CMS Releases Proposed "Sunshine" Physician Payment Reporting Rule for Drug and Device Manufacturers: Record-Keeping Requirement Delayed Until Later in 2012

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On December 14, 2011, the Centers for Medicare & Medicaid Services ("CMS") released the long-awaited Proposed Rule for implementing the so-called "Sunshine Act" physician payment reporting requirements. These proposed regulations provide some additional clarity regarding the reporting obligations for most drug and device manufacturers, contained in Section 6002 of the Affordable Care Act ("the Act"). The Act will require most drug and device manufacturers to file annual disclosure reports detailing their financial relationships with physicians and teaching hospitals.

The Proposed Rule addresses the following key issues:

- When the compliance requirements go into effect
- What entities will be "Applicable Manufacturers" and thus covered by the Rule
- What types of drugs, devices and other items are covered by the Rule
- What types of financial relationships have to be disclosed
- How those financial relationships must be reported

CMS is accepting public comments on the Proposed Rule through February 17, 2012. Input from those in the health care, drug, and device sectors will be of significant importance in shaping the Final Rule. The comment period offers those who will be potentially affected by the Rule an important opportunity to propose modifications and improvements before the Rule is finalized.

I. Implementation Timeline Delayed

The most important aspect of the Proposed Rule is that itdelays the deadline for compliance. Under the Act, data collection was technically required to begin on January 1, 2012, with the first annual data report due to CMS by March 31, 2013.

However, due to the delay in releasing the Proposed Rule, CMS has confirmed that data collection by applicable manufacturers willnotbe required until at least 90 days after the Final Rule is issued. The Final Rule is not expected to be released until March 2012 at the earliest, meaning that data collection need not start until late spring or early summer 2012.

CMS also seeks comments on whether a 90-day delay will be sufficient, and on the "specific challenges" that applicable manufacturers may face in establishing data collection and reporting systems. As such, it is possible that CMS could delay implementation further into 2012, or even to 2013.

II. Clarification of Certain Definitions

A. "Applicable Manufacturer"

The 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 would further define an "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 United States, or in a territory, possession, or commonwealth of the United States; or
2. 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 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.

CMS also proposes that if a manufacturer meets either of these definitions for at leastonecovered product, then "allpayments or transfers of value made by an applicable manufacturer to a covered recipient must be reported . . . regardless of whether theparticularpayment or other transfer of value is associated" with a covered product. (Emphases added).

Furthermore, CMS intends to interpret this definition as applying to entities that hold FDA approval or clearance for a covered product, even if the "actual physical manufacturing of the product" is contracted to another entity.

B. Definition of "Common Ownership"

CMS is considering two definitions for when an entity is an "applicable manufacturer" due to "common ownership." CMS welcomes comments on which approach is preferable, or whether another alternative is preferable.

- The first proposed definition would be "when the same individual, individuals, entity, or entities, directly or indirectly, own any portion of two or more entities."
- The alternative definition would "limit the common ownership definition to circumstances where the same individual, individuals, entity, or entities own 5 percent or more of total ownership in two or more entities."

Where multiple entities are under common ownership, the Proposed Rule would require each entity to report separatelyifeach entity meets the primary definition of "applicable manufacturer." However, ifnotall the entities under common ownership meet the definition, the Proposed Rule would allow the applicable manufacturer to decide whether to report transfers of value as a) those made by the applicable manufacturer, or b) those made by the other entity.

C. Definition of "Covered Drug, Device, Biological, or Medical Supply"

The Proposed Rule would interpret "covered drug, device, biological, or medical supply" somewhat more narrowly than the statutory definition. First, CMS proposes to limit the definition of drugs and biologicals to those that require a prescription, and thus excludes over-the-counter products. Second, CMS proposes to limit the definition of devices to those that either require premarket approval by the FDA, or require premarket notification (i.e., 510(k) clearance) to the FDA.

D. Definition of "Covered Recipients"

The Act defines "covered recipients" as physicians and teaching hospitals, and the Proposed Rule offers the following clarifications.

- Physician.The Proposed Rule notes that the Act defines "physician" as that term is used in the Social Security Act, which encompasses "doctors of medicine and osteopathy, dentists, podiatrists, optometrists and licensed chiropractors."
- Teaching Hospital. The Proposed Rule notes that "teaching hospital" is not defined in the Act, and thus proposes that "teaching hospital" be defined as an institution that receives Medicare graduate medical education ("GME") payments. CMS will publish a list of institutions that qualify as teaching hospitals under this definition.

III. Clarification of Information Required in the Payment / Transfer Report

The Act defines what categories of information must be reported for each payment or transfer of value. The Proposed Rule adopts these categories, and provides clarification as to exactly what information is required in each category. Key substantive clarifications include:

- Date of Payment. The Proposed Rule would define "date of payment" as the "date upon which a payment or transfer of value was provided to the covered recipient."

- Associated Product. CMS acknowledges that not every payment or transfer of value is "explicitly linked to a particular covered drug, device, biological, or medical supply," but proposes that when a payment or transfer is "reasonably associated" with a specific product, that product must be identified in the report.

- Nature of Payment - Categories. The Proposed Rule adopts the payment categories established by the Act, and elaborates further on several of them. Key definitions for "food and beverage" and "research" are detailed below. The Proposed Rule would also permit applicable manufacturers to submit to CMS a document outlining their "assumptions used when categorizing the natures of payments."

    - *Food and Beverage*. CMS proposes that these transfers be reported by the value of items.

        - In situations where allocating 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.

        - 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 recognizes that this is a complicated and difficult issue, and seeks comments about the most logical and practical way to report research payments.

        - 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."

        - CMS also 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<u>both</u>the teaching hospital and the physician.

IV. Clarification of Exclusions

The 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.

V. Reports on Physician Ownership and Investment Interests

The Act requires that both applicable manufacturers and applicable group purchasing organizations ("GPOs") submit reports on any payments or other transfers of value provided to the physician owners of or physician investors in said applicable manufacturers or applicable GPOs.

The Proposed Rule provides a definition of a GPO, confirms that all physicians' ownership and investment interests must be reported "regardless of whether the physician is [also] an employee of the applicable manufacturer or applicable GPO," and defines "ownership or investment interests" in more detail than does the Act.

VI. Report Submission and Correction

The area in which CMS is seeking the most input is with regard to the format of reports and the means of their submission. CMS states that it will "strive to be as flexible as possible about the data collection and submission methods," while also noting the importance of establishing a common standard "to ensure that we can aggregate the data correctly and efficiently to make it publicly available."

In addition to recommending that applicable manufacturers provide covered recipients with a "pre-submission review" of proposed data, CMS makes several other proposals regarding reporting logistics.

- Report Submission. CMS is considering whetherallapplicable manufacturers should be required to file annual reports, regardless of whether they have reportable data.
    - CMS's first proposed option is to require reports only from applicable manufacturers that had reportable data; applicable manufacturers who had no reportable data would not be required to submit a null report.
    - The second option is to require all applicable manufacturers to submit reports, regardless of whether they had any reportable data.
- 45-Day Review Period. In a departure from similar state-level reporting rules, CMS proposes to aggregate all the data it receives for a given year, and then notify every applicable manufacturer and covered recipient that the data is available for pre-review before it is released to the public. CMS proposes a variety of ways to reach relevant parties, and welcomes comments as to alternative notification methods. CMS also proposes limiting its role in arbitrating disputes between applicable manufacturers and covered recipients regarding reported data, and proposes to severely limit the right to amend submitted data after the 45-day period expires.

VII. Delayed Publication of Payments for Product Research / Development Agreements / Clinical Investigations

The Act permits several instances in which publication of a payment or transfer of value can be delayed, in the context of a product research or development agreement, or clinical investigation:

- Delay Must be Affirmatively Requested. The Proposed Rule would require that applicable manufacturers indicate annually on their reports whether a given payment is eligible for this exception and is thus entitled to a delay in its publication.

- Delay Limited to Bona Fide Research or Investigation Activities. CMS proposes that in order to be eligible for delayed publication, a payment or other transfer of value must be made in the limited context of "relationships for bona fide research or investigation activities, which, if made public, would damage the manufacturers' competitive and/or proprietary interests." Eligibility for a delay would need to be supported via a written statement or contract as well as a written research protocol.

- Certain Distinctions between Research, Development, and Clinical Investigations. CMS notes that the Act permits delayed publication "for payments or other transfers of value forresearch-relatedservices for both new medical technologies and new applications of existing medical technologies," but that the Act also limits delayed publication fordevelopment and clinical investigationssolely to "new drugs, devices, biologicals, and medical supplies." CMS believes that the distinction between "research" and "development" is not meaningful, and proposes to treat these activities similarly broadly for this purpose. However, CMS believes that "clinical investigation" does have a distinct meaning, and proposes limiting delayed publication to payments made in connection with clinical investigations ofnewproducts, but not to extend the delay provisions to payments for new applications ofexistingproducts.

Even when a delay is granted, the Act and the Proposed Rule state that the payment information will ultimately be made available at a later date, either a) upon the drug or device's FDA approval, or b) four calendar years after the date of payment, whichever is earlier.

IX. Penalties

The Proposed Rule adopts the Act's penalty provisions, proposes a set of factors that CMS could consider in imposing a given civil money penalty, and establishes a five-year record retention requirement for audit purposes.

Foley Hoag has extensive experience in advising interested companies and organizations who wish to comment or participate in the regulatory process, as well as in assisting companies in adopting, revising and implementing codes of conduct as part of a comprehensive compliance and reporting program. If you would like to speak further with someone regarding these issues, please contactColin Zickat 617 832 1275,Tad Heuerat 617 832 1187, or any member of Foley Hoag's Government Strategiesgroup.