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Is Vermont Trying to get Manufacturers to Just Stop Detailing and Sampling Altogether?

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Notice of Public Hearing on Advisability of Requiring Disclosure of Free Samples of Prescribed Products given to Vermont Health Care Providers

- Date of hearing: October 27, 2009 -- 9:30am to 11:30am
- Location: Pavilion Office Building, Third Floor, 109 State St., Montpelier VT
- Sponsored by the Vermont Attorney General and the Commission on Health Care Reform

At the end of this month, the Attorney General of Vermont will be holding a public hearing to determine if the state will modify section 4632 of Title 18 (Health Statute) to require manufacturers to disclosure information about providing free samples of prescribed product to health care providers. The Attorney General is due to report the findings to the House Committee on Health Care and the Senate Committees on Finance and on Health and Welfare no later than December 15, 2009. To give a frame of reference as to why Vermont is interested in investigating this area, Section 4632 is contained in Chapter 91, entitled, *Prescription Drug Cost Containment*. The thought process seems to be that if Vermont can collect information on samples in addition to the information the State already collects regarding the cost of marketing prescribed products, it may provide a way to keep the cost down.

The goals of the hearing are to gather information about the current system of distribution of free samples of pharmaceuticals, biologics and medical devices to Vermont prescribers, and to hear the opinion of those in the health care system as to the advisability of requiring disclosure.

The Attorney General is encouraging those who testify to address the following questions:

1. How are free samples distributed to Vermont prescribers now? By office visits or mail and upon request only, or through scheduled or unscheduled visits?
 2. What records do the manufacturers keep of the distribution of free samples? What records do the recipients keep? If any of those records are reported to a governmental agency, what is reported to which agency on what timeframe?
 3. What is the approximate volume and value of free samples being distributed in Vermont?
 4. Would disclosure of the distribution of free samples have a significant impact on the willingness of providers to accept those samples? Would it make a difference if disclosure were only to the Attorney General, and not to the public?
 5. What is your opinion on whether the distribution of free samples should be disclosed to the Attorney General's Office? What is your opinion on whether such disclosures should be released to the public?
- While the intent and goals of the hearing are understood, and the answers to the questions during the testimony may prove to be helpful, the Attorney General should spend some time investigating at least two additional areas:
1. The number of manufacturers who have chosen to eliminate Vermont prescribers from their detailing targets.
 2. The method health providers use to track drug samples once they take possession of them.

Many pharmaceutical manufacturers have chosen to eliminate Vermont territories after weighing the requirements and determining that the effort to comply was not worth the reward. The State may very well be doing its prescribers and citizens a disservice if they make it even more difficult to market prescription products to health care providers. Marketing prescription products has gotten a bad rap over the years and is often perceived as sales representatives running around dumping samples and pushing the provider to prescribe their product. In fact, both medical device and drug representatives can help a practitioner stay informed of new studies, products, and better treatments through detailing and sampling. Manufacturers may just find it harder to justify in Vermont.

The industry as a whole recognizes the regulations of the Prescription Drug Marketing Act (PDMA), and documents the distribution of drugs to practitioners. The intent of the law is to protect the public from adulterated, contaminated and diverted drugs. The only problem is that all of the storage and documentation requirements end once the drug is left with the practitioner. At the very least, storage requirements should be enforced until the public receives the samples. It is probably a whole other argument, but if the idea is to protect the public from the cost of prescription products, there should be some concern for the safety of the product as well.

The Vermont Attorney General would do well to listen carefully to the industry at these public hearing and carefully explore the pros and cons of any additional regulations. Even though there are only a handful of other states that have similar requirements, the industry is beyond frustrated by regulations passed by those that don't fully understand our business. Vermont may not have to worry about any manufacturers if they aren't careful.

With regard to the hearings:

Interested persons are encouraged to participate in the public hearing noticed above. Those wishing to testify in person or by phone must send an email to: prescribedproducts@atg.state.vt.us by October 23, 2009. A preliminary witness list with approximate times of testimony will be posted on the Attorney General's website, <http://www.atg.state.vt.us/> by October 26. Those who do not sign up in advance will be able to testify if time permits. Those who wish to submit proprietary information on a confidential basis may do so by mailing such information, marked "Confidential," to: Wendy Morgan, Office of the Attorney General, 109 State St., Montpelier VT 05609, no later than November 6, 2009.

The hearing will be taped and posted on the Attorney General's website. Questions in advance of the hearing should be directed to: prescribedproducts@atg.state.vt.us.

Source:

<http://www.atg.state.vt.us/assets/files/Free%20Samples%20Public%20Hearing.pdf>