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Editors: [Leslie Demaree Goldsmith](#) and [Carel T. Hedlund](#)

Sunshine Proposed Rule Sheds Light on Reporting Requirements

By: [Sarah E. Swank](#) and [William T. Mathias](#)

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On December 14, 2011, CMS released the much-anticipated proposed rule implementing the “sunshine” provisions of Section 6002 of the Affordable Care Act (ACA). The proposed sunshine regulation requires certain manufactures of drugs, devices, and biologics to report to CMS information regarding payments and other transfers of value to covered physicians and teaching hospital. Transfers of value include gifts, consulting fees, research activities, speaking fees, meals and travel. In addition, the proposed regulation also would require certain manufactures and group purchasing organizations (GPOs) to report ownership interests in such organizations held by physicians. CMS would make the reported information available on a searchable, public website.

The proposed regulation seeks comments about a number of aspects of the reporting requirements. Comments must be submitted by **February 17, 2012**. CMS anticipates publishing the final rule in 2012.

Proposed Delay for Data Collection

The ACA required that tracking of payments and transfers of value begin on January 1, 2012, with reporting starting on March 31, 2012. Under the proposed regulation, CMS indicates that data collection and reporting will be delayed until the final rule is published. CMS also indicates that it is considering a 90-day preparation period following publication of the final rule before data collection must begin.

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Who Must Report

Applicable Manufacturers. CMS proposes to define applicable manufacturers as an entity that manufactures a drug, device, biological or medical supplies for sale or distribution in the US that are covered by Medicare, Medicare and CHIP or is under common ownership with such an entity. This definition means that the reporting requirements would apply to covered products produced outside the US that are for sale or distributed in the US. This definition would also include products paid for as part of a fee schedule or bundled payment (e.g., the hospital inpatient prospective payment system). CMS seeks comments on its definition of applicable manufacturers.

Applicable GPOs. CMS proposes to define applicable GPOs an entity that operates in the US which purchases, arranges for or negotiates the purchase of a covered product for a group of individuals or entities, and not solely for use by the entity itself.

Who Must be included in Reports

The ACA required that applicable manufactures submit reports related to covered recipients, which included physicians and teaching hospitals. Applicable GPOs also have reporting obligations regarding physician ownership and investment.

Physician. The proposes rule defines physician consistent with the definition in the Social Security Act, which includes licensed doctors of medicine, osteopathy, dentists, podiatrists, optometrists, and chiropractors.

Teaching Hospital. CMS proposes to defined teaching hospital as any hospital that receives Medicare direct or indirect graduate medical education payments (GME or IME). CMS proposes that it will post a list of “teaching hospitals” on its website to assist in determining whether reporting obligations apply to a particular hospital.

What is Reported

The proposed regulation includes detailed requirements for what must be reported as a payment or other transfer of value. The proposed regulation also includes 13

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types of benefits that are specifically excluded from reporting. The proposed regulation also specifies the format in which the information must be reported. CMS proposes that all reports must be made electronically.

Delayed Publication for Certain Research Payments

CMS has proposed specific procedures to delay the publication of certain identified payments related to research and development.

Public Reporting

CMS proposes publish payments or other transfer of value and ownership or investment interest on a publicly available, searchable web site. CMS is considering providing covered recipients, including physicians and teaching hospitals, 45 days to review and correct information before it is made available to the public. CMS proposed dispute resolutions process requires the applicable manufacturer and applicable GPO to resolve their own disputes with teaching hospitals and physicians. If the dispute cannot be resolved, CMS will publish both accounts.

Penalties for Failure to Report

Those who fail to timely report would be subject to civil monetary penalties of up to \$150,000 for failing to report and up to \$1,000,000 for knowingly failing to report.

Record Retention and Government Audit Authority

The proposed regulation would require applicable manufacturers and GPOs to maintain supporting documentation for at least 5 years from the date the payment or other transfer of value is published in the CMS website. Under the proposed regulation, CMS would have audit and inspection authority to ensure compliance with the sunshine provisions.

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