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The Physician Payments Sunshine Act: Little Guidance, But Many Potential Risks

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The Physician Payments Sunshine Act (Sunshine Act), passed on March 23, 2010, requires all U.S. manufacturers of drugs, medical devices, biologics, and medical supplies covered under Medicare, Medicaid, or the State Children's Health Insurance Program to report payments to physicians and teaching hospitals on an annual basis to the Department of Health and Human Services (HHS).

The information that manufacturers must disclose under the Act will bring increased scrutiny to companies' physician compensation practices, and may even lead to government investigations of alleged violations of other federal statutes, including the Anti-Kickback statute, the False Claims Act, and the Stark Law. To date, however, the Centers for Medicare and Medicaid Services (CMS) has provided little guidance for manufacturers. CMS recently missed a statutory deadline to draft rules and regulations implementing the Act, and failed to meet a subsequent demand from the Sunshine Act's co-sponsors, Senators Charles E. Grassley and Herb Kohl, to provide, by October 14, 2011, information about CMS's timetable for issuing regulations and implementing the Act. These regulations are expected to instruct covered manufacturers about the procedures by which they will submit the payment information identified by the statute to HHS and by which HHS will, in turn, make that information available to the public. In the absence of regulations, companies must still be prepared to collect the data identified by the Act, even if the ultimate means by which they will submit that information to HHS is still unclear.

WHAT MUST MANUFACTURERS DISCLOSE?

The Sunshine Act requires manufacturers to report annually to HHS information about various kinds of payments to physicians and teaching hospitals, which HHS will then make publicly available. Payments that must be disclosed include cash or in-kind transfers for compensation, food, entertainment, gifts, travel, consulting fees, honoraria, research funding or grants, education or conference funding, stocks or stock options, ownership or investment income, royalties or licenses, charitable contributions, or any other transfer of value identified by HHS. The disclosure must include the name and business address of the recipient, the physician's specialty and National Provider Identifier, the amount and date of the payment, a description of the form of the payment, a description of the nature of the payment, and the name of the related drug, device, or supply.

A separate provision under the Sunshine Act also requires that manufacturers report, in addition to specific payments, any ownership or investment interest in the entity in the previous year by a physician or a physician's immediate family member, including the dollar amount invested, the value and terms of the investment, and any payments or transfers of value to the physician holding the ownership or investment interest in the entity.

Although reporting does not begin until March 31, 2013, the Sunshine Act applies to all payments made after January 1, 2012. Accordingly, companies should have mechanisms in place before that date to track all payments and interests that are covered by the Act.

The Act provides some exceptions to these reporting requirements, including payments of less than $10 (unless a physician received aggregated payments of more than $100 in a single reporting year), product samples for patient use, patient education materials that directly benefit the patient, short-term loans of a device (90 days), discounts or rebates, and payments to a physician who is an employee of the reporting company.

THE SUNSHINE ACT'S PENALTIES AND OTHER POTENTIAL RISKS

Under the Act, each failure to report is punishable with a fine of up to $10,000, with aggregate fines not to exceed $150,000 annually. In addition, each knowing failure to report can be punished with a fine of up to $100,000, with total aggregate annual fines of up to $1,000,000.

The information published under the Sunshine Act is precisely the kind of information that prosecutors are likely to mine for investigations of potential violations of other federal statutes, thereby exposing manufacturers to even greater dangers. For example, the Anti-Kickback Statute provides criminal penalties for soliciting or receiving any remuneration of any kind, either directly or indirectly, for the purpose of inducing or rewarding another party for referring services paid for by a federal government health care program. The types of payments disclosed under the Sunshine Act (e.g., food, entertainment, gifts, travel, consulting fees, honoraria, research funding or grants, education or conference funding) have commonly been the basis for Anti-Kickback liability. Violations of the Anti-Kickback Statute can also serve as the basis for liability under the False Claims Act.

Similarly, the Sunshine Act's requirement that manufacturers disclose ownership or investment interest in the entity by physicians potentially exposes manufacturers to scrutiny under the Stark Law, which carries civil penalties. The Stark Law prohibits a physician or immediate family member who has a financial relationship with an entity from referring patients to that entity for certain designated health services covered by Medicare unless an exception is available. If no exception is available, then the entity is prohibited from claiming the services under Medicare or billing any third- party entity.

Some major drug and device companies have already begun disclosing payments to physicians through online registries and websites. Some, such as Pfizer and Eli Lilly, have done so in order to comply with corporate integrity agreements entered into in order to resolve government investigations. In June 2010, Medtronic began voluntarily posting annual physician payments exceeding $5,000 on its company website. These disclosures, made in advance of reporting requirements mandated by the Sunshine Act, received substantial scrutiny and media coverage. For example, Senators Grassley and Max Baucus, in a letter to Medtronic, asked the company to produce documents related to a bone growth product, Infuse, after reports that doctors in charge of Infuse clinical trials may have been aware of and failed to report certain side effects of the product. The letter states that the "issue is compounded by the fact that some clinical investigators have substantial financial ties to Medtronic."

This is precisely the type of scrutiny that companies covered by the Sunshine Act should expect to receive once the required disclosures are collected and published by HHS.

CONCLUSION

In the already heavily regulated world in which manufacturers of drugs, medical devices, biologics, and medical supplies operate, the Sunshine Act will expose companies to even greater scrutiny. In preparing for the coming reporting deadlines under the Act, companies must consider not only how to comply with the Act, but also whether their internal processes and procedures related to physician compensation need to be revised or enhanced.

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