The Sunshine Act: A Brief Overview

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The Sunshine Act

- The Sunshine final rule implements the physician payments reporting provisions (Section 6002) of the Affordable Care Act (ACA) of 2010

- CMS issued a proposed rule in December 2011 and solicited comments from the public on its proposal

- The agency received over 370 public comments from a range of stakeholders, including:
  - Pharmaceutical and medical device manufacturers, and related trade associations
  - Health care providers, including hospitals and physicians, and related professional associations
  - Medical schools
  - CME providers
  - Consumer advocacy groups
General Requirements of the Sunshine Act

• Pharmaceutical and Device Manufacturers *must report* payments or other transfers of value made to or on behalf of physicians (or their immediate family members) and teaching hospitals to DHHS annually (hereinafter referred to as “covered recipients”). The data collection effort will begin August 1, 2013.

• Pharmaceutical and Device Manufacturers (hereinafter referred to as “applicable manufacturers”) as well as Group Purchasing Organizations (“GPOs”) *must also report* to DHHS ownership or investment interests in their organizations held by physicians or their immediate family members.
Implementation Dates for the Sunshine Act

- **August 1, 2013**
  - Applicable manufacturers must begin tracking payments or other transfers of value they provide to physicians and teaching hospitals
  - Applicable manufacturers and GPOs must begin tracking ownership or investment interests in their organizations that are held by physicians or their immediate family members

- **March 31, 2014** - First disclosure reports are due to CMS, for the period August 1, 2013 to December 31, 2013

- **September 30, 2014** - CMS will publicly post data from the 2013 reporting period
  - Going forward, data from disclosure reports will be made publicly available by each June 1
Potential Effects of the Sunshine Act

- Publication of financial relationships between applicable manufacturers and covered recipients will likely increase scrutiny of health care professionals.

- Federal and state authorities (including DOJ, OIG, and state attorneys general) could mine reported data for possible kickbacks, false claims, and violations of applicable state laws.

- Possible use by IRS to assess an applicable manufacturer’s reporting obligations with Form 1099 requirements and a covered recipient’s compliance with income tax reporting obligations.

- The media may also review the data and further publicize the information in a light that may cause concern in the community.
Applicable Manufacturers

42 C.F.R. § 403.902

- An “applicable manufacturer” is an entity that is “operating in the United States” and that falls within one of the following two categories:

  1) An entity that is engaged in the production, preparation, propagation, compounding, or conversion of a “covered drug, device, biological, or medical supply” (“covered product”), but not if such covered product is solely for use by or within the entity itself or by the entity’s own patients. This definition does not include distributors or wholesalers that do not hold title to any covered product.

  2) An entity under “common ownership” with an entity in paragraph (1) of this definition, which provides “assistance or support” to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered product.
Covered Products

42 C.F.R. § 403.902

• Generally, covered products include any drug, device, biological, or medical supply for which payment is available under Medicare, Medicaid, or the Children’s Health Insurance Program (or a waiver of such plan), either separately (such as through a fee schedule or formulary) or as part of a bundled payment (for example, under the hospital inpatient prospective payment system or the hospital outpatient prospective payment system).

• The definition is further narrowed for specific types of products:
  • For drugs and biologicals, the definition applies only to those that, by law, require a prescription to be dispensed.
  • For devices, the definition applies only to those that, by law, require premarket approval by or premarket notification to the FDA.
Payments or Other Transfers of Value

42 C.F.R. § 403.902
- “Payment or other transfer of value” means a “transfer of anything of value”
- “Indirect” Payments or other transfers of value” means “payments or other transfers of value . . . to a covered recipient . . . through a third party, where the applicable manufacturer . . . requires, instructs, directs, or otherwise causes the “third party” to provide the payment or transfer of value, in whole or in part, to a covered recipient” (emphasis added).

42 C.F.R. § 403.904
- Applicable manufacturers must report direct and indirect payments or other transfers of value they provide to covered recipients, including those provided to a third party at the request of or designated by the applicable manufacturer on behalf of a covered recipient.
Forms of Payment or Other Transfers of Value

42 C.F.R. § 403.904(d)

- Applicable manufacturers must report the form of each payment or transfer of value, or separable part of that payment or transfer of value, using one of the following designations that best describes the form of the payment or other transfer of value:
  - Cash or cash equivalent
  - In-kind items or services
  - Stock, stock option, or any other ownership interest
  - Dividend, profit, or other return on investment
The Nature of Payment or Other Transfers of Value

42 C.F.R. § 403.904(e)

• Applicable manufacturers must report the nature of each payment or other transfer of value, or separable part of that payment or transfer of value, using one of 16 designations (listed on the next slide) that best describes the nature of the payment or other transfer of value.

• If a payment or other transfer of value could reasonably be considered as falling within more than one category, an applicable manufacturer should select one category that it deems to most accurately describe the nature of the payment or transfer of value.
The Nature of Payment or Other Transfers of Value

42 C.F.R. § 403.904(e)

Nature Descriptors

- Consulting fee
- Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program
- Honoraria
- Gift
- Entertainment
- Food and beverage
- Travel and lodging
- Education
- Research
- Charitable contribution
- Royalty or license
- Current or prospective ownership or investment interest
- Compensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program
- Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program
- Grant
- Space rental or facility fees (teaching hospital only)
Contents of Disclosure Reports

42 C.F.R. § 403.904(c)

• Applicable manufacturers must report the following for each payment or other transfer of value subject to disclosure:
  • Name of the covered recipient (for physicians, the name must match that as listed in the NPPES database – his/her NPI)
  • Primary business address of the covered recipient
  • If the recipient is a physician, the specialty, National Provider Identifier, a state license number, and the state in which the license is held
  • Amount of the payment or other transfer of value
  • Date the payment or other transfer of value was provided
  • Form of the payment or other transfer of value (using one of four descriptors, discussed in more detail below);
  • Nature of the payment or other transfer of value (using one of 16 descriptors, discussed in more detail below);
Contents of Disclosure Reports (cont’d)

• The names of up to five products to which the payment or other transfer of value relates
  • For covered drugs and biologics, report the marketed name and NDC, if any
  • For covered medical devices and supplies, report either the marketed name or the therapeutic area or product category, or both.
  • If the payment is related to a product that is not a covered product, indicate “non-covered product”
  • If the payment is not related to any product, report “none”
• An indication that the payment or other transfer of value is subject to delayed publication, if applicable
Contents of Disclosure Reports (cont’d)

• If the payment or other transfer of value is provided to a third party at the request of or designated on behalf of a covered recipient, the name of the covered recipient, and the name of the entity that received the payment or “individual” if an individual received the payment

• Whether the payment or other transfer of value was provided to a physician (or an immediate family member of a physician) who holds an ownership or investment interest in the applicable manufacturer

• A statement with additional context for the payment or other transfer of value, if the applicable manufacturer so desires
Physician Ownership and Investment Interests

42 C.F.R. §403.906

- The final rule requires each *applicable manufacturer and applicable GPO* to annually report to CMS all “ownership and investment interests” in the applicable manufacturer or applicable GPO that were held by a physician or an immediate family member of a physician during the preceding calendar year.

- An *applicable GPO* is an entity that operates in the U.S. and purchases, arranges for or negotiates the purchases of covered products for a group of individuals or entities, but not solely for use by the entity itself.

- The final rule defines “immediate family member” the same as the Stark definition.
Physician Ownership and Investment Interests

42 C.F.R. §403.902

• “Ownership or investment interests” may be direct or indirect and include, but are not limited to:
  • Stock and stock options (other than those received as compensation, until they are exercised)
  • Partnership shares
  • Limited liability company memberships
  • Loans, bonds, or other financial instruments that are secured with an entity's property or revenue or a portion of that property or revenue

• “Ownership or investment interests” do not include, among others:
  • An ownership or investment interest in a publicly traded security or mutual fund
  • An interest in an applicable manufacturer or GPO that arises from a retirement plan offered by the applicable manufacturer or GPO
  • An ownership or investment interest about which an applicable manufacturer or applicable GPO did not know
Physician Ownership and Investment Interests

42 C.F.R. §403.906(b)
• Applicable manufacturers and GPOs must report the following for ownership or investment interests held by physicians or their immediate family members:
  • Name of the physician, and whether the ownership or investment interest is held by an immediate family member of the physician
  • Primary business address of the physician
  • The physician’s specialty, NPI number, a state license number, and the state in which the license is held
  • Dollar amount invested by each physician or immediate family member of the physician
  • Value and terms of each ownership or investment interest
  • Information about any direct or indirect payments or other transfers of value provided to a physician holding an ownership or investment interest
Exclusions from Reporting

42 C.F.R. § 403.904(i)

- Applicable manufacturers are not required to report the following types of payments or other transfers of value (cont’d):
  - Product samples, and coupons and vouchers that are not intended to be sold and are intended for patient use
  - Educational materials and items that directly benefit patients or are intended to be used by or with patients, including the value of an applicable manufacturer’s services to educate patients regarding a covered product
  - The loan of a covered device or a device under development, or the provision of a limited quantity of medical supplies for a short-term trial period, not to exceed a loan period of 90 days or a quantity of 90 days of average daily use, to permit evaluation of the device or medical supply by the covered recipient
  - Items or services provided under a contractual warranty (including service or maintenance agreements), whether or not the warranty period has expired, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement
Exclusions from Reporting

42 C.F.R. § 403.904(i)

- Applicable manufacturers are not required to report the following types of payments or other transfers of value (cont’d):
  - A transfer of anything of value to a physician covered recipient when the covered recipient is a patient, research subject or participant in data collection for research, and not acting in the professional capacity of a covered recipient
  - Discounts, including rebates
  - In-kind items used for the provision of “charity care”
  - A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund
  - In the case of an applicable manufacturer who offers a self-insured plan or directly reimburses for health care expenses, payments for the provision of health care to employees and their families
Exclusions from Reporting

42 C.F.R. § 403.904(i)

- The following types of payments or other transfers of value are excluded from the reporting requirements (cont’d):
  - In the case of a covered recipient who is a licensed non-medical professional, a transfer of anything of value to the covered recipient if the transfer is payment solely for the non-medical professional services
  - In the case of a covered recipient who is a physician, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of the covered recipient with respect to an administrative proceeding, legal defense, prosecution, or settlement or judgment of a civil or criminal action and arbitration
  - A payment or transfer of value to a covered recipient if the payment or transfer of value is made solely in the context of a personal, non-business-related relationship
Exclusions from Reporting

42 C.F.R. § 403.904(g), (h)

- The following types of payments or other transfers of value are excluded from the reporting requirements (cont’d):
  - Buffet meals, snacks, soft drinks, or coffee made generally available to all participants of a **large-scale conference or similar large-scale event**
  - Payments or other transfers of value provided as *compensation for speaking at a continuing education program*, so long as:
    - The event at which the covered recipient is speaking meets the accreditation or certification requirements and standards for continuing education of one of several listed organizations (*e.g.*, Accreditation Council for Continuing Medical Education; American Medical Association);
    - The manufacturer does not pay the covered recipient directly; and
    - The manufacturer does not select the covered recipient speaker or provide the third party (such as a continuing education vendor) with a distinct, identifiable set of individuals to be considered as speakers for the continuing education program
Reports Related to Research

- There are many special rules regarding reports related to research, which we will not cover in this presentation today due to the length of the material.
Review and Correction

**42 C.F.R. § 403.908(g)**

- Covered recipients will have an opportunity to review data reported on them at least 45 days *before* CMS makes the data publicly available.

- CMS will notify covered recipients when information is ready for review.

- Covered recipients may either certify that they agree with the information or formally initiate a dispute with the manufacturer or GPO that reported the data.

- If a dispute is initiated, the manufacturer/GPO and the recipient will attempt to resolve the dispute (CMS will not step in to mediate the dispute).

- If the dispute is not resolved before CMS must publicly post the data, CMS will post the data as reported by the manufacturer/GPO and mark it “disputed”. Covered recipients will have up to two years to seek correction challenge the accuracy of reported information.
References

• King and Spalding Webinar - The Sun is Rising: What You Need to Know About the Final Rule to Implement the Physician Payments Sunshine Act, February 19, 2013
• AMA Physician Payments Sunshine Act – Overview & Key Provisions
• The Advisory Board Company, The Impact of the Sunshine Act on Physician Practices
• King & Spalding Client Alert, February 4, 2013, CMS Issues Final Rule to Implement Physician Payments Sunshine Act
• Alston & Bird, Health Care Advisory, February 5, 2013, Physician Payments Sunshine Act Final Rule
• 42 CFR Parts 402 and 403, Medicare, Medicaid, Children’s Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests; Final Rule