

To: Vermont Health Care Providers

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

Date: September 24, 2010

Re: Reporting of Samples of Prescribed Products Distributed to Vermont Health Care Providers

I understand that some health care providers would appreciate clarification regarding how the 2010 statutory amendments regarding samples of prescribed products might affect doctors and other health care providers. I hope the following information is helpful.

First, as with the prior laws applicable to manufacturers' reporting of their marketing expenditures for prescribed products in Vermont, there is no requirement that health care providers themselves report such expenditures to the Attorney General's Office. The manufacturers are required to identify the recipient of such expenditures – but, with respect to samples, recipient information will not be publicly available.

Under the 2010 federal Patient Protection and Affordable Care Act, H.R. 3590, Public Law No. 11-148, manufacturers and distributors of prescription drugs are required to report to the Secretary of Health and Human Services their distributions of prescription drug samples, commencing April 1, 2012, for the prior calendar year. Vermont law, as amended in the 2010 session, also requires manufacturers to report the distribution of any samples of prescribed products (as defined under Vermont law) to Vermont health care providers to the Vermont Attorney General. The reports will be due annually, starting April 1, 2012, for the prior calendar year. Thus manufacturers must start making reports, under both state and federal law, for sample distributions beginning January 1, 2011.

Under Vermont law, a "sample" means a unit of a prescription drug, biological product, or medical device,<sup>1</sup> and includes starter packs, coupons or other vouchers that enable an individual to receive a prescribed product free of charge or at a discounted price. Manufacturers will report the recipient, the product name and type (pharmaceutical, biologic, medical device or combination product), the number of samples, the number of units in each sample, and the dosage of each unit if applicable. No monetary value will be assigned to samples.

The manufacturers' reporting will name the health care provider who requested or signed for each sample, but that information will not be available to the public under state or federal law. Under Vermont law, the Attorney General may contract with academic researchers for analysis and aggregated public reporting of the distribution of samples, but the names of health care providers may not be disclosed.

**There is no additional obligation arising from these statutory changes for health care providers to keep track of samples or to report receipt of samples.** (Providers must continue to comply with federal and state laws regarding recordkeeping or reporting of samples.)

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<sup>1</sup> These provisions do not apply to the loan or gift of medical devices for educational or evaluation purposes even though the common vernacular in the industry is, as I understand it, to identify those activities as the provision of "samples." Reporting of such loans and gifts is ongoing.

There is no obligation under Vermont law for a manufacturer of prescribed products to notify a health care provider regarding the reports they will make, or have made, of sample distributions. However, I recently attended a conference of industry compliance staff responsible for the collection and reporting of expenditures and sample distributions to Vermont and other states. From the comments made there, I think you can anticipate that manufacturers will adopt a wide variety of approaches to informing you when they intend to report your receipt of samples under state and federal disclosure laws. (The laws don't specify whether or how this should be done.) Some companies told me they are planning to send health care providers information about their reporting in advance; others may not notify you at all.

If you continue to have questions or concerns regarding the meaning or implementation of the law after reading this, please be in touch with me at [wmorgan@atg.state.vt.us](mailto:wmorgan@atg.state.vt.us). If you have concerns regarding the law itself, please be in touch with your state or federal legislators or with the Vermont Medical Society if you are a member.