Understanding the Sunshine Act: Dispersing the Clouds of Confusion

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On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act. Section 6002 of the Act, entitled "Transparency Reports and Reporting of Physician Ownership or Investment Interests," is commonly known as the "Sunshine Act." Pursuant to the Sunshine Act, certain pharmaceutical, medical device, biological product, and medical supply companies are required to disclose annually gifts and payments provided to covered recipients, and ownership and investment interests in the company that are held by covered recipients.

On December 19, 2011, the Department of Health and Human Services published in the Federal Register the much-anticipated draft regulations for the Sunshine Act. The draft regulations propose various definitions, clarifications and requirements for implementing the law, and will be followed by final regulations before they become effective. In the draft regulations, the Centers for Medicare & Medicaid Services ("CMS") requested that the public submit comments on many of the proposed requirements, definitions, and methods suggested for implementing the law. The public comment period for the draft regulations closed on February 17, 2012. To date, the final regulations have not been published.

While the Sunshine Act and the proposed regulations include many details related to disclosure obligations and open questions about how to comply, it is essential to begin preparing for the Sunshine Act disclosure requirements. Below we provide information about the requirements and some commonly asked questions.

When do companies have to file their first reports and what time period will be covered?

- Under the law, companies were to begin capturing data for reporting on January 1, 2012.
- In the proposed regulations, however, CMS recognizes that companies need direction and guidance from CMS on what data to capture and how, as well as time to prepare for compliance.
- The draft regulations propose to delay the start of data capture for reporting until 90 days after publication of the final regulations. Comments submitted by interested parties request even more time, such as 120 or 180 days, to implement the requirements after publication of the final regulations.
- The comment period closed on February 17, 2012, and currently CMS is reviewing the comments, meeting with stakeholders, and revising the regulations.

What will companies actually file?

- Companies subject to the law will file two reports: the Payment and Other Transfers of Value Report ("Payment Report"), and the Ownership and Investment Interest Report ("Ownership Report").
- Both reports will be submitted electronically as comma-separated value ("CSV") files.
- The proposed regulations suggest allowing companies to also submit an "assumptions document," which would provide information to CMS on how the company interpreted various terms, calculated payments or other transfers of value, certified data, etc.
- The chief executive officer, chief financial officer, or chief compliance officer will be required to certify that the data submitted is true, correct, and complete.

Who is subject to the law?

- "Applicable manufacturers" must submit Payment Reports; "applicable manufacturers" and "applicable group purchasing organizations" ("GPOs") must submit Ownership Reports.
- An applicable manufacturer is an entity that:
  - Engages in manufacturing a covered product, or
  - Is under common ownership of an entity engaged in manufacturing a covered product and that provides assistance or support to that entity in its manufacturing, marketing, promotion, sales or distribution activities for that product, or
  - Holds FDA approval, licensure, or clearance for a covered product, and
  - Has a covered drug, device, biological, or medical supply that is sold or distributed in the United States.
- What constitutes common ownership?
  - Common ownership occurs when the same individual, individuals, entity, or entities, directly or indirectly, own <u>any portion</u> of two or more entities.
  - The proposed regulations requested comments on whether the definition should be limited to circumstances where the same individuals or entities own 5% or more of total ownership.
- An applicable GPO is an entity that:
  - Operates in the United States or its territory, possession or commonwealth, and
  - Purchases, arranges for, or negotiates the purchase of a covered drug, device, biological or medical supply, or
  - Purchases a covered product for resale or distribution.
- The proposed regulations clarify that if a company has any one covered product, it is subject to the law and must report all payments, whether related to the covered product or not.

What is a "covered" product?

- A covered product is a covered drug, device, biological or medical supply.
- "Covered" means that payment is available for the product under Medicare, Medicaid, or CHIP.
- Under the draft regulations, CMS proposed to limit covered drugs and biological products to those that require a prescription. Similarly, covered devices and medical supplies would be limited to devices and supplies that require premarket approval by or notification to FDA, excluding certain Class I and Class II devices.

Payments to whom must be reported?

- Payments by an applicable manufacturer to a "covered recipient" must be reported.
- "Covered recipients" are physicians and teaching hospitals.
- Physicians are doctors of medicine, osteopathy, dentists, podiatrist, optometrists, and licensed chiropractors. If the individual is an employee of the applicable manufacturer, the individual is excluded from the definition.
- Companies should use the National Plan & Provider Enumeration System ("NPPES") to identify physicians and find their National Provider Identifier ("NPI") and business address for reporting.
- Teaching hospitals are institutions that receive Medicare graduate medical education payments. CMS will publish annually on its website a list of institutions qualifying as teaching hospitals.

What must applicable manufacturers report?

- Applicable manufacturers must report <u>all</u> payments and transfers of anything of value provided to covered recipients. This includes payments or other transfers of value provided indirectly to covered recipients through third parties, if the applicable manufacturer is aware of the covered recipients' identities.
- Some of the information that must be included is:
  - Name of the reporting entity;
  - Name of the covered recipient;
  - Business address of the covered recipient;
  - Specialty (only for physicians);
  - NPI number (only for physicians);
  - Amount of payment;
  - Date of payment;
  - Form of payment;
  - Nature of payment; and
  - Name of associated covered drug, device, biological or medical supply (if any).
- Under the law and proposed regulations, the "Form" of the payment will be selected from the following:
  - Cash or a cash equivalent;
  - In-kind items or services; or
  - Stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment.
- The "Nature" of the payment describes the purpose and manner of the payment or transfer of value. The proposed regulations provide several points of clarification and requests for comments, and as such the list of possible choices may change with publication of the final regulations. Currently, the "Nature" would be selected from the following list:
  - Consulting fees;
  - Compensation for services other than consulting;
  - Honoraria;
  - Gift;
  - Entertainment;
  - Food;
  - Travel;

- Education;
- Research;
- Charitable contribution;
- Royalty or license;
- Current or prospective ownership or investment interest;
- Direct compensation for serving as faculty or as a speaker for a medical education program;
- Grant; or
- Other.

What is excluded from the payment or transfer of value disclosure reports?

- The law and draft regulations provide several types of payments and transfers of value that are excluded from the disclosure requirements, which include:
  - Payments less than $10, unless the aggregate amount for the covered recipient exceeds $100 in the calendar year;
  - Product samples (note that drug samples must be disclosed under a separate section of the Patient Protection and Affordable Care Act);
  - Educational materials that directly benefit patients or are intended for patient use;
  - In-kind items for the provision of charity care; and
  - Payments through a third party when the manufacturer is unaware of the covered recipient's identity.

What ownership information must applicable manufacturers and GPOs report?

- Applicable manufacturers and GPOs must report ownership or investment interests held by physicians or the immediate family members of physicians in the applicable manufacturer or applicable group purchasing organization.
- The exemption for physician employees from the payment or transfer of value reports is <u>not</u> applicable to the ownership and investment interests reports.
- An ownership or investment interest may be direct or indirect, including:
  - Stock;
  - Stock options;
  - Partnership shares;
  - LLC memberships;
  - Loans;
  - Bonds; and
  - Other financial instruments secured with the entity's property or revenue.
- Retirement plans, stock options and securities received as compensation, and unsecured loans are not considered ownership of investment interests. These interests are excluded from the ownership or investment interest reports.
- Some of the information that must be included is:
  - Reporting entity name;
  - Recipient name;
  - Business address of the owner/investor;
  - Recipient Specialty (only for physicians);
  - Recipient NPI number (only for physicians);

- Identification of whether the interest is held by a physician's immediate family member;
- Dollar amount invested;
- Value of interest; and
- Terms of interest.

Will the data reported by applicable manufacturers and GPOs be publicly available?

- The data reported by applicable manufacturers and GPOs will be published on a publicly available website. According to the draft regulations, the data on the website will be searchable, understandable, downloadable, and easily aggregated on various levels.

When will the data be published?

- Under the law, all 2012 data reported by applicable manufacturers and GPOs must be publicly available by September 30, 2013. For each year after 2012, the data for the preceding calendar year will be published by June 30th.
- Publication of clinical data related to research or development of new covered products will be delayed. This data will be made publicly available on the first publication date after the earlier of either: the approval, licensure or clearance by the FDA of the covered drug, device, biological or medical supply; or four calendar years after the date of payment.

Are there penalties for failing to comply with the law?

- There are two classes of penalties: failure to report, and knowing failure to report.
- Failing to provide accurate and complete information will subject a manufacturer or GPO to a penalty between $1,000 and $10,000 for each payment or ownership interest not report as required. The maximum penalty in any one year is $150,000.
- Knowing failure to provide accurate and complete information as required under the law will subject a manufacturer or GPO to a penalty between $10,000 and $100,000 per violation. The maximum penalty in one reporting year is $1,000,000.

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