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Device Manufacturers Required to Report Payments to Physicians Under New "Sunshine" Regulations

On February 1, 2013, the Centers for Medicare & Medicaid Services (CMS) published a final rule which will make information publicly available about payments or other transfers of value from certain manufacturers of drugs, devices, biologicals and medical supplies covered by Medicare, Medicaid, and the Children's Health Insurance Program (CHIP) to physicians and teaching hospitals. The new regulations are called the "National Physician Payment Transparency Program: Open Payments." This is one of many steps in the Affordable Care Act designed to create greater transparency in health care markets.

The final rule, which implements Section 6002 of the Affordable Care Act, will also make information publicly available about physician (or immediate family members of a physician) ownership or investment interests in applicable manufacturers.

SUMMARY OF REPORTING REQUIREMENTS

The new law specifies that manufacturers must report annually to the Secretary of Health and Human Services all payments or transfers of value (including gifts, consulting fees, research activities, speaking fees, meals, and travel) from manufacturers to covered recipients (i.e., physicians). In addition to reporting on payments, manufacturers must report ownership and investment interests held by physicians (or the immediate family members of physicians) in such entities. The law requires CMS to provide manufacturers, covered recipients, and physician owners and investors at least 45 days to review, dispute and correct their reported information before posting it on a publicly available website. The information on the website must be easily aggregated, downloaded and searchable.

IMPLEMENTING FINAL PROVISIONS

Implementation timeline: In order to give manufacturers sufficient time to prepare, data collection will begin on August 1, 2013. Manufacturers will report the data for August through December of 2013 to CMS by March 31, 2014 and CMS will release the data publicly by September 30, 2014.

Interpretations of statutory language:

Applicable manufacturers

Applicable manufacturers are entities operating in the United States that either produce or prepare at least one drug, device, biological or medical supply that is covered by Medicare, Medicaid, or CHIP and entities under common ownership with applicable manufacturers.

Covered drug, device, biological, and medical supply

A covered drug, device, biological or medical supply is one for which payment is available under Medicare, Medicaid or CHIP and which requires a prescription to be dispensed, in the case of a drug or biological, or premarket approval by or notification to the Food and Drug Administration (FDA) in the case of a device or a medical supply that is a device.

Teaching hospital

Medicare does not define the term "teaching hospital." For purposes of determining whether a hospital is a "covered recipient" of reportable payments or transfers of value, CMS has defined a "teaching hospital" as any hospital that receives indirect medical education (IME), direct graduate medical education (GME), or psychiatric hospital IME.

Research payments

Manufacturers are required to report numerous types of payments to physicians and teaching hospitals. These are outlined in the statute and include categories such as consulting fees, food and beverages, and research payments. In certain limited instances, research payments or other transfers of value made to a covered recipient by a manufacturer under a product research or development agreement will be delayed from publication on the website. Specifically, publication of a payment or other transfer of value will be delayed when made in connection with research on or development of a new drug, device, biological, or medical supply, or a new application of an existing drug, device, biological, or medical supply; or clinical investigations regarding a new drug, device, biological, or medical supply.

Opportunity to review and correct the information prior to publication

The law requires CMS to provide covered recipients at least 45 days to review and dispute the information related to them that was submitted by manufacturers. CMS will notify the covered recipients when the reported information is ready for review. Covered recipients will be notified using an online posting and through notifications on CMS's listserves. Any disputed transfer of value will be resolved directly between the covered recipient and the relevant manufacturer. There will be a 15-day opportunity to resolve disputes before the information is published publicly, following the 45-day review and correction period.

Penalties for failure to report required information accurately, completely, and timely

The Affordable Care Act provides that violators of the reporting requirements will be subject to civil monetary penalties (CMPs), capped annually at $150,000 for failure to report, and $1,000,000 for knowing failure to report. CMS finalized that the HHS Office of Inspector General (OIG) and CMS reserve the right to audit, evaluate, or inspect manufacturers for their compliance with the reporting requirements. In order to facilitate these inspections, manufacturers must maintain all records and documents for at least five years from the date the payment or other transfer of value, or ownership or investment interest is published publicly on the website.

State law preemption

Section 6002 of the Affordable Care Act also preempts any State or local laws requiring reporting of the same types of information regarding payments or other transfers of value made by applicable manufacturers to covered recipients. No State or local government may require the separate reporting of any information regarding a payment or other transfer of value that is required to be reported under this statute, unless such information is being collected by a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight.
The final rule can be downloaded at: https://www.federalregister.gov/public-inspection.

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