

Memo

To: Manufacturers of Prescribed Products

From: Wendy Morgan, Chief of the Public Protection Division
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Vermont Office of the Attorney General

Date: March 2, 2011

Subject: Following up on 2/14/11 Conference Call: Clarification of FY11 Guide to Vermont's Prescribed Product Gift Ban and Disclosure Law and FY11 Guide to Vermont's Law on Disclosure of Samples

Question: As we prepare future guides, and assuming that the reporting years will be identical for allowable expenditures and permitted gifts and for samples, would you prefer our instructions to continue to be contained in two guides or would you rather see one integrated guide? Please let us know by emailing us at prescribedproducts@atg.state.vt.us, with "Guides" in the subject line. Thank you.

In response to some of the issues raised in the February 14, 2011 conference call, what follows is a series of clarifications to the FY11 Guide to Vermont's Prescribed Product Gift Ban and Disclosure Law and the FY11 Guide to Vermont's Law on Disclosure of Samples.

We anticipate publishing updated guidance by June 30, 2011 that incorporates the following clarifications as well as any amendments to the law passed during this legislative session. We intend to provide you with an advanced copy of the update and to schedule a conference call prior to July 1.

Manufacturers

Non-profit subsidiary: Any distributions made through the non-profit subsidiary of a manufacturer must be reported, whether or not the distributions are to indigent patient populations.

Manufacturer-supported, non-subsiary, non-profit foundation: If a manufacturer establishes and endows a non-profit foundation that is a separate legal entity with a separate board of directors, that foundation is not a manufacturer within the meaning of the statute.

Non-subsiary marketing agreement: If a manufacturer has a marketing agreement with a company which is not a subsidiary, either the manufacturer or the company can report the expenditures, but not both; expenditures shall be reported in the manufacturer’s name.

Recipients

Specialty pharmacies: If a “specialty” pharmacy is operating under the direction of one or more manufacturers, essentially filling orders for the manufacturers, it is not a health care provider even if it is licensed in Vermont. Consequently, the rules for reporting the pharmacy’s activities are the same as for manufacturers, may be done by the pharmacy or the manufacturer (but not both), and need not include PAP products sent directly to a patient.

Medical practices: The Vermont statutory scheme provides for reporting of expenditures to individual recipients except in limited circumstances such as academic institutions and certain organizations. Consequently, there will be no change to allow reporting by medical practice.

Type of recipient: Following is the type of recipient associated with licensed health care providers:

License Prefix	Type of Recipient	License Description
015	Other Health Care Provider	Dental Hygienist
016	Other Prescriber	Dentist
025	Other Health Care Provider	Licensed Practical Nurse
026	Other Health Care Provider	Registered Nurse
030	Other Prescriber	Optometrist
031	Doctor	Osteopathic Physician - Limited
032	Doctor	Osteopathic Physician
033	Pharmacist	Pharmacist
042	Doctor	Physician
047	Other Health Care Provider	Psychologist - Master
048	Other Health Care Provider	Psychologist - Doctorate
049	Other Health Care Provider	Nuclear Medicine Technologist
055	Other Prescriber	Physician Assistant
056	Other Prescriber	Podiatrist
060	Doctor	Physician - Limited Temp. Permit
075	Other Health Care Provider	Licensed Nursing Assistant
089	Other Health Care Provider	Clinical Social Worker
101	Other Prescriber	RN with APRN Endorsement
121	Other Health Care Provider	Pharmacy Technician

Table of licensed recipients: The office updates the table of active providers annually. It is up to you to find recipient licensure information if it is not in the current version of the table.

Reporting

Duplicate reporting: Manufacturers should ensure that no duplicate reporting is made. If a wholesaler or marketer who would otherwise have to report is acting at the direction of the manufacturer, either it or the manufacturer can report its activities in the name of the manufacturer, but both should not report. If the distributor is independent of the manufacturer, it must report in its own name.

ID numbers for non-licensed recipients: Over the next several months, we will assign ID numbers to institutional recipients and recipient organizations.

If you wish to submit data using a non-licensed recipient's Taxpayer ID, you must send us each non-licensed recipient's name and federal ID number as soon as possible by emailing us at prescribedproducts@atg.state.vt.us, with "Federal ID" in the subject line.

Medical devices: A demonstration or evaluation unit provided to a health care provider must be reported at fair market value. Loans and samples of medical devices may be reported at \$0 value.

Clinical trials/samples: Items, whether product or vouchers, that would otherwise constitute "samples," but which are distributed through a clinical trial or research project, are properly reported as allowable expenditures rather than samples. We will accept a \$0 reported value for them. Thus, choose "other" and indicate the type of sample (e.g., product or voucher) for nature, "bona fide clinical trial" or "research project" for purpose, and enter \$0 for value.

Nonprescription product: At this time, the Attorney General will allow the reporting of nonprescription product or vouchers for nonprescription product that are properly categorized as permitted gifts to be reported as samples. However, the report must include the name of the prescription product with which the expenditure is associated, if any. An explanation of our analysis of this issue follows.

Vermont law generally prohibits the distribution of gifts but allows for the distribution of "[s]amples of a prescribed product or reasonable quantities of an over-the-counter drug, nonprescription medical device, or item of nonprescription durable medical equipment provided to a health care provider for free distribution to patients." 18 U.S.C. § 4631a(b)(2)(A). "Samples" 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." 18 U.S.C. § 4631a(a)(13). In addition, the 2011 Samples Guide provides for reporting of non-prescribed items included in samples (e.g. nonprescription items included in a starter pack) to be reported as "Other," on the sample disclosure form with the caveat: "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*."

Thus, vouchers or coupons for nonprescription product and nonprescription products, when distributed alone – i.e. without prescribed products or vouchers for prescribed products – would

be reported as a permitted gift, not as a sample. However, manufacturers have requested that the reporting of these items be included with samples because often, like samples, they are distributed by the consumer programs within manufacturing companies and, presumably, the difficulty of separating out the nonprescription items which are properly reported as permitted gifts from those properly reported as samples would be difficult, time-consuming, and prone to error.

Finding, on balance, that requiring a distinction to be made for nonprescription product between permitted gifts and samples would not be a useful expenditure of manufacturers' resources, the Attorney General will allow such nonprescription products to be reported as samples as long as the pharmaceutical, biologic or medical device with which it is associated, if any, is provided (as would be required for permitted gifts as well). This decision may be revisited in the future, but not without notice to manufacturers sufficient to allow new reporting procedures to be put in place.

Other Samples Reporting

Out-of-state recipients of samples: Samples – whether product, vouchers, or other items – which are distributed out-of-state to out-of-state recipients who regularly practice in Vermont shall be reported.

Recipient of samples: The recipient of product samples is the person who requested the samples, not the person who signed for them as is indicated as an alternative in the 12/27/10 Samples Guide.

Vouchers created at pharmacy: Vouchers which are not created until the patient fills a prescription shall be reported as a voucher in the samples database; unlike the reporting of other vouchers, all such vouchers will have been redeemed.

Front office staff: If vouchers or other samples, other than product samples, are left with front office staff, report the ultimate recipient of the samples. For example, for a prescription drug voucher, the prescribing doctors, rather than front office staff or non-prescribing nurse, should be reported as the sample recipients.

Samples sent directly to patients: Samples that go directly to patients do not have to be reported. Moreover, manufacturers are not responsible for verifying that the patient's address is the patient's address (as opposed to the patient's aunt's address, for example) under the sample disclosure law.

Samples used in an independent study: When prescribed product is provided to an HCP for purposes of conducting an independent study that is neither a bona fide clinical trial nor a research project as defined in the statute, the product shall be reported in the samples database.

Vouchers with variable value: If the number of vouchers or percent discount associated with a voucher is variable, report the maximum amount or discount.

Units: The 2011 Samples Disclosure Form will not always easily or obviously accommodate the information you are trying to provide. Use your best judgment to provide the relevant

information. If, through your reporting, it becomes clearer what categories would accommodate a greater variety of the samples being distributed, we will change the form in the future.

Public disclosure: Under the first exception to Vermont’s public records law, “records which by law are designated confidential,” are exempt from public inspection. 1 V.S.A. § 317(c)(1). 18 V.S.A. § 4632(a)(2)(A)(ii) and (iii) provide for such confidentiality, and so the information released by the Attorney General will not “allow[] for the identification of individual recipients of samples or connect[] individual recipients with the monetary value of the samples provided.”

Other Questions and Concerns

Samples database: The samples database is now available on the Attorney General’s website.