



# Client Alert



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## CMS Issues Proposed Physician Payments Sunshine Act Regulations

On December 14, 2011, the Centers for Medicare & Medicaid Services (CMS) released its long-awaited proposed rule implementing the Physician Payments Sunshine Act (the Sunshine Act) contained in Section 6002 of the Patient Protection and Affordable Care Act. Under the Sunshine Act, two types of reports must be submitted to CMS: (1) information about certain payments or transfers of value from applicable manufacturers to covered recipients; and (2) information regarding physician ownership and investment interests in applicable manufacturers and applicable group purchasing organizations (GPOs). The proposed rule provides some additional clarity regarding these reporting obligations.

CMS is accepting comments on the proposed rule until February 17, 2012, and has indicated that it will respond to them in a final rule to be published sometime in 2012. This client alert summarizes significant aspects of the proposed rule.

### Proposed Delay

The most significant feature of the proposed rule is CMS's proposal to delay compliance with the Sunshine Act requirements until CMS releases a final rule. Under the Sunshine Act, data collection was set to begin on January 1, 2012. The proposed rule states, "a final rule will not be published in time for manufacturers and GPOs to begin collecting the information required [by the Sunshine Act] on January 1, 2012, as indicated in the statute." While manufacturers and GPOs will not be required to submit information gathered in the period between January 1, 2012, and CMS's publication of final regulations, it would still be beneficial for companies to take advantage of the delay by using the time to test implementation of new Sunshine Act policies and data collection systems. Manufacturers and GPOs who are not ready to begin collecting payment data should proceed with setting up the necessary systems before the final rule's publication.

### Clarification of Key Definitions

- **Applicable Manufacturer**  
The Sunshine Act applies to manufacturers of drugs, devices, biologicals, or medical supplies that are covered under Medicare, Medicaid, or the Children's Health Insurance Program (CHIP). The proposed rule further defines "applicable manufacturer" as an entity that is: (1) engaged

in the production, preparation, propagation, compounding or conversion of a covered drug, device, biological, or medical supply for sale or distribution in the U.S. (or U.S. territory); or (2) under common ownership with such an entity and that provides support to such entity with respect to the activities described above, or with respect to marketing, promotion, sale or distribution of a covered drug, device, biological or medical supply for sale or distribution in the U.S. CMS proposes that, if a manufacturer meets either of these definitions for at least one covered product, "all payments or transfers of value made by an applicable manufacturer to a covered recipient must be reported ... regardless of whether the particular payment or other transfer of value is associated" with the covered product. That is, once an entity meets the definition of applicable manufacturer, every single payment must be reported, even when the payments relate to non-covered products. CMS also proposes that common ownership exists where the same entity or entities directly, or indirectly, own any portion of two or more entities. Notably, CMS requests comment on an alternative definition of common ownership, such as a minimum 5 percent ownership threshold.

- **Covered Drug, Device, Biological, or Medical Supply**

A "covered drug, device, biological, or medical supply" is defined in the proposed rule as any drug, device, biological, or medical supply for which payment is available (either separately or as part of a composite payment rate) under Medicare, Medicaid, or the CHIP. The proposed rule interprets "covered drug, device, biological, or medical supply" somewhat more narrowly than the statutory definition. Specifically, CMS proposes to limit the definition of drugs and biologicals to those that require a prescription, thus excluding over-the-counter products. Further, the proposed rule limits the definition of devices to those that either require premarket approval by the Food and Drug Administration (FDA), or require premarket notification (i.e., 510(k) clearance) to the FDA, thus excluding most Class I devices and a small number of Class II devices, which are exempt from premarket notification requirements (e.g., tongue depressors and liquid crystal forehead temperature strips).

In one respect, however, CMS interprets the definition of a covered drug, device, biological or medical supply more broadly: the inclusion of products covered by a composite rate payment. The Sunshine Act simply stated that a product would be covered if payment is "available" under Medicare, Medicaid or CHIP. For products with specific codes and separate reimbursement, payment availability is clear. However, many products are indirectly paid for through procedure codes and composite rate systems such as the Medicare inpatient prospective payment system. CMS's proposed rule removes any ambiguity and broadly interprets the definition to include such indirectly-reimbursed products.

- **Covered Recipient**

The Sunshine Act defines "covered recipients" as physicians and teaching hospitals. With respect to physicians, the proposed rule notes that the Sunshine Act defines "physician" as that term is used in the Social Security Act (SSA), which encompasses "doctors of medicine and osteopathy, dentists, podiatrists, optometrists and licensed chiropractors." As to "teaching hospitals," the proposed rule notes

that “teaching hospital” is not defined in the Sunshine Act and, thus, proposes that “teaching hospital” be defined as an institution that receives Medicare graduate medical education (GME) payments. CMS will publish a specific list of institutions that qualify as teaching hospitals under this definition.

## **Clarification of Information that Must be Reported for Payments or Transfers of Value**

The proposed rule adopts the payment categories set forth in the Sunshine Act and provides clarification regarding what must be reported. For each payment and other transfer of value, CMS is proposing that the following information be required:

- name of applicable manufacturer or applicable GPO;
- covered recipient’s or physician owner’s (as applicable):
  - name;
  - specialty (physician only);
  - business street address (practice location); and
  - NPI (physician only);
- amount of payment or other transfer of value in U.S. dollars;
- date of payment or other transfer of value;
- form of payment or other transfer of value (e.g., cash, in-kind, stock, ownership interest);
- nature of payment or other transfer of value (e.g., consulting fees, entertainment, food, travel, direct research, indirect research, charitable contribution, grant, compensation for serving as a speaker);
- name of the associated covered drug, device, biological, or medical supply, as applicable;
- name of entity that received the payment or other transfer of value, if not provided to the covered recipient directly;
- whether the payment or other transfer of value was provided to a physician holding ownership or investment interests in the applicable manufacturer; and
- whether the payment or other transfer of value should be granted a delay in publication because it was made pursuant to a product research agreement, development agreement, or clinical investigation.

The proposed rule provides the following additional clarifications on the types of information to be collected:

- ***Date of Payment***  
The “date of payment” is defined in the proposed rule as the “date upon which a payment or transfer of value was provided to the covered recipient.”
- ***Associated Product***  
The proposed rule provides that when a payment or transfer is “reasonably associated” with a specific product, that product must be identified in the report.

- **Food and Beverage**

The proposed rule proposes that these transfers be reported by the value of the items. In situations where allocating value to specific covered recipients is difficult, the proposed rule would require that applicable manufacturers report the cost-per-covered-recipient present, even if certain covered recipients did not actually partake. Further, snacks or coffee offered at booths or conferences “where it would be difficult for applicable manufacturers to definitively establish the identities of the individuals who accept the offerings” would be exempt from reporting.

- **Research**

CMS proposes to define “research” payments as limited to “bona fide research activities, including clinical investigations that are subject to both a written agreement or contract . . . [and] a research protocol.” In addition, CMS proposes classifying research payments as “indirect” (when made to a non-covered recipient entity, but ultimately used to pay a physician) or “direct” (when made directly to a teaching hospital or physician). When a payment is made to a teaching hospital for research conducted by a physician, CMS proposes that such payments be reported for both the teaching hospital and the physician.

Note that the Sunshine Act defines what payments and transfers of value are excluded from the reporting requirements. The proposed rule adopts these exclusions generally, and clarifies how CMS proposes to apply certain specific exclusions, such as the educational materials exemption and the in-kind charity items exemption.

## **Reports on Physician Ownership and Investment Interests**

The second type of report required under the Sunshine Act encompasses ownership and investment interests held by physicians or their immediate family members in applicable manufacturers and applicable GPOs, along with payments or transfers of value to such physician owners or investors. CMS proposes to define applicable GPOs as any entity operating in the U.S. or a U.S. territory that purchases, arranges for, or negotiates the purchase of a covered drug, device, biological, or medical supply for a group of individuals or entities (and not solely for use by the entity itself). This definition covers traditional GPOs and entities that purchase drugs or devices for resale or distribution, such as physician-owned distributors.

Ownership or investment interests include direct or indirect ownership through debt, equity, or other means, and include stock, stock options, partnership shares, LLC memberships, loans, and bonds. Manufacturers will be required to submit one report covering payments or transfers of value and another report covering physician ownership and investment interests. However, CMS proposes that if an ownership interest is reported under a report for payment or transfers of value, a manufacturer need not duplicate such disclosure under the physician ownership or investment interest report.

## Report Submission

Prior to submitting reports, CMS recommends that manufacturers and GPOs conduct a “pre-submission review,” whereby any necessary data corrections can be made prior to submission. Specifically, CMS suggests that manufacturers and GPOs provide each covered recipient and/or physician owner or investor with a draft of the information that the manufacturer or GPO plans to report to CMS, prior to submitting the data to CMS.

Applicable manufacturers and GPOs are statutorily required to submit their reports electronically to CMS on March 31, 2013 and on the 90th day of each calendar year thereafter. CMS anticipates that applicable manufacturers and GPOs will still be required to make a report on March 31, 2013, but that the report will include only the partial amount of 2012 that is included within the final rule’s reporting period. Notably, CMS is considering requiring that all manufacturers and GPOs register with the agency, even if they have no information to report. In doing so, the chief executive officer, chief financial officer, or chief compliance officer would be required to submit an attestation that the company had no reportable payments or transfers of value and/or ownership or investment interests during the previous calendar year. The stated purpose of this universal registration and attestation process would be to help CMS better understand the relationships within the industry, as well as encourage manufacturers/GPOs to perform a more thorough evaluation to determine if they have any reportable information.

## Publication of Reports

Under the Sunshine Act, CMS is required to publish reported payment and ownership data for Calendar Year 2012 on a publicly available website by September 30, 2013, and for each year thereafter, by June 30 for data from the preceding calendar year. Furthermore, the Sunshine Act stipulates that the website must be searchable, understandable, downloadable, and easily aggregated on various levels.

In the proposed rule, CMS suggests a data structure that includes all of the content from the submitted reports, excluding the following information:

- whether the payment or other transfer of value was provided to a physician holding ownership or investment interests in the applicable manufacturer; and
- whether the payment or other transfer of value should be granted a delay in publication because it was made pursuant to a product research agreement, development agreement, or clinical investigation.

Note the Sunshine Act also requires that the website include the following:

- any enforcement actions taken under section 1128G of the Social Security Act (“SSA”) for the previous year;
- background or other helpful information on relationships between the drug and device industry and physicians and teaching hospitals; and
- publication of information on payments or other transfers of value that were granted delayed reporting, as required under section 1128G(c)(1)(C) of the SSA.

In addition to this information, CMS intends to clearly state on the website that “disclosure of a payment or other transfer of value on the website does not indicate that the payment was legitimate nor does it necessarily indicate a conflict of interest or any wrongdoing.”

## **Potential Burdens to Manufacturers Complying with the Act**

CMS estimates that approximately 1,150 applicable manufacturers will submit reports, including 150 pharmaceutical companies and 1,000 device and medical supply companies. Further, CMS estimates that, on average, smaller applicable manufacturers will have to dedicate 50 percent of a full time equivalent (FTE) employee, whereas larger applicable manufacturers may have to dedicate 5 to 15 FTE employees to comply with the reporting requirements. CMS estimates the average cost per organization to comply with the Act to be roughly \$170,000 in Year 1.

## **Penalties for Non-compliance**

The Sunshine Act provides for the imposition of civil monetary penalties (“CMPs”) for failures to report the required information in accordance with the law. Failure to submit the required information can result in a CMP of at least \$1,000, but no more than \$10,000, for each payment or transfer of value not reported, not to exceed \$150,000 annually. For a “knowing” failure to submit the required information, a manufacturer will be subject to a CMP of at least \$10,000 but no more than \$100,000, for each payment or transfer of value not reported, not to exceed \$1,000,000 annually. CMS clarified that the term “knowingly” is given the same meaning as in the federal False Claims Act, 31 U.S.C. § 3729(b).

The proposed rule states that in determining the amount of the CMP, the following factors will be considered:

- the length of time the applicable manufacturer failed to report, including the length of time the applicable manufacturer knew of the payment or other transfer of value, or ownership or investment interest;
- amount of the payment or other transfer of value or the value of the ownership or investment interest the applicable manufacturer failed to report;
- level of culpability;
- the nature and amount of information reported in error; and
- the degree of diligence exercised in correcting information reported.

In addition, the proposed rule provides that CMS, the Department of Health and Human Services, or the Office of Inspector General may audit, evaluate or inspect any applicable manufacturer for compliance with the Sunshine Act. To facilitate any potential audit, all covered manufacturers must maintain all books, records, documents and other materials sufficient to enable an audit for at least five years from the date of payment or transfer of value.

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