



# Physician Payments Sunshine Act Proposed Rule Published

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## Physician Payments Sunshine Act Proposed Rule Published

On Dec. 19, 2011, the Centers for Medicare & Medicaid Services (CMS) published proposed regulations pursuant to §6002 of the Patient Protection and Affordable Care Act, commonly known as the Physician Payments Sunshine Act (Sunshine Act). The proposed rule provides details on the process and requirements for the reporting of payments made by pharmaceutical, biological, medical device and medical supply manufacturers to physicians and teaching hospitals, as well as the reporting of financial relationships between physicians, manufacturers and group purchasing organizations (GPOs).

The proposed rule includes an announcement that applicable manufacturers and GPOs will not be required to collect payment information and information regarding financial relationships beginning on Jan. 1, 2012. Rather, such collection will be required only after CMS publishes a final rule. CMS is seeking comments on how much time reporting entities will need, following publication of the final rule, to begin complying with the data collection requirements of the Sunshine Act. Comments are due by 5 pm EST on Feb. 17, 2012.

In the proposed rule, CMS addresses a number of the issues that were of concern to stakeholders following the promulgation of the Sunshine Act. Specifically, in the regulation, CMS proposes to:

1. Maintain as two separate reporting requirements the obligation of applicable manufacturers to report transfers of value to covered recipients and the obligation of applicable manufacturers and GPOs to identify physician investors and to report transfers of value to such individuals, even though there may be some duplication of information in the reports.
2. Allow applicable manufacturers to provide a description of the assumptions used to categorize payments (travel, meals, speakers' fees, etc.) in conjunction with the submission of their annual reports.
3. Define GPOs to include physician-owned distributorships (PODs) for the purpose of the requirement to identify physician investors and report certain payments to these individuals.
4. Exempt from disclosure under the Freedom of Information Act (FOIA) payments related to research or development of new devices, drugs, biologicals or medical supplies (and new applications of existing products) where the payments are subject to delayed publication due to the need to maintain the confidentiality of proprietary information.
5. Impose civil monetary penalties upon applicable manufacturers not simply for failing to report payments in a timely manner but also for failing to furnish information that is accurate and complete.

In promulgating the proposed rule, CMS took into account stakeholder feedback from the “Open Door Forum” it held on Mar. 24, 2011, as well as guidance obtained through consultation with the Office of the Inspector General of the Department of Health and Human Services. The key provisions of the proposed regulations are as follows:

## 1. STATUTORY INTERPRETATIONS

Generally, CMS is proposing to retain the statutory definitions set forth in the Sunshine Act without significant expansion.

- **Applicable Manufacturer.** CMS proposes to define “Applicable Manufacturer” as an entity (1) that is engaged in the production, preparation, propagation, compounding or conversion of a covered drug, device, biological or medical supply for sale or distribution in the United States, or in a territory, possession or commonwealth of the United States; or (2) under common ownership with an entity described above, 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 drug, device, biological or medical supply for sale or distribution in the United States, or in a territory, possession or commonwealth of the United States. This definition incorporates foreign entities doing business in the United States, as well as entities that hold FDA approval, licensure or clearance for a product, even if they contract out the actual manufacturing to another entity. CMS seeks comments on the definition of “common ownership,” specifically regarding whether to adopt an ownership threshold of at least 5 percent.
- **Covered Drugs, Devices, Biologicals, or Medical Supplies.** The Sunshine Act defines “covered drug, device, biological, or medical supply” as any drug, biological product, device or medical supply for which payment is “available” under Medicare, Medicaid or the Children’s Health Insurance Program (CHIP). CMS proposes that drugs, devices, biologicals or medical supplies included in a composite payment rate, as well as those reimbursed separately, would be considered to be “covered” for the purpose of classifying applicable manufacturers. CMS further proposes to exclude OTC drugs and biologicals, and devices or medical supplies that do not require premarket approval or notification to the FDA (this would include many Class I and Class II devices). However, if an entity manufactures any one product that is considered “covered,” it would be subject to reporting requirements and any transfer of value by the manufacturer to a covered recipient would need to be reported, regardless of whether the transfer of value is associated with a covered item.
- **Covered Recipients.** Applicable manufacturers are required to disclose certain payments and transfers of value made to covered recipients, or to entities or individuals at the request of, or designated on behalf of, a covered

recipient. The Sunshine Act defines a “covered recipient” as a physician, other than a physician who is an employee of an applicable manufacturer, or a teaching hospital. The Sunshine Act adopts a definition of “physician” that includes doctors of medicine and osteopathy, dentists, podiatrists, optometrists and licensed chiropractors. Certain stakeholders suggested that the definition of physician be expanded to include Ph.D. researchers, but the statutory language left little room for CMS to expand the definition in that manner. CMS proposes to define a “teaching hospital” as any institution that receives direct or indirect graduate medical education payments.

- **Payments or Other Transfers of Value.** CMS is proposing to limit the forms of payment to those outlined in the Sunshine Act. CMS seeks comment on whether additional categories of payment are necessary or would be helpful.

## 2. REPORTS OF PAYMENTS BY APPLICABLE MANUFACTURERS

The two categories of information that must be reported under the Sunshine Act are: (1) reports from applicable manufacturers on payments or other transfers of value to covered recipients; and (2) reports from applicable manufacturers and applicable GPOs concerning ownership and investment interests of physicians and their immediate family members, as well as information on any payments or other transfers of value provided to such physician owners or investors. While CMS admits that there is some overlap between these two submissions, CMS proposes that the information be reported separately to ensure that relevant reporting obligations of applicable manufacturers and applicable GPOs are clearly distinguished. CMS is seeking comments on this general approach.

CMS provides details regarding certain categories of information that are required to be reported for each payment or transfer of value provided to a covered recipient. In addition to the amount of payment, these include:

- **Name.** The first and last name and middle initial of each physician covered recipient must be included in the report.
- **Business address.** The full street address of covered recipients, including the address included in the CMS-published list of hospitals for each teaching hospital and the primary practice location for each physician, should be reported.
- **Specialty and National Provider Identifier (NPI).** Applicable manufacturers are required to report specialty and NPI for physician covered recipients. In circumstances in which a physician has multiple specialties, only a single specialty should be reported for each physician covered recipient. CMS has not addressed the fact that certain physicians do not have an NPI, but given the ease of procuring one, this should not be a significant issue for reporting entities.

- **Date of payment.** CMS proposes to grant applicable manufacturers discretion to determine what date(s) to report in the event that a payment or transfer of value occurs over a period of time.
- **Associated covered drug, device, biologic or medical supply.** In circumstances in which payment is linked to a drug, device, biologic or medical supply, the applicable manufacturer should provide the name under which the product is marketed.
- **Form of payment and nature of payment.** CMS proposes that the form of payment and nature of payment should be defined as distinct from one another and that a manufacturer should report only a single category for each to avoid confusion regarding a payment that may fall into multiple categories. CMS proposes that when selecting a payment classification, manufacturers should make a reasonable determination about the nature of the payment. CMS is seeking comments on the proposal to require reporting under only one form of payment and nature of payment category.

### 3. NATURE OF PAYMENT: CHARITABLE CONTRIBUTIONS, MEALS, RESEARCH AND SPEAKING ENGAGEMENTS

The Sunshine Act lists the categories, i.e. the “nature of payment” or other transfer of value, which applicable manufacturers must use to describe each payment. To ensure consistency in reporting and selection of categories, CMS will allow applicable manufacturers to submit a description of the assumptions used when categorizing the nature of payments with their annual reports. CMS also provides an explanation regarding certain categories to provide additional context:

- **Charitable Contributions.** Charitable contributions made to, at the request of or on behalf of covered recipients by applicable manufacturers must be reported. A charitable contribution is any payment or transfer of value, not more specifically described by one of the other categories, made to an organization with tax-exempt status under the Internal Revenue Code.
- **Food and Beverage.** Above the \$10 statutorily required minimum threshold, CMS proposes that the value of any food or beverage items provided to a covered recipient should be reported. CMS acknowledges that in certain settings, such as a group meal in a group setting, it may be difficult to ascertain which covered recipients are partaking in food and beverage being offered; however, CMS proposes that in such circumstances, applicable manufacturers should report the cost per covered recipient receiving the meal, even if such recipient does not partake. CMS is seeking comment on whether there is a more equitable way to report such payments or transfers of value.
- **Research.** CMS proposes to limit reporting for research payments to bona fide research activities, including clinical trials, which are subject to both a

written agreement or contract and a research protocol. CMS proposes to use this method to distinguish the research payment category from other categories that may overlap. CMS requests comments on whether this proposed method is viable and not overly burdensome. Further, CMS proposes to separate research payments based on whether the payment went directly or indirectly to the covered recipients i.e., payments made directly to a covered recipient or paid indirectly through a hospital to a principal investigator. CMS acknowledges that it may be difficult to determine how research payments are distributed to a physician serving as a principal investigator in an indirect payment scenario. CMS proposes that for both direct and indirect research payments, applicable manufacturers must report the entire payment amount for each research payment paid to the covered recipient or research institution, rather than the specific amount provided to the covered recipient. CMS proposes that it would report the payment amount on the public website separately and, if a physician is paid indirectly, the total payment amount to the institution would be reported under the physician's NPI, but the amount would be listed separately from other payments or transfers of value to the physician. CMS also seeks comments about which existing payment category would apply to other types of research, such as postmarket research, which are not conducted pursuant to a written contract and research protocol.

- ***Speaking Engagements.*** CMS proposes to interpret this category broadly to encompass all instances in which applicable manufacturers pay physicians to serve as speakers, and not just situations involving “medical education programs.” Alternatively, CMS is considering adding another payment category to describe circumstances in which a covered recipient provides speaking services that are outside of medical education programs. CMS is seeking comments on this approach.

#### **4. REPORTS OF PHYSICIAN OWNERSHIP AND INVESTMENT INTERESTS**

The Sunshine Act requires applicable manufacturers and GPOs to report ownership and investment interests held by a physician or a physician's immediate family members in such entities.

- ***PODs Included in GPO Definition.*** The Sunshine Act defines a GPO as a “group purchasing organization (as defined by the Secretary) that purchases, arranges for or negotiates the purchase of a covered drug, device, biological, or medical supply, which is operating in the United States, or in a territory, commonwealth or possession of the United States.” CMS proposes that the definition of GPO include traditional GPOs that negotiate contracts for their members, as well as entities that purchase products for resale or distribution to third parties. Thus, physician-owned distributors (PODs) are included in CMS' definition of GPOs and would be subject to the reporting obligations if the rule is finalized as proposed.

- **Supply and Routine Device Distributors.** CMS is seeking comment on whether its proposed limitation on covered drugs, devices, biologicals and medical supplies should apply with regard to the requirement that GPOs report ownership and investment interests by physicians. As discussed above, CMS has proposed that only those drugs and biologicals that require a prescription, and only those devices that require premarket approval by or notification to the FDA, are considered “covered.” If CMS does not apply this limitation within the definition of GPOs, GPOs, including PODs that arrange for the purchase of routine devices and medical supplies will have reporting obligations under the Sunshine Act with regard to over-the-counter drugs and a broader array of devices.
- **Attestation Requirement.** In the proposed rule, CMS added the requirement that each report and any subsequent corrections to a filed report must include a certification by the chief executive officer, chief financial officer or chief compliance officer of the applicable manufacturer or GPO that the information is true, correct and complete to the best of his or her knowledge and belief. Although CMS does not address the issue, the inclusion of a certification requirement is significant as it exposes both the applicable manufacturer or GPO and its authorized representatives to potential liability under the laws prohibiting the submission of false statements to the federal government and other anti-fraud laws.
- **Ownership and Investment Reporting.** Ownership or investment interests include direct or indirect ownership through debt, equity or other means. Ownership and investment interests would not include an interest in a publicly traded security or mutual fund. CMS proposes that applicable manufacturers and GPOs report the name, address, NPI and specialty of the physician owner or investor. In addition, the reporting entity must report any payment or transfer of value provided to a physician owner or investor. To avoid the double-counting of payments, CMS proposes that where a physician is the recipient of a payment or transfer of value from an applicable manufacturer in which he or she has an ownership or investment interest, the applicable manufacturer can disclose the financial relationship within the file submitted with its reporting of transfers of value.

## 5. REPORTING MECHANICS

The Sunshine Act required manufacturers to begin collecting the reportable information beginning Jan. 1, 2012. However, CMS has stated that this requirement will not be enforced until CMS has released the final rule, thus delaying the data collection requirement by at least several months. CMS is considering providing manufacturers 90 days after publication of the final rule to prepare to collect the required data, and to require that data collection must begin after the 90th day. CMS notes that manufacturers may begin collecting this information voluntarily prior to the foregoing deadline. CMS is seeking comment on both the benefits and burdens of this approach.

- **Submission and Correction.** The Sunshine Act requires CMS to give manufacturers, GPOs, covered recipients and physician owners or investors the opportunity to review the data submitted for a period of at least 45 days prior to the data being made available to the public. After the submission due date has passed, CMS will aggregate the data and notify all applicable manufacturers, GPOs, covered recipients and physician owners or investors about the review process, which will include the specific instructions for performing this review. CMS is proposing several plans for notifying covered recipients and physician owners or investors. For instance, CMS is proposing that applicable manufacturers and GPOs collect and report to CMS the contact information and preferred method of contact for each covered recipient or physician owner or investor.
  
- **Public Availability.** CMS is required by Sept. 30, 2013 to publish on a publicly available website data reported by applicable manufacturers and GPOs for calendar year 2012. Each year thereafter, CMS must publish by June 30 data reported for the previous calendar year. The website is required to be searchable, understandable, downloadable and easily aggregated on various levels. CMS is seeking comments on how to structure the website. CMS proposes that the following information would be included on the public website:
  - Applicable manufacturer’s name;
  - Covered recipient’s name, specialty and business street address;
  - Amount of payment or other transfer of value in U.S. dollars;
  - Date, form and nature of the payment or other transfer of value;
  - Name of the covered drug, device, biological or medical supply, if applicable; and
  - Name of the entity that received the payment or transfer of value if not provided directly to the covered recipient.
  
- **Reporting of Financial Relationships.** Reporting obligations for physician ownership and investment interests would be similar, except that rather than require reporting entities to furnish information regarding the amount, date, form and nature of the payment, CMS proposes to require reporting of the following:
  - Whether the interest is held directly by the physician or by the physician’s family member;
  - The dollar amount invested;
  - Value and terms of each ownership or investment interest; and
  - Any payment or other transfer of value provided to the physician owner.
  
- **Delayed Publication.** The Sunshine Act provides for delayed publication of payments or other transfers of value from applicable manufacturers to covered recipients made pursuant to bona fide product research, development agreements or clinical investigations. The purpose of the

delayed publication is to maintain confidentiality for proprietary information relating to the development of new drugs, devices, biologicals and medical supplies.

CMS proposes that applicable manufacturers should indicate on their annual reports whether or not a payment or other transfer of value should be granted a delay in publication on the public website. Further, CMS proposes that following FDA licensure, approval or clearance, applicable manufacturers must indicate in their next annual submission that the payment should be published in the current reporting cycle. However, the delay will prevent publication for only a maximum period of four years. Thus, if a report date includes a date of payment four years prior to the current date, the payment or other transfer of value will automatically be published on the CMS website regardless of whether the applicable manufacturer indicates that publication of payment should be delayed.

CMS also proposes that delayed publication should apply to payments to covered recipients for services in connection with research on, or development of, new drugs, devices biologicals or medical supplies, as well as new applications of existing products. Conversely, CMS proposes to extend delayed publication only to clinical investigations for new drugs, devices, biologicals or medical supplies and not new applications of such products. CMS seeks comment on these proposals and whether there are better ways to distinguish among these categories for purposes of delayed publication.

CMS has also proposed that information reported by applicable manufacturers that is subject to delayed publication will be considered confidential and will not be subject to disclosure under FOIA or other similar federal, state or local laws until after the date on which the information is made available to the public via publication on the CMS website.

- **Reporting Templates.** In addition, CMS has included in the proposed rule two reporting templates, which it indicates are for illustrative purposes and are subject to change. Each template consists of a series of boxes labeled with the information required under the Sunshine Act and proposed rule, such as the name of the reporting entity, the name of the recipient and certain information about the form of payment, with respect to reporting certain payments or transfers of value, or the value of interest held, with respect to reporting physician ownership or investment interests.

## 6. PENALTIES

The Sunshine Act authorizes the imposition of civil monetary penalties (CMPs) for failure to report the required information on a timely basis in accordance with CMS' regulations. CMS proposes that if an applicable manufacturer or GPO fails to submit information required under the Sunshine Act, the entity may be subject to a CMP of

at least \$1,000, but no more than \$10,000, for each payment or other transfer of value, or ownership or investment interest not reported. The maximum CMP with respect to each annual submission for failure to report is \$150,000. For knowing failure to submit required information in a timely manner, CMPs will range between \$10,000 and \$100,000 for each payment or transfer of value, or ownership or investment interest, that is not reported. The maximum CMP for knowing failure to report timely, accurate and complete information is \$1 million for each annual submission. Importantly, CMS has interpreted the requirement to report information under the Sunshine Act as a requirement to submit information that is accurate and complete — therefore a CMP may be imposed for failure to report information in a timely, accurate and complete manner.

In determining the amount of a CMP, CMS proposes that it will weigh certain factors, including: (1) the length of time of the failure to report; (2) the amount of payment or other transfer of value, ownership or investment interest that was not reported; (3) the level of culpability; (4) the nature and amount of information reported in error; and (5) the degree of diligence exercised in correcting any information reported in error. CMS is seeking comments on its proposals related to penalties.

## **7. ANNUAL REPORTS**

Under the Sunshine Act, CMS is required to submit annual reports to Congress and the states. The report to Congress is due annually on April 1st beginning in 2013 and shall include aggregate information on each applicable manufacturer and GPO for the preceding calendar year, as well as any enforcement action taken and penalties paid. Since CMS will not receive data for the prior year until the 90th day of each year, the data submitted that year will not be ready for the April 1st report. Therefore, CMS has proposed that it will report to Congress information submitted by applicable manufacturers and GPOs during the preceding year. The reports that CMS will provide to the states will include a summary for the data submitted regarding covered recipients and physician owners or investors in each state. Since the reports to states are due later in the year than the report to Congress, CMS proposes that reports to states would include data collected during the previous calendar year that was submitted in the current year.

## **8. STATE LAW PREEMPTION**

Several states have enacted legislation creating compliance and disclosure requirements for pharmaceutical and medical device manufacturers and healthcare professionals. Similar to the Sunshine Act, such legislation is intended to bring transparency to healthcare providers' relationships with industry. Certain states, such as Colorado and Maine, have indicated that they intend to defer to the federal government in this area. However, recently enacted laws in other states, such as Connecticut and Vermont, signal that for the purposes of establishing and enforcing transparency and disclosure laws, states are not exclusively deferring to the federal government.

The Sunshine Act preempts any state or local laws requiring reporting, in any format, of the same type of information concerning payment or other transfers of value made by applicable manufacturers to covered recipients. In general, no state or local government may require the separate reporting of any information regarding a payment or other transfer of value that is required to be reported under the Sunshine Act. However, the Sunshine Act does not preempt (i) any statute or regulation of a state that requires the reporting of information by any person or entity other than an applicable manufacturer or the reporting of information to a person or entity other than a covered recipient; and (ii) the reporting of information not of the type required to be reported under the Sunshine Act.

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McGuireWoods is available to assist clients with drafting and submitting comments to CMS regarding the proposed rule. McGuireWoods advises medical device and pharmaceutical manufacturers on compliance with state marketing and transparency laws and on preparing for compliance with the Sunshine Act. If you would like to discuss your company's compliance with these statutes and regulations, please contact Kim Kannensohn at 312.750.8649, Krist Werling at 312.750.8695 or Holly Carnell at 312.849.3687.