

Answers to Submitted Questions-FY 10 - Updated 1-8-10

DATE POSTED	QUESTION	RESPONSE
Manufacturers/Reporters		
9/28/2009	We have compared the Prescribed Products Law with Vermont’s licensing law. The definitions of “manufacturer” in the new legislation and the current pharmacy statutes are very similar. Can you clarify whether the Prescribed Products Law applies to companies not required to be licensed as a “manufacturer” by the Vermont Board of Pharmacy?	With regards only to pharmaceutical products, the law applies only to pharmaceutical manufacturers which are licensed by the Vermont Board of Pharmacy.
9/28/2009	Does a CME accreditation company that uses sponsorship money from a manufacturer to pay a Vermont doctor to speak at a conference have to report the payment to the manufacturer or to the State of Vermont?	No, reporting obligations under the law apply only to manufacturers of prescribed products. See I(a) of the FY10 Guide.
9/28/2009	If an accredited CME provider engages a physician from Vermont to be a faculty member at a national meeting or local meeting do we have to report that back to the supporting companies for reporting to the state?	If a manufacturer of prescribed products donates money to a CME provider which, without any input from the manufacturer, selects a Vermont prescriber to be a presenter, neither the manufacturer nor the CME provider need report the donation. Any payment by a CME accreditation company which is not a manufacturer of prescribed products does not fall within the statute. See II(c)(9) of the FY10 Guide.
Recipients		
12/16/2009	Can 000-0000000 be used to identify people or only institutions?	Yes, however, when you submit your disclosures for FY10, you will be asked to verify that an individual with a license number of 000-0000000 is a health benefit plan administrator or a person authorized (but not licensed) to dispense or purchase prescribed products. All other individual recipients should have an individual license number. See IV(e) of the FY10 Guide.

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1/8/2010	How can we know who "regularly practices in Vermont"?	<p>You may assume that any health care provider with an active Vermont license "regularly practices" in Vermont. Gifts to these providers are prohibited, and you must report all covered expenditures to them.</p> <p>Gifts covered in the Vermont statute may be given to a Vermont licensee only if the manufacturer verifies that the licensee does not regularly practice in Vermont. All such gifts must be reported to the Attorney General. See IV(c) of the FY10 Guide on "Nature" of permitted gifts and allowable expenditures.</p>
Prescribed Products		
8/26/2009	If a company manufactures only components of a prescribed product which it then sells to a pharmaceutical manufacturer for use in a prescribed product, is it subject to the Act?	If the products do not fall within 21 U.S.C. § 321, they are not subject to the statute. See I(b) of the FY10 Guide.
8/26/2009	Does Vermont law extend to medical equipment the use of which does not require a prescription?	Yes. Any device which falls within 21 U.S.C. § 321 is a "prescribed product" under Vermont law. See I(b) of the FY10 Guide.
8/26/2009	Is the manufacturer of a diagnostic testing machine covered? The patient's physician writes a prescription for the test itself.	Diagnostic testing machines are prescribed products. See I(b) of the FY10 Guide.
8/26/2009	A physician repairing a hip fracture will select the type of rod or plate to use to fix the hip. These products are "implants" within the definition of a "device" under section 201 of the federal Food, Drug and Cosmetic Act. Are these manufacturers covered by the law?	Yes. See I(b) of the FY10 Guide.
8/26/2009	The patient's physician prescribes a course of respiratory therapy which may utilize a nebulizer to administer a drug. The patient then leases or purchases a nebulizer to use. Is this a prescription device that is covered by the law?	If the nebulizer falls within 21 U.S.C. § 321, it is covered by Vermont law. See I(b) of the FY10 Guide.

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Gifts and Allowable Expenditures - Recipients		
8/26/2009	May a health care provider act as the repository for money paid by pharmaceutical manufacturers to help pay expenses of a conference?	To not run afoul of the Vermont law, the donation should run through an academic institution or through a professional, educational, or patient organization representing or servicing health care providers or consumers, and must be reported. See II(c)(7) of the FY10 Guide.
8/26/2009	May a drug/device company provide educational grants to the University of Vermont? Is UVM considered a "health care provider" under the law or is it simply considered an academic institution?	UVM is an academic institution. Gifts to academic institutions are not banned but must be reported. See II(c)(7) of the FY10 Guide.
9/28/2009	For the PA and PA-C, they all have the same prefix of their license numbers (055). Are PAs non-prescribers and PA-Cs prescribers?	All Physicians Assistants in Vermont (i.e. professionals with a license prefix of 055) are licensed to prescribe.
Gifts and Allowable Expenditures - Educational Activities/Food		
8/26/2009	Does Vermont law prohibit nurses, or others who are not physicians, who are hired by a pharmaceutical company from presenting education programs in Vermont? Can food be provided at such programs?	Expenses for speakers at Continuing Medical Education programs are allowable if the honorarium requirements are met. Alternatively, payment to a speaker at fair market value for time presenting the program is an allowable expense under "Other reasonable fees" provision. See II(c)(10) of the FY10 Guide. Food may not be provided unless the recipient reimburses the costs of the food at fair market value. See II(a) of the FY10 Guide.
8/26/2009	If we were to provide a tour of our facility, which is outside the state of Vermont, and very modest refreshments (soda & cookies) to prospective customers, would that activity be prohibited by Vermont law?	The company cannot provide free food to a health care provider who regularly practices in Vermont. The company may provide free meals outside Vermont to a physician who is licensed in Vermont but who does not regularly practice in Vermont; the company must report such expenditures. See II (a) of the FY10 Guide.

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8/26/2009	<p>Can a pharmaceutical company provide a modest dinner at a restaurant in NH as a 'carrot' to get VT and NH physicians to attend a CME activity at the end of the work day? During dinner, a physician would speak for one hour on a new drug that this company makes. The physician would receive a modest honorarium to cover time and travel.</p> <p>What does the company need to report to the State of Vermont?</p>	<p>If the "modest" honorarium is no more than fair market value for the speaker's time, it's allowable but must be reported if the speaker is licensed in Vermont. See II(c) of the FY10 Guide. The company cannot provide free food to a health care provider who regularly practices in Vermont. The company may provide free meals outside Vermont to a physician who is licensed in Vermont but who does not regularly practice in Vermont; the company must report such expenditures. See II(a) of the FY10 Guide.</p>
9/28/2009	<p>If a provider is participating in a speaker program, would meals be allowed either in the office/hospital setting or in an outside setting? Would meals be permissible for either the speaker or attendees?</p>	<p>Free meals to prescribers and their staff are banned in or outside the prescriber's office. A speaker may provide meals as long as the prescriber reimburses the speaker for the fair market value of the meals. Free meals to non-prescribing staff of a hospital, nursing home or pharmacist are not banned at this time. See II(a) of the FY10 Guide.</p>
9/28/2009	<p>(1) If a VT health care professional is under contract as a speaker in our pharmaceutical speaker program, are we required to report the cost of the meal provided to that speaker at a speaker program? (2) If the VT health care provider is provided a meal(s) while at a speaker training program, is that meal(s) reportable? (3) If a VT health care provider is provided a meal during the scope of fee-for-service agreement, are that meal and/or other expenses reportable?</p>	<p>(1) and (2) If your program meets the requirements of "Honoraria and payment of expenses", then you can provide the meal but must report it. If it does not meet those requirements, e.g. if the speaker will not be speaking at a bona fide significant educational conference, then the expense is allowed only if it is at fair market value and must be reported. See II(c)(10) of FY10 Guide. (3) If your fee-for-service is at fair market value, then, under "Other reasonable fees," it is allowed and must be reported; it is not allowed if it is above fair market value. See II(c)(14) of FY10 Guide.</p>
12/16/2009	<p>Is it true that manufacturers of prescriber products may not provide meals to staff in a prescriber's office, or to a pharmacy benefit manager, but may provide meals to staff at a hospital, nursing home or to pharmacy staff, although such entities are included in the definition of Health Care Provider?</p>	<p>Not exactly. Manufacturers of prescribed products are prohibited from giving meals to health care professionals, including employees of prescribers who, in the course of their employment, do work related to or supportive of the provision of health care. At this time, the gift ban does not extend to staff members of a hospital or nursing home that do not work for, or at the direction of, a prescriber. See II (a) of the FY10 Guide.</p>

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Gifts and Allowable Expenditures-Educational Activities/Not Food		
11/5/2009	Is a non-profit corporation which is a professional or educational organization serving health care providers considered a “health care professional” if it is “made up of” prescribers?	No. A corporation which is providing professional and educational opportunities for prescribers, but which is not providing health care to patients or medical research, is not considered to be included within the definition of “health care professional.”
11/5/2009	May the manufacturer pay the fees to have a commercial display at a conference and must such fees be reported? Does it matter if the conference is in Vermont?	If the payment would be to a health care provider, such as a hospital, it is presently banned under the law. If the conference is in Vermont and is organized by an academic institution or a professional, educational or patient organization, it is permitted if it meets the definition of an “allowable expenditure” and must be reported. See II(c)(7) of the FY10 Guide.
11/5/2009	May a manufacturer sponsor a CME put on by a non-profit educational organization which has Vermont prescribers on its board of directors? If yes, must the sponsorship be reported?	If the non-profit is a professional or educational organization servicing health care providers and the sponsorship meets the requirements of an “allowable expenditure,” then the manufacturer may sponsor the CME and must report the expenditure. See II(b), II(c)(9), and IV(h) of the FY10 Guide.
9/25/2009	A) May a dietician who works with a physician and consults with patients in a clinical setting accept an invitation from a pharmaceutical manufacturer to attend a conference with all travel and meal expenses paid and an honorarium for attending?	A) No. Under the facts provided, the dietician is an agent of a health care provider, and the payment of expenses and compensation for attending the conference is not permitted. See II(a) and II(b) of the FY10 Guide.
	B) May the dietician attend the conference if the honorarium is declined?	B) The dietician may attend the conference but must personally pay for travel expenses and meals See II(a) of the FY10 Guide.
9/25/2009	May a company that engages consultants at fair market value provide those consultants with modest meals as they engage in their work? Must these meals be accounted for as compensation?	Reasonable fees, payments, subsidies or other economic benefit paid at fair market value to a prescriber by a pharmaceutical manufacturer are allowable but must be reported. See II(c)(14) of the FY10 Guide.

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Gifts and Allowable Expenditures - Free Samples/Donations/Loans		
12/16/2009	May free samples be provided to a health care provider? Is disclosure of the distribution of free samples required?	Samples of a prescribed product may be provided to a health care provider for free distribution to patients. No disclosure of prescription drug samples is required at this time, but free samples of medical devices or combinations of medical devices and prescription drugs must be reported. See II(c)(1) of the FY10 Guide.
12/16/2009	Many medical devices are implantable, and companies may occasionally provide a very limited quantity of free samples to Health Care Providers for implantation into patients. The sample is intended for the benefit of the patient but is also intended to give the HCP a feel for how the product functions. Would these samples fall under the disclosure exemption?	Free samples of medical devices and combinations of medical devices and chemical compounds and/or biologics must be reported. Free samples of chemical compounds and biologics, or combinations of them, need not be reported. See II(c)(1) of the FY10 Guide.
9/28/2009	Are donations of samples of prescribed products banned if they are for humanitarian needs and to be distributed abroad?	Free samples to Vermont health care providers are not banned and need not be reported if they are of prescription drugs, but must be reported if biologics or medical devices. See II(c)(1) of the FY10 Guide.
8/26/2009	Are charitable donations to non-provider entities banned under the Vermont statute?	Gifts to academic institutions and professional, educational, or patient organizations representing or servicing health care providers or consumers are not banned, but must be reported. See II(c)(7) of the FY10 Guide. Gifts to other non-provider entities are not affected by the law.
9/28/2009	If a donation from a manufacturer of prescribed products is made to a foundation of a hospital or institution, is it considered a banned gift? An allowable expenditure?	A donation to a foundation of a hospital is a gift and is banned. See II(a) of the FY10 Guide. If the institution is an academic institution, the give is not banned but must be reported. See II(c)(7) of the FY10 Guide. There is insufficient information to answer with regards to any other institution.

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8/26/2009	A manufacturer supports a benefit golf tournament by providing the golf balls. Is this allowable and must this be reported?	If the sponsor of an event meets the definition of a health care provider, then a manufacturer may not provide free balls because it is a gift. If the sponsor is an academic institution or a professional, educational, or patient organization representing or serving health care providers or consumers, the gift is allowed and must be reported. If the sponsor is neither of the above, the gift is allowed and need not be reported. See II(a) and II(c)(7) of the FY10 Guide.
8/26/2009	Do loans of medical devices less than 90 days have to be disclosed? If so, what information must be reported?	Loans less than 90 days must be reported. Loans greater than 90 days are banned. See II(c)(4) of the FY10 Guide. Only the fact of the loan need be reported; no monetary value of the loan need be reported. See IV(c) of the FY10 Guide.
9/25/2009	If a drug/device manufacturer established and endowed a charitable foundation that provides a variety of charitable donations to <i>bona fide</i> U.S. charities, may the charitable foundation provide donations to health care providers?	If the foundation is a separate legal entity and has a separate board of directors, it does not fall within the scope of the statute. See I(a) of the FY10 Guide.
Gifts and Allowable Expenditures - Market Surveys & Consultants		
12/16/2009	May a manufacturer pay health care providers to provide feedback through market research surveys? May food be provided in conjunction with the survey? Must such payments be disclosed?	Market research paid at fair market value is an allowable expenditure under the provision for "other reasonable fees at fair market value" provision; such payments must be reported. If the research is conducted through a survey, food would not be allowed unless the health care providers reimbursed the manufacturer for the food. See II(c)(14) of the FY10 Guide.
9/28/2009	We hire a vendor to conduct blind market research studies at various conferences. This is an independent third party provider of the services. This vendor provides payment to participants. Would we, as a device manufacturer for whom the studies are being conducted, be required to report the payments made by the third party vendor?	If the physician does not learn which manufacturer is paying for the survey, then the payment to the vendor does not need to be reported.
9/28/2009	If a VT health care provider is provided a meal during the scope of fee-for-service agreement with a pharmaceutical manufacturer, are that meal and/or other expenses reportable?	If your fee-for-service is at fair market value, then, under "Other reasonable fees," it is allowed and must be reported; it is not allowed if it is above fair market value. See II(c)(14) of FY10 Guide.

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9/28/2009	May a company that engages consultants at fair market value provide those consultants with modest meals as they engage in their work? Must these meals be accounted for as compensation?	Reasonable fees, payments, subsidies or other economic benefit paid at fair market value to a prescriber by a pharmaceutical manufacturer are allowable but must be reported. This may include meals as described in the inquiry, so long as the total economic benefit to the prescriber represents fair market value for services provided. See II(c)(14) of the FY10 Guide.
Gifts and Allowable Expenditures/Other		
1/8/2010	Assuming the expenses of a training, educational, scientific or similar event attended by a Vermont health care provider (including a Vermont-licensed health care professional who regularly practices in Vermont) is an allowable expenditure and/or not-banned gift, how is the value allocated to the Vermont health care provider when the event is attended by health care providers and others who are <u>not</u> licensed in Vermont?	<p>The reporting company should divide the total expenditures provided to the attendees of the event by the total number of health care providers, and then allocate the resulting quotient to each Vermont health care provider.</p> <p>If the expense is not an allowable expenditure or is a banned gift (which includes payments for “food, entertainment, travel, subscription, advance, service or anything else of value”), it can be provided to a Vermont health care professional only if the professional does not regularly practice in Vermont.</p>
9/28/2009	How does this statute apply if an employee of a medical device company is the spouse, significant other, or friend of a healthcare practitioner?	If a meal or gift is in any way business related, the employee must follow the requirements of the statute. If it is not business related, it is not the intention of this office to restrict personal gift giving.

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Other		
1/8/2010	What should we do if we find that we have inadvertently given a banned gift to a Vermont prescriber?	First, attempt to recover the gift or the cost of the gift. Then, report the gift by sending an email to prescribedproducts@atg.state.vt.us , with "banned gift" in subject line. Your report should include the value of the gift, the recipient's primary place of business, information about your attempts to recover the gift, the results of those attempts, and any other factors you wish us to consider. Failure to disclose is a separate violation from the gift ban; each violation carries a maximum penalty of \$10,000.