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Life Sciences Health Industry Alert

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Overview and Analysis of the Proposed Federal Sunshine Regulations

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Introduction

On December 19, 2011, the Centers for Medicare & Medicaid Services ("CMS") published a proposed rule (the "Proposed Rule") related to section 6002 of the Affordable Care Act, commonly referred to as the "Physician Payment Sunshine Act" (so referenced herein, or as the "Act").[1] The Physician Payment Sunshine Act requires applicable manufacturers of drugs, devices, biologicals, or medical supplies covered under Medicare, Medicaid, or CHIP to report annually to the Secretary of the Department of Health and Human Services ("Secretary") certain payments or other transfers of value to physicians and teaching hospitals. Additionally, applicable manufacturers and applicable group purchasing organizations ("GPOs") must report certain information regarding the ownership or investment interests in them that are held by physicians or their immediate family members.

The Proposed Rule comes more than two months after CMS's statutory deadline of October 1, 2011. CMS proposes an expansive reading of its statutory authority, arguably extending reporting requirements to manufacturers and payments not contemplated by Congress. Moreover, while

offering some much-needed clarification regarding certain tracking and reporting obligations under the Act, it leaves many questions unanswered. Indeed, CMS solicits comments on almost every aspect of the Proposed Rule – 60 topic areas in all. Accordingly, significant ambiguity still remains in terms of compliance with certain aspects of the Act. Comments to the Proposed Rule are due **no later than 5 p.m. ET February 17, 2012.**

This Client Alert outlines the guidance and proposals included in the Proposed Rule. As further discussed below, CMS has delayed implementation of tracking requirements under the Physician Payment Sunshine Act, but applicable manufacturers and GPOs still are advised to continue to prepare for implementation of the Act, potentially occurring during this calendar year 2012. Applicable manufacturers and applicable GPOs may do so by taking steps to ensure that tracking and reporting systems conform to the requirements of the Act and the Proposed Rule, to the extent clarity is currently available, and by closely monitoring future CMS guidance in this area.

Delayed Implementation

Pursuant to the express terms of the Act, applicable manufacturers and applicable GPOs were required to begin collecting certain information January 1, 2012, to be reported to CMS in an electronic format by March 31, 2013, and on the 90th day of each calendar year thereafter. However, pursuant to the Proposed Rule, CMS will not require applicable manufacturers or applicable GPOs to begin collecting information until after the publication of the final rule (rather than the statutory January 1, 2012 deadline). While the exact date of implementation remains unknown, CMS is seeking comments regarding the length of time necessary to begin implementation after publication of the final rule. CMS also suggests that a preparation period of 90 days following publication of the final rule might be appropriate given that Congress originally anticipated this amount of time. CMS notes in the Proposed Rule that it hopes to finalize the rule "as soon as possible" during calendar year 2012.

Summary of Proposed Regulations

I. Reports on Payments and Other Transfers of Value by Applicable Manufacturers

A. Important Definitions

Applicable Manufacturers

Pursuant to the Physician Payment Sunshine Act, an "applicable manufacturer" is a manufacturer of a covered drug, device, biological, or medical supply that is "operating in the United States, or in a territory, possession, or commonwealth of the United States." Under the Proposed Rule, CMS proposes to define applicable manufacturer extremely broadly – in some aspects arguably beyond the scope of the Act.

First, CMS characterizes 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) above that 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 proposes to define "common ownership" as occurring when the same individual, individuals, entity, or entities, directly or indirectly, own any portion of two or more entities. Alternatively, CMS states that it is considering limiting the definition of common ownership to circumstances in which the same individual, individuals, entity, or entities own 5 percent or more of total ownership in two or more entities.

Importantly, under the proposed definition of applicable manufacturer, an entity would be deemed to be an applicable manufacturer if its products were sold or distributed in the United States, regardless of where the covered product was produced or where the entity was located or incorporated. Accordingly, CMS's proposal for the term "applicable manufacturer" would capture certain ex-U.S. entities not previously expected to be covered under the Act.

CMS argues that the expansion is necessary given the global nature of the manufacturing industry. Specifically, it asserts that any entity manufacturing covered products for sale or distribution in the United States (or any entity under common ownership that provides assistance or support) should be subject to the requirements of the Act because the opportunity for undue influence or inappropriate relationships is the same for manufacturers of product sold or distributed in the United States, regardless of where the product is actually manufactured.

In addition, CMS proposes to require any entity that meets the definition of applicable manufacturer by selling or distributing in the United States at least one covered product, to report all payments or transfers of value to a covered recipient regardless of whether the particular payment or transfer of value is associated with a covered product or not.

CMS also asserts that the definition of applicable manufacturer should include entities that hold Food and Drug Administration ("FDA") approval, licensure, or clearance for a covered product, even if they contract out the actual physical manufacturing of the product to another entity.

Covered Drugs, Devices, Biologicals and Medical Supplies

CMS proposes the following definition for "covered drug, device, biological, or medical supply":

> Any drug, device, biological, or medical supply for which payment is available under Title XVIII of the Act or under a State plan under Title XIX or XXI (or a waiver of such plan), either separately, as part of a fee schedule payment, or as part of a composite payment rate (for example, the hospital inpatient prospective payment system or the hospital outpatient prospective payment system). With respect to a drug or biological, this definition is limited to those drug and biological products that, by law, require a prescription to be dispensed. With respect to a device or medical supply, this definition is limited to those devices (including medical supplies) that, by law, require premarket approval by or premarket notification to the Food and Drug Administration.

Accordingly, the term would include those products reimbursed pursuant to a composite payment rate, as well as those reimbursed separately, and would be limited to covered drugs or biologicals that require, by law, a prescription to be dispensed, and covered devices or medical supplies that require, by law, premarket approval by or notification to FDA. Pursuant to these proposed limitations, over-the-counter ("OTC") drugs and biologicals, and many Class I and certain Class II devices, would be excluded from the definition of a "covered drug, device, biological, or medical supply."

Importantly, and similar to the definition of applicable manufacturers, the Proposed Rule would require reporting by manufacturers that (1) manufacture both OTC drugs and biologicals and at least one covered drug or biological, or (2) that manufacture both devices and medical supplies exempt from premarket notification requirements and at least one covered device or medical supply. Such entities would have to report all payments or transfers of value to covered recipients, regardless of whether the payment was associated with a covered product.

Covered Recipients: Physicians and Teaching Hospitals

The Act defines a "physician" as having the meaning set forth in section 1861(r) of the Social Security Act, which includes doctors of medicine and osteopathy, dentists, podiatrists, optometrists, and licensed chiropractors. In order to identify "physician covered recipients," CMS proposes that applicable manufacturers use the National Plan & Provider Enumeration System ("NPPES"), which CMS currently maintains and updates on its website. The NPPES website reportedly includes a database of physician National Provider Identifiers ("NPI").[2] If a physician is not listed in NPPES, the applicable manufacturer would be responsible for obtaining the physician's individual NPI. With regard to physicians who do not have an NPI, CMS is considering requiring applicable manufacturers to report another unique identifier, such as a state license number.

The Act does not define the term "teaching hospital," but CMS's proposal would link the term to recipients of Medicare graduate medical education ("GME") payments. Pursuant to the Proposed Rule, CMS would publish a list of teaching hospital covered recipients on the CMS website once per year, to include the name and address of each.

B. Payments or Other Transfers of Value

Payments at the Request of or on Behalf of Covered Recipients

Under the Act, payments or transfers of value made to an individual or entity at the request of or designated on behalf of a covered recipient must be reported under the name of the covered

recipient. According to the Proposed Rule, this would also include reporting payments or other transfers of value provided to a physician through a physician group or practice. This payment or other transfer of value would be reported individually under the name of the physician covered recipient.

In order to maximize transparency, CMS also proposes that applicable manufacturers report the name of the entity or individual that ultimately receives the payment at the request of or designated on behalf of the covered recipient. Unlike covered recipients, however, these parties would not be able to review the information during the 45-day review period, discussed below, before the data was made publicly available on the CMS website.

Information To Be Reported

The Act sets forth the specific categories of information that must be reported for each payment or other transfer of value. The Proposed Rule provides additional explanation and detail on how applicable manufacturers would report the following such categories of information:

(1) *Name of the physician covered recipient:* Applicable manufacturers would report the first name, middle initial, and last name for physician covered recipients.

(2) *Business addresses:* Applicable manufacturers would report full street addresses. For teaching hospitals, manufacturers would report the address included in the CMS-published list of teaching hospital covered recipients. For physician covered recipients, manufacturers would report the physician's primary practice location, also reportedly able to be found in NPPES.

(3) Specialty and NPI: Applicable manufacturers would report only one physician specialty and use only those listed in the "provider taxonomy" field in NPPES. Additionally, applicable manufacturers would report the physician's individual NPI rather than any group NPI associated with the physician.

(4) *Date of payment:* Applicable manufacturers would use their discretion to determine whether to report ongoing payments, such as those associated with a consulting agreement, as a single line item on the date of the first payment or as multiple line items on each date of payment.

(5) *Associated covered drug, device, biological, or medical supply:* If a payment or other transfer of value is "reasonably associated" with a particular covered drug, device, biological, or medical supply, then applicable manufacturers would be required to report the name of the specific product. The product would be reported using the name under which it is marketed. If the product did not yet have a market name, then the applicable manufacturer would use the scientific name. As an alternative, CMS is considering allowing applicable manufacturers to report multiple products as related to a single payment or other transfer of value. With respect to this particular requirement, CMS also states that an applicable manufacturer that failed to report this information could be subject to penalties. Given the nature of certain marketing, education, or research efforts, and depending on the type of manufacturer involved, this requirement could be particularly difficult to meet. For example, activities of many medical device manufacturers are unlikely to be associated with one, or even multiple, covered devices. Moreover, while patients may be familiar with the brand names of drugs they are taking, that often is not the case with devices; hence, reporting by the names of associated devices is unlikely to provide much illumination for the general public.

(6) *Form of payment and nature of payment:* Under the Proposed Rule, the categories set forth in the Act for both form of payment and nature of payment would be defined as distinct from one another. With regard to payments associated with multiple categories, applicable manufacturers would be required to break out the disparate aspects of the payment that fall into multiple categories for both form of payment and nature of payment. For example, if a physician received meals and travel in association with a consulting fee, each segregable payment would be reported separately in the appropriate category (consulting fees, meals, and travel). CMS seeks comments on this proposal as well as an opposite approach that would allow applicable manufacturers to report multiple segregable categories as a single lump sum. Depending on how this issue is finalized in the final rule, applicable manufacturers will be required to arrange their tracking systems to capture form of payment and nature of payment information according to CMS's specifications. With two opposite alternatives currently on the table, efforts to begin system developments or adjustments with respect to this area will be challenging before release of the final rule.

In addition, CMS proposes to define the form and nature of payment terms by their "dictionary definitions." Not all payment categories used by manufacturers (e.g., "honorarium") are accurately categorized by dictionary definitions, however, and we believe some inconsistent reporting may result. Form of payment and nature of payment are further discussed below.

C. Form of Payment and Nature of Payment

Form of Payment

The Act lists the following forms of payment: 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; and any other form of payment determined by the Secretary. CMS does not propose to add any additional forms of payment beyond those outlined in the Act, but seeks comments on whether other categories are necessary.

Nature of Payment

CMS encourages applicable manufacturers, when selecting the nature of payment, to consider the purpose and the manner of the payment or other transfer of value. That is, applicable manufacturers would make a "reasonable determination" about the nature of payment if a payment could conceivably fall into more than one category.

To ensure consistency in the reporting and selection of categories, CMS would allow applicable manufacturers to submit with their data, a document describing the "assumptions" used when categorizing the nature of payments. Submission of an assumptions document would not be mandatory, however, and these documents would not be posted on the public website. Instead, CMS states such a practice would be helpful in allowing manufacturers to explain the reasoning behind the categories used, and also would be useful for CMS in monitoring how manufacturers are reporting data and whether there are significant differences among manufacturers. CMS is seeking comments on its proposal to allow applicable manufacturers to submit this "assumptions document" and whether CMS should make submission mandatory instead of voluntary. [3]

CMS does provide some clarification of the following nature of payment terms: (1) charitable contributions, (2) food and beverage, (3) research, and (4) direct compensation for serving as faculty or as a speaker for a medical education program. The Proposed Rule also adds a catch-all nature of payment category that reflects the statutory requirement that *all* payments or transfers of value from applicable manufacturers to covered recipients (other than those specifically excluded under the statute) must be reported.

(1) *Charitable contributions:* Payments or other transfers of value would be included in this category if they were made to an organization with tax-exempt status under the Internal Revenue Code of 1986, and were not more specifically described by one of the other nature of payment categories.

(2) *Food and Beverage:* If CMS's proposals with respect to food and beverages are finalized, applicable manufacturers would have to report the value of any food or beverage item provided to covered recipients, subject to the minimum threshold exception of $10/$100 annual aggregate. In the case of group meals provided in group settings, applicable manufacturers would be required to report the cost per covered recipient receiving the meal, even if the covered recipient does not actually partake of the meal. For example, if once during the calendar year, a sales representative brings $25 worth of bagels and coffee to a solo physician's office for a morning meeting, regardless of the number of individuals who partake (such as non-covered recipient staff members), the per-covered recipient cost would be $25. In contrast, if the food were provided to a practice group that included five physicians, the per-covered recipient cost would be $5 (and not reportable), regardless of whether all five physicians actually consumed the food. CMS seeks comments on whether this approach is practicable for large practices or hospital-based physicians, in contrast to the alternative approach of counting the number of physicians by department. Applicable manufacturers would not need to report any offerings of buffet meals, snacks, or coffee at booths at conferences or other similar events.

(3) *Research:* The Proposed Rule contains a number of controversial and/or confusing provisions in the research area. First, CMS would limit the research category to "bona fide research activities," including clinical investigations that are subject to a written agreement or contract between the applicable manufacturer and the organization conducting the research, as well as a research protocol. CMS proposes this method because it aligns with the method used to identify payments or other transfers of value eligible for delayed publication to protect the proprietary interests of applicable manufacturers. We believe not all research activities in which manufacturers engage fall within this limited definition.

In addition, CMS proposes to require manufacturers to indicate whether payments are for direct or indirect research. Direct research payments would be those made directly to a covered recipient. Indirect research payments would be those made to a non-covered recipient, such as a contract

research organization ("CRO") or other institution conducting the research, which in turn pays the physician covered recipient.

For both direct and indirect research, applicable manufacturers would be required to report the entire payment amount for each research payment (whether to the covered recipient or a research institution), rather than the specific amount that was provided to the covered recipient. Even if the research institution were not itself a covered recipient, the payment still would have to be reported individually under the name and NPI of the physician covered recipient serving as principal investigator. Indirect payment reports also would have to include the name of the entity or individual that received the payment or other transfer of value. CMS proposes that the entire amount would have to be reported because the applicable manufacturer or CRO may not know how the research payment is distributed, since the payment will include all items and activities associated with the research project, not just the physician covered recipient's payment.

If the research institution were itself a covered recipient (for example, a teaching hospital), then applicable manufacturers would be required to report the payment for *both* the teaching hospital covered recipient and the physician covered recipient(s) serving as the principal investigator(s). The payment to the teaching hospital would be treated as a direct research payment, whereas the payment to the principal investigator(s) would be treated as an indirect research payment.

Notwithstanding that applicable manufacturers would be required to report the entire research payment for the physician covered recipient, CMS would not aggregate this payment into the physician's total on the public website. Instead, for physicians, CMS would publish the payment amount separately and would not aggregate the entire amount into the physician's total. For teaching hospitals, CMS would aggregate the payment into the teaching hospital's total payment amount. CMS also is considering attributing the total payment to the covered recipient for direct research. CMS believes this may be necessary because in direct research, the covered recipient is individually receiving the payment, so the specific amount the covered recipient is receiving would be clearly defined and available to the manufacturer.

In short, we believe the research provisions as proposed will be difficult to implement, and will result in CMS's public reporting of data that is confusing and does not reflect the reality of scientific research activities today.

(4) *Direct compensation for serving as faculty or as a speaker for a medical education program:* CMS's proposal with respect to this nature of payment category would broaden the category to include all instances in which applicable manufacturers pay physicians to serve as speakers, and not just those situations involving "medical education programs." CMS is seeking comments on this approach, as well as the alternative approach of including an additional category for when speaking services are outside of medical education programs. CMS also is seeking comments regarding whether it should differentiate between continuing medical education accredited speaking engagements and all others.

D. Exclusions

In the Proposed Rule, CMS explains that it does not intend to capture purely personal transfers of value. For example, an applicable manufacturer would not be required to report transactions between a spouse who works for that manufacturer and the other spouse who is a physician covered recipient. CMS also proposes that applicable manufacturers use the "dictionary definitions" of exclusions. CMS does provide some clarification on the exclusions listed below:

(1*) Transfers of value less than $10:* Under the Proposed Rule, CMS would publish annually on its website updated threshold amounts that correspond with percentage increases in the consumer price index for all urban consumers. In addition, the proposal would require manufacturers to aggregate all reportable small payments or other transfers of value in the same nature of payment category for the same covered recipient.

(2) *Educational materials that directly benefit patients or are intended for patient use:* The Proposed Rule would limit this exclusion to "materials" (including, but not limited to, written or electronic materials), but – somewhat confusingly – exclude from the exclusion "services and other items." CMS also seeks comments on whether educational materials provided to covered recipients, but not actually given to patients (for example, medical textbooks), should be deemed to directly benefit patients so that such materials would not have to be reported. We believe that manufacturers provide multiple types of items that directly and indirectly benefit patients, complicating classification under this proposed framework.

(3) *Discounts and rebates:* CMS reminds manufacturers in the Proposed Rule of their obligations to appropriately report discounts and rebates for purposes of the Medicare and Medicaid programs, and to comply with fraud and abuse laws, including the Federal Anti-Kickback statute.

(4) I*n-kind items for the provision of charity care:* Under the Proposed Rule, the term "charity care" would be defined as items provided to a covered recipient for one or more patients who cannot pay, where the covered recipient neither receives, nor expects to receive, payment because of the patient's inability to pay. This exclusion would not apply to in-kind items provided to a covered recipient by an applicable manufacturer that would benefit both patients who can and cannot pay.

(5) *Indirect payments through a third party:* According to CMS, this exclusion hinges on whether an applicable manufacturer is "unaware" of the identity of the covered recipient. Under the Proposed Rule, an applicable manufacturer would be aware of the identity of a covered recipient if the manufacturer had actual knowledge of, or acted in deliberate ignorance or reckless disregard of, the identify of the covered recipient. Further, awareness of the identity of the covered recipient by an agent of the applicable manufacturer would be attributed to the applicable manufacturer. CMS does not specify whether its "awareness" standard applies to knowledge of the identity of the covered recipient at the time of the payment or at the time of reporting.

II. Reports on Physician Ownership and Investment Interests by Applicable Manufacturers and Applicable GPOs

A. Important Definitions

Under the Physician Payment Sunshine Act, applicable manufacturers, as well as applicable GPOs, are required to report certain information to CMS regarding ownership and investment interests held by physicians or their immediate family members in such applicable manufacturer or applicable GPO, including payments to such physician owners and investors (similar to payments to covered recipients, discussed above).

Applicable Group Purchasing Organizations

Under the Proposed Rule, the statutory definition of applicable GPO would include not only the more traditional GPOs that negotiate contracts for their members, but also entities that purchase covered drugs, devices, biologicals, and medical supplies for resale or distribution to groups of individuals or entities. This definition would include the somewhat controversial entities commonly known as physician-owned distributors ("PODs") of covered products.[4] In other words, PODs would be required to disclose their physician owners. Specifically, CMS proposes to define "applicable GPO" 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 definition would not include entities that buy covered products solely for their own use, such as some large practices or hospitals.

CMS is seeking comments on whether its proposal to limit the definition of covered devices and medical supplies to those requiring premarket approval by or notification to FDA should also apply to the definition of applicable GPO.

Physicians and Immediate Family Members

With respect to reporting information related to physician ownership and investment interests, the applicable section of the Act uses the term "physician" (as defined in section 1861(r) of the Social Security Act), as opposed to the term "covered recipient." Therefore, CMS notes that the requirement to report physician ownership and investment interests includes any physician, regardless of whether the physician is an employee of the applicable manufacturer or applicable GPO. This is in contrast to reporting payments to covered recipients, discussed above, in which case a manufacturer's physician employees would be excluded from the definition of covered recipients.

Under the Proposed Rule, the term "immediate family member" as it relates to a person would include the following: 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.

Ownership or Investment Interests

In the Proposed Rule, CMS defines an ownership or investment interest in an applicable manufacturer or applicable GPO in a similar manner as in the "Stark" physician self-referral regulation (42 C.F.R. § 411.354(b)). Accordingly, an ownership or investment interest would be defined as one that may be direct or indirect, and through debt, equity, or other means. Ownership or investment interest would include, but not be limited to, stock, stock options (other than those received as compensation, until they are exercised), partnership shares, or limited liability company memberships, as well as loans, bonds, or other financial instruments secured with an entity's property or revenue, or a portion of that property or revenue.

CMS also clarifies that applicable manufacturers would be required to report payments or other transfers of value of an ownership or investment interest made to a covered recipient under the first section of the Act (discussed above in Section III.A). Additionally, all ownership or investment interests held by a physician would have to be reported under the second section of the Act, discussed in this Section III.B, which requires reporting of payments or other transfers of value to physician owners or investors. To avoid duplicative reporting, if reporting would be required under both sections of the statute, then the applicable manufacturer would only have to report under the first section.

B. Physician Ownership or Investment Report Content

Under the Proposed Rule, an applicable manufacturer or applicable GPO would report the name, address, NPI, and specialty of the physician owner or investor. If the ownership or investment interest were held by an immediate family member of a physician, applicable manufacturers and applicable GPOs would report not only the required information for the physician, but also that the ownership or investment interest is held by an immediate family member of the physician. CMS is considering whether the immediate family member's name and relationship to the physician also would have to be reported.

With regard to payments or other transfers of value to physician owners or investors, applicable manufacturers and applicable GPOs would have to follow the reporting procedures otherwise outlined in the Proposed Rule. To avoid duplicative reporting, an applicable manufacturer would have to submit: (1) one file for all payments and other transfers of value to covered recipients, including those made to physician owners and investors, and (2) another file identifying all physician ownership or investment interests. In the file for all payments and other transfers of value, the applicable manufacturer would indicate when a covered recipient receiving the payment or other transfer of value was also a physician owner or investor.

Applicable GPOs only would be required to submit a report on physician ownership or investment interests. In the event the applicable GPO made a payment or other transfer of value to one of its physician owners or investors, it would follow the reporting procedures otherwise outlined in the Proposed Rule.

III. Report Submission and Correction Under the Act: Payments/Transfers of Value and Investment/Ownership Interests

CMS states that it recognizes that the Act and its regulations will require applicable manufacturers and applicable GPOs to collect and submit large amounts of new data, and it asserts that it is striving to be as flexible as possible with regard to data collection and submission methods. However, CMS also states in the Proposed Rule that it recognizes the need for standardization and plans to work with applicable manufacturers and GPOs to create the best system for all parties involved. In the meantime, reportedly based on its stakeholder outreach and an analysis of the data systems available, CMS proposes a potential system for data submission, as further described below.

A. Prior to Submission

CMS seeks comments on a methodology by which applicable manufacturers and applicable GPOs can make necessary data corrections prior to submission to CMS, thus lessening potential changes during the statutory review and correction period, and thereby strengthening the accuracy of the data. CMS proposes a "review period," under which – prior to submitting their data to CMS

– applicable manufacturers and applicable GPOs could provide covered recipients and physician owners and investors an opportunity to review the data they plan to report to CMS. CMS seeks comments on whether this "pre-submission review" would be useful. While such a pre-submission review could be helpful in allowing manufacturers, GPOs, and covered recipients to work through any disputes prior to submission, thereby avoiding the issue during the 45-day review period (discussed below), we are concerned that such a review also could require additional time and resources.

B. Report Submission

CMS proposes to allow applicable manufacturers and applicable GPOs to submit their reports prior to March 31, 2013, or on the 90th day of each calendar year thereafter. That is, if CMS's proposal were finalized, the requirement under the Act that data be reported "on" March 31, 2013 would be interpreted as being due "by" March 31, 2013.

CMS proposes requiring registration by applicable manufacturers and applicable GPOs with reportable information *prior* to submitting their reports. Under this registration process, applicable manufacturers and applicable GPOs would be required to identify a point of contact. After registering, the manufacturers and GPOs would submit their data electronically in a comma-separated format. The first opportunity for registration and data submission would be January 1, 2013.

Additionally, the Proposed Rule would require applicable manufacturers and applicable GPOs to submit annually, following data submission, a signed attestation certifying the truth, correctness, and completeness of the data submitted to the best of the signer's knowledge and belief. The Proposed Rule would require that such attestations be signed by the chief executive officer ("CEO"), chief financial officer ("CFO"), or chief compliance officer ("CCO"). This proposed certification requirement is not surprising, considering that CMS has been moving toward requiring similar attestations in other contexts – potentially to facilitate the future filing of false claims actions in applicable cases.

Alternatively, CMS states that it is considering an across-the-board requirement that all applicable manufacturers and GPOs must register, regardless of whether they have information to report. If an entity has no payments or transfers of value and/or ownership or investments interests to report, CMS would require the CEO, CFO, or CCO of the applicable manufacturer or applicable GPO to attest to that fact. CMS asserts that such a requirement/certification would ensure a more "thorough" evaluation on the part of applicable manufacturers and applicable GPOs.

C. Report Format

Within the Proposed Rule, CMS outlines the fields of information that would have to be reported to CMS. The identified list includes items identified in the Act, plus one addition: the name of entity that received the payment or other transfer of value, if not provided to the covered recipient directly. CMS argues that this expansion of the reported information is authorized under the discretion provided to it under the statute.

D. 45-Day Review Period for Applicable Manufacturers, Applicable GPOs, and Covered Recipients

Notifying Covered Recipients and Physician Owners and Investors

The Act requires that CMS allow applicable manufacturers, applicable GPOs, covered recipients, and physician owners and investors the opportunity to review data submitted for a period of at least 45 days before the data is made public. CMS proposes to aggregate data by individual covered recipient and physician owner/investor across applicable manufacturers and applicable GPOs. Once the data aggregation is complete, CMS states that it will notify all applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors about the procedures for the review of the data. CMS sets forth the following proposals for notifying covered recipients and physician owners and investors:

- Allow, but not require, covered recipients and physician owners or investors to register with CMS so that CMS can ensure notification, or
- Notify parties through CMS's list serves and post information on CMS's website or the *Federal Register.*

These notifications would be provided annually to announce the review and correction period, and would provide specific instructions for performing the review.

CMS also notes that it is considering an alternative approach that would require applicable manufacturers and applicable GPOs to collect and report whether covered recipients, or physician owners or investors, would like to be notified by mail or email of the processes for their review, as well as individual email addresses, if applicable.

Arbitrating Disputes

In the Proposed Rule, CMS argues that it should not be actively involved in arbitrating disputes between applicable manufacturers or applicable GPOs, and covered recipients or physician owners or investors, regarding the receipt, classification or amount of any payment or other transfer of value, or ownership or investment interest. At the same time, CMS acknowledges that it is working on identifying a streamlined and automated process for reporting disputes and changes to ensure that the review and correction process is as smooth as possible. CMS proposes the following general guidelines:

- Covered recipients and physician owners and investors could request from CMS the contact information for a specific applicable manufacturer or applicable GPO.
- CMS would not be responsible for resolving the dispute, but one party would have to notify CMS of the dispute and whether the parties reached a resolution at the end of the 45-day review period.
- If the dispute could not be resolved, the data would be labeled as contradictory and both the original submission and the modified information would appear on the publicly available website.

CMS further acknowledges that publishing disagreements in this manner could make aggregating the data difficult on the public website. Where payments are in dispute, the individual payment would be flagged as contested, but the contradictory data as corrected by the covered recipient or physician owner or investor would be used for the physician's aggregated totals.

CMS states this is preferable since the covered recipient or physician owner or investor has expressed concern about the accuracy of the information submitted by the applicable manufacturer or applicable GPO. Alternatively, CMS is considering aggregating the original data as submitted by the applicable manufacturer or applicable GPO for purposes of the physician total.

Correcting Errors

Pursuant to the Proposed Rule, the 45-day review period would be the primary opportunity to correct errors or contest the data submitted by applicable manufacturers and applicable GPOs; once the review period ended, no one could amend the data for that calendar year. While applicable manufacturers, applicable GPOs, covered recipients, and physician owners and investors would have to notify CMS as soon as possible regarding any errors or omissions, no changes will be made to the data until the following year's 45-day review period. However, only the current and previous year would be available for review and correction. Notwithstanding this limitation, CMS would have the option to make changes to the data at any time (for example, to correct mathematical mistakes).

E. Public Availability

Under the Proposed Rule, CMS seeks comments on how to structure the website for ultimate usability. The Act includes a list of specific information required to be included on the website, such as background information on industry-physician relationships. CMS does not discuss this requirement in the Proposed Rule. Accordingly, it is not clear what the content or context of such background information would be on the website. The Proposed Rule would require that the website clearly state 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.

F. Delayed Publication for Payments Made Pursuant to Product Research or Development Agreements and Clinical Investigations

In order to maintain confidentiality for proprietary information relating to the development of new products, the Physician Payment Sunshine Act provides for delayed publication of certain payments or other transfers of value related to product research or development agreements and clinical investigations. However, the requirements to implement this mandate under the Proposed Rule are not entirely clear.

CMS proposes to authorize delayed publication of payments or other transfers of value only for relationships involving bona fide research or investigation activities. In other words, to be exempt from reporting in a current year, "product research or development agreements" would have to be formalized – that is, they would have to include a written statement or contract between the applicable manufacturer and covered recipient, as well as a written research protocol. Further, delayed reporting of "clinical investigations" would be permitted only when such investigations were memorialized in a written research protocol between the covered recipient and the applicable manufacturer. This requirement would be met if a CRO were involved, as long as the manufacturer had a written agreement with the CRO, and the CRO had a written agreement with the covered recipient.

With respect to those payments and transfers of value that would be subject to delayed publication, the language of the Act distinguishes between: (1) product research or development agreements for services furnished in connection with (i) research on a potential new medical technology, (ii) a new application of an existing medical technology, or (iii) the development of a new drug, device, biological, or medical supply; and (2) clinical investigations regarding a new drug, device, biological, or medical supply.

Accordingly, depending on the term used, delayed publication could apply either to activities solely related to new products, or to activities related to both new products and new applications of existing products. Recognizing the close relationship and significant overlap among the phrases "medical technology" and "drug, device, biological, or medical supply," as well as the difficulty in separating "research" from "development," CMS proposes to consider "medical technology" broadly as "any drug, device, biological, or medical supply," and to treat "research and development" similarly.

Therefore, under the Proposed Rule, delayed publication would apply to payments in connection with:

- Research or development of new devices and new applications of existing devices, and
- Clinical investigations for new devices (but not new applications of existing devices).

Those payments subject to delayed publication would not be published on the CMS website until the earlier of:

- FDA approval, licensure, or clearance; or
- Four calendar years after the date such payment or other transfer of value was made.

Pursuant to the Proposed Rule, even if payments are subject to delayed publication, manufacturers still would be required to report the payment or transfer of value, and they would be responsible for indicating on their reports whether a payment or other transfer of value should be granted a delay in publication on the CMS website. Any payments or transfers of value subject to delayed publication would need to be reported each year with a continued indication that publication should remain delayed, and applicable manufacturers would also be required to provide any updated information on the delayed payment or other transfer of value, as necessary. Following FDA approval, licensure, or clearance, applicable manufacturers would be required to indicate on their next annual submission that the payment should no longer be granted a delay and should be published in the current reporting cycle. If the report included a date of payment four years prior to the current year, the payment or other transfer of value would be published automatically, regardless of whether the manufacturer indicated that the payment should be delayed. As it does throughout the Proposed Rule, CMS seeks comments on its proposals related to delayed publication.

G. Penalties

The Proposed Rule also discusses the penalties that may be imposed for failure to report required information on a timely basis in accordance with the regulations.

Failure to submit information would be subject to a civil money penalty ("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 as required. The maximum CMP for failure to report is $150,000. The knowing failure to submit required information in a timely manner, as the term is defined by the False Claims Act, is subject to a CMP of at least $10,000, but no more than $100,000, for each payment or other transfer of value, or ownership or investment interest not reported as required. The maximum CMP for a knowing failure to report is $1 million.

CMS proposes that the following factors would be considered in determining the amount of a CMP:

- Length of time the applicable manufacturer or applicable GPO failed to report, including the length of time the applicable manufacturer and applicable GPO 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 or applicable GPO failed to report
- Level of culpability
- Nature and amount of information reported in error
- Degree of diligence exercised in correcting information reported in error

Additionally, under the Proposed Rule, the Secretary, CMS, Office of Inspector General ("OIG"), or their designees may audit, evaluate, or inspect applicable manufacturers and applicable GPOs for their compliance with timely, complete and accurate submission of information. To allow for such audits, applicable manufacturers and applicable GPOs would be required to maintain books, records, documents, and other materials for a period of at least five years from the date the payment or other transfer of value, or ownership or investment interest is published publicly on the website.

H. Annual Reports

Under the Physician Payment Sunshine Act, CMS is required to submit annual reports to Congress and the states. If finalized as proposed under the Proposed Rule, CMS would report to Congress April 1 of each year information submitted by applicable manufacturers and applicable GPOs during the preceding year. CMS also would submit to the states by September 30, 2013 and on June 30 for each year thereafter, a summary of information collected during the previous calendar year and submitted in the current year, regarding covered recipient and physician owners and investors in that state.

I. Relation to State Laws

With respect to the preemption of state laws, the Proposed Rule does not provide any additional information regarding the statutory preemption provision, and, instead, merely restates the statutory requirements. That is, under the terms of the Physician Payment Sunshine Act, the federal law, once implemented, will preempt any statute or regulation of a state that requires an applicable manufacturer to disclose or report, in any format, the same type of information regarding payments or other transfers of value to covered recipients required under the federal law. However, the Act does not preempt any state laws that require the disclosure or reporting of information that falls outside of the scope of the Act. The Act will therefore not preempt any state laws that require the disclosure of the type of information that is not covered by the federal Act, or information that is expressly excluded from disclosure by the Act (with the exception of payments that fall below the $10 individual or $100 aggregate threshold).

IV. Conclusion

As noted, CMS has requested comments in response to many of the proposals it presents throughout the Proposed Rule. In addition, in many cases, CMS offers two wholly conflicting alternatives. Accordingly, while the Proposed Rule provides some clarification with respect to the Act, open questions still remain in many areas regarding the requirements, processes, and procedures with which applicable manufacturers and applicable GPOs will be required to comply once the final rule is issued and the Act is implemented.

Reed Smith continues to monitor payment transparency developments, including this federal requirement and similar state transparency requirements, and can provide guidance to entities regarding this developing area.

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[1] The Proposed Rule is available at 76 Fed. Reg. 78,742 (Dec. 19, 2011).

[2] At the time of this writing, we were unable to access NPIs or even physicians' names on the NPPES website.

[3] We note that CMS's Medicaid rebate payment guidance contemplates that manufacturers make "reasonable assumptions" in price reporting, but at no time has CMS suggested that the assumption documents be submitted.

[4] The Senate Finance Committee among others has questioned the legality of such entities. See http://finance.senate.gov/newsroom/ranking/release/?id=126c415e-f1a3-41e9-ab49-665a71188f1c.

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