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December 16, 2011

CMS ISSUES PROPOSED RULES ON FEDERAL "SUNSHINE" LAW FOR MANUFACTURERS AND GPOS

RESOURCE LINKS

Proposed Rules:
https://s3.amazonaws.com/public-inspection.federalregister.gov/2011-32244.pdf

Submit Comments to CMS:
http://www.regulations.gov

Federal Transparency Is Now a Reality: Challenges and Opportunities for Pharma, Devices, and PBMs:
http://www.ebglaw.com/showclientalert.aspx?Show=12676

CMS Holds First Teleconference Related to Sunshine Law for Pharmaceutical, Biotechnology, and Medical Device Companies:
http://www.ebglaw.com/showclientalert.aspx?Show=14171

IMPORTANT DATES

Deadline to Submit Comments to CMS:
February 17, 2012

First Report Due:
March 31, 2013

On December 14, 2011, the Centers for Medicare & Medicaid Services ("CMS") issued long-awaited proposed rules with a lengthy preamble (collectively referred to herein as "Proposed Rules") relevant to Section 6002 of the Patient Protection and Affordable Care Act, also known as the Physician Payment Sunshine Act. ***The Proposed Rules, along with sample reporting templates, are available at https://s3.amazonaws.com/public-inspection.federalregister.gov/2011-32244.pdf.***

Generally, the Physician Payment Sunshine Act requires applicable pharmaceutical, medical device, biological and medical supply manufacturers to report annually certain information to CMS regarding "payments and transfers of value" provided to "covered recipients." The Physician Payment Sunshine Act also requires manufacturers and group purchasing organizations ("GPOs") to report annually certain information to CMS regarding "ownership or investment interests" held by physicians and their immediate family members. ***The first report is due March 31, 2013.*** For an overview of the Physician Payment Sunshine Act, see the Epstein Becker Green health reform alert entitled "Federal Transparency Is Now a Reality: Challenges and Opportunities for Pharma, Devices, and PBMs."

The Proposed Rules outline CMS's proposals regarding the implementation of the Physician Payment Sunshine Act and seek comments relevant to these proposals. CMS notes in the Proposed Rules that the proposals were developed after soliciting feedback relevant to the implementation of the

Physician Payment Sunshine Act through an Open Door Forum on March 24, 2011,[1] and in consultation with the Office of Inspector General ("OIG") of the Department of Health and Human Services ("HHS"). ***Interested parties may submit comments to CMS until February 17, 2012.*** Comments may be submitted electronically to CMS at http://www.regulations.gov.[2] Comments will be made publicly available.

Most notably, the Proposed Rules state that the final rule will not be published in time for applicable manufacturers and GPOs to begin collecting the required information on January 1, 2012. ***As such, CMS "will not require applicable manufacturers and applicable GPOs to begin collecting the required information until after the publication of the final rule . . ." CMS also seeks comments on whether 90 days is sufficient time after the final rule is published for applicable manufacturers and GPOs to begin collecting data and on the feasibility of making the first annual report on March 31, 2013.***

This health reform alert provides an overview of the Proposed Rules relevant to manufacturers and GPOs and then discusses some key considerations for manufacturers and GPOs to consider as they evaluate the Proposed Rules and prepare for implementation.

DRAFT REGULATIONS REGARDING PAYMENTS AND TRANSFERS OF VALUE

"Applicable Manufacturer"

The Proposed Rules clarify that an "applicable manufacturer" is subject to the reporting requirements of the Physician Payment Sunshine Act if its product is sold or distributed in the United States, regardless of where the product is manufactured, or where the entity is located or incorporated. An applicable manufacturer also includes the entity that holds the approval, licensure or clearance for the product, even if the entity contracts out the actual manufacturing.

Additionally, the Proposed Rules state that any manufacturer that meets the definition of an "applicable manufacturer" is subject to the reporting requirements for all of its products, even if the payment or transfer of value is associated with a non-covered product. ***Manufacturers should consider submitting comments to CMS regarding this proposal.***

"Common Ownership"

The Physician Payment Sunshine Act states that an entity under "common ownership" with, and that "provides assistance or support" to, an applicable manufacturer also is subject to the reporting requirements. The Proposed Rules define "common ownership" as "when the same individual, individuals, entity or entities, directly or indirectly, own any portion of two or more entities" including, but not limited to, parent/subsidiary companies and brother/sister corporations. ***CMS seeks comments on this definition and whether it should consider an alternate definition for "common ownership" that would be based on an ownership interest of 5 percent or more.***

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1 For an overview of the CMS Open Door Forum, see the Epstein Becker Green health reform alert entitled "CMS Holds First Teleconference Related to Sunshine Law for Pharmaceutical, Biotechnology, and Medical Device Companies."

2 The Proposed Rules also provide information related to the submission of comments by regular mail, express mail and hand delivery.

CMS also proposes that each entity that individually meets the definition of an "applicable manufacturer" submit its own report, regardless of whether it is under common ownership with another applicable manufacturer. A manufacturer that is under common ownership with, and provides assistance or support to, an applicable manufacturer may decide whether to report individually or together with the applicable manufacturer. If reported together, the report should name all entities included in the report. Additionally, the applicable manufacturer submitting the report may decide whether to identify the payments as from the entity under common ownership.

"Covered Drug, Device, Biological or Medical Supply"

The Proposed Rules limit the definition of a covered drug or biological provided under the Physician Payment Sunshine Act to those that, by law, require a prescription to be dispensed. The Proposed Rules expressly exclude over-the-counter ("OTC") products from reporting, which is relevant only to those OTC manufacturers that do not also manufacture or sell other covered products. Similarly, the Proposed Rules limit the definition of a covered device or medical supply to those that, by law, require premarket approval by, or premarket notification to, the U.S. Food and Drug Administration ("FDA"), thereby excluding some Class I and Class II devices.

Additionally, the Proposed Rules provide that the definition of a "covered drug, device, biological or medical supply" applies to products individually "available" under Medicare, Medicaid or the Children's Health Insurance Program ("CHIP"), as well as those "available" under Medicare, Medicaid or CHIP as part of a composite payment rate or fee schedule payment.

"Covered Recipients"

Under the Proposed Rules, a "covered recipient" includes (i) a physician, as defined in section 1861(r) of the Social Security Act, who is not an employee of the manufacturer; and (ii) a teaching hospital. The Proposed Rules recommend defining a teaching hospital as an institution that receives payments for indirect medical education ("IME") or direct graduate medical education ("GME")[3] during the most recent year for which information is available. CMS proposes to publish a list of such teaching hospitals on its website once per year. ***Manufacturers should consider submitting comments to CMS regarding this proposal.***

CMS also proposes that manufacturers use the National Plan and Provider Enumeration System ("NPPES") for identifying physician National Provider Identifiers ("NPI"), which is one item that must be included in the annual report. If a physician's NPI is not available in the NPPES, the manufacturer is responsible for obtaining this information directly from the physician. ***CMS seeks comments on whether another unique identifier should be used for physicians who do not have a NPI.***

"Payment or Transfer of Value"

CMS notes in the Proposed Rules that a "payment or transfer of value" is defined broadly in the Physician Payment Sunshine Act to include all payments and transfers of value unless otherwise excluded. The Proposed Rules clarify that this definition includes payments or transfers of value provided to a covered recipient, regardless of whether the covered recipient specifically requested it.

[3] *See* §§ 1886(d)(5)(B), 1886(h) and 1886(s) of the Social Security Act. ***CMS seeks comments on whether this definition should be expanded to include hospitals with accredited resident programs that do not receive IME or GME payments.***

Additionally, CMS proposes that payments or transfers of value provided to a physician group or practice should be reported individually under the names and NPIs of the physician covered recipients. ***Manufacturers should consider submitting comments to CMS regarding this proposal.***

If a payment or transfer of value is made by a manufacturer to another individual or entity on behalf of a covered recipient, the Physician Payment Sunshine Act requires the manufacturer to report the payment or transfer of value under the name of the covered recipient. The Proposed Rules add that the applicable manufacturer also should report the name of the individual or entity that receives the payment or transfer of value on behalf of the covered recipient.

Form of Payment

Manufacturers must specify in the annual report the "form" of each payment or transfer of value. For reporting purposes, CMS proposes to use only the three categories provided in the Physician Payment Sunshine Act: (i) cash or cash equivalent; (ii) in-kind items or services; and (iii) stock, stock option or any other ownership interest, dividend, profit or other return on investment. The Proposed Rules further direct manufacturers to use the "dictionary definition" for these terms. If individual parts of a payment or transfer of value fit into more than one category, these parts should be reported individually so that the report accurately reflects the payment forms.

Nature of Payment

Manufacturers must specify in the annual report the "nature" of each payment or transfer of value. Similar to the forms of payment, the Proposed Rules state that manufacturers should report individual parts of a payment or transfer of value that fit into more than one "nature" category. ***CMS requests comments on the advantages and disadvantages of this approach versus allowing manufacturers to report a single lump sum.***

The Proposed Rules direct manufacturers to use the "dictionary definition" and to make a "reasonable determination" about the nature of the payment or transfer of value that is reported. CMS also proposes allowing manufacturers to submit with the annual report the assumptions used to make these determinations. This document would not be available publicly, and CMS may offer further guidance to manufacturers regarding these classifications. ***CMS seeks comments on this proposal.***

The Proposed Rules also provide additional detail on the following "nature" categories:

- Charitable Contributions. These are limited to a payment or transfer of value made to a tax-exempt organization that is not more specifically described by another nature category.

- Food and Beverages. For food and beverages provided in a group setting, such as a meal provided to a physician's office, the manufacturer should report the cost per physician covered recipient, even if the physician covered recipient does not participate in the meal and regardless of the actual number of meal participants. ***CMS seeks comments on this proposal and the methodology that should be used for large group practices and hospital-based physicians.***

- Direct Compensation. CMS proposes expanding the "direct compensation for serving as faculty or as a speaker for a medical education program" category to encompass all instances in which a physician covered recipient serves as a speaker on behalf of a manufacturer. ***CMS seeks comments on whether another category should be used or created for speaking services other than medical education programs and whether this category should be limited to accredited continuing medical education programs.***

- Other. CMS proposes an "other" category for payments or transfers of value that do not fit within a specific "nature" category.

Additionally, CMS proposes limiting the research category to *bona fide* research activities subject to both (i) a written agreement or contract between the manufacturer (or a clinical research organization on behalf of the manufacturer) and the organization conducting the research, and (ii) a research protocol. ***CMS requests comments on whether this category should be expanded, or whether a new category should be created for other types of research that do not fit within this definition.***

The Proposed Rules further seek to distinguish between "direct research," where a payment or transfer of value is provided directly to a covered recipient, and "indirect research," where a payment or transfer of value is made to an organization conducting the research and then provided to a physician covered recipient acting as a principal investigator. CMS proposes the following reporting protocol for direct and indirect research:

- Direct Research to a Physician Covered Recipient. Manufacturer reports the full amount of the payment or transfer of value under the physician's NPI number. ***CMS seeks comments on the appropriate way to report this information on the public website.***

- Direct Research to a Teaching Hospital Covered Recipient. Manufacturer reports the full amount of the payment or transfer of value. CMS proposes to aggregate these amounts with other payments and transfers of value received by the teaching hospital on the public website.

- Indirect Research Where the Payment or Transfer of Value Is Provided to an Individual or Entity that Is Not a Covered Recipient. Manufacturer reports the full amount of the payment or transfer of value under the name(s) and NPI(s) of the physician covered recipient(s) acting as the principal investigator(s), if the manufacturer is aware of the identity of such individual(s). The manufacturer also reports the name of the entity or individual that received the payment or transfer of value. CMS proposes that these amounts not be aggregated with other payments and transfers of value provided to the physician on the public website.

- Indirect Research Where the Payment or Transfer of Value Is Provided to a Teaching Hospital Covered Recipient. Manufacturer reports the full amount of the payment or transfer of value under the name(s) and NPI(s) of the physician covered recipient(s) acting as the principal investigator(s), if the manufacturer is aware of the identity of such individual(s). CMS proposes that these amounts not be aggregated with other payments and transfers of value provided to the physician on the public website. The manufacturer also reports the payment or transfer of value as "direct research" for the teaching hospital.

Exclusions

The Physician Payment Sunshine Act provides several categories of items that may be excluded from reporting. The Proposed Rules direct manufacturers to use the "dictionary definition" for these items. The Proposed Rules also provide the following additional guidance on exclusions:

- Food and Beverages. Meals, snacks and coffee provided at conference booths or similar events where it is difficult to establish the identity of individuals who accept these items do not need to be reported.

- Items Less than $10. Payments or transfers of value under $10 that meet the $100 threshold reporting amount should be reported as one total amount for each relevant category.

- Educational Materials. Although electronic and written materials that directly benefit patients or are intended for patient use may be excluded from reporting, services and other items are not excluded. ***Manufacturers should consider submitting comments to CMS regarding this proposal. Additionally, CMS seeks comments on whether this category should be expanded to include materials, such as medical textbooks, that are provided to covered recipients for education.***

- Charity Care. This exclusion is limited to in-kind items provided to a charitable organization for patients who cannot pay, and where the covered recipient neither receives, nor expects to receive, payment. The exclusion is not applicable if the manufacturer (i) provides in-kind items to a charitable organization for the care of all of the covered recipient's patients, or (ii) provides a payment or transfer of value that is not an in-kind item.

- Indirect Payments. The exclusion does not apply when the manufacturer has "actual knowledge, or acts in deliberate ignorance or reckless disregard of, the identity of the covered recipient." Additionally, CMS proposes that awareness by an agent of the manufacturer be attributed to the manufacturer. ***Manufacturers should consider submitting comments to CMS regarding this proposal.***

Report Content

In addition to the reporting requirements specified in the Physician Payment Sunshine Act, the Proposed Rules seek to include the following information:

- Name of Physician Covered Recipient. Provide the first name, middle initial and last name.

- Business Address. Use the physician's primary practice location provided in the NPPES, or the address of the teaching hospital provided in the list published by CMS.

- Specialty. Use a single specialty for each physician covered recipient from the "provider taxonomy" field of the NPPES.

- Payments or Transfers of Value Made over Multiple Dates. The Proposed Rules state that the manufacturer may decide whether to report (i) the total amount as a single line item using the first date that such payment or transfer of value was made, or (ii) individual amounts on the

specific date of each payment or transfer of value. ***CMS requests comments on whether it should require manufacturers to report multiple payments or transfers of value in a single, consistent manner.***

- Associated Covered Drug, Device, Biological or Medical Supply. Report the name under which the product is marketed or, if not yet marketed, its scientific name.

- Indirect Payments. Report the name of the individual or entity that receives a payment or transfer of value on behalf of a covered recipient.

The Proposed Rules recognize that there may be payments or transfers of value that are not "associated" with a covered drug, device, biological or medical supply for purposes of reporting. CMS proposes that manufacturers use a "reasonably associated with" test for determining whether to specify a covered product for each payment or transfer of value reported. The Proposed Rules also recognize that a payment or transfer of value may be "associated" with multiple products. ***CMS seeks comments on whether manufacturers should choose one product or be allowed to report multiple covered products, if applicable.***

Delayed Reporting

The Proposed Rules state that the manufacturer must indicate on the annual report whether a payment or 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. CMS also proposes to require manufacturers to include such payments or transfers of value subject to delayed reporting on subsequent annual reports. Additionally, manufacturers that receive FDA approval, licensure or clearance must indicate in their next annual submission that the payment should be made publicly available. The Proposed Rules state that failure to notify CMS appropriately may result in penalties. ***CMS seeks comments on this proposal.***

CMS also seeks comments on its proposal to limit delayed publication for payments made in connection with "clinical investigations" to new drugs, devices, biologicals or medical supplies only, whereas payments to covered recipients for services in connection with "research" on, or "development" of, drugs, devices, biologicals or medical supplies would apply to both new products and new applications of existing products.

DRAFT REGULATIONS REGARDING PHYSICIAN OWNERSHIP OR INVESTMENT INTERESTS

Definition of "Applicable GPO"

The Proposed Rules provide additional guidance regarding the definition of an "applicable GPO." Specifically, the Proposed Rules state that an applicable GPO includes an entity that purchases covered drugs, devices, biologicals and medical supplies for resale or distribution including, but not limited to, a physician-owned distributor ("POD") of covered products. The Proposed Rules expressly exclude from this definition an entity that buys covered products solely for its own use.

The Proposed Rules request comments on whether the definition of a covered device or medical supply should be limited to those that, by law, require premarket approval from, or premarket notification to, the FDA, consistent with the definition provided by the Proposed

Rules for manufacturers. CMS indicates in the Proposed Rules that this definition may not be appropriate for GPO reporting requirements.

Physician Ownership or Investment Interests

The Proposed Rules state that "ownership or investment interests" should be interpreted similar to the way in which the federal physician self-referral regulation, also known as the Stark Law,[4] is interpreted. Specifically, the interest may be direct or indirect and through debt, equity or other means, including, but not limited to, stock, stock options, partnership shares, limited liability company membership, loans, bonds or other financial instruments that are secured by an entity's property or revenue. The Proposed Rules seek to add as additional exclusions: (i) an interest in a retirement plan offered by an applicable manufacturer or GPO; (ii) stock options or convertible securities received as compensation, until the options are exercised or the securities are converted to equity; and (iii) an unsecured loan subordinated to a credit facility.

Additionally, the Proposed Rules state that the exclusion does not extend to physician employees with ownership or investment interests, even though a physician who is an employee of a manufacturer is excluded from the definition of "covered recipient" for purposes of reporting payments and other transfers of value,.

"Immediate Family Member" of a Physician

CMS proposes to define "immediate family member" of a physician 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; or spouse of a grandparent or grandchild. ***The Proposed Rules also seek comments on whether applicable manufacturers and GPOs should report the name and other required information for the physician owner or investor, as well as the name and relationship of the immediate family member, if applicable.***

DRAFT REGULATIONS REGARDING ANNUAL REPORTING

Reporting Process

The Proposed Rules require applicable manufacturers and GPOs with reportable payments or transfers of value to register with CMS prior to submitting the annual report. ***CMS also seeks comments on whether it should require a signed attestation from the reporting entity regarding the truth, correctness and completeness of the data submitted.***

Additionally, the Proposed Rules request comments on whether applicable manufacturers and GPOs without information to report should register with CMS. The Proposed Rules also seek comments on whether an attestation from the chief executive officer, chief financial officer or chief compliance officer should be required.

Report Corrections Process

The Physician Payment Sunshine Act requires CMS to establish a process for applicable manufacturers, applicable GPOs, covered recipients and physician owners and investors to review

[4] 42 C.F.R. § 411.354(b).

the submitted data before it is made publicly available. ***The Proposed Rules seek comments on this process, including the method(s) that should be used to notify covered recipients and physician owners and investors when the data is available for review.*** CMS further proposes that individuals or entities that receive a payment or transfer of value on behalf of a covered recipient not be included in this review process.

The Proposed Rules state that additional details regarding the review and correction process will be provided for public comment once they are fully developed. Generally, CMS will require the parties to handle disputes regarding the reported data, and one of the parties will provide the results to CMS within the 45-day review period. ***CMS seeks comments on how the data should be reported publicly when the dispute cannot be resolved.*** The Proposed Rules encourage manufacturers to develop a process for pre-submission review of the data to limit disputes.

The Proposed Rules state that the 45-day review period is the only opportunity to correct errors or contest data. However, CMS states that it is considering whether to allow the parties to review and amend the data during the next reporting cycle.

Penalties

The Physician Payment Sunshine Act provides for civil monetary penalties ("CMPs") when an applicable manufacturer or GPO fails to report on a timely basis in accordance with the regulations. CMS interprets these CMPs as extending to any additions or oversights identified after the reporting period and 45-day review period. The Proposed Rules state that several factors may be used to determine the amount of a CMP, including the: (i) length of time the manufacturer or GPO failed to report; (ii) length of time the manufacturer or GPO knew of the payment or transfer of value or ownership or investment interest; (iii) amount of the payment or transfer of value or ownership or investment interest that the manufacturer or GPO failed to report; (iv) level of culpability; (v) nature and amount of information reported in error; and (vi) degree of diligence exercised in correcting information reported in error***. CMS seeks comments on these factors.***

Additionally, the Proposed Rules state that the Secretary of HHS, CMS, OIG or their designees may audit, evaluate or inspect applicable manufacturers and GPOs regarding compliance with timely, complete and accurate submissions. To facilitate these rules, CMS proposes that all books, records, documents and other materials relevant to the submissions be maintained for at least five years from the date that the payment or transfer of value or ownership or investment interest is published publicly by CMS. ***Manufacturers should submit comments to CMS regarding this proposal.***

KEY CONSIDERATIONS FOR MANUFACTURERS AND GPOS

While the Proposed Rules clarify a number of points, a significant number of unanswered questions remain for further consideration and clarification. Manufacturers and GPOs should take advantage of this important opportunity to provide comments to CMS on the Proposed Rules. CMS stated that it has invested time and resources into developing Proposed Rules that are both effective and efficient, and reiterated throughout the Proposed Rules that it seeks comments on its proposals.

Comments should outline key considerations for CMS, discuss significant challenges related to implementation, and provide detailed suggestions based on experience with similar reporting requirements. Comments also could include "real world examples" of issues related to reporting for

CMS to consider. Given the public nature of this reporting and the significant potential consequences, manufacturers and GPOs are urged to devote sufficient time and resources to responding appropriately to CMS's request for comments. Epstein Becker Green is available to assist with drafting and submitting comments to the Proposed Rules.

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For more information about this issue of *IMPLEMENTING HEALTH AND INSURANCE REFORM*, please contact one of the authors below or the member of the firm who normally handles your legal matters.

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