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CMS Publishes Final Sunshine Act Rule Creating New Regulatory Landscape for Physician-Manufacturer Interactions





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The final rule (the ''Final Rule'') implementing the Physician Payments Sunshine Act (''Sunshine Act''), published in the *Federal Register* on February 8, 2013 [1/] provides key definitions and terms, broad reporting requirements, important exemptions and limitations, and additional reporting guidance.

The Sunshine Act requires manufacturers of drugs, devices, biologics, or medical supplies covered by Medicare, Medicaid, or the Children's Health Insurance Program (''CHIP'') (each a ''Covered Product'') to report payments and other transfers of value to physicians and teaching hospitals (''covered recipients''). The Sunshine Act also requires such manufacturers (collectively, ''Manufacturers'') and Group Purchasing Organizations (''GPOs'') to disclose ownership or investment interests held by physicians or their immediate family members.

[1/] Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests, 78 Fed. Reg. 4,558 (Feb. 8, 2013).

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Manufacturers and GPOs must begin collecting the required data on **August 1, 2013** and report data for the remainder of the calendar year to the Centers for Medicare & Medicaid Services (''CMS'') by **March 31, 2014**. Manufacturers and covered recipients will then have 60 days to dispute and correct reported payments. CMS will publish the data by **September 30, 2014**.

The long delay in publication of the Final Rule has been well-documented. CMS issued the proposed rule (the ''Proposed Rule'') in December 2011,[2/] and it left many questions unanswered, as explained in our analysis of the Proposed Rule previously published in *BNA's Health Care Fraud Report*.[3/] It therefore comes as no surprise that CMS received more than 300 comments on the Proposed Rule. While awaiting the Final Rule, Manufacturers and GPOs remained in the dark about many operational and implementation details and thus could not fully implement processes to comply with the Sunshine Act's data collection and reporting requirements.

The Final Rule, which creates a new subpart I under Part 403 of Title 42 of the Code of Federal Regulations, provides Manufacturers and GPOs with long-awaited guidance in many areas, and differs from the Proposed Rule in several key respects. A chart summarizing the

[2/] Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests, 76 Fed. Reg. 78,742 (Dec. 19, 2011).

[3/] Thomas S. Crane, Brian P. Dunphy & Karen S. Lovitch, *Proposed Physician Payment Sunshine Act Regulations Leave Many in the Dark*, 16 Health Care Fraud Rep. 80 (2012) (16 HFRA 80, 1/25/12).

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key differences between the Proposed Rule and the Final Rule is provided with this article.

Background

Several different concerns regarding financial relationships between providers and Manufacturers led a variety of parties to advocate for the enactment of the Sunshine Act.

First, in reports issued in 2009, the Medicare Payment Advisory Commissions (''MedPAC'')[4/]and the Institute of Medicine (''IOM'')[5/] identified policy concerns about increased utilization and costs as a result of these financial relationships. These reports spurred the introduction of the first transparency proposal that year.

Second, Manufacturers faced an increasing number of fraud and abuse enforcement actions arising out of their financial relationships with providers. Manufacturers therefore felt the need to propose a responsible alternative to enforcement that would meaningfully address these financial arrangements.

In addition, the medical community sought to address its interests during the legislative process leading to the Sunshine Act. As discussed below, the Sunshine Act and the Final Rule reflect theses differing concerns and the interests of an unusual mix of stakeholders.

MedPAC and IOM Recommendations

As noted in the Final Rule, many of the policy concerns giving rise to the Sunshine Act are reflected in the 2009 reports by MedPAC and the IOM. Although the version of the Sunshine Act passed in the Affordable Care Act[5/] is substantially narrower than the proposals made by MedPAC and the IOM, these reports provide important insight into this compromise legislation that relies on the concept of disclosure of financial ties as the remedy for these policy concerns.

The MedPAC Report found that one-quarter to one-third of physicians nationally had financial ties with Manufacturers.[6/] These estimates did not include the provision of drug samples by pharmaceutical manufacturers, which creates separate financial ties, nor did they reveal that financial relationships between Manufacturers and physicians in certain specialties, such as orthopedics and cardiology, were more widespread.

According to both reports, research pointed to potential increases in utilization and costs as a result of physician relationships with Manufacturers. At the same time, both reports recognized the benefits of interactions with Manufacturers. MedPAC emphasized that the implication should not be ''that all – or even most – of these financial ties are inappropriate or undermine physician-patient relationships.''[7/] CMS reiterated this same message in the Final Rule when it stated that ''financial ties alone do not signify an inappropriate relationship.''[8/] The IOM emphasized the special role and responsibilities of academic medical centers and their faculty regarding research and discussed the unique issues arising from industry funding for research.

The reports recognize the special concerns of teaching hospitals and academic medical centers (''AMCs''), which expressed their own concerns regarding payments from Manufacturers, particularly payments affecting clinical research, and the failure of some physicians to report financial ties, as required by their teaching hospital and/or medical school. Thus, teaching hospitals and AMCs essentially asked to be treated, for reporting and disclosure purposes, in the same manner as covered recipient physicians even though the rationale for such reporting and disclosures was very different. MedPAC believed that its recommendations for a national reporting system of payments would have the benefit of ''allowing AMCs to verify the financial interests of their clinical investigators.''[9/]

Both MedPAC and the IOM recommended disclosure of financial payments as the preferred solution to the concerns raised in the reports[10/] while acknowledging the limitations of reporting.[11/]The organizations believed that disclosure would inhibit payments to physicians without identifying a direct correlation between disclosure of financial ties and reductions in payments or reduced medical costs.[12/]

The IOM briefly discussed expanding the Stark Law to cover Manufacturers as an alternative approach, but this option never received serious legislative consideration.[13/]The Stark Law works in parallel with the federal Anti-Kickback Statute (''AKS'') by prohibiting physicians from making referrals for specified ''designated health services'' to Medicare providers if the physician and the provider have a financial relationship, unless that relationship meets an exception. Because the Stark Law does not apply to Manufacturers, enforcement authorities and whistleblowers have instead relied upon the AKS and the False Claims Act as their primary enforcement weapons.

The Sunshine Act includes many – but not all – of the features recommended by MedPAC and IOM. For example, MedPAC and the IOM recommended the reporting of drug samples and disclosure of payments to a much broader set of recipients, including pharmacies and pharmacists, health plans and pharmacy benefit managers, all hospitals and medical schools, CME sponsors, and patient and professional organizations.[14/]

Health Care Fraud Enforcement

In addition to these critical policy reports, Manufacturers were facing an increasing number of fraud and abuse enforcement actions fueled in large part by whistleblowers suits brought under the False Claims

[4/] MEDICARE PAYMENT ADVISORY COMM'N, REPORT TO THE CONGRESS: MEDICARE PAYMENT POLICY 317 (2009) (*hereinafter* ''2009 MedPAC Report'').

[5/] INST. OF MED., CONFLICT OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE (National Academies Press 2009) (*hereinafter* ''2009 IOM Report'').

[5/] Pub.L. 111-148 § 6002.

[6/] 2009 MedPAC Report at 321-23.

[7/] *Id* at 321; *see* 2009 IOM Report at 94.

[8/] 78 Fed. Reg. at 9459

[9/] 2009 MedPAC Report at 325.

[10/] 2009 MedPAC Report Recommendations 5-1, 5-2; 2009 IOM Report Recommendation 3.4.

[11/] 2009 IOM Report at 170.

[12/] 2009 MedPAC Report at 332. MedPAC noted that ''[a]lthough the Congressional Budget Office was unable to estimate the [budgetary] impact of public disclosure on Medicare spending, it believes that disclosure has the potential to reduce Medicare spending over time.''

[13/] 2009 IOM Report at 169-170

[14/] 2009 MedPAC Report at 328, 332-335 (including Recommendation 5-3); 2009 IOM Report Recommendation 3.4, and Minority Report at Appendix F.

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Act based on alleged violations of the AKS. These cases led to many criminal and civil settlements, some involving payments of hundreds of millions of dollars.

A key turning point in enforcement for device companies was the 2007 prosecution and settlement by the U.S. Attorney's Office for the District of New Jersey against five of the largest manufacturers of hip and knee implant devices. These companies paid $310 million in total criminal and civil settlements and entered into Deferred Prosecution Agreements and Corporate Integrity Agreements. Under the settlements, these companies agreed to many requirements similar to those now found in the Sunshine Act, including disclosure of payments to physicians.

Definitions – Changes and Additions

The definitions establish the entities and products to which the Sunshine Act's disclosure obligations apply. The Final Rule includes important changes to the proposed definitions as well as several new terms.

- The definition of ''***applicable manufacturer***'' expressly excludes distributors or wholesalers that do not hold title to Covered Products. In addition, CMS clarified in the Final Rule that entities such as hospitals, hospital-based pharmacies, and laboratories that manufacture a Covered Product solely for internal use or for use by their patients do not qualify as Manufacturers.
- The Final Rule adds the defined term ''***operating in the United States***'' to help establish whether an entity qualifies as a Manufacturer.
- The Proposed Rule established that an entity under ''***common ownership***'' with a Manufacturer is also a Manufacturer; the Final Rule sets the ownership threshold at five percent direct or indirect ownership of two entities by the same individual, individuals, entity, or entities. As discussed below, CMS placed limits on reporting requirements for entities under common ownership.
- The definition of ''***applicable group purchasing organization***'' includes entities that ''operate in the United States'' and purchase, arrange for, or negotiate the purchase of Covered Products for a group of individuals and entities, *but* (rather than ''and,'' as stated in the Proposed Rule) ''not for use by the entity itself.'' By making these limited changes, CMS retained a definition that includes physician-owned distributors (''PODs'').
- Whether a product is a ''***covered drug, device, biological, or medical supply***'' hinges partly on whether payments are ''available'' from Medicare, Medicaid, or CHIP. To account for the wide variety of reimbursement structures used by these government health care programs, CMS clarified that payment is ''available'' when it is part of a fee schedule, formulary, or a bundled payment.
- ''***Coveredrecipients***'' include physicians and teaching hospitals. CMS indicated that it will publish a list of ''teaching hospitals'' 90 days before data collection begins. CMS also explained that ''physicians'' must be authorized to practice and have a current license.
- The Final Rule adds the term ''***indirect payments or other transfers of value,***'' which means payments or other transfers of value made by a Manufacturer (or a GPO) to a covered recipient (or a physician owner or investor) through a third party, where the Manufacturer (or GPO) ''requires, instructs, directs, or otherwise causes the third party'' to provide the payment or transfer of value to a covered recipient (or a physician owner or investor). Indirect payments need not be reported if a Manufacturer does not know the covered recipient's identity. According to CMS, the term ''know'' has the same meaning as in the False Claims Act, which includes actual knowledge of information, deliberate ignorance, or reckless disregard.
- The phrase ''***payment or transfer of value***'' (which is defined in the Sunshine Act) means a transfer of anything of value. In contrast to long-standing interpretations of the Office of Inspector General for the Department of Health and Human Services (''OIG'') in other contexts, CMS stated that a product has ''value'' for the purposes of the Final Rule if it has ''discernible economic value on the open market. . . .''
- The new term ''***related to a covered drug, device, biological, or medical supply***'' means that a payment or other transfer of value is made in reference to or in connection with one or more Covered Products. This phrase is used in the Final Rule to identify the ''related'' Covered Product information to report to CMS for each payment or transfer of value.

Reporting of Payments or Transfers of Value

In the Final Rule, CMS kept to its basic position that as long as a Manufacturer manufactures at least one covered product, it must disclose all payments or other transfers of value whether or not related to a covered product. Within this basic structure, however, CMS made significant revisions to narrow the general disclosure rule for Manufacturers. Manufacturers must disclose direct and indirect payments or other transfers of value to covered recipients, including payments to a third party ''at the request of or designated by the applicable manufacturer on behalf of a covered recipient.''

The Final Rule also defines several limits on reporting in 42 C.F.R. § 403.904(b). First, Manufacturers for whom gross revenue from Covered Products constituted less than 10 percent of total (gross) revenue during the fiscal year preceding the reporting year must only report payments related to Covered Products.

Second, Manufacturers that qualify as Manufacturers through common ownership must only report payments or transfers of value related to a Covered Product for which they provided ''assistance or support'' to the Manufacturer engaged in the production of the Covered Product.

Third, Manufacturers with separate operating divisions that do not manufacture *any* Covered Products must only report payments to covered recipients made by these divisions if those payments related to a Covered Product from another division.

The Final Rule also gives Manufacturers the opportunity to provide information about the context of the payment. This change allows Manufacturers the flex-

ibility to report additional clarifying information about payments.

Reporting Exceptions

The Sunshine Act includes 14 exceptions from disclosure, and the Final Rule elaborates on each one. Highlights include:

- **Payments of less than $10** need not be reported unless payments to a covered recipient exceed $100 annually. The $10 threshold will increase every year according to the consumer price index. CMS clarified that Manufacturers do not have to track incidental items worth less than $10 (e.g., pens and note pads) provided at large-scale conferences. Similarly, although not a defined exception, Manufacturers do not have to track or report food or drinks, such as buffet meals or coffee, made generally available at a conference or large-scale event.
- **Educational materials and items** (CMS added ''items'' in the Final Rule) intended for use by or with patients are not subject to the reporting requirements.
- **Discounts and rebates** are excluded from the reporting requirements, which is notable because a discount or rebate on a product purchased by a physician from a Manufacturer technically is something of value flowing from a Manufacturer to physician covered recipient. The Final Rule fails to define either term, which creates ambiguity. For example, CMS did not make clear whether value in the form of a credit or a charge-back qualifies a discount. Given the breadth of the terms, CMS's failure to provide guidance is surprising.
- **Product Samples** not intended to be sold and intended for patient use are exempt from the Sunshine Act's requirements. The Final Rule clarifies that the term ''product samples'' is reasonably broad and includes devices and medical supplies, as well as coupons and vouchers that patients can use to obtain samples.

The Final Rule also establishes an exemption for certain payments related to speaking at accredited or certified CME programs because, according to CMS, such programs include safeguards ''designed to reduce industry influence.''

To fall within this exception, payments must meet a set of stringent requirements. For example, the Manufacturer cannot have selected the speaker, and the payment cannot have been made directly to the speaker. This exemption is one of several rules related to payments for speaking at CME programs or other meetings. While this rule provides an *exemption* from the reporting requirements, the other rules establish nature of payment categories for reporting speaking fees and are discussed in the next section below.

Required Information, Including the ''Form'' and ''Nature'' of Payments

The Final Rule specifies the required contents of annual reports, including the information that Manufacturers must report for each payment or transfer of value (including payments to covered recipients through third parties). The Final Rule provides that Manufacturers under common ownership may submit a consolidated report.

Some examples of the many types of data that Manufacturers must report are discussed below:

- **Related covered products** (which meet the definition ''related to a covered drug, device, biological, or medical supply'') must be reported, if the Manufacturer can tie the payments directly to certain covered products. For drugs and biologicals, the national drug code must be reported. For devices, the reported information may include either the name of the device as marketed or the therapeutic area or product category. For each payment, up to five product names may be reported. If a payment relates to a non-covered product, that information must be reported, and if the payment relates to neither a covered nor a non-covered product, the word ''none'' should be entered.
- The **covered recipient's name** must be reported and must include the middle initial and suffix of the individual.
- The **covered recipient's office suite or office number** must be furnished.
- The **covered recipient physician's national provider identification** (''NPI'') must be furnished, if the physician has obtained an NPI number.
- The **covered recipient physician's license number** must be furnished for at least one state in which the physician holds a valid license.
- **Travel-related** payments must be reported and must specify the destination to which the covered recipient traveled.

Manufacturers must also report the ''form'' and ''nature'' of payment. Some notable aspects of the form and nature of payment from the Final Rule are described below:

- **Form of payment -** Manufacturers must report the ''form'' that ''best describes'' the payment or transfer of value: cash; in-kind items or services; stock, stock option, or any other ownership interest; or dividend, profit, or return on investment.
- **Nature of payment -** Manufacturers must categorize the ''nature'' of each payment or transfer of value to a covered recipient – or any ***separable part of that payment*** – into one of the seventeen categories defined in the Final Rule that ''best describes'' the payment or transfer of value (e.g., consulting, research, charitable contributions, food and beverages, and travel). CMS added new categories related to ''space rental or facility fees'' (for teaching hospitals only) and CME programs and eliminated the catchall category ''Other.''

The Final Rule includes four different ''nature'' categories related to speaking and education:

- compensation for serving as faculty or as a speaker at an accredited or certified CME program (a new category, which applies if the payment cannot meet the terms of the related exception discussed above);
- compensation for serving as faculty or as a speaker at an unaccredited and non-certified CME program (a new category);

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- compensation for speaking at an event other than a CME program; and
- education, unrelated to speaking.

The relationships among these four categories, combined with the exemption for certain CME-related payments discussed above, are likely to lead to confusion for Manufacturers.

Reporting Research Payments

The special treatment afforded to research payments is noteworthy. Although ''research'' is one among a number of categories for classifying the nature of payments, CMS acknowledged that research payments are fundamentally different from other types of payments and thus established a separate reporting system. In doing so, CMS afforded research payments the significance they deserve rather than merely viewing them as one of many categories of payment.

The Final Rule streamlines the reporting of research payments and defines the term ''research,'' which encompasses pre-clinical trials and FDA Phase I-IV research as well as product development. To fall within the ''research'' nature of payment category, research must be subject to either a written agreement *or* a research protocol (or both). A written agreement may include an unbroken chain of agreements linking the Manufacturer with the covered recipient through other entities, such as contract research organizations or site management organizations.

CMS requires reporting of basic identifying information about physician covered recipients and total research payments. But because of the ''extremely complicated'' ways that research monies flow—with often little or no money benefitting physician investigators—CMS decided not to require Manufacturers to identify the *amount* of payments to physician covered recipients when the money is paid to another party, such as a teaching hospital. The amounts of research payments are to be listed separately on a different template from other payments or transfers of value made to covered recipients that are subject to reporting under the Final Rule.

Delayed Publication for Product Research or Development

Payments and transfers of value made under a product research or development agreement may qualify for delayed publication to preserve proprietary information. New products generally will qualify for delayed reporting. CMS stated that it will treat new generic products, including those receiving approvals under an Abbreviated New Drug Application or under the 510(k) process, as *new products* that qualify for delayed reporting.

However, delayed reporting of payments related to research on *new applications* related to an *existing* product will *not* be available if the payments fit within a subcategory of research known as ''clinical investigation'' (which CMS interpreted as research involving human subjects, including Phases I through IV clinical research for drugs and biologicals and approval trials for devices).

Manufacturers must timely report to CMS payments that qualify for delayed publication, but these payments will not be published until the earlier of the date the product receives FDA approval, or the fourth calendar year after the date of the payment. While the four-year delay in reporting may not provide sufficient confidentiality in some situations, this period is set by statute, and the Medicare Payment Advisory Commission (''MedPAC'') in its 2009 Report to Congress actually recommended a much narrower two-year delay.[16/]

Reports of Physician Ownership

The Sunshine Act also requires the disclosure of certain physician ownership or investment interests.[17/]This part of the Sunshine Act relates to the same overarching concerns about physician financial ties to industry, but with a different focus than payments or transfers of value. Here, there is a clear link to the Stark Law. The MedPAC Report focused on the types of providers that physicians can permissibly own under the Stark Law, such as ambulatory surgical centers (''ASCs''). MedPAC broadly recommended that Congress should require all hospitals and other entities that bill Medicare for services to annually report certain ownership and investment interests by physicians.[18/] Congress did not, however, adopt MedPAC's broad approach. Instead, the focus was on reporting, with certain exceptions, of physician ownership or investment interests in Manufacturers and GPOs. The Final Rule does, however, adopt key definitions from the Stark Law regulations.

Around the time of publication of the MedPAC and IOM reports, medical device manufacturers started to closely scrutinize the relatively new phenomenon of physician owned distributors (''PODs''), which were not addressed by MedPAC or the IOM. PODs are physician-owned joint ventures that negotiate the purchase and distribution of medical devices to hospitals and ASCs where physicians have privileges. Thus, PODs allow physicians to share indirectly in the supply-chain profits derived from their referrals to facilities at which the PODs do business. The Sunshine Act includes PODs in the definition of GPOs, which means that physician ownership interests in PODs must be reported.

Manufacturers and GPOs (including PODs) must submit an annual report to CMS regarding all ownership and investment interests held by physicians or immediate family members of physicians during the preceding year. CMS explained that it defined an ownership or investment interest in a Manufacturer or GPO, as well as exceptions, in a similar manner as defined under the Stark Law. Manufacturers and GPOs need not report indirect ownership or investment interests held by physicians or immediate family members of physicians about which they do not know. Although GPOs generally are not required to report payments to covered recipients, GPOs do need to report direct and indirect payments or transfers of value to physicians with an ownership or investment interest.

Review and Dispute of Reported Payments

The Final Rule provides for a 45-day period during which Manufacturers and GPOs, covered recipients,

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[16/] MEDICARE PAYMENT ADVISORY COMM'N, REPORT TO THE CONGRESS: MEDICARE PAYMENT POLICY 317 (2009) (*hereinafter* ''2009 MedPAC Report'').

[17/] 42 U.S.C. § 1320a-7h(a)(2).

[18/] 2009 MedPAC Report, Recommendation 5-4.

and physician owners or investors may review, dispute, and propose corrections to reported data attributed to them. The parties must then resolve the dispute amongst themselves, without CMS's participation.

CMS will make changes to reported information if provided to CMS no later than 15 days after the end of the 45-day review period (i.e., 60 days after the 45-day review period begins). If the dispute is not resolved, and the information is not updated before the end of the 15-day period, CMS will publish and aggregate the original and attested information but mark it as disputed. Covered recipients cannot prevent disputed data from being published. The parties may continue to try to resolve the dispute after the resolution period ends, but CMS will not make any subsequently agreed-upon changes until the next time the data is refreshed—which will occur only once annually. CMS recognized that updated data should not be incorrectly listed for an entire year, but advised that it does not have the resources to update the data more often.

The Assumptions Document

The Final Rule allows applicable Manufacturers and GPOs to submit a voluntary assumptions document that explains the assumptions and methodologies used to classify payments or other transfers of value. CMS stated that it will not make the assumptions document publicly available because it will likely contain significant detailed information. However, enforcement agencies may obtain the document from CMS or directly from the Manufacturer or GPO.

Enforcement and Penalties

Each report filed by a Manufacturer or GPO must contain an attestation that the report is timely, accurate, and complete. The Final Rule also gives CMS and the OIG rights to ''audit, inspect, investigate and evaluate'' all Manufacturer and GPO records related to their compliance with the Final Rule's requirements.

The penalties for failing to comply with the Sunshine Act can be severe. Manufacturers or GPOs who fail to ''timely, accurately, or completely'' report the required information can be subject to a civil monetary penalty (''CMP'') ranging from $1,000 to $10,000 for ***each*** payment or transfer of value, or ownership or investment interest not reported (up to $150,000), and from $10,000 to $100,000 for each ''knowing'' failure to report (up to $1,000,000). The CMPs are aggregated separately, and a Manufacturer or GPO could be subject to a maximum penalty of $1,150,000. In addition, CMS clarified that, for errors corrected during the review and correction period, Manufacturers will not be ''subject to penalties for failure to report in instances when the original submission was made in good faith.''

CMS explained that the mere reporting of payments should not lead to the conclusion that the parties involved were engaged in wrongdoing. However, CMS emphasized that compliance with the Sunshine Act's reporting requirements does not exempt Manufacturers, GPOs, covered recipients, and others from potential liability under the AKS or the False Claims Act.

It is too early to tell whether disclosure will slow investigations and prosecutions related to financial relationships between physicians and Manufacturers. Enforcement authorities hopefully will turn their focus to the truly egregious cases, such as those involving the deliberate failure to report.

Preemption

The provisions of the Sunshine Act preempt state law as of January 1, 2012. Manufacturers should continue to assess the extent to which the Sunshine Act preempts applicable state laws, such as those in effect in Massachusetts and Vermont.

There are at least two ways in which the Sunshine Act may not preempt state law. First, the Sunshine Act will likely not preempt state law *prohibitions* on certain payments or transfers of value to physicians, referred to as ''gift bans,'' because the Sunshine Act includes no such prohibitions.

Second, the Sunshine Act may not preempt state laws requiring disclosure of payments to health care practitioners other than physicians. For example, Massachusetts has advised that it will continue to require annual reporting of payments and transfers of value not reported under the Sunshine Act, including payments to nurse practitioners and physician assistants.[19/]

Conclusion and Compliance Takeaways

This new statutory and regulatory scheme will create significant burdens on Manufacturers and will publicly identify physicians and teaching hospitals in the disclosure reports. CMS estimated that the total financial burden of compliance with the Final Rule would be $269 million in the first year and $180 million in the second and subsequent years. CMS acknowledged that the size and complexity of each Manufacturer would impact its costs, but estimated that the average Manufacturer would incur labor costs of $160,000 in the first year and $136,000 in the second and subsequent years. In other words, estimated first-year implementation costs will only be $24,000 for the average Manufacturer.

According to CMS, the estimated cost of compliance for individual physicians and teaching hospitals is significantly lower—$250 per physician and $3,500 per teaching hospital in the first year. All stakeholders likely would agree that CMS has significantly underestimated the costs of compliance.

In the near term, Manufacturers must, among other things, parse the regulations, assess potential automated solutions for tracking payments, create new internal reporting process, and conduct compliance training before data collection begins on August 1, 2013. Many Manufacturers will likely need to complete at least one full annual data collection and reporting cycle to gain confidence in their new processes.

Over the long term, many open questions must be resolved. Although CMS made a passing reference in the Final Rule to its willingness to provide guidance to stakeholders, it declined to promulgate an interim final rule with the opportunity for further comment. Under that approach, CMS would have a formal process for continuing to improve the regulation and to accommodate stakeholder concerns. Instead, CMS opted for fi-

[19/] / *See* Memorandum from Madeleine Biondolillo, Massachusetts Bureau of Health Care Safety and Quality, to Massachusetts Public Health Council, Request to Promulgate Final Amendments to 105 CMR 970.000 (Pharmaceutical and Medical Device Manufacturer Conduct) (November 21, 2012).

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nality, an objective with its own benefits. Nonetheless, CMS hopefully will use the Q&A process currently available through its website as a mechanism to provide continuing guidance.

As Manufacturers and GPOs work through the implementation process, they should consider the following:

- Manufacturers should consider conducting a compliance review to verify that all reportable financial arrangements comply with the AKS.
- Manufacturers and GPOs should create an internal record of all assumptions and methodologies applied during the implementation phase and the subsequent data collection and reporting process and should carefully weigh the costs and benefits of submitting an assumptions document to CMS.
- In deciding whether to rely upon an exemption, Manufacturers should carefully evaluate whether all of the requirements of the exemption are met and document this analysis in detail. Although the regulatory scheme makes exemptions available, Manufacturers should keep in mind that application of an exemption means that reporting will not occur. In light of the potential for enforcement for failure to report, prosecutors likely will scrutinize payments that go unreported, given that disclosure is the underlying objective of the statute and regulations.
- Manufacturers should consider the advantages and disadvantages of elaborating on the context of a payment or transfer of value. Some covered recipients who receive high-dollar payments may not welcome disclosure, and thus are likely to appreciate the fact that CMS has allowed contextual information to be provided.
- Manufacturers should engage in internal auditing and monitoring activities early and often to ensure prompt identification of any implementation issues and to assess the level of compliance.

For health care providers affected by the Sunshine Act, including physicians, teaching hospitals, and all hospitals whose medical staff receive payments, the Sunshine Act affords a unique opportunity to review internal policies to determine whether mere disclosure is sufficient to manage conflicts of interest.

Among the types of payments that may still continue under the Sunshine Act, but that may remain of concern in some contexts, include meals, travel, entertainment, non-CME approved speaker fees, ghost writing, and physician ownership of companies to which they refer or with which they do business. In this sense, the Sunshine Act may ultimately lead to a much broader discussion about how to manage conflicts of interest within the health care industry.

Reference	Proposed Rule	Final Rule	Change?
Definitions (selected sections)			
§ 403.902 - Applicable Group Purchasing Organization	Applicable group purchasing organization means 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.	Applicable group purchasing organization means an entity that— (1) Operates in 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, but not solely for use by the entity itself.	Yes Incorporates the newly defined term ''operating in the United States.''

Reference	Proposed Rule	Final Rule	Change?
§ 403.902 - Applicable Manufacturer	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 and distribution in the United States, or in a territory, possession, or commonwealth of the United States.	An entity that is operating in the United States and that falls within one of the following categories: (1) An entity that is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply, but not if such covered drug, device, biological or medical supply is solely for use by or within the entity itself or by the entity's own patients. This definition does not include distributors or wholesalers (including, but not limited to, repackagers, relabelers, and kit assemblers) that do not hold title to any covered drug, device, biological or medical supply. (2) An entity 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.	Yes Clarifies that a wholesaler or distributor that does not hold title to a Covered Product is not an ''applicable manufacturer.''
§ 403.902 – Charitable Contribution	Includes, but is not limited to, any payment or transfer of value made to an organization with tax-exempt status under the Internal Revenue Code of 1986.	Includes, but is not limited to, any payment or transfer of value made to an organization with tax-exempt status under the Internal Revenue Code of 1986, which is not provided in exchange for any goods, items or services.	Yes
§ 403.902 – Charity Care	Services provided by a covered recipient 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.	Services provided by a covered recipient for a patient who is unable to pay for such services or for whom payment would be a significant hardship, where the covered recipient neither receives, nor expects to receive, payment because of the patient's inability to pay.	Yes
§ 403.902 – Common Ownership	Entities 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.	Refers to circumstances where the same individual, individuals, entity, or entities directly or indirectly own 5 percent or more total ownership of two entities. This includes, but is not limited to, parent corporations, direct and indirect subsidiaries, and brother or sister corporations.	Yes Creates a five percent threshold for common ownership, which is a term used in the definition of ''applicable manufacturer.''

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Reference	Proposed Rule	Final Rule	Change?
§ 403.902 – Covered Device	Any device for which payment is available under Title XVIII of the Act or under a State plan under Title XIX or XXI of the Act (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). 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.	Any device for which payment is available under Title XVIII of the Act or under a State plan under Title XIX or XXI of the Act (or a waiver of such plan), either separately (such as through a fee schedule) or as part of a bundled payment (for example, under the hospital inpatient prospective payment system or the hospital outpatient prospective payment system) and which is of the type that, by law, requires premarket approval by or premarket notification to the Food and Drug Administration (FDA).	No substantive change
§ 403.902 – Covered drug, device, biological 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 of the Act (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.	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 of the Act (or a waiver of such plan), either separately (such as through a fee schedule or formulary) or as part of a bundled payment (for example, under the hospital inpatient prospective payment system or the hospital outpatient prospective payment system) and which is of the type that in the case of a— (1) Drug or biological, by law, requires a prescription to be dispensed; or (2) Device (including a medical supply that is a device), by law, requires premarket approval by or premarket notification to the FDA.	Yes Clarifies that payment is ''available'' through a fee schedule or formulary, or as part of a bundled payment. *A covered drug, device, biological, medical supply is referred to as a ''Covered Product'' throughout this document.*
§ 403.902 – Covered Recipient	(1) Any physician, except for a physician who is an employee (as defined in section 1877(h)(2) of the Act) of an applicable manufacturer; or (2) A teaching hospital, which is any institution that received a payment under 1886(d)(5)(B), 1886(h), or 1886(s) of the Act during the last calendar year for which such information is available.	(1) Any physician, except for a physician who is a bona fide employee of the applicable manufacturer that is reporting the payment; or (2) A teaching hospital, which is any institution that received a payment under 1886(d)(5)(B), 1886(h), or 1886(s) of the Act during the last calendar year for which such information is available.	Yes Exempts only physicians who are ''bona fide'' employees of an applicable manufacturer.
§ 403.902 – Indirect payments or other transfers of value	N/A	Refer to payments or other transfers of value made by an applicable manufacturer (or an applicable group purchasing organization) to a covered recipient (or a physician owner or investor) through a third party, where the applicable manufacturer (or applicable group purchasing organization) requires, instructs, directs, or otherwise causes the third party to provide the payment or transfer of value, in whole or in part, to a covered recipient(s) (or a physician owner or investor).	Yes Adds this newly defined term, which appears in the general rule on disclosure (§ 403.904).

Reference	Proposed Rule	Final Rule	Change?
§ 403.902 – Operating in the United States	N/A	Means that an entity— (1) Has a physical location within the United States or in a territory, possession, or commonwealth of the United States; or (2) Otherwise conducts activities within the United States or in a territory, possession, or commonwealth of the United States, either directly or through a legally-authorized agent.	Yes Adds new defined term.
§ 403.902 – Ownership or investment interest	(1) Includes, but is not limited to the following: (i) Stock, stock option(s) (other than those received as compensation, until they are exercised). (ii) Partnership share(s); (iii) Limited liability company membership(s). (iv) Loans, bonds, or other financial instruments that are secured with an entity's property or revenue or a potion of that property or revenue. (2) May be direct or indirect and through debt, equity or other means. (3) Exceptions: (i) ownership or investment interests in a publicly traded security or mutual fund (ii) an interest arising from a retirement plan offered by the manufacturer or GPO to physician or physician's immediate family member through employment with that manufacturer or GPO (iii) stock options or convertible securities received as compensation, until converted to equity (iv) an unsecured loan subordinated to a credit facility	The Final Rule includes an additional exception: An ownership or investment interest if an applicable manufacturer or applicable group purchasing organization did not know, as defined in this section, about such ownership or investment interest.	Yes Adds an exception for ownership or investment interests of which the applicable manufacturer or applicable group purchasing organization is unaware.
§ 403.902 – Physician	Same meaning given that term in section 1861(r) of the Act.	Same meaning given that term in section 1861(r) of the Act.	No
§ 403.902 – Related to a covered drug, device, biological, or medical supply	N/A	A payment or other transfer of value is made in reference to or in connection with one or more covered drugs, devices, biologicals, or medical supplies.	Yes Adds this newly defined term, which is used in the limitations on reporting (§ 403.904(b)).
§ 403.902 – Research	N/A	Includes a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. This term encompasses basic and applied research and product development.	Yes Adds this newly defined term, which is used in disclosure requirement (§ 403.904(f)).
§ 403.902 – Third Party	N/A	Another individual or entity, regardless of whether such individual or entity is operating in the United States.	Yes Adds new defined term.

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Reference	Proposed Rule	Final Rule	Change?
§ 403.904(b) – Required information to report [Proposed] **§ 403.904(c) – Required information to report [Final]**	A report must contain all of the following information for each payment or other transfer of value: (1) Name of the covered recipient. If the payment or other transfer of value was provided to another individual or entity at the request of (or designated on behalf of) any covered recipient, the payment or transfer of value must be disclosed in the name of that covered recipient. (2) Business address of the covered recipient . . . (3) In the case of a covered recipient who is a physician, the specialty and National Provider Identifier (if applicable) of the covered recipient. (4) Amount of each payment or other transfer of value to the covered recipient. (5) Date of each payment or transfer of value to the covered recipient. (6) Form of each payment or other transfer of value, as described in paragraph (c) of this section. (7) Nature of each payment or other transfer of value, as described in paragraph (d) of this section. (8) If a payment or other transfer of value is related to marketing, education, or research specific to a covered drug, device, biological, or medical supply, the name under which the covered drug, device, biological, or medical supply is marketed. If the marketed name has not yet been selected, applicable manufacturer must indicate the scientific name. Applicable manufacturers may only report a single covered drug, device, biological or medical supply for each payment or other transfer of value. (9) The applicable manufacturer must indicate that a payment or other transfer of value is subject to delayed publication, if the payment or other transfer of value is made under any of the following arrangements: (i) In accordance with a product research or development agreement for services furnished in connection with research on or development of a new drug, device, biological, or medical supply or a new application of an existing drug, device, biological or medical supply. (ii) In connection with a clinical investigation regarding a new drug, device, biological, or medical supply.	A report must contain all of the following information for each payment or other transfer of value: (1) Name of the covered recipient. For physician covered recipients, the name must be as listed in the National Plan & Provider Enumeration System (if applicable) and include first and last name, middle initial, and suffix (for all that apply). (2) Address of the covered recipient . . . (3) Identifiers for physician covered recipients. In the case of a covered recipient who is a physician, the following identifiers: (i)The specialty. (ii)National Provider Identifier (if applicable and as listed in the NPPES). If a National Provider Identifier cannot be identified for a physician, the field may be left blank, indicating that the applicable manufacturer could not find one. (iii)State professional license number(s) (for at least one State where the physician maintains a license), and the State(s) in which the license is held. (4) Amount of payment or other transfer of value. . . . (5) Date of payment or transfer of value. The date of each payment or other transfer of value. *** (6) Form of payment or transfer of value. The form of each payment or other transfer of value, as described in paragraph (d) of this section. (7) Nature of payment or transfer of value. The nature of each payment or other transfer of value, as described in paragraph (e) of this section. (8) Related covered drug, device, biological or medical supply. The name(s) of the related covered drugs, devices, biologicals, or medical supplies, unless the payment or other transfer of value is not related to a particular covered drug, device, biological or medical supply. Applicable manufacturers may report up to five covered drugs, devices, biologicals or medical supplies related to each payment or other transfer of value. *** (9) Eligibility for delayed publication. Applicable manufacturers must indicate whether a payment or other transfer of value is eligible for delayed publication, as described in § 403.910.	Yes Changes the requirements for the report in several ways.

Reference	Proposed Rule	Final Rule	Change?
	(10) If the payment or other transfer of value is made to an entity or individual at the request of (or designated on behalf of) a covered recipient, the name of the other individual or entity that receives the payment or other transfer of value. (11) Whether the payment or other transfer of value was provided to a physician who holds an ownership or investment interest (as defined § 403.902) in the applicable manufacturer.	(10) Payments to third parties. . . . (11) Payments or transfers of value to physician owners or investors. Must indicate whether the payment or other transfer of value was provided to a physician or the immediate family of the physician who holds an ownership or investment interest (as defined § 403.902) in the applicable manufacturer. (12) Additional information or context for payment or transfer of value. May provide a statement with additional context for the payment or other transfer of value.	
§ 403.904(c) – Reporting the form of payment or other transfer of value [Proposed] **§ 403.904(d) – Reporting the form of payment or other transfer of value [Final]**	Manufacturers must indicate the form of payment or transfer of value using one of the following descriptions: (1) Cash or cash equivalent. (2) In-kind items or services. (3) Stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment.	Manufacturers must report each payment or transfer of value, or separable part of that payment or transfer of value, as taking one of the following forms: (1) Cash or cash equivalent. (2) In-kind items or services. (3) Stock, stock option, or any other ownership interest. (4) Dividend, profit or other return on investment.	Yes Requires reporting of form of separable parts of payments or transfers of value, with dividends and stocks qualifying as separate ''forms.''
§ 403.904(d)(2) – Reporting the nature of the payment or other transfer of value/Rules for categorizing natures of payment [Proposed] **§ 403.904(d)(2) – Reporting the nature of the payment or other transfer of value/Rules for categorizing natures of payment [Final]**	Manufacturers must indicate the nature of payment or transfer of value using one of the following mutually exclusive descriptions: (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) Research (10) Charitable Contribution (11) Royalty or License (12) Current or Prospective Ownership or Investment Interests (13) Direct Compensation for Serving as a Faculty or as a Speaker for a Medical Education Program (14) Grant (15) Other	Manufacturers must categorize each payment or other transfer of value, or separable part of that payment or transfer of value, with one of the following mutually exclusive descriptions: Consulting fee. Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program. Honoraria. Gift. Entertainment. Food and beverage. Travel and lodging (including the specified destinations). Education. Research. Charitable contribution. Royalty or license. Current or prospective ownership or investment interest. Compensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program. Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program. Grant. Space rental or facility fees (teaching hospital only).	Yes Mandates reporting on the nature of separable parts of payments or transfers of value. Clarifying that compensation for services includes serving as faculty or a speaker at non-CME events. Creates two new, separate categories specifically addressing speaking or serving as faculty at unaccredited/non-certified CME programs and accredited/certified CME programs. Adds a category for space rental or facility fees (teaching hospitals only). Deletes the category ''Other.''

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Reference	Proposed Rule	Final Rule	Change?
§ 403.904(e) – Special rules for research payments [Proposed] **§ 403.904(f) – Special rules for research payments [Final]**	(1) Applicable manufacturers must designate each research payment or transfer of value as direct research or indirect research. (i) Direct Research. A payment or other transfer of value provided to a covered entity directly by an applicable manufacturer or through a contract research organization (or similar entity). (ii) Indirect Research. A payment or other transfer of value provided by an applicable manufacturer (including through a contract research organization or similar entity) to a clinic, hospital, or other institution conducting the research, and that clinic, hospital, or other institution conducting the research in turn pays the physician covered recipient (or multiple physician covered recipients) serving as the principal investigator(s). (2) Payments and other transfers of value designated as research must be subject to a written agreement and research protocol. Indirect research must be reported individually under the name(s) and NPI(s) of the principle investigator; total amounts paid to institutions must be reported for each principle investigator. Direct research must be reported individually under the names(s) and NPI(s) of the covered recipient. (3) If payment is made to a teaching hospital, the payment to the teaching hospital must be reported as follows: (i) Direct research under the name of the teaching hospital. (ii) Indirect research under the name(s) and NPI(s) (if applicable) of the physician covered recipient serving as principal investigator(s). (4) For direct or indirect payments provided to physician covered recipients, CMS reports the total payment amount separately from other payments or transfers of value.	All payments or other transfers of value made in connection with an activity that meets the definition of research in this section and that are subject to a written agreement, a research protocol, or both, must be reported under these special rules. (1) Research-related payments or other transfers of value to covered recipients (either physicians or teaching hospitals), including research-related payments or other transfers of value made indirectly to a covered recipient through a third party, must be reported to CMS separately from other payments or transfers of value, and must include the following information (in lieu of the information required by § 403.904(c)): (i) Name of the research institution, individual or entity receiving the payment or other transfer of value. *** (ii) Total amount of the research payment, including all research-related costs for activities outlined in a written agreement, research protocol, or both. (iii) Name of the research study. (iv) Name(s) of any related covered drugs, devices, biologicals, or medical supplies (subject to the requirements specified in paragraph (c)(8) of this section) and for drugs and biologicals, the relevant National Drug Code(s), if any. (v) Information about each physician covered recipient principal investigator (if applicable) . . . . (vi) Contextual information for research (optional). (vii) ClinicalTrials.gov identifier (optional). (2) For pre-clinical studies (before any human studies have begun), only report the following information: (i) Research entity name . . . (ii) Total amount of payment . . . (iii) Principal investigator(s)	Yes Expands scope of reporting obligation.

Reference	Proposed Rule	Final Rule	Change?
§ 403.904(g) – Special rules for payments or other transfers of value related to continuing education programs	N/A	(1) Payments or other transfers of value provided as compensation for speaking at a continuing education program are not required to be reported, if all of the following conditions are met: (i) The event at which the covered recipient is speaking meets the accreditation or certification requirements and standards for continuing education of one of the following: (A) The Accreditation Council for Continuing Medical Education. (B) The American Academy of Family Physicians. (C) The American Dental Association's Continuing Education Recognition Program. (D) The American Medical Association. (E) The American Osteopathic Association. (ii) The applicable manufacturer does not pay the covered recipient speaker directly. (iii) The applicable manufacturer does not select the covered recipient speaker or provide the third party (such as a continuing education vendor) with a distinct, identifiable set of individuals to be considered as speakers for the continuing education program. (2) Payments or other transfers of value that do not meet all of the requirements in paragraph (g)(1) must be reported as required by this section. *** Payments or other transfers of value for speaking engagements not related to medical education should be reported under the nature of payment category ''Compensation for services other than consulting, including serving as a speaker at an event other than a continuing education program.''	Yes Creates an exclusion from reporting for compensation related to certain CME programs.

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Reference	Proposed Rule	Final Rule	Change?
§ 403.904(h) – Special rules for reporting food and beverage	N/A	(1) When allocating the cost of food and beverage among covered recipients in a group setting where the cost of each individual covered recipient's meal is not separately identifiable, such as a platter provided to physicians in a group practice setting, applicable manufacturers must calculate the value per person by dividing the entire cost of the food or beverage by the total number of individuals who partook in the meal (including both covered recipients and non-covered recipients, such as office staff). The per person value of the meal must be reported as a payment or other transfer of value only for covered recipients who actually partook in the food or beverage. (2) Applicable manufacturers are not required to report or track buffet meals, snacks, soft drinks, or coffee made generally available to all participants of a large-scale conference or similar large-scale event.	Yes
Exclusions from Reporting (selected sections)			
§ 403.904(f)(1) - Aware of identity [Proposed] **§ 403.904(i)(1) [Final]**	Transfers of value made indirectly to a covered recipient through a third party in cases when the applicable manufacturer is unaware of the identity of the covered recipient; knowledge element is defined in § 403.902.	Indirect payments or other transfers of value (as defined in § 403.902), where the applicable manufacturer is unaware of the identity of the covered recipient. An applicable manufacturer is unaware of the identity of a covered recipient if the applicable manufacturer does not know (as defined in § 403.902) the identity of the covered recipient during the reporting year or by the end of the second quarter of the following reporting year.	Yes Requires reporting of a payment if the applicable manufacturer becomes aware of the identity of covered recipient prior to the second quarter of the year following the reporting year.
§ 403.904(f)(2)(i) – De minimus [Proposed] **§ 403.904(i)(2)(i) [Final]**	For CY 2012, transfers of value less than $10, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient exceeds $100 in a calendar year.	For CY 2013, payments or other transfers of value less than $10, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient exceeds $100 in a calendar year.	No substantive change
§ 403.904(f)(2)(ii) - De minimus [Proposed] **§ 403.904(i)(2)(ii) [Final]**	For CY 2013 and subsequent calendar years, . . . the dollar amounts specified in paragraph (f)(2)(i) of this paragraph must be increased by the same percentage as the percentage increase in the consumer price index for all urban consumers (all items; U.S. city average) for the 12-month period ending with June of the previous year.	For CY 2014 and subsequent calendar years . . . the dollar amounts specified in paragraph (i)(2)(i) of this section must be increased by the same percentage as the percentage increase in the consumer price index for all urban consumers (all items; U.S. city average) for the 12-month period ending with June of the previous year. CMS will publish the values for the next reporting year 90 days before the beginning of the reporting year.	Yes States that CMS will publish the value of the de minimus amount 90 days before the beginning of the reporting year.

Reference	Proposed Rule	Final Rule	Change?
§ 403.904(i)(2)(iii) - De minimus [Final]	N/A	Payments or other transfers of value of less than $10 in CY 2013 . . . provided at large-scale conferences and similar large-scale events, as well as events open to the public, do not need to be reported nor included for purposes of the $100 aggregate threshold in CY 2013 . . . even if the aggregate total for a covered recipient exceeds the aggregate threshold for the calendar year.	Yes
§ 403.904(f)(2)(iv) - $100 in the aggregate [Proposed] **§ 403.904(i)(2)(iv) [Final]**	N/A	When reporting payments or other transfers of value under the $10 threshold for CY 2013 . . . for covered recipients that exceed the aggregate threshold for the reporting year, applicable manufacturers may (but are not required to) report all small payments to a particular covered recipient that fall within the same nature of payment category as a single payment or other transfer of value.	Yes
§ 403.904(f)(3) - Samples [Proposed] **§ 403.904(i)(3) [Final]**	Product samples that are not intended to be sold and are intended for patient use.	Product samples, including coupons and vouchers that can be used by a patient to obtain samples, which are not intended to be sold and are intended for patient use.	Yes Clarified that exclusion for product samples includes coupons or vouchers to obtain samples.
§ 403.904(f)(4) – Educational material [Proposed] **§ 403.904(i)(4) [Final]**	Educational materials that directly benefit patients or are intended for patient use.	Educational materials and items that directly benefit patients or are intended to be used by or with patients, including the value of an applicable manufacturer's services to educate patients regarding a covered drug, device, biological, or medical supply.	Yes Expands the exclusion to include an applicable manufacturer's services to educate patients.
§ 403.904(f)(5) – Loan of a device [Proposed] **§ 403.904(i)(5) [Final]**	The loan of a covered device for a short-term trial period, not to exceed 90 days, to permit evaluation of the covered device by the covered recipient.	The loan of a covered device or a device under development, or the provision of a limited quantity of medical supplies for a short-term trial period, not to exceed a loan period of 90 days or a quantity of 90 days of average daily use, to permit evaluation of the device or medical supply by the covered recipient.	Yes Expands the exclusion to cover devices under development and medical supplies, in addition to covered devices.
§ 403.904(f)(6) - Warranty [Proposed] **§ 403.904(i)(6) [Final]**	Items or services provided under a contractual warranty, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device.	Items or services provided under a contractual warranty (including service or maintenance agreements), whether or not the warranty period has expired, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device.	Yes Clarifies that the exclusion applies whether or not the warranty period has expired.
§ 403.904(f)(7) – Covered recipient as patient [Proposed] **§ 403.904(i)(7) [Final]**	A transfer of anything of value to a covered recipient when the covered recipient is a patient and not acting in the professional capacity of a covered recipient.	A transfer of anything of value to a physician covered recipient when the covered recipient is a patient, research subject or participant in data collection for research, and not acting in the professional capacity of a covered recipient.	Yes Expands the exclusion to include a covered recipient not acting in such professional capacity if he or she is a ''research subject or participant in data collection for research.''
§ 403.904(f)(8) – Discounts [Proposed] **§ 403.904(i)(8) [Final]**	Discounts, including rebates.	Discounts, including rebates.	No

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Reference	Proposed Rule	Final Rule	Change?
§ 403.904(f)(9) – Charity care [Proposed] **§ 403.904(i)(9) [Final]**	In-kind items used for the provision of charity care.	In-kind items used for the provision of charity care.	No
§ 403.904(f)(10) – Dividend or profit [Proposed] **§ 403.904(i)(10) [Final]**	A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund.	A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund.	No
§ 403.904(f)(11) – Self-insurance plan [Proposed] **§ 403.904(i)(11) [Final]**	In the case of an applicable manufacturer who offers a self-insured plan, payments for the provision of health care to employees under the plan.	In the case of an applicable manufacturer who offers a self-insured plan or directly reimburses for healthcare expenses, payments for the provision of health care to employees and their families.	Yes Applies the exclusion to an applicable manufacturer who directly reimburses healthcare expenses.
§ 403.904(f)(12) – Non-medical services [Proposed] **§ 403.904(i)(12) [Final]**	In the case of a covered recipient who is a licensed non-medical professional, a transfer of anything of value to the covered recipient if the transfer is payment solely for the non-medical professional services of the licensed non-medical professional.	In the case of a covered recipient who is a licensed non-medical professional, a transfer of anything of value to the covered recipient if the transfer is payment solely for the non-medical professional services of the licensed non-medical professional.	No
§ 403.904(f)(13) – Legal proceedings [Proposed] **§ 403.904(i)(13) [Final]**	In the case of a covered recipient who is a physician, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of the covered recipient with respect to a civil or criminal action or an administrative proceeding.	In the case of a covered recipient who is a physician, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of the covered recipient with respect to an administrative proceeding, legal defense, prosecution, or settlement or judgment of a civil or criminal action and arbitration.	Yes Expands the exclusion to include additional legal action.
§ 403.904(i)(14) – Personal relationship	N/A	A payment or transfer of value to a covered recipient if the payment or transfer of value is made solely in the context of a personal, non-business-related relationship.	Yes
Reports of Physician Ownership and Investment Interests (selected sections)			
§ 403.906(a) – General rule	Manufacturers and GPOs must make an annual report to CMS of all ownership and investment interests of physicians or immediate family members of physicians during the preceding year.	(1) Manufacturers and GPOs must make an annual report to CMS of all ownership and investment interests of physicians or immediate family members of physicians during the preceding year. (2) For CY 2013, only ownership or investment interests held on or after August 1, 2013 must be reported to CMS.	Yes Clarifies that reporting for CY 2013 begins on August 1, 2013.

Reference	Proposed Rule	Final Rule	Change?
§ 403.906(b) – Identifying information	(1) Reports must include: (1) Name of the physician, and whether the ownership or investment interest is held by an immediate family member of the physician. (2) Business address of physician, including street address, suite or office number (if applicable), city, State, and ZIP code. (3) Specialty and NPI (if applicable). If the ownership or investment interest is held by the immediate family member of a physician, the physician's specialty and National Provider Identifier must be reported. (4) Dollar amount invested by each physician or immediate family member of the physician. (5) Value and terms of each ownership or investment interest. (6) If a payment or other transfer of value is provided to a physician owner or investor, the manufacturer or GPO must report the information requested in § 403.904(b) subject to the same reporting exclusions described in § 403.904(f).	Reports must include (regardless of whether the ownership or investment interest is held by an immediate family member of the physician): (1) Name of the physician, and whether the ownership or investment interest is held by an immediate family member of the physician. (2) Business address of physician, including street address, suite or office number (if applicable), city, State, and ZIP code. (3) Specialty and NPI (if applicable), state professional license number(s) and state (for at least one state where the physician maintains a license). (4) Dollar amount invested by each physician or immediate family member of the physician. (5) Value and terms of each ownership or investment interest. (6) If a payment or other transfer of value is provided to a physician owner or investor or to a third party at the request of or designated by the applicable manufacturer or GPO on behalf of a physician owner or investor, the manufacturer or GPO must report the information as required in § 403.904(c) through (i).	Yes Clarifies reporting requirements and confirms that reports must be made regardless of whether the interest is held by an immediate family member of the physician.
Procedures for Electronic Submission of Reports (selected sections)			
§ 403.908(b) – General rules	Applicable manufacturers without reportable payments or transfers of value or reportable ownership or investment interests are not required to file a report.	Applicable manufacturers without reportable payments or transfers of value or reportable ownership or investment interests are not required to file a report.	No
§ 403.908(c) – Registration	Any applicable manufacturer or applicable group purchasing organization that is required to report under this subpart must register with CMS before March 31, 2013.	(1) Applicable manufacturers that have reportable payments or other transfers of value, ownership or investment interests, or both, are required to report under this subpart and must register with CMS within 90 days of the end of the calendar year for which a report is required. (2) Applicable group purchasing organizations that have reportable ownership or investment interests are required to report under this subpart and must register with CMS within 90 days of the end of the calendar year for which a report is required. ***	Yes Requires registration only if reporting is required.

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Reference	Proposed Rule	Final Rule	Change?
§ 403.908(d)(1) – Consolidated reports	(1) An applicable manufacturer under paragraph (1) of the definition of ''applicable manufacturer'' in § 403.902 and an entity (or entities) under common ownership with the applicable manufacturer under paragraph (2) of the definition of ''applicable manufacturer'' may, but are not required to, file a consolidated report of payments or other transfers of value to covered recipients, and physician ownership or investment interests.	Applicable manufacturers may submit consolidated reports in certain cases, but are not required to do so.	Yes Provides flexibility for consolidated reports.
§ 403.908(f) – Assumptions document	N/A	Applicable manufacturers and applicable group purchasing organizations may submit an assumptions document, explaining the reasonable assumptions made and methodologies used when reporting payments or other transfers of value, or ownership or investment interests. The assumptions documents will not be made available to covered recipients, physician owners or investors, or the public.	Yes
§ 403.908(g)(1) - 45 day review period for review and correction; General Rule	CMS must allow a 45 day period for applicable manufacturers and GPOs, covered recipients, and physician owners or investors to review and correct information prior to the information being made public.	CMS must allow a 45 day period for applicable manufacturers and GPOs, covered recipients, and physician owners or investors to review and correct information prior to the information being made public.	No
§ 403.908(g)(2) – Notification	CMS notifies the applicable manufacturers and GPOs, covered recipients, and physician owners or investors when the reported information is ready for review.	CMS notifies the applicable manufacturers and GPOs, covered recipients, and physician owners or investors when the reported information is ready for review.	No
§ 403.908(g)(3)(i) – Process	An applicable manufacturer, applicable group purchasing organization, covered recipient or a physician owner or investor may log into a secure Web site to view information reported specific to the party.	An applicable manufacturer, applicable group purchasing organization, covered recipient or a physician owner or investor may log into a secure website to view only the information reported specifically about itself.	Yes Clarifies that the applicable manufacturer views only its own information.
§ 403.908(g)(3)(ii) [Proposed] **§ 403.908(g)(3)(iii) [Final]**	If an applicable party agrees with the information reported, it may electronically certify that the information reported is accurate.	If an applicable party agrees with the information reported, it may electronically certify that the information reported is accurate.	No
§ 403.908(g)(3)(iv)	N/A	If a covered recipient or physician owner or investor disagrees with the information reported, it can initiate a dispute, which is sent to the appropriate applicable manufacturer or applicable GPO to be resolved between the parties.	Yes

Reference	Proposed Rule	Final Rule	Change?
§ 403.908(e) – Errors or omissions [Proposed] **§ 403.908(h) – Errors or omissions [Final]**	If an applicable manufacturer or applicable group purchasing organization discovers an error or omission in its annual report, it must submit corrected information to CMS immediately upon discovery of the error or omission.	(1) If an applicable manufacturer or applicable group purchasing organization discovers an error or omission in its annual report, it must submit corrected information to CMS immediately upon confirmation of the error or omission. (2) Upon receipt, CMS notifies the affected covered recipient or physician owner or investor that the additional information has been submitted and is available for review. CMS updates the website at least once annually with corrected information.	Yes
Delayed Publication for Payments Made Under Product Research or Development Agreements and Clinical Investigations (selected sections)			
§ 403.910(a) – General rule	(1) In the case of payments or other transfers of value made to a covered recipient by an applicable manufacturer under a product research or development agreement, or in connection with a clinical investigation, payments may be delayed from publication on the Web site. Publication of a payment or other transfer of value is delayed when made in connection with the following instances: (1) Research on or development of a new drug, device, biological, or medical supply or a new application of an existing drug, device, biological, or medical supply. (1) Clinical investigations regarding a new drug, device, biological, or medical supply.	In the case of payments or other transfers of value made to a covered recipient by an applicable manufacturer under a product research or development agreement, or in connection with a clinical investigation, payments may be delayed from publication on the Web site. Publication of a payment or other transfer of value is delayed when made in connection with the following instances: (1) Research on or development of a new drug, device, biological, or medical supply or a new application of an existing drug, device, biological, or medical supply. (1) Clinical investigations regarding a new drug, device, biological, or medical supply.	No
§ 403.910(c) – Date of publication	Payments must be reported to CMS on the first reporting date following the year in which they occur, but CMS does not publicly post the payment until the first annual publication date after the earlier of the following: (1) The date of the approval, licensure or clearance of the covered drug, device, biological, or medical supply by the Food and Drug Administration. (2) Four calendar years after the date the payment or other transfer of value was made.	(1) Payments must be reported to CMS on the first reporting date following the year in which they occur, but CMS does not publicly post the payment until the first annual publication date after the earlier of the following: The date of the approval, licensure or clearance of the covered drug, device, biological, or medical supply by the Food and Drug Administration. Four calendar years after the date the payment or other transfer of value was made.	No
§ 403.910(d)(1) – Indication of eligibility	Manufacturers must indicate on the report whether a payment or other transfer of value is eligible for a delay in publication.	Manufacturers must indicate on the report whether a payment or other transfer of value is eligible for a delay in publication.	No

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Reference	Proposed Rule	Final Rule	Change?
§ 403.910(d) – Notification of delayed publication [Proposed] **§ 403.910(d)(3) [Final]**	It is the responsibility of the applicable manufacturer to notify CMS during subsequent annual submissions, if the new drug, device, biological or medical supply, with which the payment is associated, is approved by the FDA.	It is the responsibility of the applicable manufacturer to notify CMS during subsequent annual submissions, if the new drug, device, biological or medical supply, with which the payment is associated, is approved by the FDA.	No
§ 403.910(d)(3) – Notification of FDA approval [Proposed] **§ 403.910(d)(4) [Final]**	Failure to notify CMS when FDA approval occurs may be considered failure to report, and the applicable manufacturer may be subject to civil monetary penalties.	Failure to notify CMS when FDA approval occurs may be considered failure to report, and the applicable manufacturer may be subject to civil monetary penalties.	No
§ 403.910(d)(4) – Publication [Proposed] **§ 403.910(d)(5) [Final]**	If, after 4 years from the date of a payment first appearing in a report to CMS, there is an indication in a report that the payment is subject to delayed reporting, it is reported regardless of the indication.	If, after 4 years from the date of a payment first appearing in a report to CMS, there is an indication in a report that the payment is subject to delayed reporting, it is reported regardless of the indication.	No
§ 403.910(e) – Confidentiality	N/A	Information submitted and eligible for delayed publication is considered confidential and will not be subject to disclosure under applicable Federal, State, or local law, until on or after the date on which the information made available to the public.	Yes
Penalties for Failure to Report (selected sections)			
§ 403.912(a) – Failure to report	Civil monetary penalty of not less than $1,000 and not more than $10,000 for each failure by a manufacturer to report a payment or other transfer of value or failure of manufacturer or GPO to report physician ownership or investment interest; total penalties for each annual submission capped at $150,000.	Civil monetary penalty of not less than $1,000 and not more than $10,000 for each failure by a manufacturer to report a payment or other transfer of value or failure of manufacturer or GPO to report physician ownership or investment interest; total penalties for each annual submission capped at $150,000.	No
§ 403.912(b) – Knowing failure to report	Civil monetary penalty of not less than $10,000 and not more than $100,000 each *knowing*failure by a manufacturer to report a payment or other transfer of value or *knowing*failure of manufacturer or GPO to report physician ownership or investment interest; total penalties for *knowing* failures for each annual submission capped at $1,000,000.	Civil monetary penalty of not less than $10,000 and not more than $100,000 each *knowing*failure by a manufacturer to report a payment or other transfer of value or *knowing*failure of manufacturer or GPO to report physician ownership or investment interest; total penalties for *knowing* failures for each annual submission capped at $1,000,000.	No
§ 403.912(c) – Total annual civil monetary penalties [Final]	N/A	The penalties imposed for failures to report and knowing failures to report will be aggregated separately and are subject to separate aggregate totals, with a maximum combined annual total of $1,150,000.	Yes

Reference	Proposed Rule	Final Rule	Change?
§ 403.912(c) – Determinations regarding the amount of civil monetary penalties [Proposed] **§ 403.912(d) – Determinations regarding the amount of civil monetary penalties [Final]**	Factors to be considered in setting amount of CMP include: (1) The length of time the entity failed to report. (2) Amount of the unreported payment. (3) Level of culpability. (4) Nature and amount of information reported in error. (5) Degree of diligence exercised in correcting information reported in error.	Factors to be considered in setting amount of CMP include: (1) The length of time the entity failed to report. (2) Amount of the unreported payment. (3) Level of culpability. (4) Nature and amount of information reported in error. (5) Degree of diligence exercised in correcting information reported in error.	No
§ 403.912(d)(1) – Record retention and audits / Maintenance of Records [Proposed] **§ 403.912(e)(1) – Record retention and audits /Maintenance of Records[Final]**	Applicable manufacturers and GPOs must maintain all books, contracts, records, documents, and other evidence sufficient to enable an audit of the applicable entity's compliance for at least 5 years after the publication of the information on CMS' Web site. HHS, CMS, or OIG may audit the records.	Applicable manufacturers and GPOs must maintain all books, contracts, records, documents, and other evidence sufficient to enable an audit of the applicable entity's compliance for at least 5 years after the publication of the information on CMS' Web site. HHS, CMS, or OIG may audit the records.	No
§ 403.912(d)(2) – Record retention and audits / Audit [Proposed] **§ 403.912(e)(2) – Record retention and audits /Audit [Final]**	HHS, CMS, OIG or their designees may audit, inspect, and evaluate any books, contracts, records, documents, and other evidence of applicable manufacturers and applicable group purchasing organizations that pertain to their compliance with the requirement to accurately and completely submit information in a timely manner in accordance with the rules established under this subpart.	HHS, CMS, OIG or their designees may audit, inspect, investigate and evaluate any books, contracts, records, documents, and other evidence of applicable manufacturers and applicable group purchasing organizations that pertain to their compliance with the requirement to timely, accurately or completely submit information in accordance with the rules established under this subpart.	No substantive change.
§ 403.912(g) – Notice, hearings, appeals, and collection	N/A	Civil monetary penalties imposed under this section are subject to the provisions set forth in subparts A and B of part 402, including those pertaining to notice, opportunity for a hearing, appeals procedures, and collection of penalties.	Yes

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Reference	Proposed Rule	Final Rule	Change?
Preemption of State Laws			
§ 403.914(a) – General rule	In the case of a payment or other transfer of value provided by an applicable manufacturer to a covered recipient, this subpart preempts any statute or regulation of a State or political subdivision of a State that requires an applicable manufacturer to disclose or report, in any format, the type of information regarding the payment or other transfer of value required to be reported under this subpart.	In the case of a payment or other transfer of value provided by an applicable manufacturer to a covered recipient, this subpart preempts any statute or regulation of a State or political subdivision of a State that requires an applicable manufacturer to disclose or report, in any format, the type of information regarding the payment or other transfer of value required to be reported under this subpart.	No