



**GLOBAL LIFE SCIENCES: US-HEALTHCARE UPDATE**

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**Vermont Bans Most Gifts to Healthcare Providers; Law’s Reach Now Extends to Medical Device Manufacturers**

In another state law development with important implications for medical device and pharmaceutical manufacturers, Vermont recently enacted new restrictions on gift-giving activities by manufacturers of drugs, devices, and biologics and amended requirements relating to the disclosure of permissible payments (VT Statute). Beginning July 1, 2009, the VT Statute bans most gifts to physicians and other health care providers and requires manufacturers to disclose to the state Attorney General the value, nature, and purpose of any “allowable expenditures” and permitted “gifts.” Significantly, the ban prohibits payments for most occasional meals and educational gifts that would otherwise be permitted under the revised Code of Ethics on Interactions with Healthcare Professionals adopted by the Advanced Medical Technology Association (AdvaMed Code) and the Code on Interactions with Healthcare Professionals adopted by the Pharmaceutical Research and Manufacturers of America (PhRMA Code).

Vermont is now the second state to enact payment disclosure requirements applicable to medical device manufacturers. The VT Statute follows closely on the heels of the new Massachusetts disclosure law, which was the first marketing cost disclosure law to reach beyond pharmaceutical companies and apply to medical device manufacturers. In light of the rapidly approaching compliance deadline, manufacturers of medical devices, pharmaceuticals, and biologics should carefully consider the impact of the new legislation and not delay in their implementation efforts. In particular, medical device manufacturers, which were not previously subject to the existing Vermont payment disclosure requirements, will need to promptly re-examine and supplement their strategies for state law compliance.

**New Ban on Manufacturer Gifts to Vermont Health Care Providers**

The VT Statute introduces a new restriction on “gifts” provided to Vermont health care practitioners by manufacturers subject to the law. Beginning July 1, 2009, medical device, pharmaceutical, and biological manufacturers will be prohibited from offering “anything of value”—including payment, food, entertainment, travel, subscriptions,

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advances or services—to health care providers within the state. The term “health care provider” is defined expansively.

There are some notable exceptions to the Vermont ban on gifts, including items that do not qualify as “gifts” because they are defined under the VT Statute as “allowable expenditures.” However, “allowable expenditures” are limited to only certain categories, including:

- payments to sponsors of significant educational, medical, scientific, or policy conferences or seminars;
- honoraria and expense reimbursement for faculty at such conferences or seminars;
- certain salary and expense support for “bona fide clinical trials” and certain other research activities;
- certain medical device technical training expenses; and
- certain royalty and licensing fees.

In addition to the allowable expenditures described above, the gift ban does not apply to certain categories of items which the VT Statute designates as “permitted” gifts. These items include, for example: samples; the short-term loan of a medical device or the provision of reasonable quantities of medical device demonstration or evaluation units; certain peer-reviewed articles or journals; medical student scholarships for attendance at certain conferences; rebates and discounts; and FDA-approved labels.

Given the broad definition of the term “gift” and the limited exceptions to that term (*i.e.*, “allowable expenditures” and “permitted” gifts), medical device, pharmaceutical, and biological manufacturers that direct marketing and promotional activities towards Vermont health care providers will need to review their existing policies, procedures, and compliance training materials governing gifts to health care providers in Vermont and determine whether such materials will need to be updated in advance of the July 1, 2009 effective date. In particular, given that the gift ban created by the new legislation is more stringent than the AdvaMed and PhRMA Codes as

well as other state laws, manufacturers should closely examine whether their practices on meals and educational gifts to Vermont health care providers are consistent with the VT Statute.

### **Disclosure Requirements**

The VT Statute revises the requirements of the existing Vermont marketing cost disclosure statute by expanding its reach to medical device and biological manufacturers, eliminating the \$25 exception, and revising the annual disclosure deadlines. Under the VT Statute, medical device, pharmaceutical, and biological manufacturers will be required to annually disclose to the Vermont Attorney General the value, nature, purpose and recipient information of any “allowable expenditures” and “permitted” gift to any health care provider, academic institution, or to a professional, educational, or patient organization representing or serving health care providers or consumers for the prior year ending June 30th. Certain payments are exempted from the disclosure requirement, including royalties and licensing fees; rebates and discounts; samples; and payments for clinical trials (subject to certain conditions). The deadlines for disclosure are set forth in the VT Statute.

### **Penalties for Non-Compliance**

Manufacturers who violate the Amended VT Statute’s requirements may be subject to a civil penalty of up to \$10,000 per unlawful gift or non-disclosure. In addition, the Vermont AG can bring an action for injunctive relief, costs, and attorney’s fees.

### **Conclusion**

Because the VT Statute imposes more stringent standards than the gift limitations and disclosure requirements in other states and as well as the standards contained in industry codes such as AdvaMed and PhRMA Codes, it may pose unique compliance challenges for manufacturers. It is also unclear how the Vermont law might be impacted by the Physician Payments Sunshine Act proposals, one of which was introduced in

Congress by Sens. Grassley (R-IA) and Kohl (D-WI) earlier this year, and another of which was a component of the House of Representatives tri-committee<sup>1</sup> draft bill that was released on June 19, 2009. If one of the proposals is enacted, it would establish a separate disclosure requirement that would be similar to, but likely more flexible than, the Vermont provision. Given the variations between the two proposals, it is unclear to what extent, if at all, any federal disclosure legislation would preempt similar state statutes. This leaves open the possibility that manufacturers could face multiple disclosure requirements even if federal legislation is enacted.

<sup>1</sup> The three committees are the Ways and Means, Energy and Commerce, and Education and Labor Committees.

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