New Gift and Entertainment Disclosure Rules to Affect Pharmaceutical and Healthcare Companies

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June 18, 2009

As you may be aware, on June 8, 2009, Vermont Governor Jim Douglas signed into law legislation regulating more strictly how manufacturers of prescription drugs, biologics, and medical devices interact with certain individuals and institutions providing medical services (such as, among others, doctors, pharmacists, health plan administrators, and hospitals). Generally, the law prohibits gifts by these manufacturers to these doctors and service providers, subject to certain exceptions. For those gifts that are allowed, the law requires detailed reporting to the state attorney general and subsequent public disclosure by that office via website. The law, which extends the scope and severity of Vermont's existing Pharmaceutical Marketing Disclosure Law, will take effect on July 1, 2009.

The new law also requires pharmaceutical manufacturers to designate "the individual responsible for the manufacturer's compliance with" this new law by July 1, 2009 via the "Compliance Officer Form." Biologics and medical device manufacturers should complete this form by no later than July 1, 2010. We have enclosed a copy of that form for your reference. In addition, the Vermont Attorney General has announced that his office will hold briefing sessions for affected companies and others on June 18 and June 23. Callers can request the information needed to join one of the briefings by emailing prescribedproducts@atg.state.vt.us. According to information provided on the June 17 version of the Attorney General briefing sessions, guidance to the new law will be revised subsequent to the series of three briefing calls, dated and posted on the Vermont Attorney General's website, www.atg.state.vt.us. In addition, requests for guidance and suggestions for clarification of the law should be sent to the above email address and will be incorporated into the guidance, where appropriate.

More specifically, the June 17 briefing session identified certain important changes to the law, including among others:

- Pharmaceutical manufacturers with expenditures above $0 for the previous fiscal year must send a $500 registration fee by July 1, 2009. Manufacturers of biological products and medical devices with expenditures to report must pay this fee annually starting July, 1, 2010;
- The new law covers only prescribed products. Non prescribed products, such as an MRI machine are not covered;
- The gift ban covers any thing of value given to a health care provider for free;

- The gift ban includes charitable donations or the provision of free clinics;
- Exceptions and allowable expenditures have been severely limited and will involve detailed disclosure; and
- The exception for disclosure of "Trade Secrets" has been eliminated.

More generally, passage of the Vermont law may reflect a growing trend to regulate interactions between manufacturers and doctors. Massachusetts passed a bill in 2008 with comparable goals, and Minnesota has had physician gift rules on its books since 2005. Additionally, several other states have pharmaceutical marketing disclosure laws and even more are currently considering similar legislation, as is the United States Congress. United States Senators Charles Grassley (R-IA) and Herb Kohl (D-WI) introduced the federal Physician Payments Sunshine Act earlier this year. That bill seeks to create transparency in the relationship between physicians and manufacturers of drugs, devices, and biologics for which payment is made under Medicare, Medicaid, and SCHIP. Although the bill has not progressed since being introduced, we expect that it will re-emerge as the Senate considers health care legislation this summer. The bill recently gained the support of the Institute of Medicine, which released a report calling for the end of all gifts (including drug samples) to doctors and medical institutions.

This new trend may yield a patchwork regulatory system that could impact even companies seasoned in compliance regimes, or those who have already voluntarily altered their sales and marketing programs to limit gift-giving. Key definitions and reporting requirements may differ from jurisdiction to jurisdiction, requiring a detailed assessment of how these requirements relate to and impact business practices. For instance, the new Vermont law permits, as "allowable expenditures," among other things, payment to the sponsor of a significant educational, medical, scientific or policy-making conference or seminar, honoraria or other payments to a health care professional serving as seminar or conference faculty in identified instances, certain payments for bona fide clinical trials and research projects that constitute a systematic investigation, identified expenses relating to technical training, and royalties and licensing fees paid to health care providers to use their patented or otherwise protected intellectual property. The law also permits the provision of certain royalties and licensing fees, rebates and discounts for prescribed products provided in the normal course of business, payments relating to certain clinical trials (which are subject to separately-applicable disclosure schedule), and certain prescription drug samples. Many of these items are defined specifically in the Vermont law. For its part, for example, the Massachusetts law restricts sponsorship or payment for continuing medical education that does not meet the Accreditation Council for Continuing Medical Education Standards For Commercial Support and restricts "any grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items to a healthcare practitioner in exchange for prescribing prescription drugs or using medical devices or for a commitment to continue prescribing prescription drugs or using medical devices."

Further, state and federal attempts to institute these new laws present opportunities for companies to influence what those rules will look like in the end. Companies involved in the manufacture or sales of drugs, devices, and biologics will face a range of challenges in complying with these new and any similar future laws, and should take every opportunity to help shape requirements in the states (including to the extent advisable during the Vermont Attorney General briefing processes identified above) or at the national level.

These new efforts to regulate manufacturers' business practices are similar in nature to the pre-

existing array of federal and state rules regulating gifts and the provision of other things of value to governmental officials and employees, as well as candidates for public office. It will remain to be seen whether payments by pharmaceutical, biologic, and medical device companies will be more subject to uniform regulation than the widely-varied political ethics laws, where the federal government, the states, and many cities and counties each impose their own requirements.

We would be glad to answer any questions you may have regarding the Vermont law or these trends more generally. Kelley Drye also can assist you to develop strategies either to comply with these new laws governing pharmaceutical, biologics, and medical device companies or to advocate for the enactment and implementation of a more coherent regime.

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Vermont Compliance Officer Form
http://www.atg.state.vt.us/assets/files/FY10%20Compliance%20Officer%20Form.pdf