

# GUIDE TO VERMONT'S PRESCRIBED PRODUCTS GIFT BAN AND DISCLOSURE LAW FOR 2012 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 HCPs and other recipients. Vermont law also requires manufacturers to disclose the distribution of samples of prescribed products to Vermont HCPs. 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, whereas disclosures of allowable expenditures and permitted gifts used to be made on a fiscal year, starting in 2013, all disclosures of allowable expenditures, permitted gifts, and samples must be made on or before April 1 for the previous calendar year.

Please read this guidance carefully as it reflects changes in Vermont law and interpretation since the 2011 Guide. This guide must be read in conjunction with [Vermont law](#), which is available at the Office's website at [www.atg.state.vt.us](http://www.atg.state.vt.us). We recommend you consult with counsel regarding nuanced questions.

## A Note on Preemption

**At some point in 2012 – the date has yet to be identified by the Centers for Medicare and Medicaid Services** - some of Vermont's disclosure requirements will be preempted by federal law. In short, while the gift ban and samples reporting will not be affected, Vermont will no longer be able to require manufacturers to disclose those allowable expenditures and permitted gifts which must also be reported to the federal government under the Physician Payments Sunshine Provision (§ 6002) of the Patient Protection and Affordable Care Act (Pub. L. No. 11-148). The federal law is narrower than Vermont's law in several ways, however; for example, only physicians and teaching hospitals are covered recipients under the federal law. Therefore, manufacturers must take care to make all non-preempted disclosures regarding allowable expenditures and permitted gifts.

The federal law does not prohibit manufacturers from making duplicative disclosures to states, it simply prohibits the states from *requiring* duplicative disclosures. At this time, the Attorney General will accept such duplicative disclosures. **Manufacturers should indicate on the compliance officer form whether they intend to submit data that will also be submitted to the federal government; the form has been amended for the purpose of gathering this information.**

## Contents

I. Threshold Questions .....	3
a. Covered Manufacturers .....	3
i. What companies must comply with Vermont’s law? .....	3
ii. What are prescribed products? .....	4
b. Covered Recipients .....	4
i. Which recipients fall under Vermont’s law? .....	4
ii. Who are Vermont health care providers?.....	5
c. Location of Expenditure .....	5
d. Expenditure Types .....	6
<u>Table of Gift Ban and Reporting Requirements</u> .....	7
II. Reporting Allowable Expenditures and Permitted Gifts.....	14
a. Instructions for Completing Reporting .....	14
<i>A Note on Special Rules for Clinical Trials</i> .....	19
III. Reporting Samples.....	22
a. Rule for Reporting.....	23
b. Instructions for Completing Reporting.....	23
IV. Registration and Reporting Deadlines .....	27
V. Public Disclosure of Reported Information.....	30
VI. Penalties for Gift Ban Violations and Failures to Report.....	30
 <a href="#">APPENDIX A</a> : Examples of Disclosures for Samples and Over the Counter Product Distribution.....	31

## 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.

Manufacturers must abide by the prescribed products gift ban and disclosure law regardless of whether the manufacturer is also required to be licensed by the Vermont Board of Pharmacy.

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. See pages 14 and 28 for the requirements regarding subsidiaries.

##### Wholesale Distributors and Retailers

Wholesale distributors of medical devices are “manufacturers” under Vermont law. Consequently, both the manufacturer and the wholesaler are liable for complying with Vermont law. Either may report expenditures, in the manufacturer’s name, but any particular expenditure shall be reported only once. 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. All other manufacturers – e.g., manufacturers of both Class I and Class II prescribed products – are “manufacturers” under the law and must report all expenditures, including those related to Class I devices.

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.

### Mergers and Acquisitions

#### **Within 30 days of a merger or acquisition, the resulting manufacturer should:**

1. **notify the Attorney General’s office of the following by sending an email to: [prescribedproducts@atg.state.vt.us](mailto:prescribedproducts@atg.state.vt.us) with “merger/acquisition” in the subject line:**
  - a. **the names of the affected manufacturers,**
  - b. **the date of merger or acquisition, and, if there will be any resulting delay in reporting, what the manufacturer’s plan for compliance with the reporting requirements is, including the date by which the manufacturer will be in compliance;**
2. **complete a new compliance officer form, if necessary, to advise the Office as to who will be responsible for disclosures.**

#### *ii. What are prescribed products?*

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.”

Note that combination products must also be reported. 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, acetaminophen, 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
- 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 Vermont “health care provider” (HCP) 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 an HCP.

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, or a partnership or corporation made up of such persons, 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 in 2011 as part of Vermont’s health care reform package, are treated the same as HCPs under Vermont’s Prescribed Product Law.

The term “regularly practices in Vermont” will require some judgment on the part of the reporting entity. An orthopedic surgeon who provides medical care in Vermont for one week out of every year “regularly practices in Vermont”; one who practices in Vermont one week one year and another week some years later, under separate agreements and with no planned interval in between, does not.

If audited, a manufacturer should be able to demonstrate through documentation how it arrived at the conclusion that a health care professional does not regularly practice in Vermont.

## **c. *Location of Expenditure***

Note that expenditures to covered recipients fall under the law whether or not the expense is incurred in Vermont. In other words, a Vermont HCP is a Vermont HCP whether or not the expenditure took place in Vermont. So, for example:

- The expense of a hotel room for a Vermont HCP 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.

**d. *Expenditure Types***

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

- Banned gifts (including, e.g., food, compensation for marketing research)
- Permitted gifts
- Allowable expenditures
- Samples (see Section III. for definition)

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. The following is a table of gift ban and reporting requirements indicating, by category, whether expenditures or gifts are permissible, what the reporting requirement is, if any, and relevant citations.

**Table of Gift Ban and Reporting Requirements**

Expenditure	Health Care Provider Recipients		Non-HCP Recipients*
	Allowed?	Reporting Required?	Reporting Required?
<b>Clinical Trials / Research</b> (See special rules for reporting clinical trial expenditures on pages 19.)			
Funding a bona fide <b>clinical trial</b> in the form 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 (as Cash, Check, Credit; Bona fide Clinical Trial); 18 V.S.A. § 4632(a)(1)(A)(iii)	Yes (same); 18 V.S.A. § 4632(a)(1)(C)
Funding a <b>research</b> project of significant interest or value to scientists or health care professionals in the form of (1) gross compensation; (2) direct salary support per health care professional; and (3) expenses paid on behalf of each health care professional.	Yes; 18 V.S.A. § 4631a(a)(1)(D)	Yes (as Cash, Check, Credit; Research Project); 18 V.S.A. § 4632(a)(1)(A)	Yes (same); 18 V.S.A. § 4632(a)(1)(C)
Payment for <b>other research, including marketing surveys.</b>	No; 18 V.S.A. § 4631a(c)	N/A	Yes (as Cash, Check, Credit; Other FMV Payment); 18 V.S.A. § 4632(a)(1)(C)
Payment for completed research conducted by a <b>syndicated research firm</b> which compensated HCPs during the course of the research.	Yes, as long as the research firm conducted the research independently of the manufacturer and not as the agent of the manufacturer (in which case there is no covered exchange between a manufacturer and a recipient); 18 V.S.A. § 4631a(b)(1)	N/A	N/A
<b>Conferences / Seminars / Promotional Events/ Professional Association Events</b>			
Providing <b>discount coupon, or voucher,</b> for conference or annual meeting.	No; 18 V.S.A. §§ 4631a(a)(5), 4631a(b)(1)	N/A	N/A

\*Non-HCP recipients include 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.

	Health Care Provider Recipients		Non-HCP Recipients*
Expenditure	Allowed?	Reporting Required?	Reporting Required?
Payment of <b>honoraria</b> and 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 (as Cash, Check, Credit; Faculty Honoraria or Expense); 18 V.S.A. § 4632(a)(1)(A)	N/A
Providing <b>scholarship</b> or other support for medical students, residents, and fellows to attend a significant educational, scientific, or policy-making <b>conference or seminar</b> of a national, regional, or specialty medical or other <b>professional association</b> .	Yes, if the recipient of the scholarship or other support is selected by the association; 18 V.S.A. § 4631a(b)(2)(E)	Yes (as Cash, Check, Credit; Scholarship/Fellowship); 18 V.S.A. § 4632(a)(1)(A)	N/A
<u>Providing scholarship for medical students, residents, and fellows to attend the significant educational, scientific, or policy-making conference or seminar of an institution.</u>	<u>Yes; while not exempted from the gift ban under the statute, the Office will not enforce the ban as it relates to such scholarships until question of permissibility is resolved by Legislature.</u>	<u>Yes (as Cash, Check, Credit; Scholarship/Fellowship).</u>	<u>N/A</u>
<b>Sponsorship</b> of a significant educational, medical, scientific, or policy-making conference or seminar.	Yes, but payment must not go directly to an HCP or pharmacist, and conference must meet statutory requirements; 18 V.S.A. § 4631a(a)(1)(A)	Yes (as Cash, Check, Credit; Conference Sponsorship); 18 V.S.A. § 4632(a)(1)(A)	Yes (same); 18 V.S.A. § 4632(a)(1)(C)
Fair market value payments for <b>promotional speaking</b> .	Yes; 18 V.S.A. § 4631a(a)(1)(H)	Yes (as Cash, Check, Credit; Other FMV Payment); 18 V.S.A. § 4632(a)(1)(A)	N/A
<b>Donating items</b> , such as iPads, to a professional association <b>to be raffled off to HCPs</b> at a conference, seminar, or professional association event.	No; 18 V.S.A. §§ 4631a(a)(5), 4631a(b)(1)	N/A	N/A
<b>Educational Materials</b>			

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	Health Care Provider Recipients		Non-HCP Recipients*
Expenditure	Allowed?	Reporting Required?	Reporting Required?
<b>Articles or journals and other educational items</b> provided to an HCP (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) whether individually, through a practice, or by distribution at conferences or seminars, for example.	Yes; 18 V.S.A. § 4631a(b)(2)(D)	Yes (as Educational Materials; Educational Materials); 18 V.S.A. § 4632(a)(1)(A)	Yes (same); 18 V.S.A. § 4632(a)(1)(C)
<b>Financial Contributions</b>			
<b>Financial contributions to Vermont recipients other than free clinics.</b>	No; 18 V.S.A. §§ 4631a(a)(5), 4631a(b)(1)	N/A	Yes (as Cash, Check, Credit; Gift to Institution/Organization); 18 V.S.A. § 4632(a)(1)(C)
<b>Financial contributions to a free clinic.</b>	Yes; 18 V.S.A. § 4631a(b)(2)(H)	Yes (as Cash, Check, Credit; Gift to Institution/Organization); 18 V.S.A. § 4632(a)(1)(A)	N/A
<b>Financial contributions to national and international charitable patient advocacy groups</b> or organizations that serve patients such as Leukemia and Lymphoma Society, Susan G. Komen for the Cure, and Doctors Without Borders	N/A	N/A	No; the Office does not require reporting of financial contributions to national and international organizations, only Vermont organizations, or Vermont chapters of national or international organizations; 18 V.S.A. § 4632(a)(1)(C)
<b>Donations made on behalf of an HCP</b> with the HCP's knowledge, whether or not the donation is attributed to the HCP by name.	No; 18 V.S.A. §§ 4631a(a)(5); 4631a(b)(1)	N/A	N/A
<b>Food</b>			
<b>Dinner at a seminar</b> 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

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	Health Care Provider Recipients		Non-HCP Recipients*
Expenditure	Allowed?	Reporting Required?	Reporting Required?
<b>Food to HCP or staff</b> , 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 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
<b>Refreshments</b> , including coffee or other snacks, <b>at a booth</b> 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
<b>Medical Devices</b>			
<b>Loan</b> of a medical device for a short-term trial period, not to exceed 120 days, to permit evaluation of a medical device by an HCP or patient.	Yes; 18 V.S.A. § 4631a(b)(2)(B)	Yes (as Loan of Medical Device; Medical Device – Loans, Demos); 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)	Yes (same); 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)
<b>Placing medical devices with recipient for use during term of contract for purchase of related items or placing related items with recipient for use with contracted-for medical devices.</b> Capital placed with a recipient for usage without payment based on a signed agreement that the recipient will purchase a set quantity of a related consumable at a set price over the course of a period of time, where, at the end of the term of the agreement, the capital is returned to the manufacturer. <b><u>Or, consumables placed</u></b>	Yes; 18 V.S.A. § 4631a(a)(5)	No; 18 V.S.A. § 4632(a)(1)(A)	No; 18 V.S.A. § 4632(a)(1)(C)

\*Non-HCP recipients include 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.

Expenditure	Health Care Provider Recipients		Non-HCP Recipients*
	Allowed?	Reporting Required?	Reporting Required?
<b><u>with recipient for usage without payment based on contracted-for use or purchase of related medical device.</u></b>			
Payment of reasonable expenses - including food, travel, and lodging-related expenses - necessary for <b>technical training</b> of individual health care professionals on the use of a medical device.	Yes, 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 HCP and the manufacturer; 18 V.S.A. § 4631a(a)(1)(E)	Yes (as Cash, Check, Credit; Medical Device Training); 18 V.S.A. § 4632 (a)(1)(A)	N/A
Provision of reasonable quantities of medical device <b>demonstration or evaluation units</b> to an HCP to assess the appropriate use and function of the product and determine whether and when to use or recommend the product in the future (typically for patient education or single-use instruments).	Yes; 18 V.S.A. § 4631a(b)(2)(C)	Yes (as Demo/Evaluation Unit; Medical Device – Loans, Demos); 18 V.S.A. § 4632(a)(1)(A)	N/A
<b>Samples / Free Products</b>			
Distribution of <b>samples</b> – i.e., units 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, that are distributed for free to patients and are intended to promote the sale of the product.	Yes; 18 V.S.A. § 4631a(b)(2)(A)	Yes (using <i>samples</i> form/database); 18 V.S.A. § 4632(a)(2)(A)(i) (Individual reports will not be disclosed to public.)	<b><u>No</u></b>
Donation to a <b>free clinic</b> of 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 (as <b><u>Other Product to Free Clinic</u></b> ; free Distribution to Patients); 18 V.S.A. § 4632(a)	N/A

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	Health Care Provider Recipients		Non-HCP Recipients*
Expenditure	Allowed?	Reporting Required?	Reporting Required?
		(1)(A) (Individual reports will not be disclosed to public.)	
<b>Free over-the-counter product</b> – i.e., over-the-counter drugs, nonprescription medical devices or nonprescription durable medical equipment – provided to an HCP for free distribution to patients, <b><u>including, e.g., lotions and eye drops.</u></b>	Yes, but only of reasonable quantities, unless to a free clinic; 18 V.S.A. § 4631a(b)(2)(A)	Yes (as <b><u>Over the Counter Product</u></b> ; Free Distribution to Patients); 18 V.S.A. § 4632(a)(1)(B). (Reports not disclosed to public.)	N/A
Prescription drugs provided through the manufacturer's <b>patient assistance program</b> for free or at a reduced price (including, e.g., through co-pay assistance).	Yes; 18 V.S.A. § 4631a(b)(2)(I)	No; 18 V.S.A. § 4632(a)(1)(A)(vii)	N/A
<b>Coupons, vouchers and discount cards distributed through pharmacies or HCPs.</b>	Yes; 18 V.S.A. § 4631a(b)(2)(A)	Yes (using <i>samples</i> form/database); 18 V.S.A. § 4632(a)(2)(A)(i) (Individual reports will not be disclosed to public.)	N/A
<b>Distribution of prescribed product through qualifying Clinical Trials and Research Projects <u>including related distribution of product, such as chemical reagents, used in the trial or project.</u></b>	Yes; the Office does not consider the distribution of such items to be a gift.	No	No
<b>Rebates and discounts</b> 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)
<b><u>Distribution of medical foods to HCPs for free distribution to patients.</u></b>	<b><u>Yes; while not exempted from the gift ban under the statute, the Office will not enforce the ban as it relates to the distribution of medical foods pending future legislation.</u></b>	<b><u>Yes (as Other; Free Distribution to Patients; Medical Food)</u></b>	<b><u>N/A</u></b>
<b>Miscellaneous</b>			
<b>Fellowship</b> for a Residency.	Yes, if it meets the four criteria of 18	Yes (as Cash, Check, Credit;	N/A

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	Health Care Provider Recipients		Non-HCP Recipients*
Expenditure	Allowed?	Reporting Required?	Reporting Required?
	V.S.A. § 4631a(b)(2)(J)	Scholarship/Fellowship); 18 V.S.A. § 4632(a)(1)(A)	
<b>Membership fees/dues</b> paid by a manufacturer to a professional, educational or patient organization.	N/A	N/A	Yes, for organizations representing or serving HCPs or consumers in Vermont (as Cash, Check, Credit; Other FMV Payment); 18 VSA § 4632(a)(1)(C)
Reasonable expenses related to the <b>interview</b> 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
<b>Labels</b> on prescribed products required by FDA.	Yes; 18 V.S.A. § 4631a(b)(2)(G)	No; the Office does not consider this a <b>sample</b> , gift or allowable expenditure requiring reporting.	No; the Office does not consider this a <b>sample</b> , gift or allowable expenditure requiring reporting.
<b>Royalties and licensing fees</b> paid to an HCP in return for contractual rights to use or purchase a patented or otherwise legally recognized discovery for which the HCP 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)
Expenses for manufacturers' <b>employees' health care</b> .	Yes; 18 V.S.A. § 4631a(a)(1)(G)	No; 18 V.S.A. § 4632(a)(1)(A)(iv)	N/A
<b>Holiday greeting cards.</b>	<b><u>Yes; 18 V.S.A. § 4631a(A)(5)</u></b>	<b><u>No; 18 V.S.A. § 4632(a)(1)(A)</u></b>	<b><u>No</u></b>

\*Non-HCP recipients include 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.

## 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 Distribution of Product through Clinical Trials and Research Projects.* The Office no longer considers the distribution of prescribed product through qualifying clinical trials or research projects to be a gift, and therefore no longer requires such distributions to be reported. **The Office also does not consider the distribution of related non-prescribed product used in the course of the trial or research, such as chemical reagents, to be gifts.** The Office will not require reporting of these distributions for past years, including 2011 (July 1, 2011 through December 31, 2011).

Donations of prescribed product to free clinics 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](#) and a [disclosure form](#) for the reporting of allowable expenditures and permitted gifts are available on the Vermont Attorney General’s website, [www.atg.state.vt.us](http://www.atg.state.vt.us). Each disclosure form covers expenditures relating to up to five prescribed products and one HCP 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.

Disclosures should be made in the corporate name of the entity making the expenditures. Thus, if the manufacturer makes expenditures through a division, those expenditures should be reported in the manufacturer’s corporate name, not in the name of the division. However, if the manufacturer of prescribed products markets those products through a subsidiary, the expenditures should be reported in the corporate name of the subsidiary. Disclosures should not be made in the name of a corporation’s “aka” or “dba.”

If a manufacturer has a marketing agreement with another company which is *not* a subsidiary or a manufacturer under the law, either the manufacturer or the other 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, both manufacturers are liable for reporting the expenditures. However, only one manufacturer needs to report; 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 Individual HCPs:

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 a multi-prescriber practice as a recipient is not allowed except for expenditures for clinical trials and research projects. Rather, the gift or expenditure must be allocated among the prescribers in the practice to which it is relevant. (See “Value/Amount of Expenditure,” below for how to allocate expenditures to individual HCPs in multi-prescriber practices.)

*Front-Office Staff:* All permitted gifts and allowable expenditures made to an individual must be allocated to a prescriber or prescribers, even when the immediate recipient is front office staff.

The Access database includes a table of the names and license numbers of HCPs with active licenses on January 2, 2012. You may also use the “[Table 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. *Caution: This table is meant to be a helpful resource for looking up an HCP’s license number, not as an exclusive list of HCPs that constitute covered recipients under the law. The table is merely a snapshot of who had an active Vermont license on a particular day, not a complete list of who has practiced under a Vermont license during the course of an entire reporting period.*

If a recipient is not on the table, 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.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.

**If the recipient does not have a Vermont license number because he/she is an inactive practitioner conducting research, you may use the following license number when reporting allowable expenditures and permitted gifts associated with that person: 999-9999999.**

*Alternative Aggregate Disclosure for gifts that are not banned and are of a fair market value below \$25 (for description, see “Value/Amount of Expenditure” below): Fill in “Aggregate” for name; the license number for aggregate disclosure is 000-0000000.*

**For Institutions and Organizations:**

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 HCPs or consumers – insert the name of the entity-recipient into the “Last Name” field, and fill in the Federal Tax ID number of the recipient. Where possible, please use the name of the entity-recipient provided in the Access database and in the “[Table of Entity-Recipients](#)” available at [www.atg.state.vt.us](http://www.atg.state.vt.us). *Caution: This table is meant to facilitate the standardization of the naming of institutional and organizational recipients and is NOT an exclusive list of entity-recipients that constitute covered recipients under the law.*

**For Members of Green Mountain Care Board:**

Members of the Green Mountain Care Board, established in 2011 as part of Vermont’s health care reform package, are treated the same as HCPs under Vermont’s Prescribed Product Law. The members of the Board, and the identification numbers that should be used in any disclosures related to them, are as follows:

Anya Rader Wallack (Chair) 999-0000001

Al Gobellie 999-0000002

Dr. Karen Hein 999-0000003

Con Hogan 999-0000004

Dr. Allan Ramsey 999-0000005

**Date Expenditure Incurred:**

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

*Alternative Aggregate Disclosure* (for description, see “Value/Amount of Expenditure” below): The date for aggregate disclosure is December 31, 2012, the last day of the reporting period.

**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 an HCP, the manufacturer may elect to report the expenditures for all Vermont HCPs 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. **For purposes of 2012 reporting, Vermont’s allocation of national expenditures is 0.25% (multiply the national total by 0.0025).**

If audited, manufacturers should be able to provide the following details about educational materials reported in the aggregate: **a description of the materials distributed, and either the cost of producing the materials for national distribution, or the amount of money budgeted for the national distribution of the materials.**

*Multi-Prescriber Practices:* The value of a permitted gift or an allowable expenditure when provided to a practice with multiple HCPs 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.
- If the gift of a reasonable quantity of over the counter anti-inflammatory medication for free distribution to patients is made to a multi-prescriber practice that includes three orthopedic surgeons, that gift would properly be divided between the three surgeons (who may distribute the medication to their patients), but should not be attributed to a

psychiatrist in the same practice (who is not likely to distribute the medication).

### **Nature of Expenditure:**

Choose the appropriate nature of expenditure from the field values provided in the drop down list:

- **Cash, Check or Credit Card;**
- **Educational Materials;**
- **Demo/Evaluation Unit;**
- **Loan of Medical Device;**
- **Other Product to Free Clinic - refers to donations of product to free clinics;**
- **Over the Counter Product - refers to reasonable amounts of OTC product distributed to HCPs for free distribution to patients;**
- **Other.** If you choose “Other” you must fill in the “Other” description field to the right of the drop down. *Do not choose “Other” unless the expenditure does not fit into any other category.*

### **Purpose of Expenditure:**

Identify the primary purpose of the expenditure from the field values in 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 payment 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 an HCP 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 an HCP 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 HCP. Note that “bona fide significant educational, medical, scientific, or policy making seminar,” is defined by statute.

**Scholarship/Fellowship:** 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.

**Fellowship salary support provided to fellows through grants from manufacturers of prescribed products are permitted gifts as long as the grants are applied for by an academic institution or hospital; the institution or hospital selects the recipient fellows; the manufacturer imposes no further demands or limits on the institution’s, hospital’s,**

**or fellow’s use of the funds; and fellowships are not named for a manufacturer, and no individual recipient’s fellowship is attributed to a particular manufacturer of prescribed products.**

**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 an HCP – whether individually, through a practice, or by distribution at a conference or seminar, for example – 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 an HCP or patient, and the provision of reasonable quantities of medical device demonstration or evaluation units to an HCP 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 HCPs or payment or reimbursement for the reasonable expenses, including travel, food, 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 HCP and the manufacturer. Note that fair market value payments to professionals for training *patients* on medical devices should be reported as an FMV Payment, not as Medical Device Training – Compensation.

**Clinical Trials and Research:** There are three kinds of allowable expenditures associated with bona fide clinical trials and qualifying research projects:

- 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, or if data as to clinical trial or research expenditures was gathered prior to July 1, 2011, and without regard to these three statutory categories in reliance on the Office’s previous practice of not requiring such specificity, the total of those fees should be reported as gross compensation.

#### *A Note on 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 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.

Each year, send the minimum clinical trial information to the Attorney General’s Office in an email to: [prescribedproducts@atg.state.vt.us](mailto:prescribedproducts@atg.state.vt.us), with “clinical trial notification” and the year of the delay in the subject line. Thus if a clinical trial started April 1, 2009, the subject line for notifications related to the 2012 report would be “Clinical Trial Notification – Year 3.” All expenses from 2009 through 2013 would be reported by April 1, 2014, and the expenses for the previous calendar year by April 1, 2015, and annually thereafter. Should the clinical trial be completed or discontinued prior to January 1, 2014, the expenses would be reported by April 1 of the year of completion. 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: <http://clinicaltrials.gov>.

Information regarding all ongoing clinical trials must be reported. The minimum information must be provided 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. The complete information must be reported on the expenditures for the trial incurred since July 1, 2009, for pharmaceutical manufacturers, or incurred 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 to the Attorney General on an annual basis either the expenditures associated with the trial or the minimum information regarding the clinical trial 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.

**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 those services.

**Free Distribution to Patients:** The provision of reasonable quantities of an over-the-counter drug, non-prescription medical device, or item of non-prescription durable medical equipment provided to an HCP for free distribution to patients, and the provision of free drugs, medical devices, biological products, or medical equipment or supplies to a free clinic are permitted gifts.

**Gift to Institution/Organization:** 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. An example of an “FMV payment” (other than payments for consulting services, see “Consulting” above) might include compensation to a health care professional for speaking at a promotional program or compensation to a health care professional for training patients on the use of a medical device. *Do not use “Other FMV Payment” unless the expenditure does not fit into any of the fields above.*

*If audited, manufacturers should be able to demonstrate through documentation the precise nature of the goods and/or services for which the fair market value payment was made.*

**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 product or products which are associated with the reported expenditure.

Choose product type from among the following on the drop down list: **Pharmaceutical, Biologic, Medical Device, Combination Product, Medical Food, and Other Over the Counter Product.**

**Pharmaceuticals, Biologics, Medical Devices and Combination Product refer to the different categories of prescribed product that are defined by federal law (see Section I.a.ii, above). Note that prescribed product is a much broader category than *prescription* product and that many prescribed products (pain killers such as ibuprofen and acetaminophen, for example) are available over-the-counter.**

**Do not choose “Other Over the Counter Product” unless the product is not a “prescribed product,” or a medical food and therefore does not fit into any of the other categories (for example, hand lotion).**

Fill in product name in the field to the right of the product type. If more than five products are associated with the reported payment or gift, the manufacturer must list the five products most relevant to the expenditure.

**In the case of products associated with Clinical Trials, please use an identifier consistent with that used for the National Clinical Trials registry. For product in research and development that does not yet have such an identifier, please use the most specific internal identifier used by the manufacturer that does not reveal a trade secret. If this is not possible, please use “RND,” or if multiple products must be reported in this manner, “RND1,” “RND2,” etc.**

### **III. Reporting Samples**

*Please see Appendix A for example sample disclosures.*

**Note: The federal Patient Protection and Affordable Health Care Act) does not preempt Vermont’s samples reporting law. Consequently, manufacturers will report samples to both the U.S. Department of Health and Human Services (HHS) and to the Vermont Attorney General.**

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.”

Prescribed product donated to free clinics 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 at least two ways, manufacturers of prescribed products which distribute samples to Vermont HCPs must report more to the Vermont Attorney General than is required to be reported to HHS. 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 HCPs.

**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, even if, e.g., the free evaluation device is a single use, disposable product that will be assessed by using it with a patient.
- 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.
- Donations of prescribed product to free clinics should not be reported as samples, but rather as a permitted gift.

**b. Instructions for Completing Reporting**

An [Access database](#) and a [disclosure form](#) 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). 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.

Except as otherwise provided below, the manufacturer need not assign a monetary 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.

Unlike federal law on product samples, only the person who requested the samples constitutes the recipient.

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

Use the “[Table of Health Care Professionals with Active Vermont Licenses](#)” provided in the Access database and at [www.atg.state.vt](http://www.atg.state.vt) to assure accuracy of the name and license number of individuals. If a recipient is not on that table, 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.

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. Where possible, please use the name provided in the Access database and in the “[Table of Entity-Recipients](#)” available at [www.atg.state.vt.us](http://www.atg.state.vt.us).

Manufacturers who distribute vouchers that are offered and redeemed at individual locations of a chain pharmacy may use 111-111111 in lieu of the individual Federal Tax ID number of the location when reporting such 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 contents block and other applicable blocks. 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 HCPs 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 HCPs, 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 make 20 disclosures of 5 units to each HCP and include the license number of each HCP.
- If, because of their specialties, only five of the HCPs in the medical practice would use the vouchers, the manufacturer should make five disclosures, disclosing 20 units for each of the five HCPs, along with the license number of each HCP.

**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 HCP. If several types of samples were delivered on the same day, complete multiple records in the Access database or multiple samples disclosure forms. As a general rule, the number of samples should approximate the number of patients that could potentially receive the Sample rather than the number of physical things (boxes of blister packs; books of coupons) given to a prescriber. For example, a book of 25 vouchers should be reported as 25 samples, not 1 sample.

**Contents:**

Check *all applicable* boxes (Prescribed Product; Vouchers, Coupons, Co-pay Cards, Etc., and Other) to describe the content of the sample (refer to the descriptions below). More detailed information is required for all checked categories. *If the only contents are educational materials or other permitted gifts, report with allowable expenditures and permitted gifts, NOT as samples.*

*Note that if there are more than three of any of the three categories of contents associated with a single sample, all of the information will not fit on the disclosure form. Such disclosures should be made through the database rather than the form.*

**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 HCPs for distribution or administration to patients under Patient Assistance Programs need not be reported.*

**Prescribed Product Type:** Indicate type of product included in or associated with the 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, “10” if 1 blister pack with 10 capsules is 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.”

*See Appendix A, examples A, E, F and G.*

## **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 HCP, 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 HCP in each sample; e.g., enter “5” if each sample contains 5 coupons. Manufacturers must report the quantity of vouchers provided to the HCP, not necessarily the quantity redeemed by patients. The number provided may equal the number redeemed, for example, if individual vouchers are generated and redeemed at a pharmacy at point of sale.

**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.”

*See Appendix A, examples B, C, D, and E.*

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

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

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, (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.

**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.
- If multiple products are promoted by the other materials, enter “multiple products: and name each product in the Description of Product/Discount field.

**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.”

*Please note that similar or equivalent “other” items, such as educational materials, can be grouped together, i.e., as “owner’s booklet and other printed materials.”*

*See Appendix A, examples D, E, and F.*

#### **IV. Registration and Reporting Deadlines**

##### **Registration:**

No later than 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 manufacturer’s compliance with the reporting requirements for that year (the “Compliance Officer”). Manufacturers having anything to report for 2012 must pay an annual registration fee of \$500.

##### **Choosing a Compliance Officer:**

A [compliance officer form](#) is at the Attorney General’s website, [www.atg.state.vt.us](http://www.atg.state.vt.us). Submit all such 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 either in addition to or in lieu of submitting the form by email. The Vermont Attorney General does not accept forms sent as a pdf or through the mail.*

Manufacturers who have nothing to report for the corresponding reporting period should not fill out a

compliance officer form. To ensure receipt of electronic updates, email [prescribedproducts@atg.state.vt.us](mailto:prescribedproducts@atg.state.vt.us) and ask to be added to the list serve.

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.

**In light of changes in federal law, the compliance officer form now contains a space for manufacturers to note whether they intend to submit data that will also be submitted to the federal government under the Physician Payments Sunshine Provision (§ 6002) of the Patient Protection and Affordable Care Act (Pub. L. No. 11-148). Please use this section to communicate with the Office about whether you are submitting such information.**

If the manufacturer markets products through a division, 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 the manufacturer of prescribed products markets products through a subsidiary, the expenditures should be reported in the name of the subsidiary, and the compliance officer form should be submitted in the name of the subsidiary.

*Manufacturers MUST complete a new compliance officer form if the compliance officer leaves the manufacturer's employ or otherwise ceases to be responsible for compliance. The Attorney General's Office must have current information as to who is responsible for compliance in case it needs to follow up regarding particular disclosures.*

**Paying the Registration Fee:**

Any manufacturer with expenditures to report must, by January 1, 2013, mail a check for \$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 put the request in writing after April 1, 2013, to [prescribedproducts@atg.state.vt.us](mailto:prescribedproducts@atg.state.vt.us) with "Refund Request" in the subject line. The Office will

process the refund in 60 days.

If a manufacturer knows that it is *possible* that it has expenditures to report but cannot be sure by January 1, 2013, it should file the compliance officer form by January 1, 2013 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](mailto: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, 2013 for the 2012 calendar year.

#### Electronic Filing:

The Attorney General’s Office will only accept electronic filings; those filings must be submitted by one of two methods. A company can make disclosures either: (1) by downloading an Access 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](mailto: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 either in addition to or in lieu of submitting the data electronically. The Vermont Attorney General does not accept expenditure reports sent as a pdf or through the mail.*

We highly recommend the first alternative as it includes a table of all Vermont HCPs with active licenses as of the beginning of the reporting period, including license numbers, as well as a table of entity-recipients. This ensures greater accuracy of submissions.

Manufacturers should make every effort to submit correct and complete data. For example, if a manufacturer is concerned that it may have the wrong license number for a prescriber, or if the manufacturer has not been able to locate the prescriber’s license number by other means, the manufacturer 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, 2013 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, 2013.***

#### 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](mailto:prescribedproducts@atg.state.vt.us), with “Data Correction” in the subject line.

## V. *Public Disclosure of Reported 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 an HCP for free distribution to patients or to a free clinic) 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.

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 and permitted gifts 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 for injunctive relief, costs, and attorney’s fees for any violation of either the gift ban or reporting requirements. In addition, a manufacturer 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. Failure to disclose is a separate violation from a violation of the gift ban.

**Any expenditure that is not an allowable expenditure or a permitted gift is a banned gift. Manufacturers that discover they have violated the gift ban should attempt to recover the banned gift or the cost of the banned gift. Gifts successfully recovered or reimbursed before the due date for disclosures for the reporting period in which the gift was given are not unlawful and do not need to be reported. The Office considers gifts which have not been recovered or reimbursed by the due date for disclosures for the relevant reporting period to be unlawful. Such gifts should be reported to the Office no later than the relevant disclosure deadline by sending an email to [prescribedproducts@atg.state.vt.us](mailto:prescribedproducts@atg.state.vt.us), with “banned gift” in the subject line. The report should include the value of the gift, the recipient’s primary place of business and license or federal tax ID number, information about the manufacturer’s attempts to recover the gift, the results of those attempts, and any other factors you wish the Office to consider.**

## APPENDIX A

At the request of industry, the Office has put together some sample disclosure forms for reporting the distribution of samples and allowable expenditures related to the distribution of reasonable amounts of over the counter products. The descriptions below correspond to the sample completed forms.

### Example A: Drug Sample – Prescribed Product

On January 10, 2012, ACME 123 Company distributed 2 samples of XYZ pill to Dr. John Q. Doe. Each sample consisted of a bottle of pills containing 50, 200 milligram pills.

### Example B: Drug Sample – Voucher

On January 10, 2012, ACME 456 Company distributed a book of 25 vouchers to APRN Janice Q. Doe. Each voucher allowed for up to \$50 savings on a prescription and two refills of pharmaceutical DEF in any of three strengths each of the aerosol or powder formulations of the product.

### Example C: Drug Sample – Voucher – Multiple Manufacturers

Manufacturers X Co., Y Co., and Z Co. have partnered to offer a voucher good for 25% off of certain of their prescription drugs. With respect to Manufacturer X's products, the voucher is good for 25% off of a single prescription of Manufacturer X Co.'s A, B, and C pills. On January 10, 2012, Manufacturers X Co., Y Co., and Z Co. distributed 50 of these vouchers to Dr. Jaye Q. Doe. Manufacturer X is reporting.

### Example D: Drug Sample – Starter Pack with Prescribed Product, Literature and Non-Prescribed (Over the Counter) Item

On January 10, 2012, QRS Company distributed 10 starter packs of HIJ pill to APRN James Doe. Each starter pack contained 1 blister pack of 14, 100 milligram pills, an FDA label, a medication guide, and 1 tube TUV medicated lotion (a non-prescribed product) for treating dry skin associated with taking Pill HIJ.

### Example E: Drug Sample – Starter Pack with Prescribed Product, Co-Pay Card and Literature

On January 10, 2012, RST LNE Company distributed 5 starter packs of NOP pill to Dr. Janelle Q. Doe. Each starter pack contained 1 bottle of 25, 50 milligram pills, 1 co-pay card allowing for up to \$20 off 6 prescriptions of a minimum, 30-day supply of NOP, a booklet entitled "Getting Started with NOP" and an FDA label.

### Example F: Medical Device Sample – Starter Pack with Prescribed Product, Literature, and Other Items

On January 10, 2012, WXY Company distributed 5 starter packs to Dr. Jeremy Q. Doe. Each pack contained a JKL blood glucose meter, a package of 10 JKL blood glucose test strips, and a JKL lancing device. Each pack also contained a carrying case, a log book for recording blood glucose levels, and an owner's booklet and other printed materials about the products in the starter pack.

**Please note that non-prescription like items, such as educational materials, can be grouped together, i.e., as “owner’s booklet and other printed materials.”**

**If there are more than three prescribed products, vouchers, etc., or other items associated with a single sample, all of the information will not all fit on the disclosure form. Such disclosures should be made through the database rather than the form.**

**Example G: Biologic Sample – Prescribed Product**

On January 10, 2012, KLMN Incorporated distributed 10 samples of RST vaccine to APRN Judith Q. Doe. Each sample included 1 vial of .5 milliliter RST hepatitis B immune globulin (HBIG) vaccine.

**Example H: Expenditures Related to Distribution of Reasonable Quantity of Over the Counter (Non-Prescribed) Product**

On January 10, 2012, ACME 789 Company distributed 5 packages of QRS Nicotine Gum to Dr. John Q. Doe for free distribution to patients. Each package contained 10 units of gum. In total, the gum had a value of \$15.

**Please note that such expenditures should be disclosed with allowable expenditures and permitted gifts rather than as samples.**

Example A

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

**2012 Samples Disclosure Form for Manufacturers of Prescribed Products**

Reporting Period: January 1, 2012 to December 31, 2012; Due Date: April 1, 2013

<b>Name of Manufacturer</b>		ACME 123 Co.		
<b>Last Name of Recipient</b>		Doe	<b>First Name</b>	John
<b>Lic. Number/ID Number of Recipient</b>		042-1234567		
<b>Date Delivered</b>		01/10/2012	<b>Number of Samples</b>	2
<b>Contents (Check all that apply)</b>				
<input checked="" type="checkbox"/> Prescribed Product <input type="checkbox"/> Vouchers, etc <input type="checkbox"/> Other (Including Non-Prescribed Items or Educational Materials)				
<b>Prescribed Product</b>				
<b>Prescribed Product Type</b>	<b>Prescribed Product Name</b>	<b>Units/Sample</b>	<b>Dosage or N/A</b>	<b>Description</b>
Pharmaceuticals <input type="checkbox"/>	XYZ Pill	50	200 mg	Bottles of pills each containing 50 pills of 200 mg XYZ
<input type="checkbox"/>				
<input type="checkbox"/>				
<b>Vouchers, Coupons, Co-Pay Cards, Etc.</b>				
<b>Prescribed Product Type</b>	<b>Prescribed Product Name, or N/A, Multiple Products, and/or Multiple Manufacturers</b>	<b>Vouchers/Sample</b>	<b>Description of Product/Discount</b>	
<input type="checkbox"/>				
<input type="checkbox"/>				
<input type="checkbox"/>				
<b>Other (Including Non-Prescribed Items or Educational Materials)</b>				
<b>Prescribed Product Type</b>	<b>Prescribed Product Name, or N/A, or Multiple Products</b>	<b>Other Sample Type</b>	<b>Description of Item/Discount/Material</b>	
<input type="checkbox"/>		<input type="checkbox"/>		
<input type="checkbox"/>		<input type="checkbox"/>		
<input type="checkbox"/>		<input type="checkbox"/>		

  
    

[Home](#)

Example B

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

2012 Samples Disclosure Form for Manufacturers of Prescribed Products

Reporting Period: January 1, 2012 to December 31, 2012; Due Date: April 1, 2013

Name of Manufacturer		ACME 456			
Last Name of Recipient		Doe	First Name	Janice	MI   Q
Lic. Number/ID Number of Recipient		101-1234567			
Date Delivered		01/12/2012	Number of Samples	25	
Contents (Check all that apply)		<input type="checkbox"/> Prescribed Product	<input checked="" 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	
<input type="checkbox"/>					
<input type="checkbox"/>					
<input type="checkbox"/>					
Vouchers, Coupons, Co-Pay Cards, Etc.					
Prescribed Product Type	Prescribed Product Name, or N/A, Multiple Products, and/or Multiple Manufacturers	Vouchers/Sample	Description of Product/Discount		
Pharmaceuticals <input type="checkbox"/>	DEF	1	Up to \$50 off product + 2 refills for three strengths each, aerosol or powder		
<input type="checkbox"/>					
<input type="checkbox"/>					
Other (Including Non-Prescribed Items or Educational Materials)					
Prescribed Product Type	Prescribed Product Name, or N/A, or Multiple Products	Other Sample Type	Description of Item/Discount/Material		
<input type="checkbox"/>		<input type="checkbox"/>			
<input type="checkbox"/>		<input type="checkbox"/>			
<input type="checkbox"/>		<input type="checkbox"/>			

[Home](#)

Example C

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

2012 Samples Disclosure Form for Manufacturers of Prescribed Products

Reporting Period: January 1, 2012 to December 31, 2012; Due Date: April 1, 2013

Name of Manufacturer		X Co.			
Last Name of Recipient		Doe	First Name	Jaye	MI   Q
Lic. Number/ID Number of Recipient		042-9876543			
Date Delivered		01/10/2012	Number of Samples	50	
Contents (Check all that apply)		<input type="checkbox"/> Prescribed Product	<input checked="" 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, Multiple Products, and/or Multiple Manufacturers	Vouchers/Sample	Description of Product/Discount		
Pharmaceuticals ▼	Multiple Manufacturers	1	25% off 1 prescription of A, B or C pill; other manufacturers are Y Co., and Z Co.		
▼					
▼					
Other (Including Non-Prescribed Items or Educational Materials)					
Prescribed Product Type	Prescribed Product Name, or N/A, or Multiple Products	Other Sample Type	Description of Item/Discount/Material		
▼		▼			
▼		▼			
▼		▼			

Next Disclosure    Submit by Email    Print for Your Records

[Home](#)

Example D

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

2012 Samples Disclosure Form for Manufacturers of Prescribed Products  
 Reporting Period: January 1, 2012 to December 31, 2012; Due Date: April 1, 2013

Name of Manufacturer		QRS Co.		
Last Name of Recipient		Doe	First Name	James MI
Lic. Number/ID Number of Recipient		101-2345678		
Date Delivered		01/10/2012	Number of Samples	10
Contents (Check all that apply)		<input checked="" type="checkbox"/> Prescribed Product <input type="checkbox"/> Vouchers, etc <input checked="" 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
Pharmaceuticals <input type="checkbox"/>	HIJ Pill	14	100 mg	Starter packs, each w/ 1 blister pack of 14, 100 mg pills
<input type="checkbox"/>				
<input type="checkbox"/>				
Vouchers, Coupons, Co-Pay Cards, Etc.				
Prescribed Product Type	Prescribed Product Name, or N/A, Multiple Products, and/or Multiple Manufacturers	Vouchers/Sample	Description of Product/Discount	
<input type="checkbox"/>				
<input type="checkbox"/>				
<input type="checkbox"/>				
Other (Including Non-Prescribed Items or Educational Materials)				
Prescribed Product Type	Prescribed Product Name, or N/A, or Multiple Products	Other Sample Type	Description of Item/Discount/Material	
Pharmaceuticals <input type="checkbox"/>	HIJ Pill	Educational Ma <input type="checkbox"/>	Medication Guide	
Pharmaceuticals <input type="checkbox"/>	HIJ Pill	Non-Prescribed <input type="checkbox"/>	1 tube TUV medicated lotion for treating dry skin associated with taking Pill HIJ	
<input type="checkbox"/>		<input type="checkbox"/>		

 
   

[Home](#)

Example E

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

2012 Samples Disclosure Form for Manufacturers of Prescribed Products

Reporting Period: January 1, 2012 to December 31, 2012; Due Date: April 1, 2013

Name of Manufacturer		RST LNE Co.		
Last Name of Recipient		Doe	First Name	Janelle
Lic. Number/ID Number of Recipient		042-3456789		
Date Delivered		01/10/2012	Number of Samples	5
Contents (Check all that apply)		<input checked="" type="checkbox"/> Prescribed Product	<input type="checkbox"/> Vouchers, etc	<input checked="" 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
Pharmaceuticals <input type="checkbox"/>	NOP Pill	25	50 mg	Starter packs, each with 1 bottle of 25, 50 mg pills
<input type="checkbox"/>				
<input type="checkbox"/>				
Vouchers, Coupons, Co-Pay Cards, Etc.				
Prescribed Product Type	Prescribed Product Name, or N/A, Multiple Products, and/or Multiple Manufacturers	Vouchers/Sample	Description of Product/Discount	
Pharmaceuticals <input type="checkbox"/>	NOP Pill	1	1 co-pay card good for up to \$20 off 6 prescriptions of min. 30 day supply of NOP	
<input type="checkbox"/>				
<input type="checkbox"/>				
Other (Including Non-Prescribed Items or Educational Materials)				
Prescribed Product Type	Prescribed Product Name, or N/A, or Multiple Products	Other Sample Type	Description of Item/Discount/Material	
Pharmaceuticals <input type="checkbox"/>	NOP Pill	Educational Ma <input type="checkbox"/>	Booklet: "Getting started with NOP"	
<input type="checkbox"/>		<input type="checkbox"/>		
<input type="checkbox"/>		<input type="checkbox"/>		

Next Disclosure      Submit by Email      Print for Your Records

[Home](#)

Example F

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

2012 Samples Disclosure Form for Manufacturers of Prescribed Products

Reporting Period: January 1, 2012 to December 31, 2012; Due Date: April 1, 2013

Name of Manufacturer		WXY Co.		
Last Name of Recipient		Doe	First Name	Jeremy
Lic. Number/ID Number of Recipient		042-8765432		
Date Delivered		01/10/2012	Number of Samples	5
Contents (Check all that apply)		<input checked="" type="checkbox"/> Prescribed Product	<input type="checkbox"/> Vouchers, etc	<input checked="" 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
Medical Devices <input type="checkbox"/>	JKL Meter	1	N/A	Starter pack, each with 1 blood glucose meter
Medical Devices <input type="checkbox"/>	JKL test strips	10	N/A	Blood glucose test strips
Medical Devices <input type="checkbox"/>	JKL lancing device	1	N/A	Blood glucose lancing device
Vouchers, Coupons, Co-Pay Cards, Etc.				
Prescribed Product Type	Prescribed Product Name, or N/A, Multiple Products, and/or Multiple Manufacturers	Vouchers/Sample	Description of Product/Discount	
<input type="checkbox"/>				
<input type="checkbox"/>				
<input type="checkbox"/>				
Other (Including Non-Prescribed Items or Educational Materials)				
Prescribed Product Type	Prescribed Product Name, or N/A, or Multiple Products	Other Sample Type	Description of Item/Discount/Material	
Medical Devices <input type="checkbox"/>	Multiple products	Other <input type="checkbox"/>	Carrying case for JKL meter, strips, lancing device	
Medical Devices <input type="checkbox"/>	Multiple products	Other <input type="checkbox"/>	Log book for recording glucose levels when using JKL meter, strips, lancing device	
Medical Devices <input type="checkbox"/>	Multiple products	Educational Material <input type="checkbox"/>	Owner's booklet and other printed materials re: JKL meter, strips, lancing device	

Next Disclosure

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[Home](#)

Example G

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

2012 Samples Disclosure Form for Manufacturers of Prescribed Products

Reporting Period: January 1, 2012 to December 31, 2012; Due Date: April 1, 2013

Name of Manufacturer		KLMN Inc.			
Last Name of Recipient		Doe	First Name	Judith	MI Q
Lic. Number/ID Number of Recipient		101-3456789			
Date Delivered		01/10/2012	Number of Samples	10	
Contents (Check all that apply)		<input checked="" 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	
Biologics <input type="checkbox"/>	RST Vaccine	1	.5 ml	Vial of Hepatitis B Immune Globulin (HGB), each with .5 ml	
<input type="checkbox"/>					
<input type="checkbox"/>					
Vouchers, Coupons, Co-Pay Cards, Etc.					
Prescribed Product Type	Prescribed Product Name, or N/A, Multiple Products, and/or Multiple Manufacturers	Vouchers/Sample	Description of Product/Discount		
<input type="checkbox"/>					
<input type="checkbox"/>					
<input type="checkbox"/>					
Other (Including Non-Prescribed Items or Educational Materials)					
Prescribed Product Type	Prescribed Product Name, or N/A, or Multiple Products	Other Sample Type	Description of Item/Discount/Material		
<input type="checkbox"/>		<input type="checkbox"/>			
<input type="checkbox"/>		<input type="checkbox"/>			
<input type="checkbox"/>		<input type="checkbox"/>			

Next Disclosure

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[Home](#)

Example H

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

**2012 Disclosure Form for Manufacturers of Prescribed Products**

**Reporting Period for Pharmaceuticals, Biologics and Medical Devices  
January 1, 2012 to December 31, 2012; Due Date: April 1, 2013**

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

<b>Name of Manufacturer</b>	ACME 789 Co.			
<b>Last Name of Recipient</b>	Doe	<b>First Name</b>	John	<b>MI</b> Q
<b>Lic. Number/ID Number of Recipient</b>	042-2345678			
<b>Date Expenditure Incurred</b>	01/10/2012			
<b>Value/Amount of Expenditure</b>	\$15.00			
<b>Nature of Expenditure</b>	Over the Counter Product <input type="button" value="v"/>			
<b>Purpose of Expenditure</b>	Free Distribution to Patients <input type="button" value="v"/>			
<b>Prescribed Product(s) (up to five) to which expenditure or gift relates.</b>				
<b>Product Type</b>	Other Over the Cc <input type="button" value="v"/>	<b>Product Name</b>	Nicotine Gum QRS; 5 packages, each with 10 units of gum	
<b>Product Type</b>	<input type="button" value="v"/>	<b>Product Name</b>		
<b>Product Type</b>	<input type="button" value="v"/>	<b>Product Name</b>		
<b>Product Type</b>	<input type="button" value="v"/>	<b>Product Name</b>		
<b>Product Type</b>	<input type="button" value="v"/>	<b>Product Name</b>		

If filing disclosures for 2012, please send a check made out to “State of Vermont”, for \$500 by January 1, 2013 to:

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

[Home](#)