

## **Physician Payment Sunshine Act: Final Rule Top 50 Things to Know**

The Physician Payment Sunshine Act [final rule](#) was released this past week. The final regulations will greatly affect the entire pharmaceutical and medical device industry. In general, the Sunshine Act requires applicable manufacturers of drugs, devices, biologicals, or medical supplies to report annually to the Secretary of HHS certain payments or other transfers of value to physicians and teaching hospitals. It also requires applicable manufacturers and applicable group purchasing organizations (GPOs) to report certain information regarding the ownership or investment interests held by physicians or the immediate family members of physicians in such entities.

In the coming days we will be posting in-depth analysis and stories regarding the final regulations. We previously wrote about the impact the regulations will have on the [continuing medical education](#) (CME) industry. In addition to providing you in-depth analysis of the final regulations we are also providing you a list of the Top 50 aspects of the final rule we think all stakeholders should be aware of. We have organized our list by topic. We will likely supplement this list as the days go by and we dig deeper into the 287 pages of the final rule.

### **General Reporting**

1. Data collection will begin on **August 1, 2013** for applicable manufacturers and applicable GPOs sufficient time to prepare. Applicable manufacturers and applicable GPOs will report the data for **August through December of 2013** to CMS by **March 31, 2014** and CMS will release the data on a public website by **September 30, 2014**. CMS is developing an electronic system to facilitate the reporting process.

2. “Applicable manufacturers should be able to **demonstrate** that they made a **good faith effort** to obtain an NPI for the physician.” A good faith effort includes, but is not limited to, specifically requesting an NPI from the physician, checking the NPPES database, and calling the NPPES help desk.”

3. CMS said it will provide **Frequently Asked Questions (FAQs) and other methods to help users find and understand this important contextual information.**

### **Conferences, CME, Food & Beverage**

4. 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: (1) The event at which the covered recipient is speaking meets the accreditation or certification requirements and standards for continuing education of one of the (i) ACCME; (ii) AAFP; (iii) ADA; (iv) AMA; or (v) AOA; (2) The applicable manufacturer does not pay the covered

recipient speaker directly; and (3) 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.

5. 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**. Applicable manufacturers **are not required** to report or track buffet meals, snacks, soft drinks, or coffee made generally available to all participants of a conference or similar events where it is difficult to identify the identity of those who partook in the offering.

6. CMS provided additional guidelines for the “reporting of payment or other transfers of value at conferences or similar events.” In general, these guidelines will apply to “conference and similar events, as well as events open to the public.” At events open to the public, CMS recognized that “it will be extremely difficult for applicable manufacturer to identify physician covered recipients.” Therefore, CMS finalized “that small incidental items that are under \$10 (such **as pens and note pads**) that are provided at large-scale conferences and similar large-scale events will be **exempted from the reporting** requirements, including the need to track them for aggregation purposes.”

### **Research Payments**

7. “Payments or other transfers of value related to research for **new applications** of products **already on the market** will be treated differently due to the statutory distinction between new products and new applications of existing products. Pursuant to the statute, payments related to research on new applications of existing products will be granted a delay **only** if the research **does not** meet the definition of “clinical investigation.” CMS recognized that clinical investigations are a subset of research; however, “the statute clearly differentiates them for purposes of **delayed publication** from research and development, and indicates that payments or other transfers of value made in connection with clinical investigations related to **new applications of existing products** should **not be granted a delay**.”

8. CMS clarified that for “purposes of determining eligibility for delayed publication under section 1128G(c)(1)(E) of the Act, **new generic products will be considered new products**, including drugs receiving approval under an Abbreviated New Drug Application (ANDA), and devices under the 510(k) process.

9. Payments for “business development activities” will not be granted a delay. Any related payments or other transfers of value that **would not** be reported as a part of the “research” nature of payment category, ... **will not** be granted delayed publication.

10. CMS, agreed that requiring both a written agreement or contract and a research protocol **is limiting for some types research**, and thus finalized that if a payment falls within the nature of payment category for research, it only needs to be subject to a written agreement or contract or a research protocol.

11. CMS clarified that “Congress clearly intended that all payments should be included on the public website, *even if a product never received FDA approval, licensure or clearance.*”

12. CMS defined “research” based on the Public Health Service Act definition of research in 42 CFR 50.603; which defines research as: “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.” CMS concluded that “this definition includes **pre-clinical research and FDA Phases I-IV research**, as well as **investigator-initiated investigations.**”

13. “material transfers (such as provision of a protein) to a researcher for discovery collaboration **does not** need to be reported **when not** part of a commercial or marketing plan and precedes the development of a new product.” CMS said that for the purposes of this regulation that due to the early stage of the research process, “the transferred material **does not** have independent value.”

14. With respect to research payments, applicable manufacturers **will not** be responsible for indicating whether a payment was **direct or indirect**. Instead, a single research payment is reported once and includes the entity paid, as well as the name of the principal investigator(s). Applicable manufacturers must report each research payment once as a single interaction

15. For pre-clinical research, which CMS said includes “laboratory and animal research that is carried out prior to beginning any studies in humans,” there is no requirement to report an “associated product, or study name.”

16. CMS finalized what should be included in the **total research payment amount**. “The amount should include the aggregated amount of any payments for services included in the written agreement/research protocol.” CMS envisioned that this would include the “costs associated with **patient care, including diagnostics, exams, laboratory expenses, time spent by health care professionals treating the patient and managing the study**, and the **provision of study drugs, devices, biologicals, and medical supplies or other in-kind items.**”

17. In addition to research payments, CMS also stated “that **meals and travel** should be reported **separately** (under the food and travel nature of payment categories) **unless** included in **written agreement** or research protocol and paid

for through the large research contract.”

### **Nature of Payment Categories; Exclusions**

18. Items “[]such as medical textbooks and journal reprints[] ... do **not** ... fall within the statutory exclusion of Educational Materials that Directly Benefit Patients or are Intended For Patient Use. **Wall models and anatomical models** which are ultimately intended to be used with a patient, *are excluded*.

19. Based on the timing of the publication of the final rule CMS finalized that the Report to Congress will be submitted annually on **April 1st, beginning April 1, 2015**, and will include aggregated information submitted by each applicable manufacturer and applicable GPO submitted during the preceding calendar year (that is, data collected in CY 2013 and submitted in March of 2014), as well as any enforcement actions taken and any penalties paid.

20. A device manufacturer may give a physician an anatomical model to help explain to patients how a procedure would work. CMS agreed that “such an item, which is given to physicians for the purpose of educating patients, **falls within the exclusion**. Similarly, if a manufacturer provides educational materials to a physician **on a flash drive to be distributed to patients**, the flash drive would also fall within the exclusion. CMS also stated that **overhead expenses**, such as **printing and time**, should be included in the exclusion as long as they are **directly related to the development of the materials**, which directly benefit patients or are intended for patient use.

### **45-Day Review**

21. Following the end of the 45-day review and correction period, applicable manufacturers and applicable GPOs will have **an additional 15 days** to correct data for purposes of resolving disputes, and after which they may submit (and provide attestation for) updated data to CMS to finalize their data submission. Undisputed data will be finalized for publication after the close of the annual 45-day review and correction period. If a dispute cannot be resolved in this time, the parties may and should continue to work to reach resolution and update the data. However, CMS will continue to move forward with publishing the original and attested data, but **will mark it as disputed**. The applicable manufacturer's or applicable GPO's most recent attested data subject to the dispute **will be the only account of the information published**.

22. CMS “plans to monitor the rate of disputes and resolutions, including whether an applicable manufacturer or applicable GPO has an abnormally high number of disputes or has an abnormally high rate of unresolved disputes.” CMS will also “monitor the volume and terms of disputes and resolutions, and plan[s] to provide additional guidance regarding situations when the cost of resolving a dispute may outweigh the benefits.”

23. CMS said “that errors and changes need to be reported to [CMS] **as soon as possible** so that [CMS] has the most accurate information possible.” CMS reiterated the responsibility that applicable manufacturers or applicable GPOs have to provide information to CMS “immediately after confirming that an update is needed or an error needs to be corrected; **failure to do so may be considered incomplete reporting and may give rise to penalties.**” More importantly, CMS clarified that it **does not** intend that errors corrected during the review and correction, and dispute resolution periods **will be subject to penalties for failure** to report in instances when the original submission was made in good faith.

### **Penalties, Enforcement, Recordkeeping, Preemption**

24. Compliance with reporting under the Sunshine Act “does not exempt applicable manufacturers, applicable GPOs, covered recipients, physician owners or investors, immediate family members, other entities, and other persons from any potential liability associated with payments or other transfers of value, or ownership or investment interests (for example, potential liability under the Federal Anti-Kickback statute or the False Claims Act).”

25. CMS finalized that a CMP may be imposed for failure to report information in a timely, accurate, or complete manner. “This includes failure to report timely or accurately an entire transaction, as well as failure to report timely or accurately certain fields related to a transaction.

26. CMS revised the final regulation “to clarify that 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. In addition, CMS finalized that the procedures in 42 CFR 402 subpart A and subpart B will apply with regard to imposition, appeal, and collection of CMPs.

27. Applicable manufacturers and applicable group purchasing organizations must maintain all **books, contracts, records, documents, and other evidence** for a period of **at least 5 years** from the date the payment or other transfer of value, or ownership or investment interest is published publicly on the website. CMS acknowledged that this policy “may require the records to be retained for **up to 9 years**” because of payments or other transfers of value eligible for delayed publication

28. 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. CMS reiterated that it **and** the HHS OIG are authorized to impose

CMPs and both agencies will have the ability to investigate failures to report timely, accurately or completely.

29. CMS said it **does “not intend** to use the assumptions document for prosecution, but acknowledge[s] that the reporting based on the assumptions **would be open to prosecution**. Specifically, CMS stated that “other HHS divisions, the Department of Justice (DOJ), or the Office of the Inspector General (OIG) could request access to the documents as part of an audit or investigation into an applicable manufacturer or applicable GPO.”

30. With respect to preemption, CMS recognized that State and local entities *may* require reporting of **nonrequired categories** of information for payments or other transfers of value reported to CMS, which **are not** required under Federal law. This includes payment categories **excluded** by the Federal law (including those listed at section 1128G(e)(10)(B) of the Act), with the exception of those that do not meet the minimum dollar threshold (\$10).

### **Covered Recipient**

31. CMS clarified the definition of “covered recipient” to mean “any physician, except for a physician who is a **bona fide employee** of the applicable manufacturer that is reporting the payment” so that applicable manufacturers do not try to “circumvent the reporting requirements by styling a physician as an “employee” and not reporting payments made to such a physician. Thus, applicable manufacturers should consult guidance from HHS-OIG regarding the bona fide employment exception in the Anti-Kickback Statute and the corresponding HHS OIG regulation at 42 CFR 1001.952(i).

32. CMS clarified that “Payments or other transfers of value to **residents** (including residents in medicine, osteopathy, dentistry, podiatry, optometry and chiropractic) will **not** be required to be reported for purposes of this regulation.”

33. CMS will be employing a **case-specific analysis** for determining whether board members, medical directors, prospective employees and retirees are “employees” of applicable manufacturers or GPOs, whose payments would be excluded from reporting.

34. CMS was “unable to state that payments to such physicians, such as **recruiting costs** paid to prospective employees, do not need to be reported.”

### **Indirect Payments**

35. CMS defined **Indirect payments or other transfers of value** 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).

1. For example, if an applicable manufacturer provided an unrestricted donation to a physician professional organization to use at the organization's discretion, and the organization chose to use the donation to make grants to physicians, those grants **would not** constitute "indirect payments" because the applicable manufacturer **did not require, instruct, or direct** the organization to use the donation for grants to physicians.

2. However, if an applicable manufacturer gave money to a medical professional society earmarked for the purpose of **funding awards or grants for physicians**, the awards or grants **would constitute** indirect payments to covered recipients and **would** be subject to the reporting requirements.

36. CMS finalized that an applicable manufacturer is "unaware" if it does not know the identity of a covered recipient, and that "know" means that the manufacturer has actual knowledge of the identity or acts in deliberate ignorance or reckless disregard of the identity. If a payment meets the definition of an indirect payment or other transfer of value, then the payment can only be excluded from the reporting requirements if the applicable manufacturer did not "know" the identity of the covered recipient.

37. CMS clarified that, for purposes of this rule only, it will **not** consider an applicable manufacturer to be acting in deliberate ignorance or reckless disregard of a covered recipient's identity in situations when the reason a payment or other transfer of value is being made through a third party is that the identity of the covered recipient remains anonymous.

1. For example, an applicable manufacturer may hire a market research firm to conduct a double-blinded market research study, which includes paying physicians \$50 for responding to a set of questions. The applicable manufacturer clearly intends a portion of the payment to be provided to physicians, but given that the reason for the third party's involvement is specifically to maintain the anonymity of the respondents and sponsor, CMS does **not** intend this to be considered a reportable indirect payment or other transfer of value.

2. However, a "manufacturer that **directs** a third party to make payments to the top billing cardiologists in a certain city or the chiefs of staff of a certain class of hospitals **should** be required to report these payments, even though they do not have actual knowledge of the identities of such individuals

38. CMS explicitly asserted that it would not expand the definition of covered

recipients to “include other provider types.” Thus, CMS recognized that it will “not be able to fully capture financial relationships between industry and prescribers, specifically non-physician prescribers such as nurse practitioners.” However, “to the extent that applicable manufacturers make payments or other transfers of value to **non-physician prescribers** to be **passed through to a physician**, they would be **indirect payments** to the physician and would have to be reported under the name of the physician.” CMS also concluded that “all physicians (including all providers types listed in the statutory definition) that have a **current license** to practice will be considered covered recipients.” CMS also recognized that the term “physician” applies to physicians **regardless** of whether the physician is enrolled in Medicare, since the “statute did not indicate that physician covered recipients be limited to those enrolled in Medicare, Medicaid or CHIP.”

### **Applicable Manufacturers**

39. Applicable manufacturers for whom total (gross) revenues from covered drugs, devices, biologicals, or medical supplies constituted less than **10 percent of total** (gross) revenue during the fiscal year preceding the reporting year are **only** required to report payments or other transfers of value that are related to one or more covered drugs, devices, biologicals or medical supplies.

40. The definition of applicable manufacturer **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.

41. “Entities based outside the United States that *do* have operations in the United States are subject to the reporting requirements.” “entities that have operations in the United States are not permitted to circumvent the reporting requirements by making payments to covered recipients indirectly through a foreign entity that has no operations in the United States.” CMS explained that “Such payments are considered to be made by the entity that is operating in the United States as an **indirect payment** or other transfer of value and **must be reported as such**, so long as the entity operating in the United States is **aware of the identity** of the covered recipients receiving the payments as required for all indirect payments or other transfers of value.

42. CMS revised the definition of “applicable manufacturer” to exclude “hospitals, hospital-based pharmacies and laboratories that manufacture a covered product solely for use by or within the entity itself or by an entity's own patients” because it was not the “intent of the statute to include these entities as applicable manufacturers.”

43. In addition, the definition of applicable manufacturer **does not** include pharmacies, including compounding pharmacies, that meet all of the following

conditions: (1) maintain establishments that comply with applicable local laws regulating the practice of pharmacy; (2) regularly engage in dispensing prescription drugs or devices upon prescriptions from licensed practitioners in the course of their professional practice; and (3) do not produce, prepare, propagate, compound, or convert drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail to individual patients

44. CMS provided clarification for what applicable manufacturers should do when a product becomes “covered” and thus, when data collection and reporting requirements will begin. Agreeing with one comment, CMS will “allow the applicable manufacturer a grace period of **180 days** following a product becoming “covered” to begin complying with the data collection and reporting requirements.

### **Covered Drug, Device, Biological or Medical Supply; Related Covered Product**

45. CMS finalized that a covered drug, device, biological or medical supply is one for which payment is available under Medicare, Medicaid or CHIP, and “**products which are reimbursed separately or as part of a bundled payment.**” Thus, CMS concluded that “bundled payment” would be interpreted as meaning IPPS, OPSS, and other prospective payment systems.

46. If a “payment or other transfer of value **is not related** to at least one covered product, then applicable manufacturers should report “**none.**” Conversely, “if the payment or other transfer of value **is related** to a specific product, which is not a covered product, then applicable manufacturers **are to report “non-covered product.”** Finally, if the payment or other transfer of value **is related to at least one covered product, as well as at least one non-covered product,** then applicable manufacturers **must report** the covered products **by name** (as required), and ***may*** include non-covered products in one of the fields for reporting associated product.”

47. With respect to reporting multiple products, CMS finalized that applicable “manufacturers may report up to **five related covered products for each interaction.**” If the interaction “was related to **more than five** products, an applicable manufacturer should report the five products which were **most closely related** to the payment or other transfer of value.”

48. For drugs and biologicals, CMS finalized that applicable manufacturers must report the **market name** of the product and **must include** the NDC (if any).” If a market name is **not yet available**, applicable manufacturers **should use** the **name registered on clinicaltrials.gov.** CMS said that reporting the NDC will greatly help CMS aggregating the data by product. However, if there is no NDC available for a product, it **does not have to be reported.**

## Payments to Group Practice

49. CMS “finalized that payments provided to a group or practice (or multiple covered recipients generally) should be attributed to the individual physician covered recipients who **requested the payment, on whose behalf** the payment was made, or who are **intended to benefit** from the payment or other transfer of value. “This means that the payment or other transfer of value does not necessarily need to be reported in the name of all members of a practice.” For example, many payments or other transfers of value may need to be divided evenly, whereas others may need to be **divided in a different manner** to represent who requested the payment, on whose behalf the payment was made, or who was intended to benefit from the payment or other transfer of value.

## Payments Designated or At the Request

50. If a covered recipient **directs** that an applicable manufacturer provide a payment or other transfer of value to a specific entity or individual, **rather than receiving it personally**, then the payment is being made "**at the request**" of such covered recipient and must be reported as described in this section (under the name of the covered recipient, but also including the name of the entity paid or "individual," in the case of an individual).

1. For example, in the event that a covered recipient directs an applicable manufacturer to “**donate a payment** or other transfer of value—to which he would have otherwise been entitled—to a particular charity, the applicable manufacturer **must report** the payment in the name of the covered recipient and provide the **name of the charity** that received the payment at the covered recipient's request.

However, if a covered recipient decides to “**neither accept the payment** or other transfer of value **nor request that it be directed** to another individual or entity, then the payment or other transfer of value that was offered by the applicable manufacturer **does not need to be reported.**”