The Proposed Rule on Transparency Reports: Shedding Light on the Sunshine Act

An Overview of the Most Important Aspects of the Proposed Regulations

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On December 19, 2011, the Centers for Medicare & Medicaid Services (CMS) of the U.S. Department of Health and Human Services (HHS) published the Proposed Rule on Transparency Reports and Reporting of Physician Ownership or Investment Interests (the "proposed rule").[1] The proposed rule, issued under the authority of Section 6002 of the Patient Protection and Affordable Care Act (the "Sunshine Act"),[2] would require applicable manufacturers of drugs, devices, biologicals, and medical supplies covered by Medicare, Medicaid, or the Children's Health Insurance Program to report annually certain payments or transfers of value provided to physicians or teaching hospitals. The proposed rule also would require applicable manufacturers and applicable group purchasing organizations (GPOs) to report annually certain physician ownership or investment interests.

Required reports must be provided to CMS in an electronic format by March 31, 2013, and on the 90th day of each calendar year thereafter. A final rule is expected to be issued during the 2012 calendar year, and CMS has proposed providing applicable manufacturers and applicable GPOs a 90-day preparation period after publication of the regulations to begin complying with the data collection requirements of the Sunshine Act. CMS also is considering requiring manufacturers to report collection of data for part of 2012 by the statutory date of March 31, 2013. In turn, CMS is required by statute to publish the reported data on a public Web site. The data must be downloadable, searchable, and easily aggregated.

Some manufacturers already have experience with reporting physician payments to government entities

due to requirements imposed by state law or because they are subject to the payment posting obligations of a corporate integrity agreement entered into with the HHS Office of Inspector General (OIG). For GPOs and other manufacturers, aggregating and reporting data on payments and other transfers of value to physicians and teaching hospitals and/or physician ownership and investment interests will be a new and agonizing experience.

In this first in a series of articles on the administrative rulemaking to implement the Sunshine Act, we provide a general overview of the most important aspects of the proposed regulations. In later articles, we will describe the likely impact of the regulations, not just to manufacturers and GPOs but also to providers and suppliers. We also will report on the public comments[3] submitted to CMS with respect to the proposed rule and on the final regulations once issued.

Reports of Payments or Other Transfers of Value by Applicable Manufacturers

What is an Applicable Manufacturer?

As a preliminary matter, a "covered drug, device, biological or medical supply" is defined by the Sunshine Act as any drug, biological product, device, or medical supply for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program.[4] The proposed rule, however, proposes to limit the definition of drugs and biologicals to those that, by law, require a prescription to be dispensed, thus excluding over-the-counter drugs and biologicals. Similarly, the proposed rule proposes to limit the definition of medical devices and supplies to those that, by law, require premarket approval by or notification to the U.S. Food and Drug Administration (FDA), thus excluding many Class I devices and certain Class II devices exempt from premarket notification requirements.[5]

An "applicable manufacturer" that will be subject to the reporting requirements is defined under the proposed rule as (1) an entity engaged in the production, preparation, propagation, compounding, or conversion of a covered product 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 such an entity, 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 for sale or distribution in the United States, or in a territory, possession, or commonwealth of the United States.[6]

A manufacturer is an applicable manufacturer if it sells or distributes a covered product in the United States, or in a territory, possession, or commonwealth of the United States, regardless of where the covered product or its components are actually produced and regardless of where the manufacturer is located or incorporated. The term "applicable manufacturer" includes entities that hold FDA approval, licensure, or clearance for a covered product even if the manufacturer contracts out the actual physical manufacturing of the product to another entity. If a manufacturer meets the definition of an applicable manufacturer, even if it sells or distributes only one covered product, it must report all payments and transfers of value to physicians or teaching hospitals regardless of whether those payments or transfers are associated with a covered product.[7]

Who or What is a Covered Recipient?

The proposed rule requires applicable manufacturers to report on payments and transfers of value to "covered recipients," which are defined as (1) a physician, other than a physician who is an employee of an applicable manufacturer; or (2) a teaching hospital. A "physician" includes doctors of medicine and osteopathy, dentists, podiatrists, optometrists, and licensed chiroprac-

tors. An "employee" includes individuals who are employed by or are an employee of an entity if the individual would be considered an employee under the usual common law rules applicable in determining the employer-employee relationship.

Although a "teaching hospital" is not explicitly defined, CMS will consider as a "teaching hospital" any institution that receives payments for indirect medical education (IME) or direct graduate medical education (GME) during the most recent year for which such information is available. The proposed definition does not capture hospitals with accredited resident programs that do not receive IME or GME payments.[8]

What is a Payment or Other Transfer of Value?

Under the proposed rule, the information that must be reported on payments or other transfers of value is defined broadly as a transfer of anything of value regardless of whether the covered recipient specifically requested it. In addition, payments or other transfers of value made to an individual or entity at the request of or designated on behalf of a covered recipient would have to be reported under the name of the covered recipient, including payments or other transfers of value provided to a physician through a physician group or practice. Applicable manufacturers also would have to report the name of the entity or individual that received the payment at the request of or designated on behalf of the covered recipient.

What Information Must Be Reported?

The proposed rule requires reporting on both the *nature* of payment and the *form* of payment for each payment or other transfer of value made by an applicable manufacturer to a covered recipient. The payment provided to a covered recipient may take the *form* of cash or a cash equivalent; in-kind items or services; stock; a stock option; or any other ownership interest, dividend, profit, or other return on investment.[9]

The following categories reflect the *nature* of payment or other transfer of value that applicable manufacturers must use to describe each payment:

- consulting fee;
- compensation for services other than consulting;
- honoraria;
- gift;
- entertainment;
- food;
- travel (including the specified destinations);
- education;
- research;
- charitable contribution;
- royalty or license;
- current or prospective ownership or investment interest;
- direct compensation for serving as faculty or as a speaker for a medical education program;
- grant; and
- any other nature of the payment or other transfer of value defined by the Secretary.

The proposed rule requires applicable manufacturers to assign each individual payment or other transfer of value, or separate parts of a payment, to one and only one of these categories. If a payment or other transfer of value for an activity is associated with multiple categories, such as travel to a meeting under a consulting contract, the travel expenses should remain distinct from the consulting fee expenses, and both categories would need to be reported to accurately describe the relationship.[10]

The proposed rule also identifies 13 categories of payments and other transfers of value that are excluded from the reporting requirements, including:

- payments and transfers of value less than $10, unless the aggregate amount transferred to, requested by, or designated on behalf of a covered recipient exceeds $100 in a calendar year;
- product samples that are not intended to be sold and are intended for patient use;

- educational materials that directly benefit patients or are intended for patient use;
- the loan of a covered device for a short-term trial period, not to exceed 90 days, to permit evaluation of the covered device;
- discounts, including rebates;
- in-kind items used for the provision of charity care;
- payments to a physician for services with respect to a civil or criminal action or an administrative proceeding (*e.g.*, a physician is retained by a manufacturer as a testifying expert at trial); and
- transfers of value made indirectly to a covered recipient through a third party in cases where the applicable manufacturer is unaware of the identity of the covered recipient.[11]

Delayed Publication of Bona Fide Research Activities

To protect proprietary information related to the development of new drugs, devices, biologicals, and medical supplies, the proposed rule proposes methods to provide for the delayed publication of payments or other transfers of value from applicable manufacturers to covered recipients made pursuant to product research or development agreements or clinical investigations. To ensure that these payments or other transfers of value are for bona fide research activities, the proposed rule proposes that delayed publication apply only to product research and development agreements that are memorialized in a written statement or contract between the applicable manufacturer and the covered recipient that includes a written research protocol.

Similarly, for a clinical investigation to qualify for delayed publication, it also must be memorialized in a written research protocol between the parties.[12] Moreover, to clarify some seemingly ambiguous language in the Sunshine Act, the proposed rule proposes that delayed publication should apply to payments for services in connection with research on, or development of, new covered products as well as new applications of existing covered products. In contrast, the proposed rule proposes limiting delayed publication for payments in connection with clinical investigation only to new covered products, and not new applications of existing covered products.[13]

The Sunshine Act requires that information about payments and other transfers of value related to qualifying research activities that are delayed from publication be made publicly available on the first publication date after the earlier of either (1) the approval, licensure, or clearance by the FDA of a covered product; or (2) four calendar years after the date of the payment. To implement this requirement, the proposed rule proposes that reports from applicable manufacturers indicate whether or not a payment or other transfer of value should be granted a delay in publication on the public Web site. Any such payments or transfers of value would need to be reported each year with a continued indication that publication should remain delayed and with any updated information, as necessary, on the payment or other transfer of value.

Following FDA approval, licensure, or clearance, applicable manufacturers would have to indicate in their next annual submission that the payment should no longer be granted a delay and should be published in the current reporting cycle. Failure to indicate to CMS in a timely fashion that a payment or other transfer of value should no longer be granted a publication delay could subject the applicable manufacturer to penalties under the Sunshine Act. If a report submitted by an applicable manufacturer includes a date of payment four years prior to the current year, the payment or other transfer of value automatically would be published, regardless of whether the applicable manufacturer indicates that publication of the payment should be delayed.[14]

Reports of Physician Ownership and Investment Interests by Applicable Manufacturers and Applicable GPOs

The Sunshine Act requires both applicable manufacturers and applicable GPOs to report certain information regarding ownership and investment interests in their entity held not only by physicians but also by the immediate family members of physicians. Applicable manufacturers and GPOs also must report any payments and other transfers of value to physician owners or investors.

What is an Applicable GPO?

An "applicable GPO" that will be subject to the reporting requirements is defined under the proposed rule as an entity that (1) operates in the United States, or in a territory, possession, or commonwealth of the United States; and (2) 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. The proposed rule notes that this interpretation of the statutory definition of applicable GPO is meant to include not just traditional GPOs that negotiate contracts on behalf of their members but also entities that purchase covered products for resale or distribution to groups of individuals or entities, such as physician owned distributors, or PODs.

The proposed definition of applicable GPO is not meant to encompass, however, entities such as large physician practices or hospitals (including physician-owned hospitals) that buy covered products solely for their own use. The definition of an applicable manufacturer required to report on physician owners and investors is the same as it is with respect to payments and other transfers of value. Consistent with what is described above with respect to reporting payments or other transfers of value, the proposed rule with respect to ownership and investment interests proposes to limit the definition of drugs and biologicals to those that require a subscription to be dispensed and to limit the definition of devices and medical supplies to those that require premarket approval by or notification to the FDA.[15]

Who is a Physician?

When addressing physician ownership and investment interests, the Sunshine Act does not use the defined term "covered recipient" but rather uses the term "physician." As such, the proposed rule interprets the requirement to report ownership or investment interests by a "physician" to include those held by *any* physician, whether or not that physician is an employee of the applicable manufacturer or applicable GPO, as well as immediate family members of the physician. The proposed rule proposes to define an "immediate family member" as a spouse; natural or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-, mother-, daughter-, son-, brother- or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.[16]

What is an Ownership or Investment Interest?

The proposed rule proposes to define an ownership or investment interest as one that may be direct or indirect, and through debt, equity, or other means. The proposed definition is meant to include stock, stock options (other than those received as compensation until such time as 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.

An ownership or investment interest will not include ownership or investment interests in a publicly traded security or mutual fund; an interest in an applicable manufacturer or applicable GPO that arises from a retirement plan offered to an employed physician (or an employed member of his or her immediate family); stock options and convertible securities received as

compensation until the stock options are exercised or the convertible securities are converted to equity; or an unsecured loan subordinated to a credit facility.[17]

What Information Must Be Reported?

With respect to reporting information about each ownership or investment interest held by a physician or the physician's immediate family member, the proposed rule proposes that applicable manufacturers and GPOs report the name, address, National Provider Identifier (NPI), and specialty of the physician owner or investor. When the ownership or investment interest is held by an immediate family member, the applicable manufacturer or GPO would report the same information with respect to the physician but also would indicate that the ownership or investment interest is held by an immediate family member. CMS indicates that it also is considering whether to require reporting of the immediate family member's relationship to the physician and the family member's name and asks for public comment.[18]

With respect to reporting information about payments or other transfers of value to physician owners or investors, the proposed rule appropriately notes that a payment or other transfer of value, including of an ownership or investment interest, made to a physician owner or investor who also is a covered recipient would have to be reported twice by an applicable manufacturer — once with respect to payments and other transfers of value to a covered recipient and again with respect to payments and other transfers of value to physician owners and investors. To address the potential for duplicate reporting and to streamline the reporting process, the proposed rule proposes that applicable manufacturers report all payments and transfers of value on one file and all physician ownership and investment interests on another file. The file containing payments and other transfers of value would include all payments and transfers of value to physician owners and investors, regardless of whether those physicians also are covered recipients. Where appropriate, however, applicable manufacturers would be required to note that the physician receiving the payment or other transfer of value is a physician owner or investor.

Because GPOs only are required to report physician ownership and investment interests, and payments or transfers of value to physician owners and investors, the proposed rule proposes that GPOs submit both on a single file.[19]

Submission and Format of Reports

Applicable manufacturers and applicable GPOs are statutorily required to submit reports electronically to CMS by March 31, 2013, and on the 90th-day of each calendar year thereafter. Following each annual report submission, CMS proposes to have the chief executive officer, chief financial officer, or chief compliance officer from each applicable manufacturer and GPO submit a signed attestation certifying to the truth, correctness, and completeness of the submitted data.

The proposed rule proposes that only applicable manufacturers that have payments or other transfers of value and/or physician ownership or investment interests to disclose for the previous year would be required to submit reports. Similarly, only applicable GPOs with physician owners or investors would be required to submit information. If an applicable manufacturer or GPO does not have any information to report, CMS indicates that it is considering requiring the chief executive officer, chief financial officer, or chief compliance officer to submit an attestation that, to the best of his or her knowledge and belief, there were no reportable payments or transfers of value and/or ownership or investment interests during the previous calendar year.[20]

For each payment and other transfer of value, the following information will be required to be submitted:

- applicable manufacturer or applicable GPO name;
- covered recipient's or physician owner's (as applicable):

  - name (for physicians include first and last name and middle initial);
  - specialty (physician only);
  - business street address (practice location);
  - 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;
- nature of payment or other transfer of value;
- 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 (Yes or No response); 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 (Yes or No response).[21]

For each physician ownership or investment interest, the following information will be required to be submitted:

- applicable manufacturer or applicable GPO name;
- ownership or investment physicians':
  - name (for physicians include first and last name and middle initial);
  - specialty;
  - business street address (practice location);
  - NPI;
- whether the ownership or investment interest is held by the physician, or an immediate family member of the physician;
- dollar amount invested;
- value and terms of each ownership or investment interest;
- for applicable GPOs only, any payments or other transfers of value provided to the physician owner or investor, including the following (applicable manufacturers should report this information with their other payments or other transfers of value and indicate that the covered recipient is a physician investor or owner):
  - 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;
  - nature of payment or other transfer of value; and
  - name of the associated covered drug, device, biological, or medical supply, as applicable.[22]

Penalties for Failure to Comply

Applicable manufacturers and applicable GPOs are subject to civil monetary penalties (CMPs) for failing to comply with the reporting requirements of the Sunshine Act. If an applicable manufacturer or applicable GPO fails to submit the required information, the applicable manufacturer or applicable GPO 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 not reported as required. The maximum CMP with respect to each annual submission for failure to report is $150,000. For a *knowing* failure to submit required information in a timely manner, an applicable manufacturer or applicable GPO may be subject to a CMP of at least $10,000, but no more than $100,000, for each payment or other transfer of value not reported as required, with a maximum CMP of $1,000,000 for each annual submission for a knowing failure to report.[23]

Miscellaneous

Other provisions of the proposed rule, including sections on state preemption, prepublication review of the data, and resolving disputes over reported data, will be discussed in the next article in the series on the likely impact of the regulations on manufacturers, GPOs, providers, and suppliers.

Endnotes:

1. 76 Fed. Reg. 78724 (2011).
2. 42 U.S.C. §1320a-7h et seq.
3. The deadline for submitting comments was Friday, February 17, 2012.
4. This series of articles will refer to covered drugs, devices, biologicals, and medical supplies collectively as "covered products." Note that "covered products" is not a term defined or used in the Sunshine Act or the proposed rule.
5. 76 Fed. Reg. 78744, 78745 (2011).
6. 76 Fed. Reg. 78743, 78744 (2011).
7. 76 Fed. Reg. 78744 (2011).
8. 76 Fed. Reg. 78745, 78746 (2011).
9. 76 Fed. Reg. 78747 (2011).
10. 76 Fed. Reg. 78748 (2011).
11. 76 Fed. Reg. 78750 (2011).
12. To account for the fact that many applicable manufacturers that sponsor research conduct their research activities through a contract research organization (CRO), the proposed rule proposes that, as long as the applicable manufacturer has a written agreement with the CRO, the CRO may have the written research agreement with the covered recipient pursuant to which payments or other transfers of value would be eligible for delayed publication.
13. 76 Fed. Reg. 78756, 78757 (2011).
14. 76 Fed. Reg. 78756, 78757 (2011).
15. 76 Fed. Reg. 78751, 78752 (2011). CMS requests public comments, however, on whether the device limitation is overly limiting with respect to applicable GPOs because GPOs often purchase, arrange for, or negotiate the purchase of routine devices and medical supplies.
16. 76 Fed. Reg. 78752 (2011).
17. 76 Fed. Reg. 78752 (2011).
18. 76 Fed. Reg. 78752 (2011).
19. 76 Fed. Reg. 78753 (2011).
20. 76 Fed. Reg. 78753, 78754 (2011).
21. 76 Fed. Reg. 78754 (2011).
22. 76 Fed. Reg. 78754 (2011).
23. 76 Fed. Reg. 78757 (2011).

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