DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Room 352-G
200 Independence Avenue, SW
Washington, DC 20201
Office of Communications

FACT SHEET

FOR IMMEDIATE RELEASE
Dec. 14, 2011

Contact: CMS Media Relations Group
(202) 690-6145

CMS proposals to implement certain disclosure provisions of the Affordable Care Act

On Dec. 14, 2011, the Centers for Medicare & Medicaid Services (CMS) published a notice of proposed rulemaking (NPRM) which would make information publicly available about payments or other transfers of value from manufacturers of drugs, devices, biologicals and medical supplies covered by Medicare, Medicaid, and CHIP (applicable manufacturers) to physicians and teaching hospitals (covered recipients).

The proposed rule, which would implement Section 6002 of the Affordable Care Act, Transparency Reports and Reporting of Physician Ownership or Investment Interests, also would make information publicly available about physician (or immediate family members of a physician) ownership or investment interests in applicable manufacturers and group purchasing organizations (GPOs).

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.

SUMMARY OF REPORTING REQUIREMENTS IN THE AFFORDABLE CARE ACT

Section 6002 specifies that applicable 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 applicable manufacturers to covered recipients. In addition to reporting on payments, applicable manufacturers, as well as applicable GPOs, must report ownership and investment interests held by physicians (or the immediate family members of physicians) in such entities. However, the law does not require applicable manufacturers or applicable GPOs to report ownership or investment interests held by teaching hospitals. The law requires CMS to provide applicable manufacturers, applicable GPOs, covered recipients, and physician owners and investors at least 45 days to review and correct the information before posting it on a publicly available website. The information on the website must be easily aggregated, downloaded and searchable.

-More-

IMPLEMENTING PROVISIONS

Implementation timeline: Applicable manufacturers and applicable GPOs will not be required to begin collecting data until after a final rule is published. The proposed rule solicits comments on how much time manufacturers and GPOs will need after a final rule is published to begin collecting data. CMS is also considering whether to require applicable manufacturers and GPOs to submit partial year data for calendar year 2012.

Proposed interpretations of statutory language:

Applicable manufacturers
CMS is proposing to define applicable manufacturer as any entity that manufactures a drug, device, biological, or medical supply for sale or distribution in the United States that is available for payment by Medicare, Medicaid, or CHIP. The statutory definition extends to entities under common ownership with an applicable manufacturer that are involved in manufacturing, marketing, selling or distributing covered products.

Applicable GPOs
Applicable GPOs are defined broadly in the statute to include entities that purchase and arrange for, or negotiate the purchase of covered drugs, devices, biologicals, or medical supplies in the United States. CMS is proposing to interpret this to include traditional GPOs that do not purchase products directly, as well as organizations that purchase products for resale or distribution. This proposed definition would include reporting of ownership and investment interests in physician-owned distributors (PODs).

Covered drug, device, biological, and medical supply
CMS is proposing that covered drug, device, biological, or medical supply includes all drugs, devices, biologicals, and medical supplies eligible for payment by Medicare, Medicaid, or CHIP, including products paid either separately as a part of a fee schedule, or bundled as a part of a composite payment system (such as the hospital inpatient prospective payment system).

Teaching hospital
The Medicare law 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 is proposing to define a "teaching hospital" as any hospital that receives either Medicare direct or indirect medical education payments.

Research payments

Applicable 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. The proposed rule provides special consideration to research payments since collaboration between physicians and teaching hospitals, and manufacturers is essential to the development of new products. Research payments often include payment for all research activities, including patient tests and supplies, and the administration of the study, so the proposed rule outlines procedures to ensure that the nature of these relationships is understood, but there is also sufficient information on the extent of the research relationship. In addition to including information on the nature of these relationships, the statute also protects applicable manufacturer's competitive interests, by allowing CMS to delay publication of certain research payments until the earlier of FDA approval of the product that is the subject of the research or four years after the payment date. CMS is proposing to require manufacturers to report these payments must be reported in the year they were made, but to delay publication until the earlier of FDA approval or four years has passed.

Opportunity to review and correct the information prior to publication

The law requires CMS to give covered recipients and physician owners and investors 45 days to review and correct the information related to them that is submitted by applicable manufacturers and applicable GPOs. CMS is proposing to notify physicians and teaching hospitals of the processes for this review through various methods of communication, including public postings and emails through CMS' list serves.

CMS is proposing to leave it to the applicable manufacturer or applicable GPO and the covered recipient or physician owner to resolve disputes about the information reported. CMS is proposing that if the dispute cannot be resolved, the transaction will be noted as disputed, and both amounts will be published.

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 at $150,000 for failure to report, and $1,000,000 for knowing failure to report. CMS is proposing that the HHS Office of the Inspector General (OIG) and CMS reserve the right to audit, evaluate, or inspect applicable manufacturers and applicable GPOs for their compliance with the reporting requirements. In order to facilitate these inspections, CMS is proposing that applicable manufacturers and applicable GPOs 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 Web site.

State law preemption

Section 6002 of the Affordable Care Act also preempts any State or local laws requiring reporting of 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. Despite the fact that manufacturers and GPOs are not required to report to the Secretary without regulations, the state law preemption clause takes effect on January 1, 2012. On and after that date, states may not require applicable manufacturers or applicable GPOs to report any information that is the same as the Federal requirements. We urge manufacturers to continue to report information to states with reporting requirements until CMS is able to finalize regulations and begin collecting this information.

CMS will accept comments on the proposed rule until Feb. 17, 2012, and will respond to them in a final rule to be published in 2012.

The proposed rule can be downloaded at:

https://s3.amazonaws.com/public-inspection.federalregister.gov/2011-32244.pdf

# # #