

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Centers for Medicare & Medicaid Services



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["The Basics of Medicare Enrollment for Physicians and Other Part B Suppliers,"](#) Fact Sheet, ICN 903768, Downloadable only.

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## Information on the National Physician Payment Transparency Program: OPEN PAYMENTS

### Provider Types Affected

This MLN Matters® Special Edition Article is intended to inform physicians and teaching hospitals of the National Physician Payment Transparency Program (OPEN PAYMENTS) being implemented by CMS to satisfy Section 6002 of the Affordable Care Act.

### What You Need to Know

The Centers for Medicare & Medicaid Services (CMS) published, on February 8, 2013, a final rule that is intended to increase public awareness of financial relationships between manufacturers of drugs, devices, biologicals and medical supplies, as well as between applicable Group Purchasing Organizations (GPOs), and physicians and teaching hospitals. Known as the "National Physician

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Payment Transparency Program: OPEN PAYMENTS," this is one of many steps in the Affordable Care Act designed to create greater transparency in the health care market.

## Background

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On February 8, 2013, CMS published a final rule, titled the "Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests." With this program, applicable manufacturers and applicable GPOs will begin tracking and reporting payments and other transfers of value made to physicians and teaching hospitals, as well as certain ownership interests held in the organizations by physicians and their immediate family members. CMS will collect the data annually, aggregate it, and publish it on a public website as required by the Affordable Care Act.

As noted by Peter Budetti, M.D., Deputy Administrator for Program Integrity of the Centers for Medicare & Medicaid Services (CMS), US Department of Health and Human Services, and Director of the CMS Center for Program Integrity in a February 1, 2013, CMS press release: "You should know when your doctor has a financial relationship with the companies that manufacture or supply the medicines or medical devices you may need. Disclosure of these relationships allows patients to have more informed discussions with their doctors."

While financial ties alone do not signify an inappropriate relationship, OPEN PAYMENTS will create public transparency, which aims to:

- Promote transparent information regarding financial relationships.
- Disclose the nature and extent of financial relationships between the industry and the physicians and teaching hospitals.
- Discourage inappropriate influences on research, education, and clinical decision-making.
- Curtail potential conflicts of interest that can compromise clinical integrity and patient care.

## Final Rule Details

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### Relevant Definitions

1. Applicable Manufacturers:

Those entities that operate in the United States and (1) are engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply, but not if such covered drug, device, biological or medical supply is solely for use by or within the entity itself or by the entity's own patients (this definition does not include distributors or wholesalers (including, but not limited to, repackagers, relabelers, and kit assemblers) that do not hold title to any covered drug, device, biological or medical supply); or (2) are entities under common ownership with an entity described in part (1) of this definition, which provide assistance or support to such entities with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological or medical supply.

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2. Applicable GPOs:

Those that operate in the United States and purchase, arrange for purchase, or negotiate the purchase of a covered drug, device, biological, or medical supply for a group of individuals or organizations that are not solely using the covered supply.

3. Covered Products:

Any drug and biologic for which payment is available under Medicare, Medicaid or the Children's Health Insurance (CHIP) program, either separately (such as through a fee schedule) or as part of a bundled payment (for example, under the hospital inpatient prospective payment system), and require a prescription to be dispensed.

Any device or medical supply for which payment is available under Medicare, Medicaid or the Children's Health Insurance (CHIP) program, either separately (such as through a fee schedule) or as part of a bundled payment (for example, under the hospital inpatient prospective payment system (IPPS)), and require premarket approval by or premarket notification to the U.S. Food and Drug Administration (FDA).

4. Teaching hospitals:

Hospitals that receive payment for Medicare direct graduate medical education (GME), IPPS indirect medical education (IME), or psychiatric hospital IME programs.

### Implementation Timeline

In order to give applicable manufacturers and applicable GPOs sufficient time to prepare after publication of the final rule, industry data collection will begin on August 1, 2013. For the 2013 OPEN PAYMENTS program cycle, it will be abbreviated with only 5 months of data to be collected and reported, as compared to the 12-month cycles in subsequent years (January through December). Then, applicable manufacturers and applicable GPOs will submit the data to CMS by March 31, 2014, and CMS will make the data publicly available by September 30, 2014. CMS is developing an electronic system to facilitate the reporting process and the reported information will be easily aggregated, downloaded, and searchable on the program website.

### Industry Data Collection Requirements

The law specifies that, annually:

- Applicable manufacturers of covered drugs, devices, biologicals, and medical supplies must report payments or other transfers of value they make to physicians and teaching hospitals to CMS.
- Applicable manufacturers and applicable GPOs must report to CMS ownership or investment interests held by physicians or their immediate family members. Payments and other transfers of value to these physicians must also be reported.
- Applicable GPOs must report to CMS payments or other transfers of value made to physician owners or investors if they held ownership or an investment interest at any point during the reporting year.

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Reportable payments or other transfers of value include such things as consulting fees, honoraria, gifts, entertainment, food and beverages, travel and lodging, and other items.

### **Research Payments**

The statute requires applicable manufacturers to report numerous types of payments to physicians and teaching hospitals, including consulting fees, food and beverages, and research payments. Please note, however, that research payments, or other transfers of value may be delayed from publication on the website until the date of FDA approval or up to 4 years from the date of report (whichever is first), when made under a product research or development agreement in connection with: 1) Research on, or development of, a new drug, device, biologic, or medical supply, or a new application of an existing drug, device, biologic, or medical supply; or 2) Clinical investigations regarding a new drug, device, biologic, or medical supply.

### **Opportunity to Review and Correct Information Prior to Publication**

The law requires CMS to provide the physicians and teaching hospitals, who are being reported about, at least 45 days to review and dispute the information related to them that was submitted by applicable manufacturers and applicable GPOs. The review and correction period starts at least 60 days before the information is made public each year. Any disputed payments or transfers of value will need to be resolved directly between the disputer (physician or teaching hospital) and the relevant applicable manufacturer or applicable GPO. After the 45 days, applicable manufacturers and applicable GPOs will have an additional 15 days to submit corrections based on any disputes identified by physicians, teaching hospitals, and physician owners/investors.

Physicians should maintain their own records of any interaction with applicable manufacturers and applicable GPOs. This can help facilitate the review of the data that is submitted about them.

CMS will notify the physician and teaching hospital communities when the reported information is ready for review using an online posting and through notifications via CMS' listserv, i.e., electronic mailing lists to which physicians may subscribe including the **CMS OPEN PAYMENTS listserv** (located at <http://go.cms.gov/openpayments> on the CMS website).

### **Penalties for Failure of Accurate, Complete, and Timely Reporting of Required Information**

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 known failure to report. These CMPs only apply to applicable manufacturers and applicable GPOs. CMS finalized that the HHS Office of Inspector General (OIG) and CMS reserve the right to audit, evaluate, or inspect the records of applicable manufacturers and applicable GPOs for their compliance with the reporting requirements. In order to facilitate these inspections, applicable manufacturers and applicable GPOs must maintain all records and documents for at least five years from the date of payments or other transfers of value or ownership or investment interest is published publicly on the website.

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### 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 government agency for public health surveillance, investigation, or other public health purposes or health oversight.

### Additional Information

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For more information, please refer to the final rule, CMS-5060-F, "Transparency Reports and Reporting of Physician Ownership or Investment Interests," which is available at <http://www.gpo.gov/fdsys/pkg/FR-2013-02-08/html/2013-02572.htm> on the Internet or email questions to [openpayments@cms.hhs.gov](mailto:openpayments@cms.hhs.gov).

There is also a dedicated CMS website for OPEN PAYMENTS, which can be found at <http://go.cms.gov/openpayments> on the CMS website.

Also available for physicians to learn more about OPEN PAYMENTS is a continuing medical education (CME) activity, "Are You Ready for the National Physician Payment Transparency Program?" Accessible via MedScape, and accredited by the Accreditation Council for Continuing Medical Education, physicians can receive a maximum of 1.00 AMA PRA Category 1 Credit™ by participating in the activity and receiving a minimum score of 70% on the post-test. Through the activity, participants will learn more about OPEN PAYMENTS, the steps involved in collecting and reporting physician data, key dates for implementation, and actions they can take to verify physician information in advance of website publication.

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