

## Memo

To: Manufacturers of Medical Devices

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

Date: August 2, 2010

Subject: FY10 Reporting of Distribution of Samples of Medical Devices

In 2010, the Vermont Legislature amended VSA section 4632 to require reporting of samples of prescribed products given to health care providers in Vermont starting January 1, 2011. In implementing the Vermont reporting requirements for samples, the Attorney General's Office interprets these 2010 enactments as requiring no disclosure of samples distributed in 2010. This is a change in the prior law which required reporting of samples of medical devices distributed beginning January 1, 2010. Consequently, manufacturers of medical devices need not collect or report sample data for 2010, and may cease collecting and preparing information regarding the distribution of samples that they were planning to disclose by October 1, 2010.

Prior to January 1, 2011, the Attorney General's Office will send manufacturers of all prescribed products further guidance regarding the required disclosure of distributions of samples made to Vermont health care providers, on or after January 1, 2011.

In preparing for January 1, 2011, please keep in mind that the Vermont definitions of samples and recipients are broader than the federal definitions. Samples includes *starter packs, coupons or other vouchers* that enable an individual to receive a prescribed product free of charge *or at a discounted price*. See 18 V.S.A. Sec. 4631a(a)(13). Covered recipients are not limited to physicians and teaching hospitals, but include anyone who regularly practices medicine in Vermont, as well as hospitals, nursing homes, pharmacists, health benefit plan administrators and others. See 18 V.S.A. Sec. 4631a(a)(7) and (8).