



## Physician Payment Sunshine Act December 19, 2011

### Background

On December 14, 2011, The Centers for Medicare & Medicaid Services (CMS) announced a [proposed rule](#) to Section 6002 of the Affordable Care Act (ACA) that added Section 1128G of the Social Security Act to the proposed rule that would require applicable manufacturers and group purchasing organizations (GPOs) to report certain information regarding their financial relationships with and ownership or investment by physicians<sup>1</sup>. The proposed rule, known as the “Sunshine rule,” is open for comments until February 17, 2012.

Applicable manufacturers are manufacturers of drugs, devices, biologicals, and medical supplies covered by Medicare, Medicaid, or the Children’s Health Insurance Program. Financial relationships include payments and gifts to physicians, consulting fees and other payments, travel reimbursements, research grants and other gifts with values over \$10 which will now be required to be disclosed by medical industry companies on an annual basis. In considering the definition of “device,” this definition is limited to those devices (including medical supplies) that require premarket approval by or premarket notification to the Food and Drug Administration.

### Timeline for Implementation

CMS acknowledged that due to the timing of the Notice of Proposed Rule Making (NPRM), a final rule will not be published in time for applicable manufacturers and applicable GPOs to begin collecting reported information on January 1, 2012, which was the date originally proposed in the ACA. Therefore, CMS will not require reporting until after the final rule is announced. In the NPRM, they seek comment on the length of time for compliance following the final rule (they are currently considering 90 days) and comments on the challenges covered entities may encounter to become compliant. Depending on the timing of the final rule, the NPRM has proposed that applicable manufacturers and GPOs be required to submit a partial year report on March 31, 2013.

It is important to note that this regulation will preempt current state and local laws requiring payment reporting under the auspices outlined in the ACA. This preemption is still scheduled to take effect January 1, 2012, **even though** manufacturers and GPOs are not legally required to report this information to HHS until the final rule is released (anticipated in the summer of 2012). However, CMS is still urging that these entities continue to comply with applicable state reporting requirements as they currently are, even though federal requirements are not yet in place.

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<sup>1</sup>CMS Proposed Rule. December 14, 2011. <https://s3.amazonaws.com/public-inspection.federalregister.gov/2011-32244.pdf>

## Penalties and Penalty Exposure

Failure to report will bring monetary penalties—manufacturers or GPOs must report or otherwise face fines. The amount for not reporting these gifts is capped at \$150,000 and a \$1 million fine for **knowingly** not reporting such gifts. Reporting to the Secretary of HHS must be on an annual basis, and these aggregated reports will be posted on a public website. However, there will be a 45 day review period for applicable manufacturers and GPOs, covered recipients, and physician owners and investors prior to posting. Holding to the above-mentioned partial year reporting date of March 31, 2013, CMS proposes that this data will be made publicly available by September 30, 2013.

## Issues of Note for HIMSS Members

- CMS estimates that roughly 150 drug or biologic manufacturers, 1,000 device or medical supply manufacturers, and 420 GPOs will be required to submit information to CMS on an annual basis pursuant to this provision<sup>2</sup>.
- Applicable manufacturers are required to report each covered entities' National Provider Identifier (NPI). However, CMS is seeking comments on potentially requiring applicable manufacturers to report another unique identifier, such as State license number, for physicians who are identified, but do not have an NPI and is requesting comments on what other unique identifiers could be used, including whether these unique identifiers are readily obtainable by applicable manufacturers.
- This rule applies to entities that hold FDA approval, licensure, or clearance for a covered drug, device, biological, or medical supply that is distributed in the U.S. This applies no matter where the product is produced or where the manufacturer is located or incorporated. This also applies if the manufacturer contracts out the actual physical manufacturing of the product to another entity.
- Similarly, any manufacturer that meets the definition of applicable manufacturer by selling or distributing in the United States at least one covered drug, device, biological, or medical supply is considered an applicable manufacturer, even though it may also manufacturer products that do not fall within that. The regulation proposes that all payments or transfers of value made by an applicable manufacturer to a covered recipient must be reported as required under section **regardless** of whether the particular payment or other transfer of value is associated with a covered drug, device, biological, or medical supply.

A Senate Special Committee on Aging Hearing on the Sunshine Act provisions of ACA is pending. HIMSS will convene a volunteer working group to formally respond to this NPRM and provide comments by the February 17, 2012, deadline. HIMSS will continue to monitor and identify any new developments around in this issue as they emerge. For more information, please contact Tom Leary, Senior Director of Federal Affairs at [tleary@himss.org](mailto:tleary@himss.org) or Stephanie Jamison, Director of Government Services at [sjamison@himss.org](mailto:sjamison@himss.org)

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<sup>2</sup> CMS Fact Sheet. December 14, 2011. <https://www.cms.gov/apps/media/press/factsheet.asp>