

# 2011 GUIDE TO VERMONT'S LAW ON DISCLOSURE OF SAMPLES OF PRESCRIBED PRODUCTS

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## **Introduction**

Effective January 1, 2011, Vermont law requires disclosure to the Attorney General, on an annual basis, of distributions 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 disclosures must be made on or before April 1 for the previous calendar year.

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### ***I. Reporters: Manufacturers***

Manufacturers of prescribed products that are subject to Vermont’s gift ban and requirements for disclosure of allowable expenditures and permitted gifts must disclose their distribution of samples. See FY11 Guide for details on covered manufacturers.

### ***II. Recipients***

Covered recipients for purposes of sample disclosure are the same as covered recipients for purposes of disclosure of allowable expenditures and permitted gifts. See FY11 Guide for details, including definition of “health care provider.”

### ***III. Reporting of 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 should not be included in the Samples Access database or Samples Disclosures Form, but will need to be reported with disclosures of allowable expenditures and permitted gifts.

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). Vermont’s requirements regarding sample reporting are broader than federal requirements in that samples of all prescribed products, not only pharmaceuticals, must be reported, and Vermont’s statutory definition of samples includes starter packs and vouchers that allow patients access to samples for free or at a discounted price. Further, prescribed products distributed under a patient assistance program through an HCP (including a pharmacist) must be reported as a product sample.

The Vermont legislature was willing to exempt pharmaceutical manufacturers from submitting to Vermont a duplicate of the information they were required to report to the HHS, if the Vermont Attorney General could obtain state- and recipient-specific information regarding manufacturer distribution of free samples from HHS. However, because the Attorney General has not been notified that he will receive recipient-specific information from manufacturers’ reports to the Secretary of HHS, all manufacturers should be prepared to 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. Similarly, if a “starter pack” contains only educational materials, then the starter pack must be reported as a permitted gift, using Aggregate or not, as the manufacturer chooses.

#### *(b) Instructions for Completing Reporting*

An Access database and a Sample Disclosure Form and for the reporting of samples are available on the Vermont Attorney General’s website, [www.atg.state.vt.us](http://www.atg.state.vt.us). Each disclosure form covers distribution of no more than one type of sample 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.

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

The manufacturer need not assign a value to a sample when reporting.

**Name of Manufacturer:** See FY11 Guide for details on who must report samples.

**Type of Recipient:** See FY11 Guide for details on types of recipients. Select Type of Recipient from drop-down list. If Other is selected, fill in Other field.

**Recipient:** See FY11 Guide for details on reporting of recipients. Fill in Last Name, First Name and Middle Initial of the recipient, as well as the State License Number of Recipient. If the recipient is not an individual, insert the name of the recipient entity into the Last Name field.

Use the “List of Health Care Professionals with active Vermont licenses” located at [www.atg.state.vt.us](http://www.atg.state.vt.us) to assure accuracy of name and license number. If a recipient is not on that list, check the websites listed in the FY11 Guide or obtain from the recipient the correct name and license number under which the recipient is providing health care services in Vermont.

Consistent with federal law on samples, the recipient is the person who requested or signed for the samples. 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. For example, if 100 vouchers for a sample drug are distributed to a practice with 20 health care providers, all of whom might distribute the vouchers to patients, the manufacturer should report 5 units to each health care provider and include the license number of each HCP. 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 HCPs, along with the license number of each HCP.

*Patient Assistance Programs:* If prescribed product is sent to a health care provider for a patient, it must be reported as a sample. If the product is sent directly to a patient, it need not be reported. Thus, prescribed products distributed under a patient assistance program through an HCP (including a pharmacist) must be reported as a product sample, even if the HCP is acting only as a conduit for the patient and has no obligation under federal law to log the sample in or out of the HCP’s practice.

**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 HCP. 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 (descriptions below): Product; Vouchers, etc.; Non-Prescribed Items; Other; and Educational Materials. More detailed information is required for all categories other than Educational Materials. *If the only contents are Educational Materials, report as part of disclosures of allowable expenditures and permitted gifts, NOT as samples.*

**Product:** If the sample includes a prescription drug, biological product or a medical device, check the box in Contents 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 records in the Access database or successive lines on the Samples Disclosure Form.

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

**Product Name:** State name of product included in sample.

**Units/Sample:** Indicate the number of prescribed products included in each sample, e.g. 7 if 7 capsules included, 10 if 10 burn pads included.

**Dosage:** Indicate dosage per unit, e.g. 50 milligrams, 200 milligrams. Use N/A if the product does not have a dosage.

**Description:** Describe product, e.g. capsule, burn pad.

**Vouchers:** If the sample includes vouchers, coupons, co-pay cards, etc. that enable a patient to obtain prescribed product for free or at a discounted price, check the box in Contents and provide detail. Vouchers obtained directly by the patient, i.e. not distributed by the manufacturer to a health care provider (including pharmacist), 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 records in the Access database or on successive lines on the Samples Disclosure Form.

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

**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 companies have partnered to offer a co-pay card or other type of voucher, enter “multiple companies” 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 companies in the partnership.

**# Vouchers:** Indicate the number of vouchers provided to the HCP in each sample, e.g. 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 product being promoted, e.g. 7 pills, 10 burn pads, up to 30 capsules, as well as the discount being offered through the voucher, e.g. \$5 rebate, \$5 off sales price, 10% discount.

**Other:** If the sample includes materials given by a manufacturer to an HCP 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, or (2) other incentives that allow a patient to access a prescribed product for free or at a discounted price, check the box(es) for Non-Prescribed Item and/or Other in Contents and provide detail. If a sample includes more than one Other item, describe each on successive records 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 product promoted by the other materials: pharmaceutical, biologic, medical device, or combination.

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

**Description of Product/Discount:** Describe the non-prescribed item or other incentive not yet described, e.g., timer, over the counter drugs or creams, a pill container divided for days of the week, as well as the discount, if any, e.g. \$5 rebate, \$5 off sales price, 10% discount.

#### ***IV. Reporting Deadlines and Filing Requirements***

**Compliance Officer for Samples Disclosures:** No later than January 1 of each year, starting in 2012, each manufacturer of prescribed products that has distributed samples must send \$500 and disclose to the Vermont Office of the Attorney General the name and address of the person responsible for the company's compliance with the samples reporting requirements. See Attorney General's website, [www.atg.state.vt.us](http://www.atg.state.vt.us), for instructions on paying the annual \$500 registration fee.

The Vermont Attorney will request the Vermont Legislature to amend Vermont's prescribed products gift ban and disclosure law to require reporting on a calendar year basis (rather than on a fiscal year basis) for consistency with federal reporting schedules. If the Vermont legislature

makes that change in 2011, by January 1, 2012, each manufacturer will be required to make only one registration (unless they prefer to list separate compliance officers for aggregate spend and for samples) and pay one \$500 fee for reporting of allowable expenditures, permitted gifts, and samples.

**Disclosure Deadline:** Manufacturers must report to the Vermont Attorney General their distribution of samples by April 1 of each year for the previous calendar year. The first report will be due April 1, 2012, covering calendar year 2011.

**Electronic Filing:** The Attorney General's office will accept only electronic filings. Submit a database of 2011 Samples Disclosures by sending the database to [webperson@atg.state.vt.us](mailto:webperson@atg.state.vt.us). Submit all Compliance Officer forms and individual 2011 Samples Disclosure Forms by email using the button at the bottom of those forms. *Do not print a form and then send it by pdf or mail.* The Vermont Attorney General does not accept forms sent by pdf or through the mail.

*See FY11 Guide for more detail on compliance officers and reporting requirements.*

#### ***V. Public Disclosure of Reported Information***

The Vermont Office of the Attorney General must produce a public annual report regarding the distribution of samples in Vermont. The Legislature stipulated that the report may not include the names or identification of recipients. Data relating to distribution of samples may be released by the Attorney General to academic researchers for analysis and aggregated public reporting, but such data cannot 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.

#### ***VI. Penalties for Failure to Report***

The Vermont Attorney General may bring a civil suit for any violation of reporting requirements and may request a penalty of not more than \$10,000 per violation. *See FY11 Guide for details.*