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VERMONT PASSES PHYSICIAN GIFT BAN AND DISCLOSURE LAW

In the latest example of the proliferation of laws aimed at sales and marketing practices in the pharmaceutical and medical device industries, the Vermont state legislature passed legislation (the Act) on May 11, 2009 that imposes a comprehensive gift ban and disclosure law prohibiting manufacturers of pharmaceutical drugs, medical devices, and biological products from offering or giving anything of value (there is no minimum dollar amount) to a healthcare professional, hospital, nursing home, pharmacist, health plan administrator, or any other person authorized to dispense or purchase prescribed products for distribution in Vermont. The law also eliminates provisions in existing law which allowed manufacturers to protect certain information under a trade secret exemption to the disclosure requirements. Civil monetary penalties may be imposed for any violation of the law.

The new gift ban in Vermont seeks to address what the legislature views as the influence of pharmaceutical companies, manufacturers of medical devices, and biological products (collectively, manufacturers) on healthcare professionals through the manufacturers' marketing practices. The legislative findings, which in part are taken from Vermont Act 80 (enacted in June 2007), assert that doctors who attend talks sponsored by pharmaceutical companies or accept gifts such as food are more likely to prescribe the manufacturers' products. Furthermore, the legislature contends that drug detailing affects prescribing patterns. Overall, the legislature finds that these marketing practices increase the costs of healthcare in Vermont.

In an attempt to reduce this perceived influence, the Vermont bill prohibits manufacturers from giving certain items of value to healthcare professionals or providers. The law distinguishes between "allowable expenditures," and those expenditures which are prohibited. The law attempts to increase transparency by requiring disclosure of all allowable expenditures and gifts, except in certain cases, such as in the case of samples. However, the law also requires the attorney general's office to conduct a study, in consultation with the commission on healthcare reform, on the advisability of modifying the law to include samples in the disclosure requirements.

Following is a summary of the key provisions of the law.

I. GIFTS

Under the Vermont law, it is unlawful for any manufacturer of pharmaceuticals, medical devices, or biological agents to offer or give any gift to a healthcare provider. "Gifts" are defined as being "anything of value provided to a healthcare provider

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for free; or . . . [a]ny payment, food, entertainment, travel, subscription, advance, service, or anything else of value provided to a healthcare provider, unless…" the good or service is an "allowable expense" (see discussion following), or the healthcare provider reimburses the costs of the item or service at fair market value. There is no minimum value exemption to the prohibition.

II. ALLOWABLE EXPENSES

"Allowable expenses" include payments by a manufacturer to the sponsor of a "significant educational, medical, scientific, or policy making conference or seminar"[1] provided that the payment is not made directly to the healthcare provider, that the funding is used for bona fide purposes, and that the program content is objective, free from industry control, and non-promotional. How the determination will be made that a program's content meets these criteria is yet to be seen, and could raise constitutional questions, particularly under the First Amendment. Similarly, honoraria and payment of faculty in Vermont may occur under the law provided there is a specific contract with the healthcare professional that establishes specific services which are restricted to medical issues and not marketing activities. Payment of gross compensation, direct salary, and investigator expenses are permitted for bona fide clinical trials and research projects.[2] Payment of necessary expenses related to the technical training of individual healthcare professionals on the use of medical devices is permitted if the expenses to be paid are described in a written agreement. Royalties and licensing fees are also permitted, as well as their reasonable fees provided at fair market value.

In addition to these allowable expenses, the law's prohibition on giving anything of value does not apply to the following:

- Samples;
- The loan of medical devices for limited periods;
- The provision of medical device demonstration or evaluation units used to assess the product's appropriate use and function;
- The provision of reprints that "serve a genuine educational function…";
- Scholarship or other support for medical students, residents, and fellows to attend significant educational, scientific, or policy-making seminars;
- Rebates and discounts; or
- Labels approved by the US Food and Drug Administration (FDA)

III. DISCLOSURE

Manufacturers of prescribed products must disclose on an annual basis the "value, nature, purpose, and recipient information of any allowable expenditure or gift…to any healthcare provider[3]…, academic institution or to a professional, educational, or patient organization representing or serving healthcare providers or consumers, except":

- Royalties and licensing fees;
- Rebates and discounts for prescribed products provided in the normal course of business;
- Payment for clinical trials…which shall be disclosed after the earlier of the date of the approval or clearance of the prescribed product by the FDA or two calendar years after the payment was made, or for clinical trials which are delayed…the manufacturer shall identify to the attorney general the clinical trial, the start date, and the web link to the clinical trial registration on the national clinical trials registry; and
- Samples[4]

1 "'Significant educational, scientific, or policy-making conference or seminar' means an educational, scientific, or policy-making seminar that . . . is accredited by the Accreditation Council for Continuing Medical Education or any comparable organization; and offers continuing medical education credit, features multiple presenters on scientific research, or is authorized by the sponsoring association to recommend or make policy." § 4631a(11).

2 "'Bona fide clinical trial' means an FDA-reviewed clinical trial that constitutes 'research' as that term is defined in 45 C.F.R. §46.102 and reasonably can be considered to be of interest to scientists or healthcare professionals working in the particular field of inquiry." § 4631a(a)(2).

3 "Healthcare provider" is defined broadly to mean "a healthcare professional, a hospital, nursing home, pharmacist, health plan benefit administrator, or any other person authorized to dispense or purchase for distribution prescribed products in this state." 18 V.S.A. § 4631a(7).

4 However, as noted, although samples are currently exempt from the disclosure requirements, the law requires the attorney general's office to conduct a study, in consultation with the commission on

The attorney general is required to issue an annual report regarding disclosure. Once the report is released, all disclosed data will be made publically available and searchable through an Internet website. In addition, the office of Vermont Health Access is required to study the disclosure data in order to determine any manufacturer influence on the prescribing patterns of healthcare providers reimbursed by Medicaid and state health programs.

Manufacturers who disclose allowable expenses are assessed a US$500 fee annually.

The law protects trade secrets from public inspection, but exempts the disclosures required by the Act from that protection.

IV. PENALTIES

Any violation of the prohibition against offering or giving anything of value may result in civil penalties up to US$10,000 per violation. Further, the Vermont attorney general may bring an action for injunctive relief, costs, and attorney's fees. Each unlawful gift is considered a separate violation.

Failure to disclose allowable expenses may result in civil penalties up to US$10,000 per violation. Each unlawful failure to disclose is considered a separate violation.

V. COMPLIANCE AND EFFECTIVE DATES

The Act requires that manufactures of prescribed products must file disclosures by October 1, 2009 for the fiscal year ending the previous June 30, 2009.

The Act takes effect on July 1, 2009, except that pharmaceutical manufacturers must file by November 1, 2009 all disclosures "based on the law in effect on June 30, 2009 required by…[the Act]…for the time period July 1, 2008 to June 30, 2009; and…manufacturers of biological products and medical devices shall file by October 1, 2010 disclosures required by…[the Act]…for the time period January 1, 2010 to June 30, 2010."

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VI. OTHER PROVISIONS

In addition to the gift ban and new disclosure obligations, other provisions of the Vermont law bear watching. First, the law establishes a new "therapeutic equivalent drug work group," which will "explore increasing the usage of generic drugs by allowing pharmacists to substitute a therapeutically equivalent generic drug from a specified list when a physician prescribes a more expensive brand-name drug in the same class." The work group is tasked with creating a sample list of generic drugs and a process for substitution of those drugs that will be considered at a future date by the Vermont legislature. Vermont already has a generic substitution law in place that allows pharmacists to substitute generic drugs that are bioequivalent to a brand drug. The work group will consist of two physicians appointed by the Vermont Medical Society, two pharmacists appointed by the Vermont pharmacy association, and three representatives of the drug utilization review board (which may or may not be state representatives). The work group is required to consult with patient groups and medical specialists in developing its recommendations, and to submit its list of therapeutically equivalent generic drugs to the board of medical practice and the board of pharmacy review for comments. The statute does not include any representation from the pharmaceutical industry in the work group. The work group's report to the legislature is due by January 15, 2010.

Second, the law establishes a "healthcare costs in corrections work group," which is tasked with reviewing recommendations of the Heinz Family Philanthropies report regarding utilization of the 340B Drug Pricing Program. The 340B program refers to a federal statute under which certain specified entities (such as Disproportionate Share Hospitals, Family Planning Clinics, and the like) are entitled to discounted prices on outpatient prescription drugs. The Vermont healthcare cost in corrections work group are required to "establish a mechanism for providing health services and prescriptions through a network of [340B eligible entities]." The work group, which consists of a number of provider-side organizations and the Vermont Association of Hospitals and Health Systems, is required to submit its

report to the commission on healthcare reform and the relevant legislative oversight committee by July 31, 2009.

VII. CONCLUSION

With the expected signature of the legislation by Vermont's governor, and with the enactment of sweeping legislation in Massachusetts, the number of states prohibiting gifts and entertainment, and requiring transparency of financial relationships continues to grow. This trend may continue in other states and could affect the scope of the Federal Sunshine Act, if such legislation is enacted later this year. Manufacturers will continue to be challenged to make changes in policies and procedures and training programs to make sure their employees understand the new restrictions imposed by these states. Response times for compliance will be very short to implement the required changes in business process. Federal legislation is likely to increase the complexity, not simplify reporting when preemption of state law is likely only to be partial.

The trend to transparency will also mean that manufacturers will continue to be challenged to aggregate their data from different functional areas to meet differing reporting requirement. Technology solutions will need to be found and business process automation will increasingly be utilized. The disclosure of data to the public will bring the next challenge: understanding the implications of the data and responding to third parties who will conduct their own analysis to support their own agendas. Responding to that data analysis may be the most significant challenge yet in this increasingly complex regulatory environment. Stay tuned for the next development in what has become a major regulatory trend.

If you would like more information about any of the matters discussed in this advisory, please contact your Arnold & Porter attorney or:

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