

# 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 by 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 also disclose their distribution of samples. *See* FY11 Guide for details on 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 “samples” 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.”

Manufacturers of prescribed products with distributions to Vermont health care providers will have to report more to the Vermont Attorney General than to the U.S. Department of Health and Human Services 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 the definition of samples also includes starter packs and vouchers that allow patients access to prescribed products for free or at a discounted price.

The Vermont legislature was willing to exempt pharmaceutical manufacturers from submitting to Vermont a duplicate of the information they were already required to report to the HHS, if the Vermont Attorney General would be able to obtain state- and recipient-specific information regarding manufacturer distribution of free samples of prescription drugs. However, because the Attorney General has not been notified that he will receive recipient-specific information from manufacturers’ reports to the Secretary of HHS, manufacturers should be prepared to report 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 the distribution of an evaluation or demonstration unit of a medical device as a “sample,” the distribution must be reported as a permitted gift, not as a sample.*

#### *(b) Categories of Samples*

Disclosure of samples shall be in the following categories:

**“Product Samples:”** prescription drugs, biological products or medical devices. The distribution of the product sample may be accompanied by educational materials or other non-prescription product. A product sample can have any number of units of a drug or medical device, and may or may not be designated by the manufacturer as a “starter pack.”<sup>1</sup>

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<sup>1</sup> Packs or kits that do *not* include a prescribed product, and include only such items as educational material or other aids for the patient to use the prescribed product, are not “samples.” Such kits must be reported as permitted gifts; for Nature of Expenditure use “other.” Examples: a kit with educational materials and a pedometer, a timer, over the counter drugs or creams, or a pill container divided for days of the week.

“**Vouchers:**” vouchers, coupons, co-pay cards, etc, distributed to a health care provider that enable a patient to obtain prescribed product for free or at a discounted price. Manufacturers must report the quantity of vouchers provided to the health care provider, not the quantity redeemed by patients. Vouchers obtained directly by the patient, i.e. not distributed through a health care provider, need not be reported.

“**Other:**” any other distribution by which a manufacturer provides, through a health care provider, incentives that allow a patient to access a prescribed product for free or at a discounted price. *Do not use “other” unless the sample does not fit into one of the supplied categories.*

*(c) Other Reporting Fields*

See FY11 Guide for details on what must be reported with regards to recipient information, date, and product type.

Reporting of samples must include:

- Product type (pharmaceuticals, biologics, medical devices, or combination product)
- Number of samples provided
- Number of units in each sample (e.g. 5 pills, 30 pills, 1 device)
- Dosage of each unit (use N/A if not applicable)
- Product Name
- Recipient

Consistent with federal law, the recipient is the person who requested or signed for the samples. If the samples did not include prescribed product and no health care provider requested or signed for them, the number of units (or partial units) must be allocated among the relevant healthcare providers. For example, if 100 vouchers for a sample drug were distributed to a practice with 10 health care providers, all of whom might distribute the vouchers to patients, the manufacturer should report 10 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 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.

For vouchers, the report must also include the amount of discount or the incentive (e.g. free, 20% off, \$5 refund).

If the sample is neither a product sample nor a voucher, use the block for “Other” and provide a description of the item in addition to the product name.

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

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

**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. A sample disclosure form and database for the reporting of samples to be submitted by April 1, 2012, covering calendar year 2011, is available on the Attorney General's website.

**Compliance Officer:** No later than January 1 of each year, starting in 2012, each manufacturer of prescribed products that has distributed samples must disclose to the Vermont Office of the Attorney General the name and contact information for the person responsible for the company's compliance with the samples reporting requirements.

**Electronic Filing:** 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 or 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.* Forms sent by pdf or through the mail are not considered submitted by the Vermont Attorney General.

*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. The report may include, in the aggregate, the distribution based on specialty of recipient but 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 seek penalties of not more than \$10,000 per violation. *See FY11 Guide for details.*