GUIDE TO VERMONT'S PRESCRIBED PRODUCTS GIFT BAN AND DISCLOSURE LAW FOR DISCLOSURES OF 2017 DATA—DUE APRIL 1, 2018

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Introduction

Vermont law bans most gifts and requires manufacturers of prescribed products – including pharmaceuticals, biological products, and medical devices – to register with the Attorney General's Office and disclose allowable expenditures made and permitted gifts given to Vermont Health Care Providers ("Vermont HCPs") and certain 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.

Please read this guidance carefully as it reflects any changes in the Office's interpretation of the law since the 2017 Guide; as usual, substantive changes are **in bold.** This guide must be read in conjunction with Vermont law, which is available on the Office's website. We recommend you consult with counsel regarding questions requiring a nuanced interpretation of the law.

A Note on Preemption

As of January 1, 2012, some of Vermont's disclosure requirements are preempted by the Physician Payments Sunshine Provision (§ 6002) of the Patient Protection and Affordable Care Act (Pub. L. No. 11-148). In short, while the gift ban and samples reporting are **not preempted by the Patient Protection and Affordable Care Act**, Vermont may not require manufacturers to disclose those allowable expenditures and permitted gifts which are required to be reported to the federal government under the Physician Payments Sunshine Provision of the Patient Protection and Affordable Care Act.

The federal law is narrower than Vermont's law in several ways. For one 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.

Moreover, the federal law does not prohibit manufacturers from making preempted disclosures to states, it simply prohibits the states from *requiring* preempted disclosures. At this time, the Attorney General will accept such preempted disclosures. Manufacturers should indicate on the compliance officer form whether they intend to submit data that is also being submitted to the federal government for RY 2017.

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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 certain 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, Retailers, and Leasing Companies

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. However, a company leasing non-exempt products and/or equipment is subject to Vermont's Prescribed Products Gift Ban and Disclosure law as it is engaged in the marketing and distributing of non-exempt products. (See 18 V.S.A. § 4631(9)).

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. In addition, the definition of prescribed product no longer includes "prescription eyeglasses, prescription sunglasses, or other prescription eyewear." As a result, manufacturers whose only prescribed products were these items are no longer manufacturers under the law and need not report.

All other manufacturers – i.e., manufacturers of both Class I and Class II prescribed products and manufacturers of prescription eyewear and other prescribed products – are "manufacturers" under the law and must report all expenditures, including those related to Class I devices or prescription eyewear.

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 a final product.

Mergers and Acquisitions

Within 30 days of a merger or acquisition, the resulting manufacturer or manufacturers shall complete a new compliance officer form to advise the Attorney General's Office as to who will be responsible for disclosures.

We no longer require an email notification of mergers and acquisitions, or accept a delay in reporting due to any such merger or acquisition. All reporting must be done in a timely manner.

Each manufacturing entity which was in existence or newly formed during a reporting period will be responsible for filing disclosures. For example:

- Company A merges with Company B on June 1 to form Company AB. Company A and Company B would need to file separate disclosures for the time period between January 1 through May 31. Then Company AB would need to file its own disclosures for the time period between June 1 and December 31.

- Company A acquires Company B on June 1. Company B would need to file a separate disclosure for the period of time between January 1 and May 31. Company A would file its disclosure for the entire year.

- Company A acquires Company B and forms new entity C on June 1. Company A and Company B would need to file a separate disclosure for the period of time between January 1 and May 31. Company C would file its disclosure for the entire year.

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, a biological product as defined in section 351 of the Public Health Service Act, 42 U.S.C. § 262, for human use, or a combination product as defined in 21 C.F.R. § 3.2(e)," but does not include "prescription eyeglasses, prescription sunglasses, or other prescription eyewear."

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.

Covered Recipients -- 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; and
- 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 report expenditures to recipients who do not fall within the above categories.

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. Members of the Green Mountain Care Board are assigned numbers for reporting (see page 20 of this guidance).

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.

Location of Expenditure

Note that activities with 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 or sampling 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.

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 arepermissible, what the reporting requirement is, if any, and relevant citations.

Table of Gift Ban and Reporting Requirements

	Health Care Provider Recipients		Non-HCP Recipients*
Expenditure	**Allowed?**	**Reporting Required**	**Reporting Required?**
Clinical Trials / Research (See special rules for reporting clinical trial expenditures on page 19.)			
Funding a bona fide **clinical trial** 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)	Yes (same); 18 V.S.A. § 4632(a)(1)(C)
Funding a **research** 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 **other research, including marketing surveys.**	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 **syndicated research firm** 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

	Health Care Provider Recipients		Non-HCP Recipients*
Expenditure	**Allowed?**	**Reporting Required**	**Reporting Required?**
Conferences / Seminars / Promotional Events/ Professional Association Events			
Providing **discount coupon**, or **voucher**, for conference or annual meeting.	No; 18 V.S.A. §§ 4631a(a)(5), 4631a(b)(1)	N/A	N/A
Payment of **honoraria** 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 **scholarship** or other support for medical students, residents, and fellows to attend a significant educational, scientific, or policy-making **conference or seminar** of a national, regional, or specialty medical or other **professional association**.	Yes, if the recipient of the scholarship or other support is selected by the association; 18 V.S.A. § 4631a(b)(2)(E)	Yes (as Cash, Check, Credit; Scholarship/ Fellowship); 18 V.S.A. § 4632(a)(1)(A)	N/A
Providing **scholarship** for medical students, residents, and fellows to attend the significant educational, scientific, or policy-making **conference or seminar** of an **institution**.	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.	Yes (as Cash, Check, Credit; Scholarship/ Fellowship)	N/A

	Health Care Provider Recipients		Non-HCP Recipients*
Expenditure	**Allowed?**	**Reporting Required**	**Reporting Required?**
Sponsorship of a significant educational, medical, scientific, or policy-making conference or seminar or CME event.	Yes, but payment must not go directly to an HCP or pharmacist, funding must be used for bona fide educational purposes (food may be provided for all conference participants) and all program content must be objective and free of industry control and not promote a specific product; 18V.S.A. § 4631a(a) (1)(A). In order to be considered a "significant educational, medical, scientific, or policy-making conference or seminar" a program must meet statutory requirements including that the event must be a certified CME; 18 V.S.A. § 4631a(a)(A)(14) .	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 **promotional speaking**.	Yes; 18 V.S.A.§ 4631a(a)(1)(H)	Yes (as Cash, Check, Credit; Other FMV Payment), even if, at the HCP's request, the payment is made to a charity or other third party, whether or not the donation is attributed to the HCP by name; 18 V.S.A. § 4632(a) (1)(A)	N/A

	Health Care Provider Recipients		Non-HCP Recipients*
Expenditure	**Allowed?**	**Reporting Required**	**Reporting Required?**
Donating items, such as iPads, to a professional association **to be raffled off to HCPs** at a conference, seminar, or professional association event.	No; 18 V.S.A. §§ 4631a(a)(5), 4631a(b)(1)	N/A	N/A
Educational Materials			
Articles or journals and other educational items 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)
Financial Contributions			
Financial contributions to Vermont recipients other than free clinics.	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)
Financial contributions to a free clinic.	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
Financial contributions to national and international charitable patient advocacy groups 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)
Donations made on behalf of an HCP 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

	Health Care Provider Recipients		Non-HCP Recipients*
Expenditure	**Allowed?**	**Reporting Required**	**Reporting Required?**
Food			
Dinner at a seminar or conference at which the meal is organized and paid for by the manufacturer.	No; 18 V.S.A. §§ 4631a(a)(5), 4631a(b)(1)	N/A	N/A
Food to HCP or staff, 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 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
Food to HCP as part of fair market value compensation package for service – e.g., service on advisory board, consulting, or speaking.	Yes; 18 V.S.A. 4631a(a)(1)(H)	Yes (as Other; Other FMV Payment); 18 V.S.A. § 4632(a)(1)(A)	N/A
Refreshments, including coffee or other snacks, **at a booth** at a conference or seminar.	Yes; 18 V.S.A. § 4631a(b)(2)(K)	No; 18 V.S.A. § 4632(a)(1)(A)(v)	N/A
Medical Devices			
Loan 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)

	Health Care Provider Recipients		Non-HCP Recipients*
Expenditure	**Allowed?**	**Reporting Required**	**Reporting Required?**
Placing capital equipment with recipient at no cost based on an agreement that the recipient will purchase related consumables, or providing consumables to recipient at no cost as part of a contracted-for use or purchase of a related piece of capital equipment.	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)
Payment of reasonable expenses - including food, travel, and lodging-related expenses - necessary for **technical training** 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 **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 (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
Samples / Free Products			
Distribution of **samples** – i.e., units of prescription 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 *samples* form/database); 18 V.S.A. § 4632(a)(2)(A)(i) (Individual reports will not be disclosed to public.)	No
Donation to a **free clinic** 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 (using *samples* form/ database); 18 V.S.A. § 4632(a)(1)(A) (Reports not disclosed to public.)	N/A

	Health Care Provider Recipients		Non-HCP Recipients*
Expenditure	**Allowed?**	**Reporting Required**	**Reporting Required?**
Free over-the-counter drugs, nonprescription medical devices or nonprescription durable medical equipment, medical food or infant formula provided to an HCP **for free distribution to patients**, including, e.g., distribution of medical food for patient trialing.	Yes, but only of reasonable quantities, unless to a free clinic; 18 V.S.A. § 4631a(b)(2)(A)	Yes (using *samples* form/ database); 18 V.S.A. § 4632(a)(1)(B). (Reports not disclosed to public.)	N/A
Prescription drugs provided through the manufacturer's **patient assistance program** 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
Coupons, vouchers and discount cards distributed to patients **through pharmacies or other HCPs.**	Yes; 18 V.S.A. § 4631a(b)(2)(A)	Yes (using *samples* form/database); 18 V.S.A. § 4632(a)(2)(A)(i) (Reports not be disclosed to public.)	N/A
Coupons, vouchers and discount cards distributed directly to patients or to patients through a non-HCP covered recipient.	N/A	N/A	No

Distribution of prescribed product and supplies through qualifying **Clinical Trials** and **Research Projects** including: • chemical reagents, and medical supplies such as blood pressure cuffs, used in the trial or project; • loaned medical devices used in the trial or project.	Yes; the Office does not consider the distribution of such items to be a gift.	Yes, although not as such. The Office expects the cost of such distribution to be included in the disclosure of Clinical Trial and Research Project expenses (as Cash, Check, Credit; and either Bona fide Clinical Trial or Research Project); 18 V.S.A. § 4632(a)(1)(A)	Yes, although not as such. The Office expects the cost of such distribution to be included in the disclosure of Clinical Trial and Research Project expenses (same); 18 V.S.A. § 4632(a) (1)(C).
Rebates and discounts for prescribed products provided in the normal course of business.	Yes; 18 V.S.A. § 4631a(b)(2)(F)	No; 18 V.S.A. § 4632(a)(1)(A)(ii)	No; 18 V.S.A. § 4632(a)(1)(C)(ii)

	Health Care Provider Recipients		Non-HCP Recipients*
Expenditure	**Allowed?**	**Reporting Required**	**Reporting Required?**
Miscellaneous			
Fellowship for a Residency.	Yes, if it meets the four criteria of 18 V.S.A. § 4631a(b)(2)(J)	Yes (as Cash, Check, Credit; Scholarship/ Fellowship); 18 V.S.A. § 4632(a)(1)(A)	N/A
Membership fees/dues paid by a manufacturer to a professional, educational or patient organization.	N/A	N/A	Yes, for organizations representing or serving HCPs or consumers in Vermont (as Cash, Check, Credit; Other FMV Payment); 18 VSA § 4632(a)(1)(C)
Reasonable expenses related to the **interview** by a manufacturer of prescribed products in connection with a bona fide employment opportunity.	Yes; 18 V.S.A. § 4631a(a)(1)(G)	No; 18 V.S.A. § 4632(a)(1)(A)(iv)	N/A
Labels on prescribed products required by FDA.	Yes; 18 V.S.A. § 4631a(b)(2)(G)	No; the Office does not consider this a sample, gift or allowable expenditure requiring reporting.	No; the Office does not consider this a sample, gift or allowable expenditure requiring reporting.
Royalties and licensing fees 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' **employees' health care.**	Yes; 18 V.S.A. § 4631a(a)(1)(G)	No; 18 V.S.A. § 4632(a)(1)(A)(iv)	N/A
Holiday greeting cards.	Yes; 18 V.S.A. § 4631a(A)(5)	No; 18 V.S.A. § 4632(a)(1)(A)	No

	Health Care Provider Recipients		Non-HCP Recipients*
Expenditure	**Allowed?**	**Reporting Required**	**Reporting Required?**
Prescription Pads	No, unless the purpose and function of a prescription pad is predominantly educational, does not favor one manufacturer over another (by, e.g., omitting or deemphasizing the products of competitors), and the prescriber's access to the prescription pad benefits patients. 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)

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 products used in the course of the trial or research, such as chemical reagents, to be gifts.

Contrary to previous guidance, donations of prescribed product to free clinics should be included in the samples Access database or samples disclosures form.

Instructions for Completing Reporting

An Excel Spreadsheet and a disclosure form for the reporting of allowable expenditures and permitted gifts are available on the Office's website. Each disclosure form covers expenditures relating to up to five prescribed products and one HCP on one day. Manufacturers are encouraged to use the online form to submit disclosures but may

also use the AGO supplied Excel Spreadsheet found online for larger numbers of disclosures when submitting data to the Attorney General's office.

Name of Manufacturer:

See above for details on which manufacturers must report allowable expenditures and permitted gifts. Note that the definition of prescribed products no longer includes "prescription eyeglasses, prescription sunglasses, or other prescription eyewear." As a result, companies that manufacture *only* these items are no longer manufacturers under the law and need not report.

Disclosures should be made in the corporate name of the entity making the expenditures and gifts. 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." Each corporate entity making the expenditure should file separately and shall not combine its disclosures with other corporate entities regardless of common parent entity. For example, if Co. ABC owns Subsidiary Company XYZ and Subsidiary Company 123, both Co. XYZ and Co. 123 must report separately and not combine its disclosure requirements into Parent Co. ABC's report.

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:

<u>For Individual HCPs:</u>

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 that a multi-prescriber practice may be reported as the recipient of 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.)

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

You may also use the "Table of Health Care Professionals with Active Vermont Licenses" which will be available on the Office's website in January, 2018, to ensure 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 assistants, radiologist assistants, anesthesiologist assistants, podiatrists, and physicians who hold limited temporary permits may be found at: https://webmail.vdh.state.vt.us/CAVU/Lookup/LicenseLookup.aspx.

State license numbers for Advanced Practice Registered Nurses; Dentists; Dental Assistants; Dental Hygienists; Hearing Aid Dispensers; Licensed Nurses Aids; Licensed Practical Nurses; Naturopathic Physicians; Nuclear Medicine Technologists; Nursing Home Administrators; Opticians; Optometrists; Osteopathic Physicians; Pharmacists; Psychologists; Radiation Therapist; Radiologic Technicians; Registered Nurses, and others who may be authorized to dispense or recommend prescribed products for humans may be found at: https://secure.vtprofessionals.org/

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) with 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 last name; the license number for aggregate disclosure is 000-0000000.

For Institutions and Organizations:

For any recipient who does not have a license – e.g., 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" that will be available on the Office's website in January, 2018. *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:

Robin Lunge, J.D., MHCDS	999-0000100
Maureen Usifer	999-0000101
Kevin Mullin	999-0000102
Tom Pelham	999-0000103
Jessica Holmes, Ph.D.	999-0000104
Susan J. Barrett, J.D.	999-0000105

Direct and Indirect Recipients:

When an expenditure is remitted to one entity or person ("direct recipient"), but routed to another entity or person ("ultimate recipient"), and only one of the recipients constitutes a covered recipient, only disclose the name of the covered recipient.

If both the direct and ultimate recipients are covered recipients (e.g., research funding remitted to a hospital that ultimately benefit a physician), disclose the direct recipient only.

Date Expenditure Incurred:

Indicate the date on which the expenditure was made or gift given to the covered recipient. For medical device loans that span two reporting periods, please report the loan only once, in connection with the second reporting period. Report the date the loan ended as the expenditure date.

Alternative Aggregate Disclosure (for description, see "Value/Amount of Expenditure" below): The date for aggregate disclosure is December 31, 2017, 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. All expenditures should be reported with a positive value. The receipt of money back from a covered recipient (e.g., unused grant money) need not be reported. Negative numbers that are reported will be deleted for purposes of analysis and reporting.

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 of the unit.

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. With respect to educational brochures, for example, "cost of production" means cost of materials and printing. 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 2017 data reporting, Vermont's allocation of national expenditures is 0.23%(multiply the national total by 0.0023).**

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 permitted 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 permitted 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** (This category is intended to be broad. For example, when payment is remitted directly to a third party (e.g., an airline) for the permitted payment of an HCP's expenses (e.g., for travel connected to medical device training), manufacturers should choose "Cash, Check or Credit Card.");
- **Educational Materials;**
- **Demo/Evaluation Unit;**
- **Loan of Medical Device;**
- **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.*

Note: "Other Product to Free Clinic" and "Over the Counter Product" have been eliminated as those items are now reported in the samples database or on the samples form.

Purpose of Expenditure:

Identify the 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 (including pharmacists), (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; 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: ago.prescribedproducts@vermont.gov with "clinical trial notification" in the subject line. The minimum information is: the name of the manufacturer, 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.

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.

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.*

Note: "Free Distribution to Patients" has been eliminated as those items are now reported using a samples form or samples database.

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, or Combination Product.**

Note: "Other Over the Counter Product" and "Medical Food" have been eliminated as these items are now reported using a samples form or samples database.

Pharmaceuticals, Biologics, Medical Devices and Combination Product refer to the different categories of prescribed product that are defined by federal law (see Section I, 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.

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. If all of a manufacturer's products are associated with the reported payment or gift, and the manufacturer manufactures more than five products, the manufacturer must list its top five products as measured by gross revenue. Should a manufacturer be unable to list the top five products without divulging a trade secret, the manufacturer should indicate "brand promotion" in the product name field.

For pharmaceuticals and biologics, report the marketed name of the drug or biological. For medical devices, report either (1) the marketed name under which the medical device is or was marketed, or (2) the therapeutic area or product category.

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 and Other Product***

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.

See PPACA §6002, 42 U.S.C.A § 1128 G(d)(3)(A), and 42 U.S.C.A § 1128 G(d)(3)(B))

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."

Contrary to prior guidance, prescribed products donated to free clinics should be included in the samples Access database or samples disclosures form rather than with disclosures of allowable expenditures and permitted gifts.

In addition, an amendment to the law that became effective on January 1, 2012, decreases the amount of information manufacturers are required to report about the distribution of over-the-counter drugs, nonprescription medical devices, and items of nonprescription durable medical equipment.

As a result, only the product, dosage, number of units, and recipient information of these products need be reported. An amendment to the law that became effective on July 1, 2012 clarifies that the distribution of medical food and infant formula is a permitted gift, and that only the product, dosage, number of units, and recipient information of those products need be reported as well. These are the same categories of information required to be reported of samples; thus, manufacturers should disclose the distribution of such over-the-counter product using the samples form and the samples database. For the sake of simplicity, manufacturers should also report the provision of free prescription or over-the-counter drugs, medical devices, biological

products, medical equipment, combination products, medical food, infant formula or medical equipment or supplies to a free clinic with samples.

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.

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.

Instructions for Completing Reporting

An Excel Spreadsheet and a disclosure form for the reporting of samples and other product are available on the Vermont Attorney General's website. These are different from the database and form for the disclosure of allowable expenditures and permitted gifts. Manufacturers are encouraged to use the online form to submit disclosures but may also use the AGO supplied Excel Spreadsheet found online for larger numbers of disclosures when submitting data to the Attorney General's office.
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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.

The manufacturer need not assign a monetary value to a sample or other product when reporting.

Name of Manufacturer:

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

Name and License/ID Number of Recipient:

See Section II, 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" (Available in January, 2018) provided in the Access database and on the Office's website 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, 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 on the Office's website.

Manufacturers that distributed vouchers that are offered and redeemed at pharmacies may name the pharmacy itself as the recipient, and report the pharmacy's Federal Tax ID number as the ID number. Manufacturers that distribute vouchers that are offered and redeemed at individual locations of a chain pharmacy must report the vouchers as having gone to the individual pharmacy, and must identify the individual pharmacy by location and by the individual Federal Tax ID number of the location. So, for example, vouchers distributed through the Montpelier Rite Aid should be reported with Recipient Name: "Rite Aid – Montpelier," and ID Number of Recipient: (the Federal Tax ID Number of the Montpelier Rite Aid).

If the recipient of the sample or other product is a hospital, or nursing home, simply name the recipient and fill out the contents block and other applicable blocks. If 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, "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 or other product were distributed to the HCP.

Number of Samples: For each type of sample or other product delivered on the delivery date, indicate the number of samples or other product distributed to the HCP. If several types of samples or other product 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 or other product should approximate the number of patients that could potentially receive the sample or other product 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; **ten sets of blister packs with 12 pills each should be reported as ten samples with 12 units per sample.**

Contents:

Check *all applicable* boxes (Product; Vouchers, Coupons, Co-pay Cards, Etc., and Other) to describe the content of the sample or other product distribution (refer to the descriptions below). More detailed information is required for all checked categories. *If the only contents are educational materials, 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.

Product:

If the sample or other product distribution includes a product, check the box in "Contents," above, and provide detail. A product sample can have any number of units of a product, and may or may not be called a "starter pack." If a sample or other product distribution includes more than one product, describe each 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.

Product Type: Indicate type of product included in or associated with the sample or other product distribution: pharmaceutical, biologic, medical device, combination, medical food, infant formula, or medical equipment/supplies.

Product Name: State the name of the product included in the sample or other product distribution. For pharmaceuticals and biologics, report the marketed name of the drug or biological. For medical devices, and medical equipment/supplies, report either (1) the marketed name under which the device or medical supply is or was marketed, or (2) the therapeutic area or product category.

Units/Sample: Indicate the number of products included in each sample or other product distribution; 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."

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.

Product Type: Indicate type of product promoted by the voucher: pharmaceutical, biologic, medical device, combination product, medical food, infant formula, or medical equipment/supplies.

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.
- For pharmaceuticals and biologics, report the marketed name of the drug or biological. For medical devices, and medical equipment/supplies, report either (1) the marketed name under which the device or medical supply is or was marketed,or (2) the therapeutic area or product category.

Vouchers/Sample: Indicate the number of vouchers provided to the HCP in each sample; e.g., enter "5" if each sample contains 5 coupons, **as well as the number of units per voucher**. 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 sale price," or "10% discount."

Other (Including Other 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 Other 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.

Product Type: Indicate type of prescribed product promoted by the non-

prescribed or other materials: pharmaceutical, biologic, medical device, combination **product, medical food, infant formula, or medical equipment/supplies.**

Product Name: State name of the 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 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."

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

Registration:

No later than January 1, 2018, 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 2018 must pay an annual registration fee of $500 by January 1, 2018.

Choosing a Compliance Officer:

A compliance officer form is on the Attorney General's website. 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 receive electronic updates, you can sign up for the Office's List Serve here: http://list.state.vt.us/guest/RemoteListSummary/VermontPrescribedProductsLaw.**

As long as it is made clear on the compliance officer form, manufacturers may designate a single personresponsible for reporting the activities of the entire company, or may designate different people responsible for reporting different product types: (1) pharmaceutical products, (2) biological products, and (3) medical devices), or different activities ((1) samples, (2) allowable expenditures and permitted gifts, and (3) aggregate expenditures).

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

If the manufacturer 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 or samples to report for 2017 must, by January 1, 2018, 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, 2018, to ago.prescribedproducts@vermont.gov 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, 2018, it should file the compliance officer form by January 1, 2018, 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 ago.prescribedproducts@vermont.gov 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, 2018 for the 2017 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 ago.prescribedproducts@vermont.gov, 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, 2018, deadline for all submissions is not met for any data that is returnedto the manufacturer for corrections unless it is resubmitted with no errors* ***by April 1, 2018.***

Correcting or Supplementing Submitted Reports:

If you find that you have submitted incorrect or incomplete 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: ago.prescribedproducts@vermont.gov, 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 allowableexpenditures 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, medical equipment and supplies, medical food, or infant formula provided to an HCP for free distribution to patients or to a free clinic) publicly 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 considered unlawful by the Office 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 ago.prescribedproducts@vermont.gov, 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.