

COMBINED GUIDE TO VERMONT'S PRESCRIBED PRODUCTS GIFT BAN AND DISCLOSURE LAW FOR 2011 DISCLOSURES

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Introduction

Vermont law bans most gifts and requires manufacturers of prescribed products – including pharmaceuticals, biological products, and medical devices – to register with the Attorney General's Office and disclose allowable expenditures made and permitted gifts given to Vermont health care providers and other recipients. Effective January 1, 2011, Vermont law also requires manufacturers to disclose the distribution of samples of prescribed products to Vermont health care providers. Under Vermont law, "sample" includes starter packs, coupons, and vouchers that enable an individual to receive a prescribed product free of charge or at a discounted price.

The Vermont Legislature has recently passed amendments to the prescribed product law. Among other things, those amendments change the reporting period for disclosures of allowable expenditures and permitted gifts. Thus, on or before April 1, 2012, manufacturers must disclose expenditures and gifts given during the last half of 2011 (July 1, 2011 through December 31, 2011). April 1, 2012 is also the deadline for disclosing samples that were distributed during 2011 (January 1, 2011 through December 31, 2011). Thereafter, starting in April 2013, all disclosures (of allowable expenditures, permitted gifts, and samples) must be made on or before April 1 for the previous calendar year.

Previously, guidance regarding (1) the gift ban and disclosure of allowable expenditures and permitted gifts and (2) the samples disclosure requirement, has been published in separate guides. To simplify the process of disclosure, and in accordance with the industry's expressed preference, the Office will now publish one comprehensive guide.

Please read this guidance carefully as it reflects changes in Vermont law and interpretation since the latest version of the applicable guides.

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I. Threshold Questions

a. *Covered Manufacturers*

i. *What companies must comply with Vermont’s law?*

General Rule:

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 disclose to the Vermont Attorney General certain expenditures and the distribution of samples to Vermont health care providers and other institutions and organizations.

Wholesale Distributors and Retailers:

Wholesale distributors of medical devices are “manufacturers” under Vermont law. 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.

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.

Medical Devices:

Manufacturers whose only prescribed products are (1) classified as Class I by the U.S. Food and Drug Administration, (2) exempt from pre-market notification under Section 501(k) of the federal Food, Drug and Cosmetic Act, and (3) are sold over-the-counter without a prescription, are not “manufacturers” under the law.

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.

Subdivisions, Mergers and Acquisitions:

If a manufacturer 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, permitted gifts, and samples.

If two manufacturers merge or one company purchases another during the reporting period, their data will be combined for the corresponding report regardless of whether the expenditures were made when the manufacturers were separate or combined. By sending an email to the prescribed products address (prescribedproducts@atg.state.vt.us) with “merger/acquisition” in the subject line, the resulting manufacturer should (1) notify the Attorney General’s Office of the names of the merging manufacturers and the date of merger, and (2) complete a new Compliance Officer Form. Manufacturers that have merged or purchased another manufacturer during the reporting year need send only one registration fee for the year. Merging and acquiring manufacturers should take care to obtain the information that will need to be disclosed at the time of transfer and report that information on the regular schedule for disclosure.

ii. *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.”

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.

b. Covered Recipients

i. Which recipients fall under Vermont's 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 (see the next subsection)
- 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
- Members of the Green Mountain Care Board (see the next subsection)

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

ii. 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
 - a. is authorized by law to prescribe or recommend prescribed products (such as a licensed clinical social worker or a licensed psychologist), *and*
 - b. 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.

Members of the Green Mountain Care board, established as part of Vermont's health care reform package, are treated the same as health care providers under Vermont's Prescribed Product Law.

Note that expenditures to covered recipients fall under the law whether or not the expense is incurred in Vermont. In other words, the law cannot be circumvented by taking the recipient out of Vermont. So, for example:

- 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 as an allowable expenditure.

- Taking a physician who regularly practices in Vermont out to dinner in New Hampshire is a banned gift.

c. *Expenditure Types*

Expenditures regulated by Vermont’s prescribed products law fall into four categories:

- Banned gifts (including, e.g., food and compensation related to marketing research)
- Permitted gifts
- Allowable expenditures
- Samples

Expenditures and gifts not permitted by Vermont law are banned. Whether an expenditure has 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.

II. *Reporting Allowable Expenditures and Permitted Gifts*

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.

Reporting of Distributions through Patient Assistance Programs: We will not require reporting of distributions through Patient Assistance Programs for past years, including FY11 (July 1, 2010 – June 30, 2011), even though the statutory provision eliminating Patient Assistance Program reporting does not go into effect until July 1, 2011.

Samples distributed through clinical trials or qualifying research projects should not be included in the Samples Access database or Samples Disclosures Form, but must be reported with disclosures of allowable expenditures and permitted gifts.

a. *Instructions for Completing Reporting*

An Access database [hyperlink] and a sample disclosure form [hyperlink] for the reporting of allowable expenditures and permitted gifts are available on the Vermont Attorney General's website, www.atg.state.vt.us. In addition, a [sample reporting form](#) is attached to this guide. Each disclosure form covers expenditures relating to up to five prescribed products to one health care provider on one day. Manufacturers are encouraged to use the Access database as the more efficient method of compiling and submitting the data to the Attorney General.

Name of Manufacturer:

See above for details on which manufacturers 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.

If a manufacturer has a marketing agreement with a company which is not a subsidiary, either the manufacturer or the company can report the expenditures, but not both; expenditures shall be reported in the manufacturer's name. In cases in which a manufacturer has a marketing agreement with a company which is not a subsidiary and also constitutes a manufacturer under the law, the expenditures shall be reported in the name of the "owner"/NDA-holder manufacturer as opposed to the partner manufacturer.

Name and License/ID Number of Recipient:

For Individuals:

Fill in the last name, first name, and middle initial of the recipient, as well as the state license number of the recipient.

In order to ensure 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).*

Multi-Prescriber Practices: Reporting for multi-prescriber practices is not allowed except for expenditures for clinical trials. (See "Value/Amount of Expenditure," below for how to report expenditures to practices.)

The Access-based database includes a table of the names and license numbers of health care providers with active licenses as of July 1, 2011. You may also use the "List of Health Care Professionals with Active Vermont Licenses" [hyperlink] located at www.atg.state.vt.us to assure accuracy of name and license number. If a recipient is not on that list, check the following websites, or obtain from the recipient the correct name and license number under which the recipient is providing health care services in Vermont.

License numbers for physicians, physician and anesthesiologist assistants, podiatrists, and physicians who hold limited temporary permits may be found at: <http://www.docboard.ore/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.

For Institutions and Organizations:

If the recipient is not an individual, insert the name of the recipient-entity into the “Last Name” field, and fill in the Federal Tax ID number of the recipient.

Use the Federal Tax ID number 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.

Date Expenditure Incurred:

Indicate the date on which the expenditure was made or gift given to the covered recipient.

Value/Amount of Expenditure:

Provide the fair market value of the economic benefit associated with the expenditure or gift, rounded to the nearest dollar.

For *loans* of medical devices, report a monetary value of \$0. However, for permitted gifts of medical device demonstration and evaluation units, report the fair market value.

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 manufacturer may report a value of 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. **At this time, the Office anticipates that Vermont’s allocation of national expenditures will remain at 0.28% (multiply the national total by 0.0028). The Office will notify manufacturers by July 1, 2011 should it need to update that percentage.** 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. For example:

- 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 of Expenditure:

Choose nature of expenditure from the drop down list. If you choose “Other” you must fill in the “Other” description field to the right of the drop down.

Purpose of Expenditure:

Identify the primary purpose of the expenditure from the drop down box. *Do not choose “Other” or “Other FMV Payment” unless the expenditure does not fit into any of the other supplied categories.*

Conference Sponsorship: A payments to the sponsor of a significant educational, medical, scientific, or policy-making conference or seminar is an allowable expenditure, provided (1) the payment is not made directly to a health care provider or pharmacist, (2) the funding is used solely for bona fide educational purposes, and, at the sponsor’s discretion, meals and food for conference participants, and (3) all program content is objective, free from industry control, and does not promote specific products.

Faculty Honoraria/Speaker Fee and Faculty Expense: Honoraria and payment of the expenses of a health care provider who serves on the faculty at a bona fide significant educational, medical, scientific, or policy-making conference or seminar constitute allowable expenditures as long as (1) there is an explicit contract with specific deliverables which are restricted to medical issues, not marketing activities, and (2) the content of the presentation is determined by the health care provider. Note that “bona fide significant educational, medical, scientific, or policy making seminar,” is defined by statute.

Scholarship: Scholarship 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 is a permitted gift as long as the recipient of the scholarship or other support is selected by the association.

Educational Materials: The provision, distribution, dissemination, or receipt of peer-reviewed academic, scientific, or clinical articles or journals and other items such as patient brochures or posters that serve a genuine educational function provided to a health care provider for or for the benefit of patients is a permitted gift.

Medical Device – Loans, Demos: The loan of a medical device for a maximum trial period of 120 days to permit evaluation of the device by a health care provider or patient, and the provision of reasonable quantities of 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 are permitted gifts.

Medical Device Training – Compensation and Medical Device Training – Other Expenses: Payment to health care providers or payment or reimbursement for the reasonable expenses, including travel and lodging-related expenses, necessary for technical training of individual health care professionals on the use of a medical device constitute

allowable expenditures as long as 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.

Clinical Trials and Research: There are three kinds of allowable expenditures associated with bona fide clinical trials and qualifying research projects (see the following subsection for more detail):

- Gross compensation for the Vermont location or locations involved;
- Direct salary support per health care professional and/or principal investigator; AND
- Expenses paid on behalf of health care professionals and/or investigators.

Designate which kind of expenditure you are reporting by choosing the appropriate value from the “Purpose of Expenditure” drop down menu. 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.

Expenses for clinical trials must be reported, but not until the earlier of (a) the reporting year in which the Food and Drug Administration has approved or cleared the prescribed product for the use for which the clinical trial is being conducted, or (b) the reporting year which is four calendar years after the date the payment was made.

Note: You must notify the Vermont Attorney General with minimum information about any clinical trial for which disclosure of an expenditure is delayed. (See the following subsection for more detail.)

Consulting: Compensation to a recipient for consulting services constitutes an allowable expenditure as long as the compensation constitutes a payment of fair market value (or an “FMV” payment) for the consulting services.

Gift to Institution/Organization: The provision of free prescription drugs, or over-the-counter drugs, medical devices, biological products, medical equipment or supplies, or financial donations to a free clinic are permitted gifts.

Other FMV Payment: If you choose “Other FMV Payment,” you must fill in the “FMV Payment Description” field below the drop down menu. An “FMV Payment” is a reasonable fee, payment, subsidy, or other economic benefit provided by a manufacturer of prescribed products to a covered recipient at fair market value. See 18 V.S.A. § 4631a(a)(1)(H). An example of an “FMV payment,” other than payments for consulting services, see “Consulting” above, might include compensation to a health care provider for speaking at a promotional program.

Other: If you choose “Other,” you must fill in the “Other” description field to the right of the drop down. *Do not use “Other” unless the expenditure does not fit into any of the fields above.*

Product Type and Name:

The manufacturer must identify the type and name of the prescribed product or products 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. Choose product type from the drop down list. Fill in product name in the field to the right of the product type.

b. *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: As noted in Section II. a., above, 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.

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 for the use for which the clinical trial is being conducted or four 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’s Office in an email to: 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.

Information regarding all ongoing clinical trials must be reported, providing the minimum information if the trial is less than four calendar years old and the FDA has not approved or cleared the prescribed product for the use for which the trial is being conducted, 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.

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 reporting period in which the trial began and for subsequent years until (1) all expenses are reported, (2) four years have elapsed, (3) the FDA has approved the product, or (4) the trial has been discontinued, whichever occurs first.

III. Reporting Samples

The statutory definition of “sample” is: “a unit of a prescription drug, biological product, or medical device that is not intended to be sold and is intended to promote the sale of the drug, product, or device. The term includes starter packs and coupons or other vouchers that enable an individual to receive a prescribed product free of charge or at a discounted price.”

Samples distributed through clinical trials or qualifying research projects should not be included in the Samples Access database or Samples Disclosures Form, but must be reported with disclosures of allowable expenditures and permitted gifts.

In two distinct ways, Manufacturers of prescribed products who distribute samples to Vermont health care providers must report more to the Vermont Attorney General than is required to be reported to the U.S. Department of Health and Human Services (HHS) under the HR 3590 (The Patient Protection and Affordable Health Care Act), which does not preempt Vermont law. First, Vermont’s requirements regarding sample reporting are broader than federal requirements in that samples of all prescribed products – not only pharmaceuticals – must be reported. Second, Vermont’s statutory definition of samples includes starter packs and vouchers, co-pay cards and other items that allow patients access to samples for free or at a discounted price.

The Vermont legislature is willing to exempt pharmaceutical manufacturers from submitting to Vermont a duplicate of the information they are required to report to the HHS, if the Vermont Attorney General can obtain state- and recipient-specific information regarding manufacturer distribution of free samples from HHS. However, because the Attorney General has not yet been notified that he will receive recipient-specific information from manufacturers’ reports to the Secretary of HHS, all manufacturers must report directly to the Vermont Attorney General their distribution of *all* types of samples to *all* Vermont health care providers.

a. *Rule for Reporting*

Rule: If an item arguably could fall into either of two categories requiring disclosure, one of which is an allowable expenditure or permitted gift, and the other a sample, the manufacturer must report the item as the expenditure or gift, NOT as a sample. For example:

- Though a manufacturer may refer to an evaluation unit or demonstration unit of a medical device as a “sample,” the distribution of such a unit must be reported as a

permitted gift under Vermont law, not as a sample.

- If a “starter pack” contains only educational materials, then the starter pack must be reported as a permitted gift – in the aggregate or not – as the manufacturer chooses.
- Samples distributed through clinical trials or qualifying research projects should not be reported as samples, but rather with allowable expenditures and permitted gifts.

b. *Instructions for Completing Reporting*

An Access database [hyperlink] and a disclosure form [hyperlink] for the reporting of samples are available on the Vermont Attorney General's website, www.atg.state.vt.us. In addition, a [sample reporting form](#) is attached to this guide. These are different from the database and form for the disclosure of allowable expenditures and permitted gifts. Manufacturers are encouraged to use the Access database as the more efficient method of compiling and submitting the data to the Attorney General.

Samples may include product, vouchers and similar financial incentives, educational materials, non-prescribed items, and other items. Manufacturers must indicate the contents of a sample or starter pack and provide details.

We will not require reporting of distributions made through patient assistance programs for past years, including FY11 (July 1, 2010 through June 30, 2011), even though the statutory provision eliminating patient assistance program reporting does not go into effect until July 1, 2011.

Except as otherwise provided below, the manufacturer need not assign a value to a sample when reporting.

Name of Manufacturer:

See Section II. a., above, for details on reporting manufacturer name.

Name and License/ID Number of Recipient:

See Section II. a., above, for more details on reporting of recipients.

Fill in the last name, first name, and middle initial of the recipient, as well as the state license number of the recipient. If the recipient is not an individual, insert the name of the recipient-entity into the “Last Name” field, and fill in the Federal Tax ID number of the recipient.

Use the “List of Health Care Professionals with Active Vermont Licenses” located at www.atg.state.vt. to assure accuracy of name and license number. If a recipient is not on that list, check the websites listed in Section II. a., above, or obtain from the recipient the correct name and license number under which the recipient is providing health care services in Vermont.

Unlike federal law on samples, only the person who requested the samples constitutes the recipient. If the samples do not include prescribed product and the recipient is a hospital, nursing

home, or pharmacy, simply name the recipient and fill out the Prescribed Product block. If the samples do not include prescribed product and the recipient is a medical practice, the number of units (or partial units) must be allocated among the relevant healthcare providers in the medical practice, as discussed in Section II.a., “Value/Amount of Expenditure,” for multi-prescriber practices. For example:

- If 100 vouchers for a drug are distributed to a practice with 20 health care providers, all of whom might distribute the vouchers to patients, or if the manufacturer’s sales representative does not know which providers might distribute the vouchers, the manufacturer should report 5 units to each health care provider and include the license number of each health care provider.
- If, because of their specialties, only five of the health care providers in the medical practice would use the vouchers, the manufacturer should report 20 units for each of the five health care providers, along with the license number of each health care provider.

Date Delivered and Number of Samples:

Date Delivered: Indicate the date on which the samples were distributed to the HCP.

Number of Samples: For each type of sample delivered on the delivery date, indicate the number of samples distributed to the health care provider. If several types of samples were delivered on the same day, complete multiple records in the Access database or multiple Samples Disclosure Forms.

Contents:

Check *off all applicable* boxes to describe the content of the sample (refer to the descriptions below). More detailed information is required for all categories. *If the only contents are educational materials, report with allowable expenditures and permitted gifts, NOT as samples.*

Prescribed Product:

If the sample includes a prescribed product check the box in “Contents,” above, and provide detail. A product sample can have any number of units of a prescribed product, and may or may not be called a “starter pack.” If a sample includes more than one prescribed product, describe each prescribed product on successive lines in the Access database or successive lines on the Samples Disclosure Form. *Prescribed product delivered to patients or to health care providers for distribution or administration to patients under Patient Assistance Programs need not be reported.*

Prescribed Product Type: Indicate type of product included in sample: pharmaceutical, biologic, medical device, or combination.

Prescribed Product Name: State the name of the product included in the sample.

Units/Sample: Indicate the number of prescribed products included in each sample; e.g., enter “7” if 7 capsules are included per sample, “50” if 5 blister packs with 10 capsules per blister pack are included per sample, “200” if a sample inhaler contains 200 inhalations, or “10” if 10 burn pads are included per sample.

Dosage: Indicate dosage per unit; e.g. enter “50 milligrams per capsule” or “100 milligrams per inhalation.” Use N/A if the product does not have a dosage, for example, for burn pads.

Description: Describe product; e.g., enter “capsule,” “inhaler,” “burn pad.”

Vouchers, Coupons, Co-Pay Cards, Etc.:

If the sample includes vouchers, coupons, co-pay cards, or the like, that enable a patient to obtain prescribed product for free or at a discounted price, check the box in “Contents,” above, and provide detail. Vouchers obtained directly by the patient, i.e., not distributed by the manufacturer to a doctor, pharmacist, or other health care provider, need not be reported.

If a sample includes more than one kind of voucher, coupon, co-pay card or similar incentive, describe each on successive lines in the Access database or on the Samples Disclosure Form.

Prescribed Product Type: Indicate type of product promoted by the voucher: pharmaceutical, biologic, medical device, or combination.

Prescribed Product Name: State name of product promoted by the voucher.

- Use N/A if the vouchers are not tied to particular products.
- If multiple products are promoted by the voucher, enter “multiple products” and name each product in Description of Product/Discount.
- If multiple manufacturers have partnered to offer a co-pay card or other type of voucher, enter “multiple manufacturers” and in Description of Product/Discount name *each product* of the reporting manufacturer offered through the voucher, as well as the names of the other manufacturers in the partnership.

Vouchers/Sample: Indicate the number of vouchers provided to the health care provider in each sample; e.g., enter “5” if each sample contains 5 coupons. Manufacturers must report the quantity of vouchers provided to the health care provider, not the quantity redeemed by patients.

Description of Product/Discount: Describe the quantity and nature of the product being promoted; e.g. enter “7 pills,” “10 burn pads,” or “up to 30 capsules.” Also describe the discount being offered through the voucher; e.g., enter “\$5 rebate,” “\$5 off sales price,” or “10% discount.”

Other, (Including Non-Prescribed Items and Educational Materials):

If the sample includes materials given by a manufacturer to a health care provider for

distribution to patients including (1) non-prescribed items that allow a patient to more readily use a prescribed product but that would otherwise be a banned gift, (2) other incentives that allow a patient to access a prescribed product for free or at a discounted price, or (3) educational materials, check the box for “Other (including Non-Prescribed Items and Educational Materials) in “Contents,” above, and provide detail. If a sample includes more than one “Other” item, describe each on successive lines in the Access database or on successive lines on the Samples Disclosure Form.

A sample, including a starter pack or kit, must be reported as a permitted gift and not as a sample if it contains *only* educational material or other permitted gifts.

Do not use “Other” unless the sample does not fit into one of the supplied categories.

Product Type: Indicate type of prescribed product promoted by the non-prescribed or other materials: pharmaceutical, biologic, medical device, or combination.

Prescribed Product Name: State name of the prescribed product promoted by the non-prescribed or other materials. Use N/A if the other materials are not tied to particular prescribed products.

Other Sample Type: Indicate the type of material included in the sample by choosing “Non-Prescribed Item,” “Educational Materials” or “Other” from the drop-down menu.

Description of Item/Discount/Material: Describe the non-prescribed item or other incentive or material; e.g., “timer,” “over the counter drugs,” “over the counter creams,” “a pill container divided for days of the week,” or “diabetes pamphlet.” Also, describe the discount, if any; e.g., “\$5 rebate,” “\$5 off sales price,” “10% discount.”

IV. Registration and Reporting Deadlines

Registration:

No later than January 1, 2012, each manufacturer of prescribed products that has distributed samples during the previous calendar year and made allowable expenditures or given permitted gifts during the previous six months (July 1, 2011 through December 31, 2011) must disclose to the Vermont Office of the Attorney General the name and address of the person responsible for the manufacturer’s compliance with the reporting requirements corresponding to those reporting periods. The Attorney General’s Office refers to that person as the “Compliance Officer.” These manufacturers must pay a \$250 registration fee. Any manufacturers reporting *only* the distribution of samples for 2011 (January 1, 2011 through December 31, 2011) must pay a \$500 registration fee.

No later than January 1 of each year, starting on January 1, 2013, each manufacturer of prescribed products that has distributed samples, made allowable expenditures and/or given permitted gifts during the previous calendar year must disclose to the Vermont Attorney General’s Office the name and address of the person responsible for the company’s compliance

with the reporting requirements for that year. Manufacturers having anything to report for the year must pay an annual registration fee of \$500.

Choosing a Compliance Officer:

A form identifying the compliance officer [hyperlink] is at the Attorney General's website, www.atg.state.vt.us. Submit all Compliance Officer Forms by email using the button at the bottom of the form. *Do not print a form and then send it as a pdf or by mail. The Vermont Attorney General does not accept forms sent as a pdf or through the mail.*

As long as the Compliance Officer Form is clear, manufacturers may designate a single person responsible for reporting the activities of the entire company, or may designate different people responsible for reporting different product types, ((1) pharmaceutical products, (2) biological products, and (3) medical devices), or different activities ((1) samples, (2) allowable expenditures and permitted gifts, and (3) aggregate expenditures).

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.

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.

Paying the Registration Fee:

Mail or send by overnight delivery a check for the applicable amount (\$250 or \$500), 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.

If you send in a registration fee and later determine that you have no expenditures to report and would like a refund, you must, between April 1 and May 1, put the request in writing to prescribedproducts@atg.state.vt.us with "Refund Request" in the subject line. We will issue refunds after May 1.

If a manufacturer knows that it is *possible* that it has expenditures to report but cannot be sure by January 1, it should file the Compliance Officer Form by January 1 indicating "no expenditures to

report.” As soon as the manufacturer determines that it has expenditures to report, the company must file a new Compliance Officer Form and send in the registration fee. The Attorney General’s Office will use the most recent compliance officer information.

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.

Reporting Deadlines:

Manufacturers must report to the Vermont Attorney General their allowable expenditures, permitted gifts, and distribution of samples by April 1 of each year for the previous calendar year. The report due April 1, 2012 will cover the distribution of samples during calendar year 2011, and allowable expenditures made and permitted gifts given from July 1, 2011 through December 31, 2011 only. On April 1, 2013 and for every year thereafter, each April 1 report will include expenditures, gifts and samples for the previous calendar year.

Electronic Filing:

The Attorney General’s office will accept only electronic filings, and only electronic filings of two kinds. 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 by email to webperson@atg.state.vt.us, 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. *Do not print a form and then send it as a pdf or by mail. The Vermont Attorney General does not accept forms sent as a pdf or through the mail.*

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

Manufacturers 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 April 1 deadline for all submissions is not met for any data that is returned to the manufacturer for corrections unless it is resubmitted with no errors **by April 1.***

Correcting Submitted Reports:

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, with "Data Correction" in the subject line. We will email you an acknowledgement of receipt.

V. *Public Disclosure of Reported Information*

a. *What happens to disclosed information?*

The Vermont Office of the Attorney General must produce public annual reports regarding allowable expenditures and permitted gifts and the distribution of samples in Vermont. After the report is issued, the Attorney General will make all disclosed data (other than the recipients of samples and over-the-counter drugs, nonprescription medical devices, or items of nonprescription durable medical equipment provided to a health care provider for free distribution to patients) 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. Again, 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”?*

Manufacturers were previously permitted to designate the disclosure of allowable expenditures and permitted gifts as “trade secret.” After July 1, 2009, manufacturers may no longer do so. Consequently, although information designated in previous years’ disclosures as trade secret will be kept confidential, data covering allowable expenditures made and permitted gifts given from July 1, 2009 on will be released to the public after the annual report is issued.

VI. *Penalties for Gift Ban Violations and Failures to Report*

The Vermont Attorney General may bring a civil suit in 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 action or failure to act that violates the law constitutes a separate violation.

State of Vermont Prescribed Products Law - Table of Expenditures (6.6.11 Draft)

Nature of Expenditure	Health Care Providers		Non-HCP Recipients *
	Allowed?	Reporting Required?	Reporting Required?
Clinical Trials / Research			
Bona fide clinical trial expenses of (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.	Yes; 18 V.S.A. § 4631a(a)(1)(C)	Yes; 18 V.S.A. § 4632(a)(1)(A)(iii);	Yes; 18 V.S.A. § 4632(a)(1)(C)
Research project of significant interest or value to scientists or health care professionals; limited to (i) gross compensation; (ii) direct salary support per health care professional; and (iii) expenses paid on behalf of each health care professional.	Yes; 18 V.S.A. § 4631a(a)(1)(D)	Yes; 18 V.S.A. § 4632(a)(1)(A)	Yes; 18 V.S.A. § 4632(a)(1)(C)
NEW: Other Research, including marketing surveys.	No; 18 V.S.A. § 4631a(c)	N/A	Yes; 18 V.S.A. § 4632(a)(1)(C)
Conferences / Seminars			
Discount coupon , or voucher , for conference or annual meeting.	No; 18 V.S.A. §§ 4631a(a)(5), 4631a(b)(1)	N/A	N/A
Honoraria and payment of the expenses of a health care professional serving in the faculty at a bona fide significant educational, medical, scientific, or policy-making conference or seminar.	Yes, provided statutory requirements are met; 18 V.S.A. § 4631a(a)(1)(B)	Yes; 18 V.S.A. § 4632(a)(1)(A)	N/A
Scholarship 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.	Yes, if the recipient of the scholarship or other support is selected by the association; 18 V.S.A. § 4631a(b)(2)(E)	Yes; 18 V.S.A. § 4632(a)(1)(A)	N/A
Sponsorship of a significant educational, medical, scientific, or policy-making conference or seminar.	Yes, but not to a health care professional or pharmacist, and conference must meet statutory requirements; 18 V.S.A. § 4631a(a)(1)(A)	Yes; 18 V.S.A. § 4632(a)(1)(A)	Yes; 18 V.S.A. § 4632(a)(1)(C)
Educational Materials			
Articles or journals and other educational items provided to a health care provider (peer-reviewed academic, scientific, or clinical articles or journals, brochures, posters or other items that serve a genuine educational function and are for the benefit of patients.)	Yes; 18 V.S.A. § 4631a(b)(2)(D)	Yes; 18 V.S.A. § 4632(a)(1)(A)	Yes; 18 V.S.A. § 4632(a)(1)(C)

* Non-HCP includes academic institutions, nonprofit hospital foundations, and professional, educational, or patient organizations representing or serving health care professionals or consumers located in or providing services in Vermont

State of Vermont Prescribed Products Law - Table of Expenditures (6.6.11 Draft)

Nature of Expenditure	Health Care Providers		Non-HCP Recipients *
	Allowed?	Reporting Required?	Reporting Required?
Financial Contributions			
Financial contribution to HCP recipients other than free clinics.	No; 18 V.S.A. §§ 4631a(a)(5), 4631a(b)(1)	N/A	Yes; 18 V.S.A. § 4632(a)(1)(C)
Financial contributions to a free clinic.	Yes; 18 V.S.A. § 4631a(b)(2)(H)	Yes; 18 V.S.A. § 4632(a)(1)(A)	N/A
Food			
Dinner at a seminar or conference at which the meal is organized and paid for by the manufacturer.	No; 18 V.S.A. §§ 4631a(a)(5), 4631a(b)(1)	N/A	N/A
Food, including but not limited to the following: lunch provided in a doctor's office at which information on a drug is discussed; coffee and donuts for non-prescribing staff in a physician's office in Vermont; dinner provided in New Hampshire to a physician who regularly practices in Vermont; food provided at a manufacturer's display in Vermont other than at of a conference or seminar.	No, unless the HCP reimburses the pharmaceutical manufacturer for fair market value of the food; 18 V.S.A. §§ 4631a(a)(5)(B)(ii), 4631a(b)(1)	No. An expenditure that has been reimbursed is neither a permitted gift nor an allowable expenditure and need not be reported.	N/A
Refreshments, including coffee or other snacks at a booth at a conference or seminar.	Yes; 18 V.S.A. § 4631a(b)(2)(K)	No; 18 V.S.A. § 4632(a)(1)(A)(v)	N/A
Medical Devices			
NEW: Loan of a medical device for a short-term trial period, not to exceed <u>120 days</u> , to permit evaluation of a medical device by a health care provider or patient.	Yes; 18 V.S.A. § 4631a(b)(2)(B)	NEW: Yes, 18 V.S.A. § 4632(a)(1)(A)(vi), unless the loan results in the purchase, lease, or other comparable arrangement of the medical device after issuance of a certificate of need pursuant to chapter 221, subchapter 5 of Title 18, in which case the loan need not be reported; 18 V.S.A. § 4632(a)(1)(A)(vi)	N/A
Reasonable expenses necessary for technical training of individual health care professionals on the use of a medical device if 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.	Yes; 18 V.S.A. § 4631a(a)(1)(E)	Yes; 18 V.S.A. § 4632(a)(1)(A)	N/A

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State of Vermont Prescribed Products Law - Table of Expenditures (6.6.11 Draft)

Nature of Expenditure	Health Care Providers		Non-HCP Recipients *
	Allowed?	Reporting Required?	Reporting Required?
Reasonable quantities of 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. These devices are typically provided for patient education purposes or as a single-use instrument.	Yes; 18 V.S.A. § 4631a(b)(2)(C)	Yes; 18 V.S.A. § 4632(a)(1)(A)	N/A

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State of Vermont Prescribed Products Law - Table of Expenditures (6.6.11 Draft)

Nature of Expenditure	Health Care Providers		Non-HCP Recipients *
	Allowed?	Reporting Required?	Reporting Required?
Samples / Free Products			
Samples of prescribed products, including starter packs and coupons or other vouchers that enable an individual to receive a prescribed product free of charge or at a discounted price, for distribution to patients.	Yes; 18 V.S.A. § 4631a(b)(2)(A)	Yes; 18 V.S.A. § 4632(a)(2)(A)(i) (Reports will not be disclosed to public.)	Yes; 18 V.S.A. § 4632(a)(1)(C)
Donation to a free clinic of free prescription drugs or over-the-counter drugs, medical devices, biological products, medical equipment or medical supplies.	Yes; 18 V.S.A. § 4631a(b)(2)(H)	Yes; 18 V.S.A. § 4632(a)(1)(A)	N/A
Free product - over-the-counter drugs, nonprescription medical devices or nonprescription durable medical equipment provided to a health care provider for free distribution to patients.	Yes, but only of reasonable quantities, unless to a free clinic; 18 V.S.A. § 4631a(b)(2)(A)	Yes; 18 V.S.A. § 4632(a)(1)(B). (Reports will not be disclosed to public.)	N/A
Labels , including package inserts, approved by the FDA for prescribed products.	Yes; 18 V.S.A. § 4631a(b)(2)(G)	Yes; 18 V.S.A. § 4632(a)(1)(A)	N/A
Free prescription drugs provided to an HCP on behalf of an individual through the manufacturer's patient assistance program .	Yes; 18 V.S.A. 4631a(b)(2)(I)	NEW: No; 18 V.S.A. § 4632(a)(1)(A)(vii)	N/A
Rebates and discounts for prescribed products provided in the normal course of business.	Yes; 18 V.S.A. § 4631a(b)(2)(F)	No; 18 V.S.A. § 4632(a)(1)(A)(ii)	No; 18 V.S.A. § 4632(a)(1)(C)(ii)
Miscellaneous			
Fellowship for a Residency.	Yes, if it meets the four criteria of 18 V.S.A. § 4631a(b)(2)(J)	Yes; 18 V.S.A. § 4632(a)(1)(A)	N/A
Membership fees/dues paid by a manufacturer to a professional, educational or patient organization.	N/A	N/A	Yes, for organizations representing or serving health care providers or consumers in Vermont; 18 V.S.A. § 4632(a)(1)(C)
Reasonable expenses related to the interview by a manufacturer of prescribed products in connection with a bona fide employment opportunity.	Yes; 18 V.S.A. § 4631a(a)(1)(G)	No; 18 V.S.A. § 4632(a)(1)(A)(iv)	N/A
Labels on prescribed products.	Yes. Required by FDA.	No. AG does not consider this a gift or allowable expenditure requiring reporting.	No. AG does not consider this a gift or allowable expenditure requiring reporting.
Royalties and licensing fees paid to a health care provider 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.	Yes; 18 V.S.A. § 4631a(a)(1)(F)	No; 18 V.S.A. § 4632(a)(1)(A)(i)	No; 18 V.S.A. § 4632(a)(1)(C)(i)

* Non-HCP includes academic institutions, nonprofit hospital foundations, and professional, educational, or patient organizations representing or serving health care professionals or consumers located in or providing services in Vermont

**Vermont Office of Attorney General
109 State Street
Montpelier, VT 05609-1001**

2011 Disclosure Form for Manufacturers of Prescribed Products

**Reporting Period for Pharmaceuticals, Biologics and Medical Devices
July 1, 2011 to December 31, 2011; Due Date: April 1, 2012**

You must disclose allowable expenditures and gifts which are not banned.

Name of Manufacturer			
Last Name of Recipient		First Name	MI
Lic. Number/ID Number of Recipient			
Date Expenditure Incurred			
Value/Amount of Expenditure			
Nature of Expenditure		<input type="checkbox"/> If "Other"	
Purpose of Expenditure		<input type="checkbox"/> If "Other"	
FMV Payment Description			

Prescribed Product(s) (up to five) to which expenditure or gift relates.

Product Type	<input type="checkbox"/>	Product Name	
Product Type	<input type="checkbox"/>	Product Name	
Product Type	<input type="checkbox"/>	Product Name	
Product Type	<input type="checkbox"/>	Product Name	
Product Type	<input type="checkbox"/>	Product Name	

If filing disclosures for 2011, please send a check made out to "State of Vermont", for \$250 by January 1, 2012 to:

Office of the Attorney General
ATTN. Public Protection Division
109 State Street
Montpelier, VT 05609-1009

2011 Pharmaceutical Gift Disclosure Field Values

Nature of Expenditure

- Cash, Check or Credit Card
- Educational Materials
- Demo/Evaluation Unit
- Loan of Medical Device
- Other

Purpose of Expenditure

- Conference Sponsorship
- Faculty Honoraria/Speaker Fee
- Faculty Expense
- Scholarship
- Educational Materials
- Medical Device – Loans, Demos
- Medical Device Training - Compensation
- Medical Device Training - Other Expenses
- Bona fide Clinical Trial - Gross Compensation
- Bona fide Clinical Trial - Salary Support
- Bona fide Clinical Trial - Expenses
- Research Project - Gross Compensation
- Research Project - Salary Support
- Research Project - Expenses
- Consulting
- Gift to Institution/Organization
- Other FMV Payment
- Other

Product Type

- Pharmaceuticals
- Biologics
- Medical Devices
- Combination Product

**Vermont Office of Attorney General
109 State Street
Montpelier, VT 05609-1001**

2011 Samples Disclosure Form for Manufacturers of Prescribed Products

Reporting Period: January 1, 2011 to December 31, 2011; Due Date: April 1, 2012

Name of Manufacturer					
Last Name of Recipient				First Name	MI
Lic. Number/ID Number of Recipient					
Date Delivered		Number of Samples			
Contents (Check all that apply)		<input type="checkbox"/> Prescribed Product		<input type="checkbox"/> Vouchers, etc	
		<input type="checkbox"/> Other (Including Non-Prescribed Items or Educational Materials)			
Prescribed Product					
Prescribed Product Type	Prescribed Product Name	Units/Sample	Dosage or N/A	Description	
▼					
▼					
▼					
Vouchers, Coupons, Co-Pay Cards, Etc.					
Prescribed Product Type	Prescribed Product Name or N/A	Vouchers/Sample	Description of Product/Discount		
▼					
▼					
▼					
Other (Including Non-Prescribed Items or Educational Materials)					
Prescribed Product Type	Prescribed Product Name or N/A	Other Sample Type	Description of Item/Discount/Material		
▼		▼			
▼		▼			
▼		▼			

Next Disclosure

Submit by Email

Print for Your Records

2011 Samples Disclosure Field Values

Product Type

- Pharmaceuticals
- Biologics
- Medical Devices
- Combination Product

Sample Type

- Non-Prescribed Item
- Educational Material
- Other