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CLIENT ALERT

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Health Care Reform Legislation Imposes New Marketing Disclosure Requirements on Drug and Device Manufacturers

The recently enacted Patient Protection and Affordable Care Act (the "Act") requires prescription drug and medical device manufacturers to disclose publicly gifts and other payments made to doctors and teaching hospitals. These new requirements, which expand upon similar existing requirements in several states, are sure to draw the attention and resources of drug and device companies and influence the manner in which they do business.

In recent years a handful of states have enacted laws requiring that drug (and in some states, device) manufacturers aggregate and disclose the amount they spend in those states on the advertising and marketing of drugs and devices, as well as on payments to doctors in the form of gifts, grants, honoraria, food, consulting fees, travel and so forth. Aggregating and reporting the amount a firm spends in this patchwork of states has become increasingly difficult for firms as the number and complexity of both business operations and (sometimes conflicting) legal requirements have increased.

The new federal law applies nationwide. It provides that drug and device manufacturers must report in "electronic form" any "payment or other transfer of value" to a doctor. The Act defines "payment or other transfer of value" broadly, to include "a transfer of *anything of value*." Even so, the law specifically exempts from disclosure certain payments, including:

- Payments made to a doctor indirectly through a third party, where the manufacturer is unaware of the identity of the doctor;
- Payments less than $10, unless the aggregate amount paid to a doctor during the calendar year exceeds $100;
- Product samples;
- Educational materials that directly benefit patients;
- The loan of a device for a short-term trial period;
- Discounts or rebates; and
- In-kind contributions used for charity care.

The precise manner in which manufacturers will be required to disclose doctor payments will be established in regulations issued by the U.S. Department of Health and Human Services ("HHS"). At a minimum, the Act requires that

disclosures must include, for each payment, the following information:

- The name of the doctor receiving the payment;
- The doctor's address, practice specialty and National Provider Identifier number;
- The amount and date of the payment;
- The form of the payment (e.g., cash or cash equivalent, in-kind items or services, stock, etc.);
- The nature of the payment (e.g., consulting fees, compensation for nonconsulting services, honoraria, gifts, entertainment, food, travel, education, research, charitable contributions, royalty or license fees, speaker program fees, grants, etc.); and
- If the payment is related to a drug or device, the name of the drug or device.

Under the Act, all industry payments to doctors — gifts, grants, honoraria, food, consulting fees, etc. — will be made public. The Act requires that the information that is disclosed (including doctor names, addresses and the amount of industry payments they have received) be "made available through an Internet website" maintained by HHS that is searchable and "contains information that is able to be easily aggregated and downloaded."

Manufacturers must collect information about doctor payments beginning on January 1, 2012, and submit their first disclosure reports by March 31, 2013, disclosing doctor payments made during "the preceding calendar year." HHS then must post the first round of disclosure reports on the Internet by September 30, 2013. Every year thereafter, manufacturers must submit disclosure reports on or about March 31st, and HHS must post them on the Internet by June 30th.

There are stiff penalties for noncompliance. Manufacturers who fail to make the required disclosures are subject to significant penalties, even if the failure is inadvertent. Under the statute, a manufacturer is strictly liable if it "fails to submit" the information required "in a timely manner" and, in such instances, "shall be subject to a civil money penalty of not less than $1,000, but not more than $10,000, *for each payment*." The penalty is even stiffer for manufacturers that "*knowingly* fail to submit" physician payments information: they "shall be subject to a civil money penalty of not less than $10,000, but not more than $100,000, *for each payment*."

Some drug and device manufacturers had hoped that the new federal law would preempt the confusing patchwork of state laws that currently exist. The Act's preemption provision, however, preempts only a portion of state aggregate spend laws, establishing a floor, not a ceiling. Specifically, the Act operates to "preempt any statute or regulation of a State" that requires manufacturers to "disclose or report" the "type of information" required by the federal statute. Thus, the requirements of the new federal law do not preempt any different or additional requirements that are — or may be — imposed by states. As a consequence, beginning in 2012, drug and device manufacturers will be required to aggregate and disclose to HHS certain federally specified doctor payments made in all 50 states and, in addition, to aggregate and disclose to various states additional types of state-specified doctor payments that stricter state laws require.

We would be pleased to discuss how these changes will affect your business and how, in addition to complying with existing state requirements, your company can begin to prepare to comply with these new federal requirements.