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

# MEDICARE NEWS

**FOR IMMEDIATE RELEASE**
Dec. 14, 2011

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

**Affordable Care Act "sunshine" rule increases transparency in health care**

The Centers for Medicare & Medicaid Services (CMS) announced today a proposed rule that will increase public awareness of financial relationships between drug and device manufacturers and certain health care providers. This is one of many steps under the Affordable Care Act designed to increase transparency in the health care system, which can lead to better care at lower costs.

"When people are faced with the difficult task of choosing the right doctor, they need all the information they can gather. If your doctor is taking money from manufacturers of prescription drugs, suppliers of wheelchairs or other devices, you deserve to know about it," said Peter Budetti, M.D. CMS deputy administrator for Program Integrity. "Disclosure of these relationships will discourage the inappropriate influence on clinical decision-making that sometimes occurs while still allowing legitimate partnerships."

The proposed rule would require manufacturers of drugs, devices, biologicals, and medical supplies covered by Medicare, Medicaid, or the Children's Health Insurance Program to report to CMS payments or other transfers of value they make to physicians and teaching hospitals. The proposed rule would also require manufacturers and group purchasing organizations (GPOs) to disclose to CMS physician ownership or investment interests.

This increased transparency is intended to help reduce the potential for conflicts of interest that physicians or teaching hospitals might face as a result of their relationships with manufacturers.

Drug and biologic manufacturers, medical device or supply manufacturers, and GPOs would be affected by the new reporting requirements. These organizations, as well as the physicians and teaching hospitals, would be allowed an opportunity to review and correct information prior to its publication.

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The Affordable Care Act provides that violators of the reporting requirements will be subject to civil monetary penalties (CMPs), capped at $150,000 annually for failing to report, and $1,000,000 for knowingly failing to report.

CMS is proposing that data collection will not begin on Jan. 1, 2012 and that manufacturers and GPOs do not need to begin data collection until final regulations are issued. Depending on the timing of the final rule, CMS is proposing that manufacturers and GPOs will be required to submit a partial year on Mar. 31, 2013. Once the data has been submitted, CMS will aggregate manufacturer submissions at the individual physician and teaching hospital level, provide them with a 45-day period to confidentially review and, if necessary, correct the data, and make the data publicly available by Sep. 30, 2013.

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

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