# CMS Releases Long-Awaited Sunshine Act Final Rule

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The Centers for Medicare & Medicaid Services (CMS) recently released the long-awaited final rule that implements the Physician Payment Sunshine Act.

The Sunshine Act, as previously noted on this blog, requires drug, medical device, and other manufacturers to annually report payments made to physicians and teaching hospitals for consulting, research, speaking, entertainment, travel, or food, if the payment is in excess of ten dollars.

The final rule deals with details such as who is covered by the law, when they must begin collecting data, and what payments are covered or excluded.

The text of the final rule is located here and is summarized below.

## Reporting requirements

- Group purchasing organizations (GPOs) and manufacturers must begin collecting data on August 1, 2013. They will collect data through December 2013 and will have until March 31, 2014, to report it to CMS. CMS is currently working on an electronic system for the reporting process.

- GPOs and manufacturers must make a good faith effort to obtain a physician's National Provider Identifier (NPI). This includes, but is not limited to, specifically requesting an NPI from the physician, checking the National Plan & Provider Enumeration System (NPPES) database, and calling the NPPES help desk.

- A Report to Congress will be submitted every year in April, beginning in 2015. The first 2015 report will summarize the data collected in 2013.

## Covered recipient

- A "covered recipient" is any physician, except for a bona fide employee of a manufacturer or GPO. CMS chose this definition so manufacturers could not avoid reporting requirements by merely designating a physician as an "employee," when in reality that person is not a true bona fide employee.

- Payments or transfers of value to residents do not have to be reported.

- Board members, medical directors, prospective employees, and retirees will be reviewed on a case-by-case basis to determine if payments to such parties are excluded under the law.

**Applicable manufacturers**

- "Applicable manufacturers" do not include "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."

- The definition also does not include pharmacies that meet certain conditions regarding the routine practice of pharmacy.

**Payments to a Group Practice/Teaching Hospital**

- Payments to a group practice do not necessarily have to be reported in the name of all members of the practice. The payments should be attributed to the individual physician who requested the payment, on whose behalf the payment was made, or who was the intended beneficiary of the payment.

- Payments made to one covered recipient, i.e., a physician, through another covered recipient such as a teaching hospital, should be reported in the name of the recipient that ultimately receives the payment. For example, if an applicable manufacturer provides a payment to a teaching hospital intended for a physician employee of the teaching hospital, then the payment should be reported in the name of the physician.

**Conferences, Food & Beverage, CME**

- Manufacturers/GPOs must report the per-person value of a meal as a payment only for recipients who actually partake in the food or beverage.

- Manufacturers/GPOs do not have to report buffet meals/snacks/soft drinks made available to all participants of a conference or event where it is difficult to identify who partook.

- Small, incidental items provided at conferences that are worth less than $10, such as pens and note pads, are exempted from reporting requirements.

**Exclusions**

- Educational materials given to physicians for their own education, but do not "directly" benefit patients, are not excluded. These items may include medical

textbooks and journal reprints, in spite of the potential for "downstream benefits" accruing to patients.

- Materials such as wall models and anatomical models, which are ultimately intended to be used with a patient, are excluded from the reporting requirements.

**Data review**

- Manufacturers, GPOs, and covered recipients will have the opportunity to review the data submitted to CMS for at least 45 days before it is made available to the public.

- Manufacturers and GPOs will also have an additional 15 days to correct data and resolve disputes. If parties are unable to resolve a dispute, CMS will still publish the data, but will mark it as disputed.

- Only two years of data will be available on the CMS website for review and correction. Recipients will be able to review only the previous year's data in order to correct disputes.

- Failure to alert CMS to errors or updates of data may be considered incomplete reporting and could lead to penalties.

**Penalties and enforcement**

- If a manufacturer or GPO fails to submit the required information, it may be subject to a civil monetary penalty (CMP) of at least $1,000, but no more than $10,000, for each payment or transfer of value not reported.

- The maximum CMP for failure to report an annual submission is $150,000.

- CMS may impose a CMP 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.

- When determining penalty amounts, CMS will consider the following factors: length of time the party failed to report, amount of the payment not reported, level of culpability, nature and amount of information reported in error, and the degree of diligence exercised in correction information.

- The relevant regulatory agencies – HHS, CMS, OIG – are authorized to audit, inspect, and investigate any books, contracts, records, documents, and any other evidence that pertains to compliance with the law.

**Preemption**

- The Physician Payment Sunshine Act preempts any State law or regulation that requires a manufacturer to disclose or report similar information.

- However, States may require reporting of excluded categories or non-required categories of information that are not covered under the law.

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