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Proposed Physician Payment Sunshine Act Regulations Leave Many in the Dark



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Pharmaceutical and medical device manufacturers as well as group purchasing organizations (GPOs) finally received some insight into how the Centers for Medicare & Medicaid Services intends to implement the Physician Payment Sunshine Act (Sunshine Act), which was enacted as part of the Patient Protection and Affordable Care Act.[1] On Dec. 14, 2011, CMS published a Proposed Rule (Proposed Rule)[2] that addresses certain crucial details but left many questions unanswered pending review of comments from manufacturers and other interested parties.

Of immediate importance is the postponement of the Jan. 1, 2012, start date for the collection of data by manufacturers of drugs, devices, biologicals, or medical supplies covered by Medicare, Medicaid, or the Children's Health Insurance Program (Manufacturers) and by GPOs regarding payments or other transfers of value (including ownership and investment interests) given to physicians and teaching hospitals.

According to the Proposed Rule, CMS will not require Manufacturers and GPOs to begin collection until after publication of final regulations later in 2012 and a subsequent "preparation period."[3]

This delay offers Manufacturers and GPOs a significant advantage because they otherwise would have had to implement a data collection system without the benefit of final regulations.

The data collection and reporting obligations imposed by the Sunshine Act cannot be taken lightly because failure to comply can result in significant civil monetary penalties ("CMPs"), ranging from $1,000 to $10,000 for *each* payment or other transfer of value that is not reported (up to a maximum of $150,000) and from $10,000 to $100,000 for *each* knowing failure to report (up to a maximum of $1 million).

CMS has solicited comments on many aspects of the Proposed Rule, which underscores the likelihood that the Proposed Rule and the final regulations will look substantially different. It also indicates that CMS will consider feedback from stakeholders.

Interested parties—including Manufacturers, GPOs, physicians, and teaching hospitals—should take the opportunity to influence the final regulations by submitting comments no later than Feb. 17, 2012. This article examines a number of the issues on which CMS has requested input.

I. OVERVIEW OF THE PROPOSED RULE

Throughout the preamble to the Proposed Rule, CMS discussed the factors that influenced its decision mak-

[1] The Affordable Care Act is comprised of the Patient Protection and Affordable Care Act ("PPACA"), Pub. L. 111-148, 124 Stat. 119 (2010), and the Health Care and Education Reconciliation Act of 2010, Pub. L. 111–152, 124 Stat. 1029 (2010). The Sunshine Act is Section 6002 of PPACA (codified at 42 U.S.C. 1301 *et seq*.)

[2] Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests, 76 Fed. Reg. 78742 (Dec. 19, 2011).

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[3] 76 Fed. Reg. at 78743.

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ing and, in some cases, described alternative approaches still under consideration. Among other things, the Proposed Rule:

- defined key terms, including applicable manufacturer and GPO; covered drug, device, biological, or medical supply (referred to as a ''covered product'' throughout); covered recipients; and teaching hospital;
- discussed the process for confirming whether a physician or teaching hospital is a covered recipient;
- detailed the process for identifying reportable payments and other transfers of value;
- outlined the procedures for submitting and correcting reports, including the report format;
- described how reports will be made publicly available;
- articulated the factors that will be considered when imposing CMPs for non-compliance; and
- addressed preemption of similar state laws, such as the Massachusetts Pharmaceutical and Medical Device Code of Conduct (known as the ''gift ban'' law).[4]

II. TOPICS FOR COMMENT

A. Burden on Applicable Manufacturers and Covered Recipients

One theme that runs through the Proposed Rule is that CMS sought to reduce the regulatory burden on Manufacturers and GPOs. CMS previously indicated that this concern may have been a factor leading to the delayed publication of the Proposed Rule.

In response to a letter from Senators Chuck Grassley (R-Iowa) and Herb Kohl (D-Wis.) expressing ''severe disappointment'' regarding CMS's failure to propose regulations by the Oct. 1 statutory deadline, the CMS administrator noted that, consistent with Executive Order 13563 (which directs all federal agencies to take steps to reduce regulatory burden), CMS was ''carefully reviewing this statutory requirement and working hard to ensure [CMS] meet[s] these goals.''[5]

1. Costs of Implementation and Resource Requirements

CMS is interested in learning more about the level of effort that will be necessary to comply with the requirements of the Sunshine Act and the implementing regulations and thus requested comments on the operational challenges, burdens, and costs resulting from the Proposed Rule, especially those that may arise when setting up the necessary data collection and reporting systems.[6]

In particular, CMS has asked for ''empirical data'' from firms of varying sizes on the expected costs of implementation, the extent to which current systems meet the proposed requirements, and the extent to which affected parties would ''modify their practices to avoid reporting costs,''[7] meaning that CMS anticipates that at least some Manufacturers may decide that the costs of reporting outweigh the benefits of offering payments or other transfers of value to covered recipients.

Another issue raised by CMS was the amount of time and effort Manufacturers will need to dedicate to data collection and reporting. According to the Proposed Rule, smaller Manufacturers will need to allocate 0.5 employees while larger Manufacturers may have to dedicate 5 to 15 full-time employees.[8] A GPO will need a 0.1 FTE employee for year 1 and a 0.075 FTE employee in following years.

The Proposed Rule also discussed the burden on covered recipients—physicians and teaching hospitals (''Covered Recipients'').

For example, CMS believes that teaching hospitals, which will need to review more payments or other transfers of value and will have more complex relationships than physicians, would need to spend an average of 10 hours per year reviewing the submitted data.

Stakeholders should look closely at CMS's estimates. CMS has acknowledged that it had difficulty estimating the regulatory burden of the Proposed Rule. Comments from Manufacturers may help to clarify the level of effort they expect will be necessary.

The estimate ranges from 3 hours for small teaching hospitals that receive few payments or other transfer of value, to 60 hours for teaching hospitals that have lengthy disputes.[9]

Stakeholders should look closely at CMS's estimates. CMS has acknowledged that it had difficulty estimating the regulatory burden of the Proposed Rule. Comments from Manufacturers may help to clarify the level of effort they expect will be necessary. In particular, the estimates regarding resources and effort that small Manufacturers and teaching hospitals may need to expend appear to be low.

2. Compliance Preparation Period

Although CMS will not require Manufacturers and GPOs to begin collecting data under the Sunshine Act until after the publication of final regulations, it has proposed a ''preparation period'' of 90 days.[10] CMS asked for comments from Manufacturers and GPOs on whether this time period is sufficient.

Stakeholders should comment on the operational, implementation, and compliance issues associated with initiating the collection of required data so that CMS can accurately estimate the time and effort it will take.

[4] M.G.L. c. 111N; *see also* 105 CMR 970.000.

[5] Letter from Donald M. Berwick, M.D., Administrator, Centers for Medicare & Medicaid Services to Senator Herb Kohl, Chairman, Senate Special Committee on Aging (Oct. 28, 2011), available at: http://www.grassley.senate.gov/about/upload/Sunshine-Act-CMS-Response.pdf.

[6] 76 Fed. Reg. at 78743.

[7] 76 Fed. Reg. at 78760.

[8] 76 Fed. Reg. at 78759.

[9] 76 Fed. Reg. at 78761.

[10] 76 Fed. Reg. at 78743.

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For example, after CMS publishes final regulations, Manufacturers and GPOs will need to take many time-consuming steps, including analysis and interpretation of the final regulations; configuration of software systems, which often will require dependence on external vendors; revision of policies and procedures; and development and implementation of a compliance training program.

The fact that CMS apparently had difficulty drafting the Proposed Rule leads to the conclusion that implementation will be anything but simple. Affected parties therefore should carefully consider whether 90 days will give them enough time to prepare.

B. Definitions

The Proposed Rule defines a number of terms that are at the heart of the Sunshine Act, and they include: applicable manufacturer; covered drug, device, biological, or medical supply; teaching hospital; and applicable group purchasing organization.

1. Applicable Manufacturer

CMS solicited comments on its proposed interpretation of ''applicable manufacturer,'' which is defined in the Sunshine Act.[11] In the Proposed Rule, CMS expanded on the Sunshine Act by defining ''applicable manufacturer'' as an entity that is:

> (1) Engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply for sale or distribution in the United States, or in a territory, possession, or commonwealth of the United States; or
>
> (2) Under common ownership with an entity in paragraph (1) of this definition, which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply for sale or distribution in the United States, or in a territory, possession, or commonwealth of the United States.[12]

The Proposed Rule broadened the Sunshine Act's definition in a number of ways. First, a manufacturer that sells or distributes *at least one* covered drug, device, biological, or medical supply in the United States must report on *all* payments or other transfers of value given to covered recipients, even if not in connection with a covered product.[13] Manufacturers should consider commenting on this expansive interpretation of the definition. Given that reporting of the type of data required by the Sunshine Act is unprecedented, Manufacturers should consider urging CMS to take a more measured approach, which would give all affected parties — including CMS — the opportunity to analyze whether requiring Manufacturers to collect and report data related to uncovered products is necessary or appropriate.

Second, although not included in the definition of ''applicable manufacturer'' in the Sunshine Act, a manufacturer of a covered product is deemed to be an ''applicable manufacturer'' if its products are *sold or distributed* in the United States—regardless of where the covered product is produced or where the manufacturer is located or incorporated. CMS included this clarification because the Sunshine Act defines an ''applicable manufacturer'' to mean one that is ''*operating*'' in the United States.[14]

Third, the Proposed Rule defined entities under ''common ownership'' to mean those ''that are owned, in whole or in part, by the same individual, individuals, entity, or entities, directly or indirectly. This includes, but is not limited to, parent corporations, direct and indirect subsidiaries, and brother or sister corporations.''[15]Alternatively, CMS may establish a threshold to meet the definition of ''common ownership'' where the same individual or entity ''owns 5 percent or more of total ownership in two or more entities.''[16] CMS has solicited comments on this definition and, specifically, whether 5 percent is an appropriate threshold if it decides to take this approach. In other contexts, such as Medicare enrollment, CMS has applied a 5 percent threshold when seeking ownership information.

In addition to commenting on the appropriate test for common ownership, Manufacturers and other interested parties also should request guidance on the circumstances in which an entity under common ownership is considered to be ''provid[ing] assistance or support'' to the Manufacturer.

2. Covered Drug, Device, Biological, or Medical Supply

The Proposed Rule defines ''covered drug, device, biological, and medical supply'' to include all drugs, devices, biologicals, and medical supplies that are eligible for payment by Medicare, Medicaid, or the Children's Health Insurance Program, including products reimbursed separately under a fee schedule or bundled as a part of a composite payment system (such as the hospital inpatient prospective payment system).[17] The definition excludes over-the-counter (OTC) drugs and also limits covered devices and medical supplies to those that require premarket approval or notification to the Food and Drug Administration (FDA).

If CMS adopts this definition, it would exempt, for example, manufacturers of OTC drugs or simple devices or supplies (such as tongue depressors) from the Sunshine Act's requirements, unless the manufacturer produces other covered products for sale or distribution in the United States.[18] This definition seems to exempt laboratories using laboratory-developed test kits, which are currently regulated under the Clinical Laboratory Improvement Amendments rather than through the

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[11] Section 6002 of the Affordable Care Act added section 1128G to the Social Security Act (Act). Section 1128G(e)(9) of the Act defines a '' 'manufacturer of a covered drug, device, biological, or medical supply' as—: Any entity which is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply (or any entity under common ownership with such 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 drug, device, biological, or medical supply).''

[12] 76 Fed. Reg. at 78743-44; *see also* Social Security Act, § § 1128G(e)(2), (9).

[13] 76 Fed. Reg. at 78744, 78767.

[14] 76 Fed. Reg. at 78744, 78767; *see also* Social Security Act, § 1128G(e)(2).

[15] 76 Fed. Reg. at 78767.

[16] 76 Fed. Reg. at 78744.

[17] 76 Fed. Reg. at 78745, 78767.

[18] 76 Fed. Reg. at 78744.

FDA device approval process, but such laboratories should consider seeking firm guidance on this issue.

As noted above, Manufacturers would need to report *all* applicable payments or transfers of value to covered recipients related to covered as well as non-covered products. For the reasons discussed above, Manufacturers, as well as covered recipients should consider urging CMS to limit the reporting requirements to covered products, which would greatly simplify implementation.

3. Covered Recipients: Physicians and Teaching Hospitals

The Sunshine Act defines a ''covered recipient'' to mean a physician and a teaching hospital,[19] which CMS referred to as ''physician covered recipients'' and ''hospital covered recipients.''[20] Under the Proposed Rule, the term ''physician'' has the same meaning as in section 1861(r) of the Social Security Act (''Act''), which ''includes doctors of medicine and osteopathy, dentists, podiatrists, optometrists and licensed chiropractors.''[21] CMS proposed that Manufacturers identify each physician covered recipient by the physician's National Provider Identifier (''NPI''), which can be found through the National Plan & Provider Enumeration System (NPPES) available on CMS's website.[22]

If a physician is not listed in the NPPES, the Manufacturer must obtain the NPI directly from the physician. CMS requested comments on whether it should use a different unique identifier for physicians who do not have an NPI.

The term ''teaching hospital,'' however, is not defined by the Sunshine Act or any other federal law. CMS proposed that it should include any hospital that receives graduate medical education (GME) payments through the Medicare program.

Specifically, the Proposed Rule defined a ''teaching hospital'' as any institution that received Indirect Medical Education (IME) payments, direct GME payments, or psychiatric hospitals IME payments ''during the most recent year for which such information is available.''[23]

CMS recognized that this definition may not capture hospitals with accredited residency programs that do not receive IME or GME payments, which are difficult to identify based on Medicare payment data. To allow Manufacturers to identify hospital covered recipients, CMS proposed to publish a list and sought comments on this idea.[24]

Stakeholders should point out to CMS that the list will have no utility unless CMS makes clear that it is the definitive list of hospital covered recipients for reporting purposes and publishes it well in advance of each reporting period.

4. GPOs

As expected, CMS extended the definition of GPO to include physician-owned distributors (POD), which likely will cause controversy. A growing phenomenon over the past five years, PODs take many forms, but a POD typically is a joint venture formed by groups of physicians to sell and distribute devices to hospitals where the physician-owners perform procedures that involve implantation of those same devices. Congress and industry stakeholders have questioned whether PODs implicate the federal Anti-kickback Statute (AKS) because physician-owners profit from the sale and distribution of devices they implant.

Because the definition of ''applicable manufacturer'' does not reference distributors,[25/] some have questioned whether the Sunshine Act requires reporting by PODs. CMS resolved this issue by observing that a GPO must be arranging for or negotiating the purchase of covered devices and then noting that Congress gave CMS the authority to define GPOs.[26] But critics may respond that Congress expressly excluded distributors from the Sunshine Act and that CMS is overreaching because a POD would not be considered a GPO under any common definition of that term. Although CMS will likely receive numerous comments on this issue, CMS has given this matter substantial consideration due to Congressional and stakeholder interest in PODs to date. It is therefore doubtful that CMS will retreat from its interpretation in the Proposed Rule.

C. Information That Must Be Collected and Reported

The Proposed Rule described the requirements of the transparency reports that Manufacturers and GPOs must submit to CMS and also detailed a procedure for allowing covered recipients to review and dispute the data before publication.

CMS asked for comments on various aspects of the transparency reports,[27]which, under the Proposed Rule, must contain the following information for *each* payment or other transfer of value:

- name and business address of the covered recipient (or if the payment or other transfer of value is made to a third party at the covered recipient's request, the name of the recipient);
- the specialty and NPI (if applicable) for physician covered recipients;
- amount, date, form, and nature of each payment or other transfer of value;
- the name under which the covered product is marketed, or the scientific name if the market name has not been selected, if the payment or other transfer of value can be ''reasonably associated'' with a particular product;
- whether the payment or other transfer of value is subject to delayed publication because the payment was furnished under a research or development agreement or a clinical investigation; and
- whether the payment or other transfer of value was provided to a physician who holds an ownership or investment interest in the applicable manufacturer.

1. Covered Product Associated With Each Payment or Transfer of Value

The Sunshine Act requires that the transparency report include the name of the covered product associated with the payment if the marketing, education, or research is ''specific to'' a covered product, but, as a practical matter, Manufacturers may have difficulty con-

[19] Social Security Act, § 1128G(e)(6).
[20] 76 Fed. Reg. at 78746.
[21] 76 Fed. Reg. at 78745.
[22] 76 Fed. Reg. at 78746.
[23] 76 Fed. Reg. at 78745-46, 78767.
[24] 76 Fed. Reg. at 78746.
[25] Social Security Act, § 1128G(e)(2), (9).
[26] 76 Fed. Reg. at 78751.
[27] 76 Fed. Reg. at 78746.

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necting each payment or other transfer of value to only one particular product.

For example, a cardiac device manufacturer may have a consulting arrangement with a cardiology subspecialist who implants or otherwise uses several products and who serves as a consultant with respect to both products.

An additional complexity is the fact that device manufacturers often market a line or family of products, rather than a single product. The Proposed Rule acknowledged that not every financial relationship between a Manufacturer and a covered recipient is linked to a specific covered product, but CMS would nevertheless require this information where the payment or other transfer of value is ''reasonably associated'' with a specific covered product.

CMS requested input on whether it should instead allow a Manufacturer to report multiple covered products for a single payment or other transfer of value.

Stakeholders should consider whether CMS's proposed approach would present practical challenges. If so, providing CMS with pertinent examples, such as the one detailed above, may be an effective way to illustrate the problem.

2. Form, Nature, and Value of the Payment

The Sunshine Act differentiates between the form and nature of each payment or other transfer of value to a covered recipient. The form of payment describes the payment itself (e.g., cash or cash equivalents; in-kind items or services; or stock options, or any other ownership interest, dividend, profit, or return on investment) while the nature of payment relates to its purpose (e.g., gifts, entertainment, food, travel, etc.).

CMS adopted the categories for describing the form and nature of payment set forth in the Sunshine Act and proposed to define them according to their dictionary definitions.

In addition, CMS intends to require a Manufacturer to report only one form and one nature of payment for each payment or other transfer of value, which could present difficulty because some transactions involve several forms of payment.

The Proposed Rule offered an example. If a physician receives meals and travel expenses in connection with a consulting fee, CMS would require the manufacturer to report the information as ''three separate line items: consulting fees, meals, and travel.''[28] These line items presumably describe the nature of payment.

CMS did not, however, make clear how the Manufacturer should report the form of payment in this example; it merely stated that the Manufacturer should ''break out the disparate aspects of the payment that fall into multiple categories for both form of payment and nature of payment.''[29]

CMS requested input on both the ''usefulness'' of data reported under a single form of payment and nature of payment and on any ''operational issues'' manufacturers might face in collecting and reporting data in this way.[30]

Recognizing that an alternative approach may be easier for Manufacturers to implement, CMS also sought input on the advantages and disadvantages of allowing a transaction that involves multiple types of payment to be reported as a single entry.

Thus, in the example of a consulting fee arrangement, the fee, meals, and travel would be reported as a single item, but CMS expressed concern that it would make the public disclosure database confusing.

As an operational matter, Manufacturers should consider how they will capture and report the information as CMS proposes. If the Proposed Rule does not comport with a Manufacturer's current business processes, the data collection and reporting obligations might impose substantial administrative burdens. Manufacturers should examine existing sources of data that can be utilized, consider the necessary changes, and investigate which approach would be easier to implement.

a) Food and Beverage

Manufacturers should note CMS's guidance on reporting food or beverages provided to covered recipients. Where the covered recipient is easily identifiable, the Manufacturer would report the food provided to the covered recipient (if more than $10). Where a Manufacturer provides a group meal, however, tracking the data would be more complex.

CMS therefore proposed that Manufacturers report the cost per covered recipient ''receiving the meal''—even if the covered recipient does not actually partake in the meal. For example, as discussed in the Proposed Rule, if a Manufacturer's sales representative brings $25 worth of bagels and coffee to a solo physician's office for a morning meeting, the per covered recipient cost is $25—regardless of the number of individuals, such as non-covered office staff, who consume the food and beverages.

If the practice group has 5 physicians, then the cost per covered recipient would be $5, even if they do not all partake in the meal. While this approach may offer simplicity, it may result in reporting payments or other transfers of value that technically did not occur if, for example, one or more of the physicians are not in the office that day.

Of particular benefit to Manufacturers, CMS would not require buffet meals, snacks or coffee at booths at conferences to be reported because it would be difficult for Manufacturers to identify the physician covered recipients who participated.[31]

Outside of the food and beverage context, CMS offered scant guidance on how Manufacturers should value payments and other transfers of value. In other contexts, such as under the Stark Law and the AKS, the concept of ''fair market value'' applies, but CMS did not expressly adopt that approach here.

b) Research

CMS has proposed a process for reporting research payments (a category for nature of payment), acknowledging that reporting of payments or other transfers of value made in connection with research presents certain unique issues. As a threshold matter, Manufacturers must report all research-related payments pursuant to a written agreement and research protocol. Due to the ''complexities of the flow of research payments,'' CMS will require Manufacturers to report such payments in two categories: ''direct research'' and ''indirect research.''[32]

[28] 76 Fed. Reg. at 78747.
[29] *Id*.
[30] *Id*.
[31] 76 Fed. Reg. at 78748-49.
[32] 76 Fed. Reg. at 78749.

The Proposed Rule defined ''direct research'' payments as those ''provided to a covered entity directly by an applicable manufacturer or through a contract research organization (or similar entity).''[33] Indirect research payments are those given by a Manufacturer (including through a contract research organization) to a ''clinic, hospital, or other institution conducting the research. . .that pays the physician covered recipient (or multiple physician covered recipients) serving as the principal investigator(s).''[34]

For physician covered recipients, direct research payments must be reported under the name and NPI of the physician who receives the payment while indirect research payments must be reported under the name and NPI of the physician serving as the principal investigator.

A different process applies to hospital covered recipients. Manufacturers must classify direct research payments under the name of the teaching hospital; those same payments will also be reported as indirect research payments under the name of the principal investigator. CMS proposed this approach ''to maintain consistency''[35] even though it is mandating double reporting of these payments.

Stakeholders should consider how they structure and track research payments and comment on the proposed process for reporting research payments made to teaching hospitals, which requires double counting of payments. In addition, CMS apparently does not distinguish the costs to provide a drug or device used to conduct research from other research costs. Creating two subcategories to distinguish these two categories of payments could be useful information in evaluating payments to covered recipients.

D. Exclusions from Disclosure

Certain payments and transfers of value are exempt from disclosure. The Proposed Rule discussed certain exclusions in detail, but did not add any exclusions to those defined in the Sunshine Act.

One exclusion is for payments or transfers of value of less than $10, but Manufacturers must still track such payments because they must be reported if the annual aggregate amount for a covered recipient exceeds $100. If the aggregate limit is met, Manufacturers must then report each payment or transfer of value separately.

For example, if a Manufacturer provides a physician with 5 meals worth $9 each (a total of $45), a speaker fee of $150, and pens worth $5, the manufacturer must report three separate items: $150 for the speaker fee under ''direct compensation for serving as faculty or as a speaker for a medical education programs [sic]''; $45 for meals; and $5 for the pens as ''gifts.''[36]

Stakeholders should consider the relationship between this exclusion and CMS's proposal to require Manufacturers to report *all* payments or transfers of value to covered recipients as long as they have a covered product even when the payment or transfer relates to non-covered products. Because of this interpretation, the value of this exception for *de minimus* payments will likely be significantly diminished.

Another statutory exclusion is for discounts and rebates. As many stakeholders are already aware, this area of law is complex and uncertain, but CMS provided limited guidance in the Proposed Rule.

For example, while a covered recipient's purchase of a covered product is not covered by the Sunshine Act, several forms of payments or other transfers of value associated with the purchase—such as credits, refunds, and charge-backs made directly by manufacturers or through distributors—should be exempt, which could be accomplished by defining the term ''discount or rebate'' more broadly.

In addition, CMS should clarify that bundled discounts, which combine services or other things of value into one product price under a contractual agreement, also are exempt from the Sunshine Act's reporting requirements.

The Sunshine Act also excludes product samples that the Manufacturer does not intend to sell but that are given to covered recipients for patient use.[37] CMS did not discuss this exclusion, but many issues require clarification. Because the term ''sample'' as defined under the Food, Drug & Cosmetic Act applies only to drugs, Manufacturers should consider asking CMS to clarify that devices used in this same manner also qualify as product samples. The same issue arises with respect to other products as well. For example, Manufacturers provide discounts on reagents that covered recipients use for purposes of equipment calibration or CLIA proficiency testing rather than for performance of patient testing.

E. Report Submission and Correction Process

1. Registration and Attestations

CMS has proposed that only Manufacturers with information to report must register and file reports. Alternatively, CMS is considering—and seeking comments on—requiring ***all*** Manufacturers and GPOs to register with CMS.

Under this alternative approach, even if a Manufacturer or GPO has no information to report, the chief executive officer, chief financial officer, or chief compliance officer would have to attest that, ''to the best of his or her knowledge and belief, there were no reportable payments or transfers and value and/or ownership or investment interests during the previous calendar year.''[38] According to CMS, this approach would allow for a better understanding of financial relationships and would ensure that applicable manufacturers and GPOs perform a thorough evaluation to determine whether they have any reportable information. CMS requested comment on both the benefits and burdens of this approach and plans to make a final determination based on the comments received.[39]

Requiring an attestation from Manufacturers that have no data to report seems to disregard the fact that the threat of imposition of substantial CMPs for noncompliance are meant to—and should—serve as a deterrent.

When deciding whether to comment, Manufacturers and GPOs should also consider that any attestation or certification can independently give rise to civil or criminal liability if the attestation is knowingly or inten-

[33] 76 Fed. Reg. at 78768.
[34] 76 Fed. Reg. at 78768-69.
[35] 76 Fed. Reg. at 78749.
[36] 76 Fed. Reg. at 78750-51.
[37] Social Security Act, § 1128G(e)(10)(B)(ii).
[38] 76 Fed. Reg. at 78753-54.
[39] 76 Fed. Reg. at 78754.

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tionally false or misleading based on the information disclosed or omitted.

2. 45 Day Correction Period

Under the Sunshine Act, Manufacturers, GPOs, covered recipients, and physician owners and investors must have at least 45 days before data in the transparency reports is made available to the public to review and correct the data.

The Proposed Rule discussed alternative approaches to permit meaningful review and the opportunity to correct errors. CMS made clear that it does not want to arbitrate disputes—the parties are responsible for resolving any conflicts—but CMS is considering a means by which payments can be flagged as contested.[40] CMS asked for suggestions on how best to handle unresolved disagreements.

Covered recipients in particular should consider commenting on this aspect of the Proposed Rule. Given the potential for negative reaction from the public regarding reportable transactions, covered recipients should ensure that the final regulations allow ample opportunity to review the data and dispute any errors.

F. Audits and Penalties

The Secretary, CMS, and the Office of Inspector General of the U.S. Department of Health & Human Services (''OIG'') may audit, evaluate, or inspect a Manufacturer's or GPO's compliance with the Sunshine Act. To facilitate this review, CMS would require Manufacturers and GPOs to maintain, for five years, all books, records, documents, and other materials sufficient to enable an audit, evaluation, or inspection of compliance with legal requirements.[41] Manufacturers and GPOs should consider the breadth of the document retention requirement and the potential burden that it may place on them.

The Proposed Rule also identified factors CMS may consider when determining the amount of CMPs,[42] and they include:

- the length of time the applicable manufacturer or 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 at issue;
- level of culpability;
- nature and amount of information reported in error; and
- degree of diligence exercised in correcting information reported in error.

Given the potential for imposition of significant CMPs, Manufacturers and GPOs should evaluate whether these factors allow for consideration of all possible mitigating circumstances.

G. Preemption of State Law

For some Manufacturers, a fundamental question that remains unanswered is to what extent the Sunshine Act preempts the myriad state disclosure laws with which Manufacturers must already comply. Indeed, the administrative burden for manufacturers weighs more heavily if they must comply with separate state and federal reporting obligations.

According to the Proposed Rule, preemption took effect on Jan. 1 2012, even though final regulations have not been published yet. Given the level of uncertainty about what the final regulations will require, Manufacturers may have difficulty determining all circumstances in which state law will be preempted.

One state agency has offered some guidance on this issue. On December 28, 2011, the Massachusetts Department of Public Health (''DPH'') issued a letter to manufacturers who must comply with the Massachusetts gift ban law stating that manufacturers **must** collect and submit reports until CMS issues a final rule and that certain other requirements are not preempted.[43] The Massachusetts law includes requirements that go beyond just reporting obligations, and it provided a list of examples of requirements that will remain in effect, including the prohibition on specific types of transactions and interactions between pharmaceutical and medical device companies and Massachusetts health care practitioners.

H. Final Comments

The Sunshine Act was created out of an unusual confluence of events. Pharmaceutical and medical device manufacturers were under significant scrutiny as a result of their financial relationships, which led to many large settlements with the government for alleged violations of the AKS. Even so, many in Congress believed that AKS enforcement efforts were insufficient.

At the same time, many academic medical centers believed that physicians and manufacturers were not following their internal conflict of interest rules. Manufacturers wanted to be responsive to these concerns, and also to avoid more enforcement activity. The compromise was disclosure. But it remains to be seen whether this approach alone will cure the perceived problems that gave rise to the Sunshine Act.

In the Proposed Rule, CMS recognized the limits of disclosure, stating that ''financial ties alone do not signify an inappropriate relationship.''[44] The problem, it noted, is that the information provided through the reporting process cannot ''differentiate beneficial, legitimate financial relationships from those that create conflict of interests or are otherwise improper.''[45]

In addition, although CMS recognized the importance of collaboration between industry, physicians, and academic medical centers, it noted that these financial arrangements ''can also introduce conflicts of interests that may influence research, education, and clinical decision-making in ways that compromise clinical integrity and patient care, and may lead to increased health care costs.''[46]

CMS concluded, however, that ''transparency can shed light on the nature and extent of relationships, and

[40] 76 Fed. Reg. at 78755.
[41] 76 Fed. Reg. at 78758.
[42] 76 Fed. Reg. at 78757-58.
[43] Letter from Massachusetts Department of Public Health to Pharmaceutical and Medical Device Manufacturers (Dec. 28, 2011), available at: http://www.mass.gov/eohhs/docs/dph/quality/healthcare/pcoc/ma-pharm-code-of-conduct-circular-letter-12-28-2011.pdf
[44] 76 Fed. Reg. at 78743.
[45] *Id.*
[46] *Id.*

may dissuade inappropriate conflicts of interest from developing.''[47]

Though larger policy issues remain, in the coming months CMS will grapple with the details involved in developing final regulations. While the comment period remains open, Manufacturers, GPOs, and other interested parties should consider submitting comments on the aspects of the Proposed Rule that raise concern as well as those that are favorable to their position.

In addition to addressing specific issues, interested parties should consider commenting on the broader questions raised in the Proposed Rule, especially those related to the regulatory burdens associated with implementation. Given the breadth of issues on which CMS requested input, it undoubtedly will make substantial changes to the Proposed Rule.

[47] *Id*.

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