

**Audio Title: Information on the National Physician Payment Transparency Program: Open Payments**

**Audio Date: 12/02/2013**

**Run Time: 12 minutes**

**ICN: 908961**

Welcome to Medicare Learning Network® Podcasts at the Centers for Medicare and Medicaid Services, or “CMS”. These podcasts are developed and produced by the Medicare Learning Network® within CMS, and they provide official information that health care professionals can trust.

Are you a physician or health care professional working in a teaching hospital and participating in the National Physician Payment Transparency Program, or “Open Payments” program?

If so, you will benefit from this podcast! Open Payments are implemented by CMS to satisfy Section 6002 of the Affordable Care Act or ACA.

On February 8, 2013 CMS published the Open Payments final rule intended to increase public awareness of financial relationships between the following (7) groups:

- manufacturers of drugs, devices, biological and medical supplies,
- Group Purchasing Organizations, or “G-P-O’s” and
- physicians and teaching hospitals. This rule is one of many steps in the Affordable Care Act designed to create greater transparency in the health care market.

**Let’s begin our discussion today with Background information on Open Payments.**

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.” This program requires applicable manufacturers and GPOs to track and report payments and other transfers of value made to physicians and teaching hospitals, including 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 required by the Affordable Care Act.

While financial ties *alone* do not signify an inappropriate relationship, OPEN PAYMENTS will create public transparency in (4) ways:

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



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## **Now we'll review (4) Relevant Definitions for Open Payments:**

### **First, Applicable Manufacturers, or**

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, however 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 (This includes, but is 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 we just described which provide assistance or support to them with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological or medical supply.

### **Second, Applicable GPOs**

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.

### **Third, Covered Products are**

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 inpatient hospital prospective payment system, or IPPS), 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, and require premarket approval by or premarket notification to the U.S. Food and Drug Administration (FDA) and

### **Fourth, Teaching hospitals**

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

## **Next we'll discuss the Implementation Timeline and Industry Data Collection Requirements**

Industry data collection began on August 1, 2013, giving applicable manufacturers and GPOs sufficient time to prepare after publication of the final rule. 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).

After the data collection is complete, applicable manufacturers and GPOs will submit the data to CMS by March 31, 2014. CMS will make the data publicly available by September 30, 2014. CMS is developing an electronic system to facilitate the reporting process. The reported information will be easily aggregated, downloaded, and searchable on the program website.

## **Moving on to Industry Data Collection Requirements**

The law specifies (3) activities to be conducted annually:

- Applicable manufacturers of covered drugs, devices, biologicals, and medical supplies must report to CMS payments or other transfers of value they make to physicians and teaching hospitals.

- Applicable manufacturers and 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.

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.

### **Let's look at Research Payments requirements**

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). Payment 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 the same.

### **Next we'll look at the Opportunity given physicians and teaching hospitals 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 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 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, that is 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).

### **Now we'll address the 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 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 GPOs for their compliance with the reporting requirements. In order to facilitate these inspections, applicable manufacturers and 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 interests published publicly on the website.

## In closing, we'll explain 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.*

## To learn more about Open Payments

Download the MLN Matters article on this topic, by going to the CMS website at [www.cms.gov](http://www.cms.gov) and click on “Outreach and Education” at the top of the page. From that page, scroll down to the Medicare Learning Network section and click on the MLN Products link.

**More questions?** To learn more about **the National Physician Payment Transparency Program: Open Payments** contact your Medicare Administrative Contractor or visit our website at [www.cms.gov](http://www.cms.gov). Click on “Outreach and Education” at the top of the page. Scroll down to the Medicare Learning Network® section and click on the MLN Products link.

Click on <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1303.pdf> on the CMS website.

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