

## US Department of Health and Human Services Issues Final “Sunshine” Rule Imposing Reporting Requirements on Payments to Physicians and Teaching Hospitals

The Centers for Medicare & Medicaid Services (CMS) has announced a final rule that will implement section 1128G of the Social Security Act, as added by section 6002 of the Affordable Care Act. The new rule will impose reporting requirements on manufacturers of drugs, devices, and biological or medical supplies, as well as on group purchasing organizations (GPOs) concerning certain financial dealings with physicians and teaching hospitals. Organizations must begin collecting data for the new reports on August 1, 2013.

### Two Forms of Annual Reporting

Under the new rule, applicable manufacturers must report annually to the Health and Human Services (HHS) Secretary all payments or other transfers of value given to physicians or teaching hospitals. In addition, applicable manufacturers and applicable GPOs must report ownership and investment interests held by physicians or their immediate family members.

### Only Manufacturers and GPOs Must Report; Physicians and Teaching Hospitals Should Monitor Submissions

The new rule will apply to manufacturers of drugs, devices and biological and medical supplies that are covered by Medicare, Medicaid, or CHIP. The requirements apply only to manufacturers operating in the United States:

that have a physical location in the United States (including territories, possessions, or commonwealths) or that otherwise conduct activities within the United States, either directly or through an agent.

Distributors and wholesalers are excluded from the requirement, so long as they do not hold title to any covered drug, device, or biological or medical supply. However, an entity that is under common ownership with an applicable manufacturer, and that provides services relating to the covered items, will be required to make reports.

Similarly, GPOs are subject to the rule if they operate in the United States and purchase or otherwise arrange for or negotiate the purchase of a covered drug, device, or biological or medical supply for a group of individuals or entities. If the purchase is solely for use by the entity, the reporting requirement is not triggered.

Physicians and teaching hospitals are not required to make the reports, but they should remain attentive to the new process in order to ensure the accuracy of any reports relating to them. Physicians and hospitals should consider registering with CMS in order to receive notification when new reports are available for review.

## Form of Reports

Manufacturers will be required to report all payments or other transfers of value that they give to physicians or teaching hospitals, including consulting fees, compensations for services other than consulting, honoraria, gifts, entertainment, food and beverage, travel and lodging, education, research, charitable contributions, royalties or licenses, current or prospective investment or ownership interests, faculty or speaker compensation, grants, and space rentals. Third-party payments must be included in the reports as well. For example, a manufacturer must report a payment by a third party to a physician if that payment was made at the manufacturer's behest. Similarly, manufacturers must report a payment that was made to a third-party recipient at the request of, or on behalf of, a physician.

Payments under \$10 are excluded from reporting, unless the aggregate transfer to a given recipient exceeds \$100 in a calendar year. (This *de minimus* exclusion will increase with inflation in future years.) The rule also excludes a variety of other defined transfers, including samples and demonstratives intended for patient use only, in-kind items used for the provision of charity care, payments to employees and their families for healthcare expenses, and dividends or profits from ownership interests.

Along with identifying information such as the date and recipient, the report must include the amount, form, and nature of the payment or transfer and must identify the covered drug, device or biological or medical supply to which it relates, if applicable. In addition, CMS' final rule accedes to public comment that had requested that manufacturers and GPOs be allowed to submit brief explanations of the context of the physician and hospital payments. In many cases, it may be to a manufacturer's benefit to include this additional information. These context explanations will be included in the public posting.

The ownership and investment interests reports will provide identifying information concerning the physician or family member, as well as the dollar amounts invested and the value and terms of the ownership or investment interests.

"Ownership or investment interests" encompasses both direct and indirect interests, including stock and stock options, partnership shares, limited liability company membership, and loans, bonds, or other secured financial instruments. Interests in a publicly traded security or mutual fund are excluded, as are certain other defined interests, including those interests about which the manufacturer or GPO did not know.

Each report must be accompanied by an attestation from the Chief Executive Officer, Chief Financial Officer, Chief Compliance Officer, or other officer that the information reported is timely, accurate, and complete to the best of his or her knowledge or belief. An organization may also submit an "assumptions" document, explaining the reasonable assumptions made and methodologies used when creating the report. Assumptions documents will not be made public, but may be used by CMS to refine the reporting system.

## Information Will Be Publicly Posted

The data collected from manufacturers and GPOs will be shared with the public via website posting in a format designed to facilitate aggregation, downloading, and searching. The rule allows for delayed posting of certain payments made in connection with research and development activities—including clinical trials—that may warrant confidential treatment.

Before the information is released to the public, physicians, hospitals, manufacturers, and GPOs will be afforded at least 45 days to dispute and correct the reported information. CMS will make online postings when the information is available for review. Physicians and teaching hospitals may also register with CMS to receive notification about the review process.

## Data Collection Commences August 1, 2013; Reports Follow on March 31, 2014

Covered manufacturers and GPOs must begin collecting data relating to their physician payments and physician ownership/investment interests on August 1, 2013. The data for the initial August-December 2013 time period must be reported to HHS by March 31, 2014. CMS intends to release this first data set by September 30, 2014.

Thereafter, reporting will continue on an annual basis. Entities must register with CMS and make their reports within 90 days of the end of the calendar year for which the report is required.

## Audit Authority and Penalties For Failure To Report

Pursuant to the Affordable Care Act, companies that fail to report under these new requirements will be subject to civil fines of between \$1,000 and \$10,000 for each payment, transfer of value, or ownership or investment interest not timely and accurately reported, with the annual total penalty capped at \$150,000 for each manufacturer or GPO. For knowing failure to report, the penalty increases to \$10,000-\$100,000 per instance, capped at \$1 million annually.

Applicable manufacturers and GPOs are subject to audit or inspection by the HHS Office of Inspector General and the CMS. To facilitate the inspections, manufacturers and GPOs will now be required to maintain relevant records and documents for at least five years.

## State Law Preempted

Pursuant to the Affordable Care Act, no state or local government may require separate reporting of the information required by the new rule, unless the information is being collected by a governmental agency for public health surveillance, investigation, or other public health or oversight purposes.

*For more information about the new rule or any other matter raised in this Legal Update, please contact any of the following lawyers..*

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