The Physician Payment Sunshine Act

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Overview

As we all wait for the United States Supreme Court’s decision on the constitutionality of the Patient Protection And Affordable Care Act, the pharmaceutical and medical device manufacturer’s, as well as group purchasing organizations, are working to implement policies and procedures to comply with section 6002 of the Act which is referred to as the Physician Payment Sunshine Act (“Sunshine Act”). The Sunshine Act requires such manufacturers and group purchasing organizations (“GPOs”) to report to the Department of Health and Human Services (“HHS”) any “payment or other transfer of value” to physicians and teaching hospitals. The reports will be due to HHS starting on March 31, 2013, for the calendar year 2012 reporting period and for every calendar year thereafter. The term “payment or other transfer of value” is very broadly defined with a very low threshold. Anything over $10 with certain exceptions must be reported. The failure to report may result in monetary penalties, the amount which varied depending on whether the failure to report is “knowing.”

Although state laws are not the focus of this QuickCounsel, in-house counsel should be aware that several states (including California, Connecticut, the District of Columbia, Maine, Massachusetts, Minnesota, Nevada, Vermont and West Virginia) have similar laws and others are considering such laws (e.g., Colorado, Illinois, Maryland and Texas). This QuickCounsel will address the changes proposed under the Sunshine Act and the implications for the healthcare industry.

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Background

On December 14, 2011, the Centers for Medicare and Medicaid Services (“CMS”) released its proposed rule (“Proposed Rule”), (the Proposed Rule was subsequently published in the Federal Register on December 19, 2011, 76 Fed. Reg. 78742-78773, to be codified at 42 C.F.R. Parts 402 and 403) addressing the implementation of the Sunshine Act. The comments to the Proposed Rules submitted by manufacturers and other interested parties reveal that the Proposed Rule, while addressing certain pertinent details of the Sunshine Act, have left certain questions unanswered or ambiguous.

Nevertheless, the originators of the Sunshine Act, Senators Chuck Grassley, R-Iowa, and Herb Kohl, D-Wis. submitted a letter in April 4, 2012, to CMS asking that the agency issue a final rule on the Sunshine Act in the next three months reinforcing their view of the risks associated with industry-physician financial relationships. Among the concerns of such
relationships are the potential for industry-induced bias resulting in the following:

a. - risks to patients (treatment decisions that are not based solely on the interest of the patient);
b. - risks to health care programs (increased costs and unfair competition); and
c. - risks to scientific research (corrupting research independence and the standards of scientific integrity).

Statutory Provisions

The Sunshine Act requires that beginning March 31, 2013, and on the 90th day of each calendar year thereafter, any applicable manufacturer that provided a payment or other transfer of value to a covered recipient (to an entity or individual at the request of or designated on behalf of a covered recipient) shall electronically report to HHS such information for the proceeding calendar year.

Reporting Requirements

The applicable manufacturer must report the following information for any applicable payment or transfer of value:

i. - The name of the covered recipient.

ii. - The business address of the covered recipient, and in the case of a covered recipient who is a physician, the specialty and National Provider Identifier (“NPI”) of the covered recipient.

iii. - The amount of payment or other transfer of value.

iv. - The dates on which the payments or other transferred value was provided to covered recipient.

v. - A description of the form of the payment or transfer of value: cash or cash equivalent; in kind items of service; stock, stock option, or any other ownership interest, dividend, profit, or other return on investment; or any other form of payment or transfer of value as defined by HHS regulations.

vi. - A description of the nature of the payment or transfer of value indicated as: consulting fees; compensation for services other than consulting; honoraria; gift; entertainment; food; travel (including the specified destinations); education; research; charitable contribution; royalty or license; current or prospective ownership or investment interest; direct compensation for serving as a faculty or as a speaker for a medical education program; grant; or any other nature of payment or other transfer of value as defined by HHS.

vii. - If the payment or other transfer of value is related to marketing, education, or research specific to a covered drug, device, biological or medical supply, the name of the covered drug, device, biological, or medical supply must be reported.

Physician Ownership

In addition to the requirements set forth above, any applicable manufacturer or applicable GPO must also submit the following information regarding any ownership or investment interest (other than an ownership or investment interest in a publicly traded security and mutual fund, as described in section 1877(c) of the Social Security Act) held by a physician (or immediate family member of such physician as defined for purposes of section 1877(a) of the Social Security Act (“SSA”):

- The dollar amount invested by each physician holding such an ownership or investment interest.
- The value in terms of each such ownership or investment interest.
- Any payment or other transfer of value provided to a physician holding such an ownership or investment interest.
- Any other information regarding the ownership or investment interest deemed appropriate by HHS.

**Penalties for Noncompliance**

Any applicable manufacturer or GPO that fails to submit information as required in a timely manner in accordance with rules or regulations promulgated to carry out the Sunshine Act shall be subject to a civil money penalty of not less than $1,000, but not more than $10,000 for each payment or other transfer of value or ownership or investment interest not reported as required. The total amount of civil money penalties imposed with respect to each annual submission information by an applicable manufacturer or GPO shall not exceed $150,000. However, any applicable manufacturer or a GPO that “knowingly” fails to submit information as required shall be subject to a civil money penalty of not less than $10,000 but not more than $100,000 for each payment or other transfer of value or ownership or investment interest not reported as required. The total civil money penalty exposure for failing to knowingly provide the required information with respect to each annual submission of information shall not exceed $1 million.

**Public Availability**

The Sunshine Act requires that no later than September 30, 2013, and on June 30 of each calendar year beginning thereafter the information submitted by the applicable manufacturers and GPOs with respect to the preceding calendar years will be made publicly available through an internet website that has the following characteristics:

- Searchable in a format that is clear and understandable
- Information is presented by the name of the applicable manufacturer or GPO, the name of the covered recipient, the business address of the covered recipient, the specialty of the covered recipient, the value, payment or transfer or value, the date on which the payment or transfer of value was provided to the covered recipient, the form of the payment or other transfer of value and the name of the covered drug, device, biological, or medical supply description of any enforcement actions taken related to the Sunshine Act during the preceding year
- Background information on industry-physician relationships
- Any other information HHS has determined would be helpful to the average consumer.

The NPI of the covered recipients will not be made available to public on the internet website. Additionally, manufacturers, group purchasing organizations and covered recipients will have 45 days to review the submitted information and submit corrections prior to the information being made available to the public.

The Sunshine Act does recognize that there may be instances where delay of publication of payments may be necessary because of product research or development agreements and clinical investigations. Accordingly, it provides that with respect to such payments the payment information will not be made publicly available until the earlier of the following:

i. - The date of the approval or clearance of the covered drug, device, biological, or medical supply by the Food and Drug Administration.
ii. - Four calendar years after the date such payment or other transfer of payment was made.

The Sunshine Act also requires HHS to provide an annual report to Congress no later than April 1 of each year beginning 2013. The report must include the aggregated information submitted by each applicable manufacturer and GPO during the preceding year and a description of any enforcement action taken during that year. HHS must also make reports to States beginning no later than September 30, 2013, and on June 30 of each calendar year thereafter. The report is to include a summary of the information submitted during a preceding year with respect to covered recipients in the State
Preemption of State Laws
The Sunshine Act provides that in the case of a payment or other transfer of value provided by an applicable manufacturer that is received by a covered recipient on or after January 1, 2012, the Sunshine Act will preempt any statute or regulation of a State or of a political subdivision of a State that requires applicable manufacturers to disclose or report the type of information covered by the federal law. The Sunshine Act will not preempt any statute or regulation of the State or a political subdivision addressing the disclosure or reporting of other information.

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Proposed Rule
The Proposed Rule addressed several key issues providing clarification and guidance to the Sunshine Act. The following are some of the key issues that were addressed in the Proposed Rule:

- Restricted the application of the Sunshine Act to manufacturers of prescribed drugs and biologics and to manufacturers of medical devices for which pre-market approval by or pre-market notification to the U.S. Food and Drug Administration is required. This effectively excluded manufacturers of over-the-counter drugs and manufacturers of Class I devices and some Class II devices.
- Clarified the applicability of the law to any manufacturer of covered product sold or distributed in the United States, regardless of where the product is produced.
- Required applicable manufacturer to report all payments or transfer of value, even those that are not associated with a covered drug, device, biological or medical supply.
- Defined “teaching hospital” as any institution receiving Medicare graduate medical education payment.
- Required disclosure of third party of a transfer of value is provided indirectly to a physician or teaching hospital through the third party.
- Clarified that manufacturers do not have to report indirect transfers of value when the identity of the physician or teaching hospital recipient is not known to them.
- Manufacturers are allowed to include the assumptions used in preparing these reports submitted to CMS without having the assumption posted on the public website.
- Defined the scope of research and development to be subject to delayed publication.
- Established a process for review, correction, and resolution of dispute concerning information reported to CMS.

The over 300 comments submitted to CMS reflect the industries and other interested parties believe that the Proposed Rule failed to provide guidance on certain key elements including:

- Guidance on what constitutes an entity support of the manufacturer and distribution and marketing activity of a manufacturer. Whether and when a manufacturer must report transfers of value made by independent distributors who participate in the marketing of a product, in particular, physician-owned distributorships.
- How the law applies to interactions with individuals, teaching hospitals, or representatives.
- How to value transfers when the transfer is not cash or there is not an established market value.
- Clarification on the scope of the exclusion from reporting requirements for medical device
samples and for educational materials.

The preamble to the Proposed Rule indicates that CMS is concerning alternative to several of its proposals thereby suggesting that there may be significant changes between the Proposed Rule and any final rule. Given the large number of interested parties that have submitted comments to CMS prior to the February 17, 2012 deadline it appears certain that significant changes will be made to the final rule once CMS reviews those comments.

Conclusion

The changes presented by the Physician Payment Sunshine Act will substantially impact the hospital-industry relationship. To protect themselves from liability and government scrutiny, in-house counsel must be aware of these changes. This QuickCounsel provides an overview of those changes and the implications for the healthcare industry.

Additional Resources

- Physician Relationships Remain the Focus: Revisions to the AdvaMed Code of Ethics on Interactions With Healthcare Professionals (Foley & Lardner 2009)
- Testimony Confirms OIG’s Ongoing Focus on Vendor Relationships With Physicians (Foley & Lardner 2008)
- New Developments in Payment and Public Reporting of Quality of Care (Foley & Lardner 2008)

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