

CLIENT ALERT September 2009

Vermont is the most recent state to regulate sales and marketing conduct. Vermont's law, effective June 8, 2009, defines certain "allowable expenditures" and requires reporting of these expenditures while exempting other expenditures or items from the reporting obligations. Like the Massachusetts statute that also recently took effect, this statute requires annual reporting to the government.

INTRODUCTION

The new Vermont legislation prohibits most gifts and imposes reporting obligations on pharmaceutical and medical device manufacturers for certain permitted forms of remuneration, called "allowable expenditures." The law became effective on June 8, 2009. There are many similarities between the Massachusetts statute and the new Vermont law. Like the Massachusetts statute, the Vermont law prohibits pharmaceutical and medical device manufacturers from making most gifts to physicians and other health care professionals authorized to prescribe or recommend prescribed products. The term "health care providers" is broadly defined to include health care professionals, hospitals, nursing homes, pharmacists, benefit plan administrators, and other persons in a position to dispense or purchase for dispensation prescribed products in Vermont. The new law requires reporting on certain permitted forms of remuneration by October 1, 2010. Failure to comply can result in civil penalties, up to \$10,000 per violation. Each instance a manufacturer fails to disclose a gift constitutes a violation of the law.

GIFT PROHIBITION

Vermont's law prohibits most gifts. It defines a gift as anything of value provided for free. This includes food, travel, entertainment, services, subscriptions, advances, or anything else of value that is provided. The new legislation allows certain expenditures, exempts certain items, and allows gifts that are reimbursed at fair market value by the health care professional. Allowed expenditures and exempt items are listed below.

Exempt Items

- Equipment lent for limited periods of evaluation
- Reasonable quantities of medical device demonstration or evaluation units

- Peer-reviewed educational information (e.g., journal reprints) or other items of genuine educational value for the benefit of patients
- Rebates and discounts provided in the normal course of business
- Samples for use by patients without charge
- Scholarship or other support for medical students, residents, and fellows for conferences and seminars

These exemptions are similar to the ones found in the new Massachusetts law.

REPORTING ON ALLOWED EXPENDITURES (items above are exempt from reporting)

Vermont's new statute requires reporting of most allowable expenditures. Allowable expenditures include the following:

- Educational conference support
- Honoraria and expenses for faculty at conference (contract required)
- Bona fide clinical trials
- Research projects
- Technical training on medical devices (contract required)
- Royalties or license fees paid to health care providers in return for rights to a patented or otherwise legally recognizable discovery
- Other reasonable fee, payments, subsidies, or other economic benefits provided by a manufacturer

The first reports are due by October 1, 2010 for the preceding fiscal year ending June 30, 2010. Information reported will be publicly available on a web site beginning in 2011. Each July 1, manufacturers are required to disclose to the Vermont Office of the Attorney General the name and address of the person responsible for the manufacturer's compliance reporting requirements.

Certain information relating to clinical trials may be delayed under conditions defined by the law. Similar reports are required for reportable allowed expenditures provided to academic institutions and professional, educational or patient organizations representing or serving health care providers or consumers.

Penalties for Noncompliance

Civil penalties, up to \$10,000 per violation may be imposed along with attorney's fees and other costs. Each "unlawful failure to disclose" shall constitute a separate violation. Injunctive relief is also available.

WHAT TO DO WITH THESE REPORTING REQUIREMENTS AND MY COMPLIANCE PROGRAM?

All of these statutes, the recent prosecutions of Synthes executives, this month's gargantuan Pfizer fraud settlement of \$2.3 billion, as well as the recent articles about Senator Grassley's pursuit of Dr. Polly, a spinal surgeon from the University of

Minnesota, who has consulted with Medtronic suggest the government scrutiny of relationships between industry and the medical community are not subsiding. It is imperative that companies understand the myriad of state reporting obligations that do exist and comply with them. Thought also needs to be put into what a company's compliance program should look like. Do you have a code on interactions with health care professionals and standard operating procedures to accompany it on topics like off-label dissemination, grants for CME and investigator-initiated trials, hiring consultants and the like? Have you taken some time to simply reflect as a management team on what you do and don't have in place and are you potentially engaged in conduct that might draw prosecutorial attention or even the attention of a whistleblower (in-house or a competitor)?

HOW CAN WE HELP?

Our firm has put together compliance programs covering the company's code of conduct, AdvaMed Code (if the company is a signatory to it), Anti-kickback Statute, False Claims Act, advertising and promotion under the Food, Drug and Cosmetic Act, and HIPAA (for sales reps) for over 60 companies and trained management and field sales forces for years in fun and interesting ways to help them understand, not just what they can't do, but what they can do in the field in their relationships with physicians.

We've also conducted attorney-client privileged and work product "reviews" (an abbreviated, far less expensive audit) that gives management a snapshot at how an outside prosecutor might look at their firm's sales and marketing activities.

We also have developed a package of materials to help you make the reports required to be sent to the State of Massachusetts.

Finally, we help counsel firms day to day on practical issues like how to properly discount, bundle products or consign their product or offer reimbursement guarantees or conduct referral seminars or pay physicians for properly constructed retrospective chart reviews, or how to engage a consulting physician lawfully, among many other programs, without violating the Anti-kickback Statute. We also counsel on how to provide reimbursement advice without violating the False Claims Act. And we review promotional programs and ad copy for compliance with FDA's advertising and promotion regulations. We can help you strategize how to conduct lawful pre-approval communications or post-marketing programs.

In sum, we have comprehensive long-standing experience into how products are marketed and the laws that affect what you want to do to make your product a success. We want to help you get there and to be appropriately aggressive, but still compliant.