

# GUIDE TO VERMONT'S PRESCRIBED PRODUCTS GIFT BAN AND DISCLOSURE LAW FOR FY11 DISCLOSURES

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## Introduction

Vermont law bans most gifts and requires registration and disclosure of allowable expenditures and permitted gifts by manufacturers of pharmaceuticals, biological products, and medical devices. The registration deadline is July 1, and the reporting deadline is October 1.

Please read this guidance carefully. Any section with text underlined has been added or substantially changed from the FY10 Guide. Any item labeled “*NEW*” has been added or amended since the FY11 Guide was first published on July 1, 2010.

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**I. *Manufacturers***

*(a) What companies must comply with Vermont’s law?*

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

**NEW:** The federal definition of “device,” incorporated into Vermont law at 18 V.S.A. § 4631a(a)(12), includes components of medical devices. 21 U.S.C. § 321(h). Nevertheless, Vermont does not consider a manufacturer of components that are eventually incorporated into medical devices to be a “manufacturer” for purposes of the Vermont gift ban and disclosure law unless the manufacturer also fabricates the final product.

**NEW:** An entity that does not manufacture but is only a retailer of a prescribed product does not fall under the statute. For example, a retailer of medical oxygen or medical devices is not subject to the gift ban and need not report to the Attorney General.

Wholesale distributors of prescription drugs and biological products as well as retailers and pharmacists licensed under Chapter 36 of Title 26, Vermont Statutes Annotated, are not “manufacturers” under the law. Wholesale distributors of medical devices are treated as “manufacturers” under Vermont law.

**NEW:** If a company has multiple divisions, some of which market prescribed products to Vermont health care providers and institutions, and some of which do not, the entire company is bound by the Vermont gift ban and must report allowable expenditures and permitted gifts.

If the manufacturer of prescribed products markets those products through a subsidiary, the expenditures should be reported in the name of the manufacturer, and the Compliance Officer Form should be submitted in the name of the manufacturer.

**NEW:** If two companies merge or one company purchases another during the reporting year, their data will be combined for the FY11 report regardless of whether the expenditures were made when the companies were separate or combined. Using the prescribed products email ([prescribedproducts@atg.state.vt.us](mailto:prescribedproducts@atg.state.vt.us)), please (1) notify the Attorney General’s Office of the names of the merging companies and the date of merger, and (2) complete a new Compliance Officer

Form. Companies that have merged (or purchased another manufacturer) during the reporting year need send only one \$500 fee for the year.

*(b) 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, a compound drug or drugs, or a biological product as defined in section 351 of the Public Health Service Act, 42 U.S.C. § 262 for human use.”

**NEW:** The federal definition of “combination product” is available at 21 C.F.R. 3.2(e).

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

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

## **II. Recipients**

*(a) Which recipients fall under Vermont law?*

Expenditures from manufacturers of prescribed products to the following recipients are regulated by Vermont’s prescribed products law:

- Vermont health care providers, including health care professionals
- Academic institutions located in or providing services in Vermont
- Nonprofit hospital foundations located in or providing services in Vermont
- Professional, educational, and patient organizations representing or serving health care providers or consumers located in or providing services in Vermont

For purposes of complying with Vermont law, manufacturers do not have to keep track of expenditures to recipients who do not fall within the above categories.

*(b) Who are Vermont health care providers?*

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 hospital foundation that is organized as a nonprofit entity separate from a hospital is not a health care provider.

A “health care professional” is any of the following:

1. A person who regularly practices in Vermont, and
  - is authorized by law to prescribe or recommend prescribed products (such as a licensed clinical social worker or a licensed psychologist), *and*
  - is licensed or otherwise lawfully providing health care in Vermont; or
2. A partnership or corporation made up of persons described in 1. above; or
3. An officer, employee, agent, or contractor of a person described in 1. above 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.

### ***III. Expenditures***

Expenditures regulated by Vermont's prescribed products law fall into three categories:

- Banned gifts
- Permitted gifts
- Allowable expenditures

Whether or not permitted gifts or allowable expenditures have to be reported depends on both the recipient and the nature of the expenditure. Attached is a [table of expenditures](#) indicating the category of expenditure, reporting requirements, and relevant citations.

### ***IV. Reporting Requirements***

*(a) What are the deadlines for disclosure?*

**No later than July 1, 2011**, 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 FY11 (ending June 30, 2011) must also pay a \$500 registration fee by July 1, 2011.

Manufacturers of prescribed products with no expenditures to report who file the Compliance Officer Form need not pay the fee and need not take further action.

**No later than October 1, 2011**, 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 expenditures during the 12-month period ending June 30, 2011.

**Anticipated change in reporting period:** The federal Patient Protection and Affordable Care Act of 2010, Public Law 111-148, and Vermont law on reporting of some samples or free samples are on a calendar year reporting schedule. Consequently, in 2011 the Vermont Attorney General will request an amendment to Vermont's prescribed products gift ban and disclosure law to move all of Vermont's reporting requirements to a calendar year.

*(b) 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.” Once the company determines that it has expenditures to report, the company must file a new Compliance Officer Form and send in the \$500 registration fee. We will use the most recent compliance officer information.

*(c) How does the company identify the compliance officer?*

A form identifying the compliance officer is at the Attorney General’s website at: [www.atg.state.vt.us](http://www.atg.state.vt.us); under “Issues” on left, click on “Disclosures of Marketing Expenditures for Prescription Drugs, Biological Products and Medical Devices,” and then on “Compliance Officer Form.” 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.

In addition to identifying the person responsible for overall compliance, the Compliance Officer Form allows a company to designate an additional person responsible for collecting and reporting the data. Both will receive updates electronically from the Attorney General’s Office.

**NEW:** If the manufacturer of prescribed products markets those products through a subsidiary, the expenditures should be reported in the name of the manufacturer, and the Compliance Officer Form should be submitted in the name of the manufacturer.

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](mailto:prescribedproducts@atg.state.vt.us).

*(d) How does the company pay the annual \$500 registration fee?*

Mail or send by overnight delivery a check for \$500.00, made out to “State of Vermont,” to:

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

We do not accept credit cards.

**NEW:** If you send \$500 and later determine that you have no expenditures to report and wish a refund, you must, between October 1 and November 1, put the request in writing to [prescribedproducts@atg.state.vt.us](mailto:prescribedproducts@atg.state.vt.us) with “Refund Request” in the subject line. We will issue refunds after November 1.

To request the Vermont Attorney General's Tax ID number or W-9 form, write us at: [prescribedproducts@atg.state.vt.us](mailto:prescribedproducts@atg.state.vt.us) with "Tax ID" in the subject line.

*(e) How does the company make disclosures?*

A company can make disclosures either (1) by downloading an Access-based database from the website, entering the data, and returning the database to the Attorney General's office, or (2) by entering the data through a form on the Attorney General's website. Either process will require the username and password submitted in the Compliance Officer Form.

We highly recommend the first alternative as it includes a list of all Vermont health care providers with active licenses as of July 1 of the reporting year, including license numbers. This ensures greater accuracy of submissions.

Companies should make every effort to submit correct data. For example, if a company is concerned that it may have the wrong license number for a prescriber, the company should communicate with the prescriber to get the correct information before submitting the data.

Data that does not comply with this Guide will be returned to the Compliance Officer for corrections and resubmission. *The October 1, 2011, 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**.*

*(f) 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](mailto:prescribedproducts@atg.state.vt.us), with "data correction" in the subject line. We will email you an acknowledgement of receipt.

## **V. What to report**

*(a) What must be disclosed?*

The "value, nature, and purpose, and recipient information" of most permitted gifts or allowable expenditures to a covered recipient must be disclosed to the Vermont Office of the Attorney General, as well as the prescribed product or products being marketed, if any.

The Disclosure Form has field values for the following categories:

- Date expenditure incurred
- Type of Recipient – e.g. doctor, other prescriber, hospital/clinic
- Nature of Expenditure – e.g. cash or check, educational materials, loan of medical device
- Purpose of Expenditure – e.g. conference sponsorship, medical device training, gift

- Product Type – pharmaceuticals, biologics, medical devices

In addition, the product name must be disclosed, along with the value of the expenditure (except for samples).

There are special disclosure rules for clinical trials and samples, outlined below in sections (f) and (g).

*(b) What is “recipient information”?*

The names and types of recipients must be identified, e.g. doctors; other prescribers, health benefit plan administrators; hospitals or clinics; nursing homes; pharmacists; any other health care providers; academic institutions; nonprofit hospital foundations; and professional, educational, or patient organizations representing or serving health care providers or consumers. To be a covered recipient (triggering the Vermont reporting requirements), the individuals must be located or regularly practicing in Vermont, and the institutions and organizations must be located or providing services in Vermont.

**Vermont Licensees** -- In order to ensure individual recipients are accurately identified, manufacturers must include the Vermont license number of the health care professional or pharmacist. *All license numbers are in the form of three digits, dash, seven digits (i.e. xxx-xxxxxxx).*

The Access-based database includes a table of the names and license numbers of health care providers with active licenses as of July 1, 2010. 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 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 license number.* If you are unable to find a Vermont license number for a health care professional, contact the recipient directly for his or her license number or for the license number(s) of the appropriate health care professional(s) to whom the expenditure should be associated.

**Other Recipients** -- Use a license number of “000-0000000” for any recipient who does not have a license, i.e. hospitals; nursing homes; health benefit plan administrators; others authorized to dispense or purchase prescribed products for distribution; academic institutions; and professional, educational, and patient organizations representing or serving health care providers or consumers.

(c) *Must all expenditures to health care professionals with Vermont licenses be reported?*

**NEW:** Expenditures for a Vermont licensee who regularly practices in Vermont must be reported, whether or not the expense is incurred in Vermont. Vermont licensees who do not regularly practice in Vermont no longer fall under the statute.

*Examples:*

- The expense of a hotel room for a Vermont health care provider who is on the faculty of a conference outside Vermont must be reported.
- Taking a Vermont physician who regularly practices in Vermont to dinner in New Hampshire is banned, i.e. the law cannot be circumvented by taking the Vermont physician out of Vermont.

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

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

- *Loans of medical devices and samples of medical devices and combination medical devices and prescription drugs:* report a monetary value of \$0.
- *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 health care provider, the manufacturer may elect to report the expenditures for all Vermont health care providers 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 reportable value is the portion of the manufacturer’s total national cost attributable to Vermont, which shall be calculated as the percentage of Vermont physicians as compared to all physicians nationally. For FY11, use 0.28% as Vermont’s allocation of national expenditures (multiply the national total by 0.0028). The license number for aggregate disclosure is 000-0000000.
- *Multi-prescriber practices:* The value of a permitted gift or an allowable expenditure when provided to a practice with multiple healthcare providers 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, loan of medical devices, samples of medical devices or combination medical

devices and prescription drugs, other, or an out-of-state gift or allowable expense to a Vermont-licensed prescriber. *Do not use “other” unless the expenditure does not fit into one of the supplied categories.*

- **NEW:** ~~An “out-of-state gift or allowable expenditure” can be used for a Vermont licensed health care provider *only if you verify that the recipient does not regularly practice in Vermont and you report the value, nature (e.g. food, travel, lodging), and purpose of the expenditure.*~~ [See Notice posted on AG website re FY10 Disclosures] If the recipient does regularly practice in Vermont, the gift ban applies, and you should determine whether the payment is a permitted gift, or an allowable expenditure.

**Purpose** – Identify the primary purpose of the expenditure, e.g. conference sponsorship; faculty honoraria or expenses for serving on seminar faculty; seminar scholarship for unidentified medical students; patient education (to be used if the nature of expenditure is educational materials or demonstration unit); technical training on a medical device (trainee compensation or other expenses); bona fide clinical trial; research project; consulting or survey expenses; or a gift to academic institution, nonprofit hospital foundation, or to a professional, educational, or patient organization representing or serving health care providers or consumers located in or providing services in Vermont. *Do not use “other” unless the expenditure does not fit into one of the supplied categories.*

- Expenses for clinical trials must be reported, but not until the earlier of (a) the fiscal year in which the Food and Drug Administration has approved or cleared the prescribed product or (b) the fiscal year which is two calendar years after the date the payment was made. See section (f) below.

*Note:* You must notify the Vermont Attorney General of any clinical trial for which disclosure of an expenditure is delayed. Send an email to [prescribedproducts@atg.state.vt.us](mailto:prescribedproducts@atg.state.vt.us).

*(e) Do the prescribed products being marketed have to be identified?*

Yes, the manufacturer must identify the type and name of the prescribed product or products being marketed which are 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.

*(f) What are the special rules for clinical trials?*

**Definitions** – Allowable expenditures for clinical trials are limited to payments for “bona fide clinical trials.” A “clinical trial” is a 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.

**Allowable expenditures** -- The only allowable 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.

Send the minimum clinical trial information to the Attorney General in an email to: [prescribedproducts@atg.state.vt.us](mailto:prescribedproducts@atg.state.vt.us), with “clinical trial notification” in the subject line. The minimum information 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.

*(g) What are the special rules for samples or free samples?*

Under Vermont law, “samples” of prescribed products is defined to include starter packs and coupons or other vouchers for distribution to patients that enable the individual to receive a prescribed product free of charge *or at a discounted price*. The various forms of samples will be reported on separately. Coupons and vouchers must be reported by the quantity provided to health care providers, not the number redeemed by patients.

There are two types of samples to be reported to Vermont, with different reporting requirements:

- **NEW:** ~~Free samples of medical devices and combination medical devices and prescription drugs must be reported for distributions on or after January 1,~~ [See Notice posted on AG website re FY10 Disclosures]
- Samples of prescribed products that fall outside the reporting requirements of the Patient Protection and Affordable Care Act of 2010, Public Law 111-148, such as samples to health care providers who are not physicians and samples (coupons or vouchers) that allow a patient to receive product free or at a discounted price, must be reported for distributions on or after January 1, 2011.
- Samples of prescription drugs being reported to the U.S. Department of Health and Human Services (HHS) under the Patient Protection and Affordable Care Act of 2010 will not need to be reported to the Vermont Attorney General *if HHS will provide recipient-specific information to Vermont*. Until such time as the Vermont Attorney General announces that HHS *will* provide Vermont with recipient-specific distribution of samples, manufacturers should plan on reporting to Vermont on the distribution of samples occurring on or after January 1, 2011.

**NEW:** Reporting of samples will not be required until April 1, 2012, for calendar year 2011.

Unlike for other expenditures, the value of samples is not required to be reported. The recipient information, as described below, must be reported to the Attorney General but will not be publically available. The person signing for the samples should be reported as the recipient.

## **VI. Public disclosure of reported information**

### *(a) What happens to disclosed information?*

The Vermont Office of the Attorney General must file the FY 2011 annual report with the Vermont legislature and the Governor by April 1, 2012. After the report is issued, the Attorney General will make all disclosed data (other than the recipients of samples) publically available and searchable on an internet website.

Data relating to distribution of samples may be released by the Attorney General to academic researchers for analysis and aggregated public reporting as long as the data sent to the researchers does not include the names or license numbers of individual recipients. Any public reporting of the distribution of samples will not allow for the identification of individual recipients.

### *(b) May a company designate any of the disclosed 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 and later years, covering expenditures made from July 1, 2009 on, will be released to the public after the annual report is issued.

***VII. Penalties for failure to comply with gift ban or to report***

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.