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CMS Issues Proposed Regulations on New Disclosure and Reporting Requirements Related to Manufacturers and GPOs

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Introduction

On May 17, 2010, K&L Gates LLP issued a client alert on the new law "Transparency Reports and Reporting of Physician Ownership or Investment Interests"[1] (the "Sunshine Act") issued under the Patient Protection and Affordable Care Act of 2010 ("PPACA").[2] Click here to view this alert. The Sunshine Act mandated the government to establish regulations and reporting procedures by October 1, 2011, but it missed the deadline. On December 19, 2011, the Centers for Medicare and Medicaid Services ("CMS") issued proposed regulations which are the topic of this updated alert. CMS requests comments to be submitted by **February 17, 2012**.[3] Given CMS's broad interpretation of the Sunshine Act and the penalties associated with failure to comply, manufacturers and group purchasing organizations ("GPOs") should strongly consider submitting comments on the proposed rule. CMS is specifically requesting input on its proposals as well as the challenges and burdens entities may encounter in collecting the data.

Delayed Reporting Effective Date

The Sunshine Act requires (1) ***applicable manufacturers*** to disclose payments and other transfers of value to teaching hospitals and physicians ("covered recipients"), and (2) both ***applicable manufacturers*** and ***applicable GPOs*** to disclose ownership or investment interests held by physicians or their immediate family members ("IMFs") and any payments or other transfers of value to an owner/investor physician.[4]

While the Sunshine Act requires that the first disclosure be made on **March 31, 2013** in regard to the preceding **calendar year 2012**,[5] due to CMS's delay in publishing regulations, CMS proposes to finalize the regulations during the early part of calendar year 2012 and only require information from the remaining part of 2012 to be reported by the March 31, 2013 submission date. CMS is soliciting comments on the amount of time entities will need to gather the information – for instance, whether 90 days is sufficient.[6]

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[1] Section 1128G of the Social Security Act (42 U.S.C. § 1320a-7g)).
[2] On March 23, 2010, President Obama signed into law the comprehensive health care overhaul known as PPACA, Pub. Law 111-148, as amended by the reconciliation bill (H.R. 4872) signed on March 30, 2010.
[3] 42 CFR 78742 (December 19, 2011).
[4] *See* PPACA § 6002(a)(1) and (a)(2).
[5] *See* PPACA § 6002(a)(1).
[6] *See* 42 CFR at 78743.

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Payments and Other Transfers of Value

In the proposed regulations, CMS provides further clarification on certain definitions, provides guidance on certain exceptions in the Sunshine Act, proposes some additional carve-outs, and outlines the proposed process for reporting the information.

Applicable Manufacturers

The Sunshine Act defines an applicable manufacturer to include (1) any entity that engages in the "production, preparation, propagation, compounding, or conversion of a covered drug, device, biological or medical supply" (a "covered item") ("Type I") and (2) any entity under common ownership with a Type I entity that provides assistance or support with respect to the "production, preparation, propagation, compounding, conversion, marketing, promotion, sale or distribution" of a covered item ("Type II").[7] The Sunshine Act further defines an applicable manufacturer as one that ***operates*** in the "United States, or in a territory, possession, or commonwealth of the United States."[8]

CMS arguably broadens the definition of applicable manufacturers under the proposed regulations. CMS states that entities will be applicable manufacturers if ***one*** of their covered items is sold or distributed in the United States, even if their products are manufactured and/or the manufacturer's business is located outside of the U.S. CMS also proposes that applicable manufacturers include an entity that holds the Food and Drug Administration ("FDA") approval, licensure or clearance for a covered item, even if it contracts out the manufacturing function. Once an entity falls within the definition of applicable manufacturer, CMS states then it is subject to the Sunshine Act and must disclose ***all*** payments and other transfers of value to covered recipients, even if a payment is in no way related to an actual covered item.[9]

For Type II entities, CMS proposes to define "common ownership" as "when the same individual, individuals, entity, or entities, directly or indirectly, own ***any portion*** of 2 or more entities." This includes, but is not limited to, parent companies, direct and indirect subsidiaries, and brother/sister corporations. In the alternative, CMS is also considering limiting the ownership to 5 percent or more of total ownership and is seeking comment on whether the 5 percent threshold is appropriate.[10] The 5 percent threshold would mirror ownership definitions in other health care laws – e.g., Medicare enrollment.

Covered Drug, Device, Biological, or Medical Supply

Under the Sunshine Act, a covered item includes any drug, device, biological, or medical supply for which payment is ***available*** under Medicare, Medicaid or Children's Health Insurance Program state plans (or waivers of such plans). CMS is proposing that even in cases where the payment under a federal program is indirect, if it is being provided through a bundled or composite rate payment, it will be considered payment that is "available" under those programs (e.g., inpatient PPS, outpatient PPS, or ESRD PPS).[11]

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[7] PPACA § 6002(e)(2) and (e)(9).
[8] PPACA § 6002(e)(2).
[9] *See* 42 CFR at 78744.
[10] *See id*.
[11] *See* 42 CFR at 78744-78745.

In addition, CMS is proposing two limitations to the definition of covered items. First, covered drugs or biologicals would be limited to those that require a prescription to be dispensed; this would eliminate "over-the-counter" items. Secondly, CMS is also proposing to limit covered devices (including medical supplies) to those that require premarket approval by or notification to the FDA. CMS notes that this will result in excluding many Class I devices and certain Class II devices which are exempt from premarket notification requirements (21 U.S.C. § 360(l) or (m)). For example, CMS notes that tongue depressors and elastic bandages would be excluded.[12]

Teaching Hospitals as Covered Recipients

Covered recipients include physicians (other than a physician who is an employee of an applicable manufacturer) and teaching hospitals. While the Sunshine Act defines "physician" and "employee," there is no definition for "teaching hospitals." CMS proposes to define a "teaching hospital" as any institution that received payments under any of the following statutory programs during the last calendar year for which such information is available: (1) IPPS Indirect Medical Education (§1886(d)(5)(B) of the Social Security Act); (2) Direct Graduate Medical Education (§1886(h) of the Social Security Act); or (3) Psychiatric Hospitals Indirect Medical Education (§1886(s) of the Social Security Act).[13]

Reporting by Applicable Manufacturers

CMS proposes that when dealing with a system of commonly owned entities, each entity that meets the Type I definition will need to report separately. However, for systems with Type I and Type II entities, CMS proposes that they can choose whether to report collectively or individually. If they report collectively, then the report will need to clearly name all of the entities and may identify the separate payments from each entity or combine them.[14] CMS also proposes that if a payment is provided in accordance with a joint venture or other cooperative agreement between two or more applicable manufacturers, then the payment must be reported in the "name of the applicable manufacturer that actually furnished the payment" to the covered recipient, unless their written agreement requires all payments be reported by one of the applicable manufacturers -- the payments must be reported only once by only one applicable manufacturer.[15]

Identifying the Covered Item

The Sunshine Act requires the applicable manufacturer to report the name of the covered item associated with any payment related to "marketing, education or research." CMS interprets this to mean any reasonable association with a covered item. For example, "[i]f a sales representative takes a physician to dinner to explain the benefits of the applicable manufacturer's new product, the name of the product must be included since it was associated with the dinner."[16] CMS proposes using the name under which the covered item is marketed, or if there is no market name, the scientific name. Only one covered item should be reported even if multiple products relate to the payment. Although,

[12] *See* 42 CFR at 78745.
[13] *See* 42 CFR at 78745-78746.
[14] *See* 42 CFR at 78744.
[15] *See* proposed regulations § 403,908(d)(3) at 42 CFR at 78770.
[16] *See* 42 CFR at 78747.

as an alternative proposal, CMS is considering allowing applicable manufacturers to report the multiple covered items related to the payment.[17]

Identification of Covered Recipient

If the covered recipient is a physician, then the applicable manufacturer must report the physician's National Provider Identifier ("NPI") and specialty. CMS suggests that applicable manufacturers use the National Plan & Provider Enumeration System ("NPPES") to obtain a physician's NPI, but makes clear that even if it is not listed,[18] the applicable manufacturer is still responsible for tracking down the NPI and reporting it. CMS is considering requiring other identifying information if there is no NPI – for example, a state license number. CMS is seeking comment on this proposal. For teaching hospitals, CMS proposes to publish a list of hospitals on an annual basis that receive medical education on its website.[19]

In situations where a covered recipient requests that a payment be made to another entity or person, CMS proposes that these payments be reported under the name of the covered recipient and the reporting entity should also report the name of the entity or person who received the payment. If payments are made to a physician group or practice, CMS proposes that the payments should be reported individually under the name(s) of the physicians who are covered recipients.[20]

Form and Nature of Payments

Both the ***form of each payment*** and the ***nature of each payment*** must be reported. CMS proposes that for each payment or other transfer of value, the applicable manufacturer may only use one category for the nature of payment and one category for the form of payment. CMS is not proposing any additional ***form of payment*** categories, but is seeking comments. CMS does provide some guidance on several of the ***nature of payment*** categories as discussed below. In order to provide an opportunity to explain the categorizations, CMS also proposes to allow the applicable manufacturer to submit a separate document explaining its assumptions in reporting the data (which would not be posted publicly).[21]

(1) Food and Beverage Category. For all payments or transfers of value, the Sunshine Act carves out anything valued at less than $10, with an aggregate calendar year limit of $100 (with price index increases).[22] For meals provided in group settings (e.g., a buffet), CMS proposes reporting the cost per covered recipient even if a particular individual did not consume the food. CMS uses the following example:

> "[I]f once during the calendar year, a sales representative from an applicable manufacturer 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 is $25…[.] However, if the practice group includes

[17] *See id*.
[18] NPI Registry: https://nppes.cms.hhs.gov/NPPES/NPIRegistryHome.do. Database can be downloaded at: http://nppes.viva-it.com/NPI_Files.html.
[19] *See* 42 CFR at 78746-78747.
[20] *See* 42 CFR at 78746.
[21] *See* 42 CFR at 78747-78748.
[22] *See* 42 CFR at 78750.

> five physicians, then the per-covered recipient cost is $5 (regardless of whether all five physicians actually consumed any of the food provided), so the payment need not be reported."[23]

CMS is considering an alternative approach for large group practices or meetings with specific hospital-based physicians – e.g., counting the number of department specific physicians as opposed to all physicians. CMS is also considering an additional carve out for food or beverages provided at conferences or similar events where identifying specific covered recipients would be difficult.[24]

(2) Research Category. CMS is proposing to 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 is soliciting comments on this approach. [25]

Because research payments often involve multiple parties, CMS provides a proposal on how to report and disclose such payments.[26] The reporting entity must separate the categories of research payments between direct and indirect payments. A "direct research payment" is one that is provided directly to a physician covered recipient or teaching hospital by an applicable manufacturer or a contract research organization ("CRO")[27] or similar entity (e.g., site management organization).[28] An "indirect research payment" is one made by an applicable manufacturer or CRO (or similar entity) to a clinic, non-teaching hospital, or other research institution where such organization then pays the physician covered recipients serving as principal investigators. In order to maintain consistent reporting, CMS proposes that payments provided to teaching hospitals (a covered recipient) and then paid by such hospital to a physician covered recipient, must be reported for both the teaching hospital (as direct) and the physician (as indirect).[29]

The research payment should be reported individually under the names and NPIs of the physician covered recipients who served as the principal investigators (whether the payment was direct or indirect). Any payments reported as indirect research must also include the name of the entity or individual that received the payment. CMS acknowledges that payments made for clinical research may include all items and services, including those of the physician principal investigator. Physicians may be receiving a flat salary from the hospital, making the indirect physician payment difficult to determine. Therefore, CMS proposes that for both direct and indirect payments, the total payment amount for the clinical research must be reported. CMS is seeking comments on how to report the specific information for physician covered recipients on the website.[30]

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[23] 42 CFR at 78748.

[24] *See* 42 CFR at 78748-78749.

[25] *See* 42 CFR at 78749.

[26] CMS notes in the proposed rule that the reporting requirements will in some cases be duplicative of the requirements under FDA regulations at 21 CFR part 54. *See* 42 CFR at 78750.

[27] CRO as defined by 21 CFR 312.3(b).

[28] *See* 42 CFR at 78749.

[29] *See id*.

[30] *See id*.

(3) Charitable Contribution Category. CMS clarifies that this category includes any payment or other transfer of value made to a federally tax-exempt organization under the Internal Revenue Code of 1986 if such payment or transfer of value is not more specifically described by another category.[31]

(4) Direct Compensation for Faculty/Speaker Medical Education Program. Unlike the other categories that are more limiting, CMS is proposing that all payments or other transfers of value to physicians to serve as speakers, whether for medical education or otherwise, be included in this category. CMS is seeking comment on this proposal and whether it should be limited to CME-accredited speaking engagements.[32]

(5) Other. Finally, CMS proposes to add a "catch all" category for payments or other transfers of value that do not fit into one of the statutory categories.[33]

Exclusions from Payments or Other Transfers of Value

The Sunshine Act specifically excludes certain types of payments or other transfers of value.[34] CMS provides some guidance on certain categories of excluded items and also proposes another potential carve out, as discussed below.

(1) Personal Transfers. CMS does not intend for ***"purely personal transfers of value"*** to be included in the reporting and disclosure requirements. For example, an employee of an applicable manufacturer that gives a gift to her spouse who happens to be a covered recipient. CMS solicits comments on how to incorporate this into the final regulation. [35]

(2) Transfers of Value Less than $10. The Sunshine Act exempts from the reporting requirements payments or other transfers of value less than $10, except if the total payments provided to a covered recipient during the year exceed $100.[36] CMS provides a few examples of the application of this exclusion:

> "*Example 1*: An applicable manufacturer takes a physician out to lunch four times during the year and each lunch costs $9. The applicable manufacturer has no other relationships with the physician. Since the aggregate cost of the four meals is $36 for the year, these payments would not need to be reported."[37]
>
> "*Example 2*: An applicable manufacturer provides a physician with five meals, each worth $9, a speaker fee of $150, and pens worth $5. The aggregate amount is greater than $100 so all the payments need to be reported. The speaker fee should be reported as $150 under 'direct compensation for serving as faculty or as a speaker for a medical education programs,' the meals would be reported together as food for $45, and the pens would be reported as gifts for $5."[38]

[31] *See* 42 CFR at 78748.
[32] *See* 42 CFR at 78750.
[33] *See id*.
[34] *See* PPACA § 6002(e)(10)(B).
[35] *See* 42 CFR at 78750.
[36] *See* PPACA § 6002(e)(10)(B)(i).
[37] *See* 42 CFR at 78750.
[38] 42 CFR at 78750-78751.

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In order to avoid reporting payments of less than $10 individually when the total annual amount is triggered, CMS proposes all small payments or other transfers of value in the same **nature of payment** category should be reported as one total amount for that category.[39]

(3) Educational Materials That Directly Benefit Patients or Are Intended for Patient Use. CMS clarifies that this exclusion only includes materials (e.g., written or electronic) and does not cover items or services. CMS is considering whether this exclusion should include materials given to covered recipients for education purposes (e.g., medical textbooks) as opposed to being provided to the patients themselves.[40]

(4) In-Kind Items for the Provision of Charity Care. CMS proposes to define charity care as "services provided to a covered recipient specifically for a patient who cannot pay, where the covered recipient neither receives, nor expects to receive, payment because of the patient's inability to pay."[41] However, charity care would not include any in-kind items to a covered recipient for the care of all patients. CMS uses the example of the donation of an imaging machine to a charitable, tax-exempt hospital that would be used for both paying and nonpaying patients – this would not be excluded as an in-kind item for charity care. [42]

(5) Indirect Payments through a Third Party. The Sunshine Act excludes the reporting of payments made through a third party when the applicable manufacturer is unaware of the covered recipient's identity. CMS proposes that an applicable manufacturer will have the requisite knowledge/awareness if it has "actual knowledge, or acts in deliberate ignorance or reckless disregard of, the identity of the covered recipient."[43] This standard mirrors the "knowledge" standard under the False Claims Act and other health care fraud and abuse laws. CMS also proposes to impute onto the applicable manufacturer any awareness of its agents. For example, CMS noted that a payment made through a third party to the department chairs at a hospital would need to be reported because the names of the department chairs are publicly available.[44]

(6) Delayed Publication for R&D and Clinical Investigations. With respect to payments and other transfers of value related to research and development ("R&D") or clinical investigations, the applicable manufacturer is required to submit the information to CMS; however, the publication of the data on the CMS website is subject to a delay. CMS proposes that the delay will stay in place until the first publication date after the earlier of either: (1) the approval, ***licensure*** or clearance by the FDA of the covered drug, device, biological or medical supply; or (2) four-calendar years after the date of payment. This is consistent with the statutory language, with the added concept of FDA licensure.[45]

With respect to what items are subject to the delay, the Sunshine Act uses terminology such as "medical technology." CMS proposes to interpret "medical technology" broadly as any drug, device, biological or medical supply as well as consistently refer to "research and development." CMS therefore proposes the following would be subject to the delay:

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[39] *See* 42 CFR at 78750.
[40] See 42 CFR at 78751.
[41] 42 CFR at 78751.
[42] *See id*.
[43] 42 CFR at 78751.
[44] *See id*.
[45] *See* 42 CFR at 78756.

- Payments to covered recipients for services in connection with ***"research on, or development of, a new*** drug, device, biological, or medical supply," as well as ***"new applications*** of an existing drug, device, biological or medical supply."
- Payments in connection with ***clinical investigations for a "new*** drug, device, biological, or medical supply" but ***not new applications*** of existing drugs, devices, biologicals or medical supplies.[46]

Under the proposed regulations, the applicable manufacturer will bear the burden of indicating the "delay status" when it submits the data (both at the inception and annually thereafter). Once FDA approval, licensure or clearance has been obtained, the applicable manufacturer is required to submit that information to CMS in the next annual submission; failure to do so may be considered a failure to report and result in civil monetary penalties. Regardless, the data will be published automatically by the fourth year.[47]

R&D and clinical investigations must include a written agreement and research protocol between the applicable manufacturer and covered recipient. In cases where applicable manufacturers contract with a CRO, as long as there is a written agreement between them, the CRO may enter into the written research agreement with the covered recipient in lieu of the applicable manufacturer.[48]

Ownership or Investment Interests

In the proposed regulations, CMS also provides further clarification of certain defined terms and proposals on reporting information related to ownership or investment interests.

Applicable GPOs

In the proposed regulations, CMS views that the Sunshine Act not only covers traditional GPOs that negotiate contracts for their members but also GPOs that purchase covered items for resale or distribution. For example, CMS views ***physician-owned distributors*** of covered items to be within this definition.[49] However, CMS proposes that this definition would not include an entity that buys covered items ***solely for its own use***. For example, large practices or hospitals that purchase such covered items for their own use.[50]

As discussed above, CMS is proposing to limit the definition of drugs and biologicals to those that require a prescription to be dispensed. However, CMS believes that the proposal to limit the definition of devices and medical supplies to only those that require premarket approval by or notification to FDA may be too narrow for GPOs given their business operations and is seeking comments on this limitation.[51]

[46] *See* 42 CFR at 78757.
[47] *See* 42 CFR at 78756-78757.
[48] *See* 42 CFR at 78756.
[49] *See* 42 CFR at 78751-78752.
[50] *See* 42 CFR at 78752.
[51] *See id.*

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Ownership or Investment Interests

The Sunshine Act did not define the term "ownership or investment interests." Borrowing from the federal Physician Self-Referral law ("Stark"),[52] CMS proposes to define an "ownership or investment interest" as one that may be "direct or indirect, and through debt, equity, or other means." It includes, but is not limited to, "stock, stock options (other than those received as compensation, until they are exercised), partnership shares, limited liability company memberships, as well as loans, bonds, or other financial instruments that are secured with an entity's property or revenue or a portion of that property or revenue."[53]

CMS proposes to carve out of an ownership or investment interests: (1) "an ownership/investment in a publicly traded security or mutual fund" as described in Stark; (2) "an interest in an applicable manufacturer or applicable GPO that arises from a retirement plan offered by that applicable manufacturer or applicable GPO to the physician (or a member of his or her immediate family) through the physician's (or IMF's) employment with that applicable manufacturer or applicable GPO"; (3) "stock options and convertible securities received as compensation, until the stock options are exercised or the convertible securities are converted to equity"; or (4) "an unsecured loan subordinated to a credit facility."[54]

Reporting Charts and Duplicative Reporting

CMS proposes the format of how payments and other transfers of value and ownership and investment interests should be reported under the Sunshine Act.[55] CMS requires that the information be electronically submitted in an excel work sheet that is saved as a comma-separate value file ("CSV").[56] CMS noted that there could be duplicative reporting when dealing with physician owners/investors who also receive payments or other transfers of value from applicable manufacturers or GPOs. CMS proposes that applicable manufacturers should submit one file ("Chart One") for all of their payments or other transfers of value and another file ("Chart Two") for all their physician ownership/investment interests. Chart One should note that the physician receiving the payment is a physician owner/investor, in order to prevent double counting of payments.[57]

Where an applicable GPO has payments or other transfers of value to report for a physician owner/investor, CMS proposes that it use the data elements from the payments and other transfers of value report contents for such information; however, the GPO is only required to report payments to physician owners/investors.[58]

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[52] 42 U.S.C. § 1395nn; 42 CFR 411.351 et al.

[53] 42 CFR at 78752.

[54] 42 CFR at 78752.

[55] A sample of the charts is located in the Federal Register at 42 CFR at 78772-78773, and CMS states it will place a copy of the spreadsheets on Regulations.gov.

[56] *See* 42 CFR at 78754.

[57] *See* 42 CFR at 78752-78753.

[58] *See* 42 CFR at 78753.

Report Submission and Corection[59]

Pre-Review: While CMS would not make it a mandatory step, CMS recommends that the reporting entity provide each covered recipient/owner with information it plans to submit to CMS.

Registration and Submission: Reporting entities would need to register with CMS prior to submitting data and also designate a contact person. The first registration date would be January 1, 2013. All applicable entities would need to register. If they have nothing to report, the CEO, CFO or COO would need to submit an attestation. CMS proposes that the reporting entity be able to submit the data **by** March 31, 2013 or the 90th day of each year thereafter. Attestations of the accuracy of the information would need to be submitted by the CEO, CFO or COO.

45-Day Review Period: Pursuant to the Sunshine Act, reporting entities and covered recipients/owners will have 45 days to review the information submitted to CMS. CMS will permit covered recipients/owners to register with CMS in order to get notification of when the information is ready for review. If a dispute between the reporting entity and the covered recipient or owner/investor as to the reported information is not resolved by the parties at the end of the 45-day period, any entity involved may report the dispute and CMS will identify the information as "contested" and report both the original submission and any modified information. CMS is soliciting comments on how to notify covered recipients and physician owners/investors and how to publish contested data.

Publication: CMS will publish the information for 2012 by September 30, 2013. For each year thereafter, CMS will publish the data for the preceding calendar year by June 30th.

Corrections: After the expiration of the 45-day review period, CMS states that any errors or omissions must be reported immediately; however, CMS reserves the right to hold any changes until the data is refreshed for the following reporting year.

Penalties

The Sunshine Act imposes civil money penalties ("CMP") for violations by applicable manufacturers or applicable GPOs. In the proposed regulations, any failure to report information timely, accurately, or completely would subject the reporting entity to a CMP. CMS clarifies that after the expiration of the 45-day review period, any additions or oversights would subject the reporting entities to CMP.[60] Failures to submit information in a timely, accurate and complete manner are subject to a CMP of at least $1,000, but not more than $10,000 for each payment/ownership or investment interest not reported in accordance with the Sunshine Act. The maximum CMP with respect to each annual submission is $150,000. A "knowing" failure will be subject to a CMP of at least $10,000, but no more than $100,000 for each payment/ownership or investment interest not reported in accordance with the Sunshine Act. The maximum CMP with respect to each annual submission for a knowing failure is $1,000,000.[61]

CMS also proposes the following factors be considered when determining the amount of the CMP would include, but not be limited to: (1) the length of time that the data failed to be reported, including how long the reporting entities knew of the failure to report; (2) amount of the non-reported

[59] *See* 42 CFR at 78753-78755.
[60] *See* 42 CFR at 78757.
[61] *See* 42 CFR at 78757-78758 and 78771.

payment; (3) level of culpability; (4) nature and amount of incorrect information; and (5) degree of diligence exercised in correcting the information.[62]

Books and Records

Pursuant to the Sunshine Act, applicable manufacturers and applicable GPOs must maintain all books, records, documents and other materials sufficient to enable an audit, evaluation or inspection of their compliance with the law. CMS proposes that they be required to maintain their books and records for a period of at least 5 years from the date the payment or other transfer of value or ownership/investment interest is published publicly on the website. CMS also provides that in addition to CMS, the U.S. Department of Health and Human Services and Office of Inspector General or their designees have the ability to audit and inspect all such books and records.[63]

Relation to State Laws

The Sunshine Act preempts any state or local laws that require the same information to be reported, unless such information is being collected by a federal, state, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight. In the proposed regulations, CMS proposes that such government agencies shall include, but not be limited to, those that (1) are charged with "preventing or controlling disease, injury, or disability" or (2) "conduct oversight activities authorized by law, including audits, investigations, inspections, licensure or disciplinary actions, or other activities necessary for oversight of the health care system."[64] CMS does not offer any further guidance on what agencies fall within these broad definitions.

[62] *See* 42 CFR at 78757-78758.
[63] *See* 42 CFR at 78758.
[64] 42 CFR at 78758.

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Payment or other Transfer of Value

***Note*: This is not the format or chart required to be used by CMS. Please see the CMS published charts.**

Category		CMS Proposals/Commentary[i][65]
Reporting Entity Applicable Manufacturers		Include Name
Recipient Name Teaching Hospital or Physician (Covered Recipients) Physician (or IMF) Owner or Investor		For physician covered recipients, CMS proposes reporting the first name, last name, and middle initial.
Recipient Business Street Address Teaching Hospital or Physician (Covered Recipients) Physician (or IMF) Owner or Investor		Include: Street Address, Suite/Office #, City, State and ZIP code. For teaching hospital covered recipients, CMS proposes using only the address included in the CMS-published list of teaching hospitals. For physician covered recipients, CMS proposes using the physician's primary practice location address. The practice location can be found in NPPES as the "provider business practice location."
Recipient Specialty Physician Covered Recipients Only		If using NPPES, CMS suggests using the "provider taxonomy" field when reporting the physician specialty. CMS proposes reporting only a single specialty for each physician covered recipient and using only the specialties available for the "provider taxonomy" field in NPPES.
Recipient National Provider Identifier (NPI) Physician Covered Recipients Only		For NPI, CMS proposes that the applicable manufacturer report the physician's individual NPI, rather than any group NPI with which the physician may be associated.
Amount of Payment (U.S. Dollars)		
Date of Payment		Applicable manufacturers must provide the date of payment. Some may be provided over multiple dates (e.g., consulting agreement with monthly payments). CMS proposes allowing the reporting entity to report the total payment on the date of the first payment as a single line item, or to report each individual payment as a separate line item. CMS is also considering requiring multiple payments to be reported in a single consistent manner.
Form of Payment*		See discussion above
Nature of Payment**		See discussion above
Name of Associated Drug, Device, Biological, or Medical Supply ***if necessary**		See discussion above

[65] *See* 42 CFR at 78746-78748 and 78754.

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Category		CMS Proposals/Commentary
Entity Paid Name		If the payment is made to an entity or individual at the request of (or designated on behalf of) a covered recipient, include the name of the entity/individual who received the payment.
Physician Owner or Investor (y/n)		See discussion above
Delayed Publication (y/n)		See discussion above

***Form of Payment Categories**: (1) cash or cash equivalent; (2) in-kind items or services; and (3) stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment.

****Nature of Payment Categories**: (1) consulting fee; (2) compensation for services other than consulting; (3) honoraria; (4) gift; (5) entertainment; (6) food and beverage; (7) travel and lodging; (8) education; (9) direct research; (10) indirect research; (11) charitable contribution; (12) royalty or license; (13) current or prospective ownership of investment interests; (14) direct compensation for serving as a faculty or as a speaker for a medical education program; (15) grant; and (16) other.

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Physician Ownership or Investment Interest

*__*Note*__: **This is not the format or chart required to be used by CMS. Please see the CMS published charts.**

*All payments or other transfers of value provided to physician owners or investors must be reported on the Payment & Transfer of Value table and designated as to a physician owner or investor.

Category		CMS Proposals/Commentary[66]
Reporting Entity Applicable Manufacturers -- Type I and Type II GPOs		Include Name
Recipient Name Physician (or IMF) Owner or Investor		For physician owners or investors, CMS proposes reporting the first name, last name, and middle initial. For IMF owners or investors, CMS proposes reporting not only the required information for the physician, but also that the ownership or investment interest is held by an IMF of the physician. CMS is considering whether to require the reporting of the IMF's relationship to the physician, as well as his/her name. CMS is seeking comments.
Recipient Business Street Address Physician (or IMF) Owner or Investor		Include: Street Address, Suite/Office #, City, State and ZIP code. For physician owners or investors, CMS proposes using the physician's primary practice location address. The practice location can be found in NPPES as the "provider business practice location."
Recipient Specialty Physician Owners or Investors Only		If using NPPES, CMS suggests using the "provider taxonomy" field when reporting the physician specialty. CMS proposes reporting only a single specialty for each physician owner or investor and using only the specialties available for the "provider taxonomy" field in NPPES. For IMF owners or investors, the physician's specialty must be reported.
Recipient National Provider Identifier (NPI) Physician Owners or Investors Only		For NPI, CMS proposes reporting the physician's individual NPI, rather than any group NPI with which the physician may be associated. For IMF owners or investors, the physician's NPI must be reported.
Interest Held by IMF (y/n)		
Dollar Amount Invested		
Value of Interest		
Terms of Interest		

***Form of Payment**: See categories in above chart

****Nature of Payment**: See categories in above chart

[66] *See* 42 CFR at 78746-78748 and 78753-78754.

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