, if any.

Any expense to an *active* Vermont prescriber or to a Vermont institution covered by the law which is not exempt must be reported.

What is exempt from disclosure?

The following items, if given to a health care provider (see definition above on page 2), to an academic institution, or to a professional, educational, or patient organization representing or serving health care providers or consumers, need not be reported as long as the conditions are met:

- **Free samples** of prescribed products provided to a health care professional for free distribution to patients, and the **labels** for those samples.
- **Rebates and discounts** for prescribed products provided in the normal course of business.
- **Royalties and licensing fees** paid to health care providers in return for contractual rights to use or purchase a patented or otherwise legally recognized discovery for which the health care provider holds an ownership right.

Clinical trials have special rules for disclosure outlined below on page 8.

What is required in reporting the “value, nature, and purpose” of permitted gifts and allowable expenditures?

Note: Allowable expenses and gifts are permitted only if they meet the criteria set forth in “What is not banned?” above at page 3.

Value - The fair market value of the economic benefit, rounded to the nearest dollar. For *loans* of medical devices, no monetary value of the loan need be reported, but the fact of the loan must be reported.

- *Alternative Aggregate Disclosure:* For gifts that are not banned but are of a fair market value below \$25, such as a small number of educational brochures provided to a prescriber, the manufacturer may elect to report the expenditures for all Vermont prescribers or institutions in the aggregate. For items that are not customarily sold (such as educational brochures for patient use), the value is the manufacturer’s cost of production. For items that are produced for national use, the value is the portion of the manufacturer’s cost attributable to Vermont.
- *Multi-prescriber practices:* The value of a permitted gift or allowable expenditure provided to a practice with multiple prescribers must be allocated among the relevant prescribers. If the gift is a \$160 model of a leg used to explain what occurs when a knee is replaced, and the office has two physicians who might use it and three who would not, the expense should be divided by two and attributed to the two who would use the model. If the manufacturer does not know how many physicians in the office would use the model, the expense should be divided by five and attributed to each physician in the practice.

Nature – Identify the nature of the economic benefit given, e.g. cash/check, educational materials (such as books, journals, or brochures), donated demonstration or evaluation units of medical devices, or other. *Do not use “other” unless the expenditure does not fit into one of*

the supplied categories.

Purpose – Identify the primary and secondary purposes of the expenditure, e.g. conference sponsorship, speaker honoraria or expenses for serving on seminar faculty, marketing, research project expenses, seminar scholarship for unidentified medical students, technical training on medical devices expenses, or other. *Do not use “other” unless the expenditure does not fit into one of the supplied categories.*

Do the prescribed products being marketed have to be identified?

Yes, the manufacturer must identify the prescribed product or products being marketed, if they are any associated with the reported expenditure. If more than five prescribed products are associated with the reported payment or gift, the company must list the five prescribed products most relevant to the expenditure.

What is “recipient information”?

The names and types of recipients must be identified, e.g. prescribers, health benefit plan administrators, hospitals, nursing homes, pharmacists, and any other person authorized to dispense or purchase for distribution prescribed products.

Prescribers and pharmacists -- In order to ensure recipients are accurately identified, manufacturers 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, 2009. If you do not find a recipient’s 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, clinical social workers, psychologists, and others who may be authorized to dispense, or to recommend prescribed products for humans may be found at:
<http://www.sec.state.vt.us/seek/lrspseek.htm>.

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, email us at:
prescribedproducts@atg.state.vt.us.

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 for distribution), use a license number of “000-0000000.”

Must all expenditures to prescribers with Vermont licenses be reported?

Expenditures for a prescriber with an active Vermont license must be reported, whether or not the expense is incurred in Vermont.

Examples: The expense of a hotel room for a Vermont prescriber who is on the faculty of a conference outside Vermont must be reported. Taking a Vermont prescriber whose primary practice is in Vermont to dinner in New Hampshire is banned, i.e. the law cannot be circumvented by taking the Vermont prescriber out of Vermont. Taking a Vermont prescriber whose primary practice is in New Hampshire to dinner is not banned, but must be reported.

Only expenditures on prescribers with *active* Vermont licenses need be reported. Thus, marketing expenditures to an Ohio physician who holds an inactive Vermont license need not be reported.

What are the special rules for clinical trials?

Definitions -- Expenditures for clinical trials are limited to payments for “bona fide clinical trials.” A “clinical trial” is any study assessing the safety or efficacy of prescribed products administered alone or in combination with other prescribed products or other therapies, or assessing the relative safety or efficacy of prescribed products in comparison with other prescribed products or other therapies. A “bona fide clinical trial” includes only 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.

Authorized expenditures -- The only authorized expenditures for a clinical trial are: (1) gross compensation for the Vermont location or locations involved, (2) direct salary support per principal investigator and other health care professionals per year, and (3) expenses paid on behalf of investigators or other health care professionals paid to review the clinical trial.

If the clinical trial is funded through a “per enrolled patient fee” that does not itemize component costs, the total of those fees should be reported as gross compensation under (1) above, with no expenditures under (2) above.

Confidentiality provisions -- If a clinical trial contract entered into before July 1, 2009, contains confidentiality provisions protecting the identity of or amount of any expenditure to a recipient, the names and amounts must be reported but will be kept confidential by the Attorney General’s Office.

Any contract for a clinical trial entered into on or after July 1, 2009, must not contain a confidentiality clause that would violate Vermont’s disclosure law.

Delayed disclosure/Minimum information -- Expenditures for bona fide clinical trials shall be

disclosed after the earlier of the date of the approval or clearance of the prescribed product by the Food and Drug Administration or two calendar years after the date the payment was made, *except that* for a clinical trial for which disclosure is delayed, the manufacturer shall identify minimum information to the Attorney General regarding the clinical trial. The minimum information to be report is: the name of the clinical trial, the start date, and the web link to the clinical trial registration on the national clinical trials registry.

Thus, for any bona fide clinical trial, the manufacturer shall report either the expenditures associated with the trial or the minimum information regarding the clinical trial to the Attorney General at the close of the fiscal year in which the trial began.

Beginning October 1, 2010, information regarding all ongoing clinical trials must be reported, providing the minimum information if the trial is less than two calendar years old and the FDA has not approved or cleared the prescribed product, and otherwise providing complete information on the expenditures for the trial since July 1, 2009, for pharmaceutical manufacturers, or since January 1, 2010, for manufacturers of biological products or medical devices. Expenditures made prior to those dates need not be reported.

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

No. Unrestricted grants for CME must be disclosed 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.

The costs of maintaining a table at a conference or seminar which is not limited to Vermont prescribers or institutions need not be reported.

Public disclosure of reported information

What happens to disclosed information?

The Vermont Office of the Attorney General must file an annual report with the Vermont legislature and the Governor by April 1, 2011. After the report is issued, the Attorney General will make all disclosed data publically available and searchable on an internet website.

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

After July 1, 2009, manufacturers may no longer designate any of the disclosed information as “trade secret.” Consequently, although information designated in previous years’ disclosures as trade secret will be kept confidential, data received for FY10, covering expenditures made between July 1, 2009, and June 30, 2010, will be release to the public after the FY10 report is issued.

Penalties for failure to comply with gift ban or 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 injunctive relief, costs, and attorney's fees for any violation of either the gift ban or reporting requirements. In addition, a company that fails to comply with the gift ban or fails to disclose under the law may be assessed a civil penalty of not more than \$10,000 per violation. Each individual violation constitutes a separate violation.