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# Questions and Answers On the Physician Payment “Sunshine” Act Proposed Rule

January 25, 2012

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# Agenda

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- Overview of the Physician Payment Sunshine Act Proposed Rule
  - Purposes of the Sunshine Act
  - Key Proposals Under the Proposed Rule
- Questions & Answers

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## Background: Purposes of the Sunshine Act

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- Government concern regarding conflicts of interest and inappropriate influence
- Disclosure is intended to:
  - Make certain payments transparent
  - Increase public awareness
  - Discourage inappropriate conflicts of interest
- Through its Proposed Rule, the Centers for Medicare and Medicaid Services (“CMS”) seeks comments on how best to balance the need to discourage inappropriate conflicts of interest without dissuading the development of beneficial arrangements

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## Background: Issuance of the Proposed Rule

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- On December 19, 2011, following a period of significant pressure from members of Congress, CMS issued its long-awaited Proposed Rule, implementing the Physician Payment Sunshine Act (the “Act”)
- The Proposed Rule includes numerous proposals that impact manufacturers, including:
  - Delayed Reporting
  - Definitions of Applicable Manufacturer, Common Ownership, and Covered Recipients
  - Reporting Educational Materials
  - Reporting Food and Beverage
  - Reporting Research
  - Reporting Compensation for Speaking Arrangements
  - Reporting Indirect Payments Through a Third-Party
  - Opportunity to Amend and Disputed Reports
  - Attestation
  - Penalties and Relation to Fraud and Abuse Laws
- CMS is accepting comments on the Proposed Rule until February 17, 2012

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## Background: Delayed Data Tracking

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- Due to the timing of the Proposed Rule, CMS “will not require applicable manufacturers . . . to begin collecting the required data until after the publication of the final rule”
  - The Agency is seeking comments from stakeholders as to the feasibility of collecting the required data for a portion of calendar year 2012 and reporting this information to CMS by the initial statutory deadline of March 31, 2013
  - The Agency proposes a 90-day “preparation period,” following the issuance of the final rule to afford manufacturers additional time to comply with the Act’s data collection requirements
  - CMS also seeks input on the specific operational challenges manufacturers may face in establishing data collection and reporting mechanisms
- CMS states that it recognizes that some manufacturers may begin to collect data voluntarily in advance of the effective date of the final rule

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# Background: Definition of Applicable Manufacturer

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- CMS seeks to expand the reach of the reporting obligations to include any manufacturer that “sells or distributes” a covered product in the U.S., regardless of where the entity is located or incorporated
  - Physical location or country of incorporation is not relevant
- Under the Proposed Rule, any manufacturer that meets the definition of applicable manufacturer by selling or distributing in the U.S. at least one covered product is considered an applicable manufacturer, even though it may also manufacture non-covered products
  - Requires manufacturers to report all payments or transfers of value made to a covered recipient regardless of whether the particular payment or other transfer of value is associated with a covered product
- Covered Recipients themselves have no reporting obligations under the Act

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## Background: Definition of Common Ownership

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- CMS is considering two alternative definitions of the term “common ownership” as it is used in the definition of “applicable manufacturer”:
  - Broader Proposal: When the same individual or entity, directly or indirectly, owns any portion of two or more entities
  - Slightly Narrower Proposal: When the same individual or entity, directly or indirectly, owns 5% or more of two or more entities
- Depending on the relationships among affiliated entities, a manufacturer may be required to submit separate annual reports for each affiliated entity or may be permitted to submit combined reports for entities under common ownership
- These proposals have potentially significant implications for entities that have operations, affiliates, or partners outside of the U.S.

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## Background: Definition of Covered Recipient

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- Under the Act, the term “covered recipient” is defined to include physicians and teaching hospitals
- Proposed Rule definition for “Covered Recipient”:
  - **Physician** - CMS proposes to use the statutory definition for “physician,” which is defined to include U.S.-licensed physicians, doctors of osteopathy, dentists, podiatrists, optometrists, and licensed chiropractors
    - The definition of “physician” excludes those physicians who are employees of the manufacturer
  - **Teaching Hospital** - CMS proposes to define “teaching hospitals” as those institutions that receive Medicare graduate medical education payments
    - CMS will annually publish an exhaustive list of such institutions on the Agency’s website

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## Background: Reporting Educational Materials

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- The Act excludes only educational materials “that directly benefit patients or are intended for patient use”
- CMS proposes to limit this exception to “materials (such as pamphlets),” whether written or electronic, that directly benefit patients and are intended for patient use
  - CMS clarified that this exception does not include “services or other items”
  - CMS is seeking comments on whether certain materials provided to covered recipients that do not actually go to patients, such as medical textbooks, should be included under this exception

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## Background: Reporting Food and Beverage

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- CMS proposes that in instances where a manufacturer provides a meal in a group setting (e.g., buffet-style food in a physician's office), the manufacturer should report the cost per covered recipient receiving the meal, even if the covered recipient is not actually partaking in the meal
  - Here, CMS proposes to impute the cost of the meal to the covered recipient
  - This provision could have broader implications
  - CMS is soliciting comments on whether this approach is feasible, or whether an alternative approach should be adopted
- CMS proposes to exempt from the reporting requirements manufacturer offers of buffet meals, snacks or coffee at booths at conferences or other similar events

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# Background: Reporting Research

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- The definition of “research”:
  - CMS seeks comment on whether its proposed definition of “research” or another payment category would cover payments or other transfers of value to covered recipients for research-related activities (e.g., post-marketing research, studies without research protocols, or research or studies not conducted pursuant to a written contract)
- Two proposals for delays publication:
  - Proposal One: CMS proposes that research payments must be timely reported as with all other payments covered by the Act, but that CMS will delay publication of research payments to covered recipients for services in connection with research on, or development of new covered products, as well as new applications of existing covered products
  - Proposal Two: CMS proposes limiting delayed publication for those payments in connection with clinical investigations for new covered products only
- CMS also proposes to require:
  - Classification of research payments as direct or indirect
  - Dual reporting for research payments to teaching hospitals
  - Lump sum reporting for indirect research payments

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## Background: Reporting Compensation for Speaking Arrangements

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- The Act requires manufacturers to report direct compensation to physicians serving as speakers or faculty for a “medical education program”
- CMS proposes to broaden this payment category to encompass all instances where the applicable manufacturer may pay a covered physician to serve as a speaker (e.g., dinner programs)
- CMS seeks comments on whether a separate payment category should be created to capture speaking arrangements that fall outside the context of medical education programs

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## Background: Reporting Indirect Payments

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- The Act excludes indirect payments made by an applicable manufacturer to a covered recipient through a third party when the applicable manufacturer is unaware of the covered recipient's identity
- CMS proposes to interpret the awareness standard as when an applicable manufacturer has “actual knowledge of, or acts in deliberate ignorance or reckless disregard of, the identity of the covered recipient”
  - CMS justifies this standard as consistent with the knowledge standard under the federal False Claims Act and other fraud and abuse laws

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# Background: Opportunity to Amend and Disputed Reports

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- CMS proposes to limit revisions to submitted reports to a 45-day review period
  - Parties would not again have the opportunity to amend previously reported information until the data is refreshed for the following reporting year
- CMS encourages applicable manufacturers, to provide each covered recipient and physician owner or investor with pre-submission notice of the information contained in draft reports, although CMS does not propose to make this a requirement
- For disputed reports, CMS has proposed requiring at least one entity involved in a dispute to report to CMS that a reporting dispute exists and the results of that dispute at the end of the 45-day review period
  - In cases where a dispute is not resolved among the parties, CMS intends to publish both submissions but will use the covered recipient's data for tabulation of summary figures

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## Background: **Attestation**

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- CMS proposes to require an authorized representative (*i.e.*, CEO, CFO, or CCO) from each applicable manufacturer to submit a signed attestation certifying the truth, correctness, and completeness of the data submitted under each annual report
  - “Best of his or her knowledge and belief” standard
- CMS is also considering a proposal to require applicable manufacturers to submit an attestation even where there are no reportable payments or ownership or investment interests during the previous calendar year

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# Background: Penalties and Relation to Fraud and Abuse Laws

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- **Penalties**

- The Act provides for civil monetary penalties ranging from at least \$1,000 to not more than \$10,000 per payment for failure to report on a timely basis
- For knowingly failing to submit the required information in a timely manner, manufacturers may be subject to penalties of at least \$10,000 but no more than \$100,000 per payment
- Secretary of HHS, CMS, or OIG may audit applicable manufacturers for their compliance with the submission requirements of the Act and regulations

- **Relation to Fraud and Abuse Laws**

- CMS made clear that compliance with the Act and any implementing regulations does not exempt manufacturers from potential liability associated with any payments made to physicians or teaching hospitals under the health care fraud and abuse laws (*e.g.*, the federal Anti-Kickback Statute and the federal Civil False Claims Act)

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## **Q & A: Definition of Applicable Manufacturer**

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**Does the Act apply to start-up and / or biotech companies that do not have an approved product in the U.S.?**

**If there is reimbursement by the federal health care programs for any of the procedures involved in a clinical trial conducted by the start-up/biotech company, does that change the answer?**

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## **Q & A: Definition of Applicable Manufacturer**

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**If a manufacturer is headquartered in the U.S., but does not sell or distribute any products in the U.S., is the manufacturer an “applicable manufacturer” for purposes of the Act and required to report?**

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## **Q & A: Definition of Applicable Manufacturer**

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**Are applicable manufacturers required to report payments or transfers of value made by the manufacturer's foreign affiliates to U.S. physicians?**

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## **Q & A: Definition of Covered Recipient**

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**Are applicable manufacturers required to report payments or transfers of value made to U.S. physicians while the physician is outside of the U.S.?**

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## **Q & A: Payments to Employees of Covered Recipients**

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**Are applicable manufacturers required to report payments or transfers of value, such as meals, provided to non-covered recipient staff members of a physician's office or hospital?**

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## **Q &A: Educational Items**

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**Are applicable manufacturers required to report educational items, such as posters and anatomical models, that are provided to a covered recipient and not passed on to a patient?**

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## **Q & A: Charity Care Exception**

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**If an applicable manufacturer donates equipment to a non-profit hospital, is the donation reportable?**

**Are contributions of products to charitable, non-profit organizations reportable when the recipient organization acts as an intermediary between the donating manufacturer and the covered recipient(s)?**

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## **Q & A: De Minimis Exception**

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**How should an applicable manufacturer treat reprints of journal articles distributed to physicians for purposes of Sunshine Act reporting?**

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## **Q &A: Food and Beverage**

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**How should an applicable manufacturer track payments for food and beverages in the context of group meals where the manufacturer is unable to determine who participates in the meal?**

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## **Q &A: Food and Beverage**

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**Are applicable manufacturers required to report the provision of refreshments, such as coffee and donuts, given to covered recipients at conferences?**

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## Q & A: Research Payments

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**Are applicable manufacturers required to report payments or transfers of value made on their behalf by contract research organizations (“CROs”) to covered recipients on behalf of the manufacturer?**

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## **Q & A: Research Payments**

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**How should an applicable manufacturer report research payments made indirectly to a covered recipient through a third-party, such as a private clinic or university?**

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## **Q & A: Research Payments**

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**During the publication delay period, are applicable manufacturers required to report research payments that are subject to the delay?**

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## **Q & A: Report Format**

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**Can an applicable manufacturer report payments using the physician's state license number, if the manufacturer does not have the physician's national provider identifier ("NPI") number?**

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## Q & A: Report Format

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**How should an applicable manufacturer report a payment to a physician-consultant for services that are performed multiple times over the course of a year?**

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## **Q & A: Indirect Payments**

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**Are applicable manufacturers required to report payments or transfers of value made to a covered recipient through a third-party patient advocacy organization?**

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## Q & A: Executive Liability

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**Could the applicable manufacturer's authorized representative who certifies the company's Sunshine report be subject to personal liability for any errors or omissions in the report?**

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## Contact Information

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