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Vermont Bans Gifts and Expands Disclosure Requirements for Payments to Health Care Providers

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On June 8, 2009, Vermont Governor Jim Douglas signed into law Act No. 59 (the "**Act**"),[1] which amends Vermont's existing pharmaceutical marketing disclosure law ("**FY09 Law**").[2] The Act, effective July 1, 2009, includes a ban on certain gifts to health care providers and expands reporting requirements to medical device and biological product manufacturers.[3]

Pharmaceutical manufacturers will file annual disclosures by November 1, 2009, for the reporting period July 1, 2008, to June 30, 2009, as required by the FY09 Law. Pharmaceutical manufacturers, as well as biological product and medical device manufacturers, will file their first reports in accordance with the Act by October 1, 2010, for the period January 1, 2010, to June 30, 2010.

This Alert provides an overview of the Act and discusses some of the key challenges for manufacturers of pharmaceuticals, medical devices and biological products as they consider compliance with the Act.

OVERVIEW OF THE ACT

Scope

The Act broadens the scope of the FY09 Law to include manufacturers of medical

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[1] The full text of the bill is available at: http://www.leg.state.vt.us/docs/2010/bills/Passed/S-048.pdf.

[2] 18 V.S.A. § 4632 (as of June 30, 2009).

[3] The Act also is applicable to companies "engaged in the production, preparation, repacking, distributing or labeling" of pharmaceuticals, biological products and medical devices. Pharmacists and wholesale distributors of pharmaceuticals and biological products are excluded. *See* Guide to Vermont's Prescribed Products Law for FY10 Disclosures (August 25, 2009) *at*: http://www.atg.state.vt.us/issues/pharmaceutical-manufacturer-payment-disclosure.php ("**Guide FY10**").

devices and biological products. In expanding the scope of the law, the Vermont legislature specifically noted fraud and abuse enforcement actions by the federal government against device manufacturers and concluded that there is "little or no difference in the marketing of biological products and prescription drugs." [4]

Ban on "Gifts"

As of July 1, 2009, manufacturers are prohibited from providing "anything of value to a health care provider for free," unless otherwise permitted by the Act. "Health care provider" is defined broadly to include a health care professional,[5] hospital, nursing home, pharmacist, health benefit plan administrator, or "any other person authorized to dispense or purchase for distribution prescribed products" in Vermont. The Vermont Attorney General released guidance that, among other things, provides that the ban applies to health care providers that "regularly practice in Vermont," regardless of whether the item of value is provided within or outside the state.[6]

Banned "gifts" include "any payment, food, entertainment, travel, subscription, advance or service." However, the Act enumerates several permissible gifts and "allowable expenditures." The Act further divides the permissible gifts and allowable expenditures into items that do not need to be reported and items that do need to be reported beginning with the 2010 reporting period.

Permitted Gifts; No Reporting

- Free samples of prescription drugs intended for distribution to patients. This also includes vouchers and discount coupons for samples;[7]
- Labels and package inserts approved by the federal Food and Drug Administration ("**FDA**");
- Rebates and discounts provided "in the normal course of business."

Permitted Gifts; Reporting Required

- Short-term loans of medical devices for evaluation purposes;
- Reasonable amounts of medical device evaluation or demonstration units;
- Peer-reviewed academic, scientific, or clinical articles for professional or patient education purposes.

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[4] S. 48 § 2(b)(9-10).

[5] "Health care professional" also is defined broadly to include a person authorized to prescribe or recommend a prescribed product; partnership or corporation of persons authorized to prescribe or recommend; and an officer, employee, agent or contractor of a person authorized to prescribe or recommend.

[6] *See* Answers to Submitted Questions – FY10 (last updated September 28, 2009) *at*: http://www.atg.state.vt.us/issues/pharmaceutical-manufacturer-payment-disclosure.php.

[7] *See* Guide FY10 *at*: http://www.atg.state.vt.us/issues/pharmaceutical-manufacturer-payment-disclosure.php.

- Educational items that serve a genuine educational function and are for the benefit of patients;
- Scholarships and other support for medical students, residents, and fellows to attend significant educational, scientific, or policy-making meetings if the recipient is selected by the association;
- Gifts to academic institutions or professional, educational or patient organizations.

Allowable Expenditures; No Reporting

- Royalties and licensing fees paid to health care professionals with ownership rights.

Allowable Expenditures; Reporting Required

- Payments to sponsors of a "significant educational, medical, scientific, or policy-making conference or seminar," provided that no payment is made directly to a health care provider, the funds are used for *bona fide* educational purposes, and the content is not controlled by a manufacturer;
- Honoraria and expenses for faculty at a significant educational, medical, scientific, or policy-making conference, provided that there is an explicit agreement with the health care professional and the content of any presentation is determined by the health care professional;
- Direct salary and expenses for the conduct and review of "*bona fide* clinical trials" and research projects;
- Reasonable expenses for the technical training of health care professionals on the use of medical devices if the expenses are reasonable and set out in a written agreement;
- Other fees, payments, subsidies, or economic benefits provided by a manufacturer at fair market value.

Reporting Obligations

Beginning in 2010, all manufacturers must identify by name and address the individual responsible for the manufacturer's compliance with the Act by July 1st each year. Manufacturers also must file annual reports detailing allowable expenditures and permissible gifts provided to health care professionals and providers and pay an annual filing fee of $500. For each payment reported by the manufacturer, the manufacturer must provide the value, nature, purpose, recipient information including state license number, and the prescribed product(s) being marketed.

The Vermont Attorney General is authorized by the Act to seek injunctive relief and to impose a civil penalty of not more than $10,000 per violation for failing to comply with the Act. Each failure to disclose is a separate violation.

Public Disclosure

The Act requires the Vermont Attorney General to make all disclosed data publicly available on a searchable Web site. Although the FY09 Law allowed manufacturers to designate certain disclosed information as a "trade secret" under the state public records act, the Act amends the state public records law to expressly exclude disclosures required by the Act. Therefore, all information reported under the Act will be made public.

The Act allows manufacturers to delay reporting payments for *bona fide* clinical trials. Specifically, manufacturers must report expenditures for *bona fide* clinical trials after the earlier of: (1) the date of the approval or clearance of the prescribed product by the FDA; or (2) two calendar years after the date the payment was made. However, manufacturers must identify minimum information to the Attorney General regarding the clinical trial, including the name, start date and Web link to the clinical trial registration on the national clinical trials registry. A contract for a clinical trial entered into on or after July 1, 2009, may not contain a confidentiality clause that violates the Act.[8]

KEY COMPLIANCE CHALLENGES

The Act provides a number of key compliance challenges for pharmaceutical, biological product and medical device manufacturers. ***Manufacturers should consider carefully the compliance challenges associated with the gift ban and reporting obligations during the transition year, as well as future reporting periods***.

- ***All manufacturers must develop and/or update systems, policies, processes, procedures and training to reflect the changes made by the Act.*** This may be more challenging for biological product and medical device manufacturers that were not previously subject to marketing restrictions and disclosure requirements in Vermont. Manufacturers will need robust systems to capture all payments to Vermont health care providers, including payments provided outside the state.

- ***Manufacturers must educate sales, marketing and medical staff on appropriate interactions with Vermont-licensed health care providers.*** The training should be provided to all employees that interact with Vermont health care providers. Notably, the Act prohibits representatives from providing free meals to health care providers, regardless of the value, a restriction that is more stringent than industry codes of conduct.[9] Similarly, manufacturers may not provide gifts and other things of value, including items with a *de minimis* value.

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[8] *See* Guide FY10 *at*: http://www.atg.state.vt.us/issues/pharmaceutical-manufacturer-payment-disclosure.php.

[9] Industry codes of conduct generally permit manufacturers to offer modest meals or refreshments in conjunction with a scientific, educational, or business meeting. *See* Code on Interactions with Healthcare Professionals developed by the Pharmaceutical Research and Manufacturers of America, http://www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf; and the Code of Ethics on Interactions with Health Care Professionals developed by the Advanced Medical Technology Association, http://advamed.org/MemberPortal/About/NewsRoom/NewsReleases/advamed-code-revision approved.htm.

- ***Manufacturers must consider the impact of the limited delayed disclosure provisions for payments in connection with a* bona fide *clinical trial.*** Manufacturers should also note that this limited protection does not apply to payments made in connection with significant clinical trials or research projects that do not qualify as "*bona fide.*"

- The Vermont Attorney General stated that submissions that are returned to the manufacturer for correction that are not resubmitted without errors by October 1st do not satisfy the statutory deadline.[10] ***Manufacturers should consider submitting reports in advance of the October 1st deadline to allow for the data to be reviewed and corrected, if necessary.***

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[10] *See* Guide FY10 *at*: http://www.atg.state.vt.us/issues/pharmaceutical-manufacturer-payment-disclosure.php.