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Physician Payment Sunshine Act: Requirements And Unresolved Questions

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On January 1, 2012, the provisions of the Physician Payment Sunshine Act ("the Sunshine Act" or "the Act") go into effect, barring any last minute delay caused by the failure of the Center for Medicare and Medicaid Services ("CMMS") to issue the proposed regulations to implement the provisions of the Act. According to reports, the proposed CMMS rules implementing the Act, which were to be published by October 1, 2011, are under review at the Office of Management and Budget. The Act is Section 6002 of the Patient Affordable Care Act, enacted as part of the healthcare reform legislation in March 2010. The Sunshine Act will require pharmaceutical and medical device companies to put into effect comprehensive procedures and systems to collect data on payments made to individual physicians and teaching hospitals relating to drugs and devices that are reimbursed under a federal healthcare program.

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While there are currently a few states that already require such reporting in one form or another,[1] and while some companies already post such information on their website as result of Corporate Integrity Agreements or other settlements with the federal government, the Sunshine Act will apply to all pharmaceutical and medical device companies, including companies that do not yet market products, whose products are or will be reimbursed under a federal healthcare program. Counsel in all such companies need to be aware of the provisions of the Sunshine Act to ensure that their companies comply with it, and they should be aware of some of the issues that remain unclear in the absence of proposed regulations from CMMS.

The Sunshine Act requires manufacturers of human drug products devices and medical supplies reimbursed under federal healthcare programs to report to the CMMS cash, money, items and other things of value provided to certain physicians and teaching hospitals. Specifically, the Sunshine Act requires the reporting of any "payment or transfer of value" in any amount from a "manufacturer" to a "covered recipient." "Payment or transfer of value" is defined as the following:

- consulting fees;
- services fees for services other than consulting;
- honoraria;
- gifts;
- entertainment;
- food;
- travel;
- education;
- research;
- charitable contributions;
- royalties/ license payments;
- current or prospective ownership or investment interest in the company;
- direct compensation for servicing or facility or as a speaker for a medical education program;
- grants such as research grants, grants to study clubs, or sponsorships;
- and any other items of value as defined in regulations to be promulgated by CMMS.

It does not, however, include the following:

- any payment or item less than $10.00 in value, unless the aggregate total for a specific covered recipient totals more than $100.00 in a calendar year;
- product samples intended solely for patient use;
- educational materials that benefit patients or are for patient use;
- discounts such as reductions in price on goods provided in normal course of business to all entities;
- items used for providing charity care;
- other exclusions as set forth in Section 1128G(e)(B) of the Sunshine Act or to be promulgated CMMS regulations.

Payments and transfers of value that need to be collected for subsequent reporting are limited to payments to "covered recipients" relating to a "covered" product – a drug, device or medical supply item. A "covered recipient" is a physician or a teaching hospital. A "covered product" is a product that is or will be reimbursed under a federal healthcare program.

All of this data is to be collected and reported to CMMS on an annual basis. The first report is due by March 31, 2013, for calendar year 2012. Subsequent annual reports are due by the ninetieth day of each calendar year thereafter. The information is to be submitted electronically and will need to include, for *each* payment or transfer of value to a covered recipient, the following:

- the name of the "covered recipient" to

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whom the "payment or transfer of value" is made;

- the business addresses of the "covered recipient";
- if a physician, the physician's specialty;
- National Provider Identifier ("NPI");[2]
- the amount of "payment or transfer of value";
- the date of the "payment or transfer of value";
- the form of "payment or transfer of value," such as cash, check or wire, in-kind items or services, stock, dividend or other equitable interest and other form of payment.

CMMS is to make this data available on an Internet website no later than September 30, 2013, and each June 30th thereafter. The Internet website is to be searchable and in a "clear and understandable" format. It is to

- contain information that is presented by the name of the applicable manufacturer or applicable group purchasing organization, the name of the covered recipient, the business address of the covered recipient, the specialty of the covered recipient, the value of the payment or other transfer of value, the date on which the payment or other transfer of value was provided to the covered recipient, the form of the payment or other transfer of value, the nature of the payment or other transfer of value, and the name of the covered drug, device, biological, or medical supply, as applicable;
- contain information that is able to be easily aggregated and downloaded;
- contain a description of any enforcement actions taken to carry out this section, including any penalties imposed during the preceding year;
- contain background information on industry physician relationships;
- in the case of information submitted with respect to a payment or other transfer of value relating to delayed reporting of payments on products not yet approved, list such information separately from the other information and designate such separately listed information as funding for clinical research.

The National Provider Index numbers of the covered recipients receiving payments are not to be included on the CMMS website. CMMS is to provide each manufacturer, covered recipient and group-purchasing organization forty-five (45) days to review and submit corrections to such data, forty-five (45) days or more in advance of the proposed publication of the data.

As noted above, the data needs to be collected not just for marketed products but for products in research and development. Such data is not, however, to be made immediately available. The data is to be made available on the *earlier* of the approval or clearance of the product by the Food and Drug Administration ("FDA") and four (4) years after the payment or transfer of value was made. The Sunshine Act provides that such data is confidential until such time and is not disclosable under the Freedom of Information Act.

Failure to report a payment or transfer of value may result in civil money penalties in the amount of $1,000 to $10,000 per payment or transfer of value not reported, up to $150,000 for an annual submission. If the failure to report was done "knowingly," the failure may result in civil money penalties of $10,000 to $1,000,000 for each payment or transfer of value not reported, up to $1,000,000, for an annual submission. The term "knowingly" is to be given meaning in Section 3729(b) of title 31 of the U.S. Code.[3]

While the provisions of the Sunshine Act may seem to be clear, there are numerous questions that manufacturers need an answer to in order to determine what their obligations are under the Act. The following is a list of some of the issues that remain unclear in the absence of even proposed CMMS regulations.

"Teaching Hospital": While the Act does define "physician" as being defined in Section 1861(r) of the Social Security Act,[4] the Act does not define how manufacturers are to determine if a hospital is a "teaching hospital."

"Recordkeeping": The Act does not contain any provisions for how long records are to be kept to support annual reports made to CMMS.

> "Manufacturer": Manufacturer is defined as: a covered drug, device, biological, or medical supply or any entity that is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply (or any entity under common ownership with such entity that provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply).

What remains unclear is whether it is the NDA, PMA or regulatory approval holder that is required to report this information as the "manufacturer." Is a company that is a third-party contract manufacturer for another party required to file the report? In addition, even if manufacturer and regulatory approval holder are the same entity, what if a third party distributes the product or co-promotes it as a "covered" product? Who is to collect the data and report in such a case? Is the obligation on the "manufacturer," the distributor or both?

Payments related to a "covered" product: While in some cases it may be easy to determine that a specific payment or transfer of value was related to one specific "covered" product, what does a company do when, for example, a physician consultant provides a variety of services relating to a number of products? Does one report the total compensation paid for each product? Or does one divide the payments between products?

Electronic reporting: The Act requires that reporting be done electronically, but does not specify how.

These are just a few of the many unresolved issues facing companies as they begin the process of collecting the data necessary to comply with the reporting requirements of the Act. Until further clarification is provided, companies should be advised to collect as much data as possible to ensure compliance.

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[1] Currently, West Virginia, the District of Columbia and Vermont require such reporting. The Act will pre-empt such state laws, but not with regard to information not required by the Act.

[2] The NPI database can be found at www.npi-search.com.

[3] That section defines "knowing" and "knowingly" to mean: "that a person, with respect to information has actual knowledge of the information; acts in deliberate ignorance of the truth or falsity of the information; or acts in reckless disregard of the truth or falsity of the information; and require no proof of specific intent to defraud."

[4] The term "physician," when used in connection with the performance of any function or action, means "(1) a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action (including a physician within the meaning of section 1101(a)(7)), (2) a doctor of dental surgery or of dental medicine who is legally authorized to practice dentistry by the State in which he performs such function and who is acting within the scope of his license when he performs such functions, (3) a doctor of podiatric medicine for the purposes of subsections (k), (m), (p)(1), and (s) of this section and sections 1814(a), 1832(a)(2)(F)(ii), and 1835 but only with respect to functions which he is legally authorized to perform as such by the State in which he performs them, (4) a doctor of optometry, but only for purposes of subsection (p)(1) with respect to the provision of items or services described in subsection (s) which he is legally authorized to perform as a doctor of optometry by the State in which he performs them, or (5) a chiropractor who is licensed as such by the State (or in a State which does not license chiropractors as such, is legally authorized to perform the services of a chiropractor in the jurisdiction in which he performs such services), and who meets uniform minimum standards promulgated by the Secretary, but only for the purpose of sections 1861(s)(1) and 1861(s)(2)(A) and only with respect to treatment by means of manual manipulation of the spine (to correct a subluxation) which he is legally authorized to perform by the State or jurisdiction in which such treatment is provided. For the purposes of section 1862(a)(4) and subject to the limitations and conditions provided in the previous sentence, such term includes a doctor of one of the arts, specified in such previous sentence, legally authorized to practice such art in the country in which the inpatient hospital services (referred to in such section 1862(a)(4)) are furnished."