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## **Health Care Reform Means New Disclosure Rules**

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Last week, President Barack Obama signed H.R. 3590, the Patient Protection and Affordable Care Act. Among its many provisions is one that, in time, is sure to draw the attention and resources of drug and device manufacturers: a provision requiring that industry payments to doctors be publicly disclosed.

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.

Some states have imposed “gift bans,” providing only narrow exceptions for doctor payments that are permissible (and usually requiring that such permissible payments be reported). Other states have enacted de minimis exceptions, so that payments falling below a certain threshold do not have to be reported.

These “state aggregate spend” laws have been described by industry leaders as a “confusing myriad” of requirements that are “overly burdensome and costly for those required to report.” 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 has increased.

The new federal law, enacted last week, 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:

- 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.

In addition to disclosing payments to doctors, manufacturers must also disclose “information regarding any ownership or investment interest ... held by a physician (or an immediate family member of such physician ... ) in the applicable manufacturer,” though such ownership in a manufacturer does not include ownership of publicly traded stocks or mutual funds.

The precise manner in which manufacturers will be required to disclose doctor payments has yet to be determined. It will be established in regulations issued by the U.S. Department of Health and Human Services. 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 of the payment;
- The 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.

Doctors and manufacturers cannot arrange payments to avoid disclosure. The act provides that if a doctor asks a manufacturer to provide something of value to someone else, then the manufacturer must disclose the payment as if it were made to the doctor directly.

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 Web site” maintained by HHS that is searchable and “contains information that is able to be easily aggregated and downloaded.”

In addition, the act requires HHS to include on the Web site a “description of any enforcement actions,” “background information on industry-physician relationships,” and any other information that “would be helpful to the average consumer.”

Payments to doctors for help in researching and developing new drugs and devices are treated differently, since disclosure of the research might jeopardize a manufacturer’s confidential commercial information. Under the act, a special accommodation is made for payments for doctor services furnished in connection with:

- “Research on a potential new medical technology or a new application of an existing medical technology”;
- The “development of a new drug, device, biological or medical supply”; or
- A “clinical investigation regarding a new drug, device, biological or medical supply.”

For such research-related payments, HHS will not publish payment information on the Internet until after either (1) the U.S. Food and Drug Administration has approved or cleared the drug or device or (2) four years have elapsed since the payment to the doctor was made, whichever is earlier.

In addition, the act provides that information about research-related payments to doctors is exempt from disclosure under the Freedom of Information Act until after the information is published on HHS’ doctor payments disclosure Web site.

Fortunately, drug and device manufacturers have time to prepare for these new federal requirements. Under the Act, HHS is required to issue regulations establishing the procedures for the submission and Internet posting of doctor payments by Oct. 1, 2011. Manufacturers must collect information about doctor payments beginning on Jan. 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 Sept. 30, 2013. Every year thereafter, manufacturers must submit disclosure reports on or about March 31 (the act says “on the 90th day of each calendar year”), 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.”

HHS will have every incentive to enforce disclosure requirements vigorously; the act provides that all of the civil money penalties the government collects for manufacturer noncompliance “shall be used” for further enforcement efforts.

Some drug and device manufacturers had hoped that the new federal law would preempt the confusing patchwork of state laws that have proliferated around the country. The act’s preemption provision, however, does not do that.

Instead, it 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. For example, the act does not preempt the gift bans imposed by Minnesota and Massachusetts.

By its terms, the act does not preempt any state law that requires a manufacturer to disclose or report information “not of the type required to be disclosed under” the federal statute. (There is one exception: The act states that its de minimis exception for payments less than \$10, unless the aggregate amount paid by a manufacturer to a physician during the calendar year exceeds \$100, does preempt state laws that have a different — higher or lower — threshold.)

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.

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