



Open Payments

An Explanation of Section 6002 of the Affordable Care Act

O P E N P A Y M E N T S

**CREATING PUBLIC TRANSPARENCY
INTO INDUSTRY - PHYSICIAN
FINANCIAL RELATIONSHIPS**

Center for Program Integrity

February, 2014

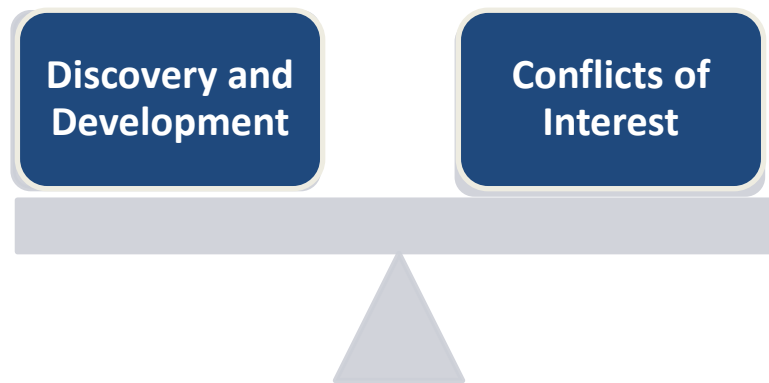
CMS Disclaimer: This information is a summary of sections of the NPPTP. This information is a summary of the final rule implementing the National Physicians Payment Transparency Program (Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests [CMS-5060-F], codified at 42 CFR Parts 402 and 403) The summary is not intended to take the place of the final rule which is the official source for information on the program.

Statute and Regulations

- Statute: Section 6002 of the Patient Protection Affordable Care Act
- Final Rule: Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests
 - Published February 8, 2013

Industry-Physician Relationships

- Collaborations between physicians and the medical industry can be beneficial by promoting **discovery and development** of new technologies that improve health and/or lower costs.
- Financial relationships may also influence professional judgment and **conflicts of interest** can potentially arise.



Program Requirements

- **Applicable manufacturers** of covered products AND entities under **common ownership** with applicable manufacturers who also provide **assistance and support** are required to
 - report annually to CMS
 - report payments or other transfers of value made to **covered recipients** and physician owners/investors
 - report certain **ownership or investment interests** held by **physician owners or investors** or their **immediate family members**
- **Applicable group purchasing organizations (GPOs)** are required to
 - report annually to CMS
 - report certain ownership or investment interests held by physician owners or investors or their immediate family members
 - report payments or other transfers of value to physician owners or investors

Industry

Applicable Manufactures

- Entities that operate in the US and that either produce or prepare at least covered one drug, device, biological, or medical supply covered by Medicare/Medicaid/CHIP or operate under common ownership (5% ownership interest) and provides assistance and support to applicable manufacturers.

Applicable Group Purchasing Organizations

- Entities that operate in the US and that purchase, arrange for, or negotiate the purchase of covered drugs, devices, biologicals, or medical supplies

Terms:

Common Ownership

- An individual or entity that owns 5 % or more ownership in an applicable manufacturer either directly or indirectly, which includes parent corporations, and direct or indirect subsidiaries.

Terms:

Assistance & Support

- Providing a service that is necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological or medical supply.

Covered Recipients

- **Covered Recipient Physicians**

- Doctors of Medicine/Osteopathy, Dental Surgery/Dental Medicine, Podiatric Medicine, Optometry, and Licensed Chiropractors
- Legally authorized by the State to practice

Note, for the purpose of this program:

- Fellows are included in the definition of a covered recipient
- Medical residents are excluded from the definition of physicians

Covered Recipients

Continued

- **Covered Recipient Teaching Hospitals**
 - The hospitals that CMS has recorded as receiving a payment(s) under Medicare direct graduate medical education (GME), indirect medical education (IME) or psychiatric hospitals IME programs.
 - List posted annually by CMS
- Industry has been instructed for the 2013 program cycle:
 - To be collect and report using an institution's legal business name
 - To report data separately for each legal business name, TIN, and address combination appearing on the list
- CMS has provided Industry with a supplement to the 2013 list is to ensure that applicable manufacturers and applicable GPOs are aware of the various institutions owned or operated by the legal entities, so they can collect the appropriate data; this should respond to various inquiries we have received.

Physician Owners/Investors and Their Immediate Family Members

- **Physician Owners or Investors**
- **Physician Owners or Investors' Immediate Family Members:**
 - Spouse
 - Natural or adoptive parent, child, or sibling
 - Stepparent, stepchild, stepbrother, or stepsister
 - Father-, mother-, daughter-, son-, brother-, or sister-in-law
 - Grandparent or grandchild
 - Spouse of a grandparent or grandchild

Covered Product

- **Drugs and biologicals:**

- 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),
- Require a prescription to be dispensed

- **Devices and medical supplies:**

- 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 for devices (including medical supplies which are devices)
- Require premarket approval by or premarket notification to the U.S. Food and Drug Administration (FDA).

Three Types of Reporting Categories

General Payments

- *Captures* payments or other transfers of value not made in connection with a research agreement

Research Payments

- *Captures* payments or other transfers of value made in connection with a research agreement

Ownership & Investment Interest

- *Captures* ownership or investment interests

Types of Payments

- This program captures payments or other transfers of value:
 - Paid directly to physicians and teaching hospitals (known as **Direct Payments**)
 - Paid indirectly to physicians and teaching hospitals (known as **Indirect Payments**)
- It also collects information on payments designated by physicians or teaching hospitals to be paid to another party (known as **Third Party Payments**)

Direct Payments

- Payments or other transfers of value provided by the applicable manufacturer or applicable group purchasing organization directly to covered recipients or physicians holding an ownership or investment interest.

Examples of Direct Payments

Scenario	Reported
1. University Teaching Hospital accepts a \$10,000 grant paid by check from ABC drug manufacturer on August 5, 2013.	University Teaching Hospital information <ul style="list-style-type: none">Name, address, TIN from the teaching hospital list published annually by CMS Payment information <ul style="list-style-type: none">Form of payment, date of payment, and nature of payment
2. Root Canal Specialty, LLC contracts with Dr. Jane White to speak at three dental school lectures on the 5 th of August, September, and October in 2013 for \$5,000 per lecture. During the discussion, Dr. White will market Root Canal Specialty's prescription toothpaste, SparkleRx.	Dr. Jane White information <ul style="list-style-type: none">Name, business address, NPI, license number, primary and specialty type Payment information <ul style="list-style-type: none">Form of payment, date of payment, amount of payment, and nature of payment, drug informationMarketed name of the covered drug (SparkleRx)

Indirect Payments

- Payments or other transfers of value made by an applicable manufacturer (or applicable GPO) to a physician or teaching hospital **through a third party.**
- Applicable manufacturer (or applicable GPO) **requires, instructs, directs, or otherwise causes** the third party to provide the payment to a physician or teaching hospital.

Examples of Indirect Payments

Scenario	Reported
1. Asthma Relief, LLC contracts with an advertisement agency to create an newsletter valued at \$35, regarding cutting edge treatments for asthma. The newsletter is targeted toward top prescribers of Asthma Relief, LLC drugs and is provided on December 7, 2013.	Information about top prescribers <ul style="list-style-type: none">Name, address, NPI, license number, specialty (\$35 will be attributed to two medical doctors that are provided the newsletter) Payment information <ul style="list-style-type: none">Form of payment, date of payment, and nature of payment

Note: Information about the intermediary (green text) will not be reported under this program. 17

Third Party Payments

- Payments or other transfers of value provided to a third party **at the request of or designated on behalf of** a physician or teaching hospital.

Example of Third Party Payments

Scenario	Reported
<p>1. Asthma Relief, LLC provides Dr. Henry Jones with a \$500 check for serving as a speaker at a round table discussing easybreathingRx, and runfreeRx on August 5, 2013. Dr. Jones requests that Asthma Relief, LLC provide the compensation to a charity.</p>	<p>Dr. Henry Jones information</p> <ul style="list-style-type: none">• Name, address, NPI, license number, specialty (\$500 will be attributed Dr. Henry Jones) <p>Payment information</p> <ul style="list-style-type: none">• Form of payment, date of payment, and nature of payment, indication that the payment was designated to an entity and that the entity was a charity, as well as, the name of the entity <p>Drug information</p> <ul style="list-style-type: none">• The marketed name of the covered drugs (easybreathingRx, runfreeRx)

2013 Collection Year

Industry will:

Collect information on payments and other transfers of value, as well as ownership or investment interests held by physicians and their family members



August – December 2013

Industry will:

Register and submit 2013 information to CMS



Early 2014

Industry will:

Correct disputed information



Early to Mid-2014

CMS Public Website:

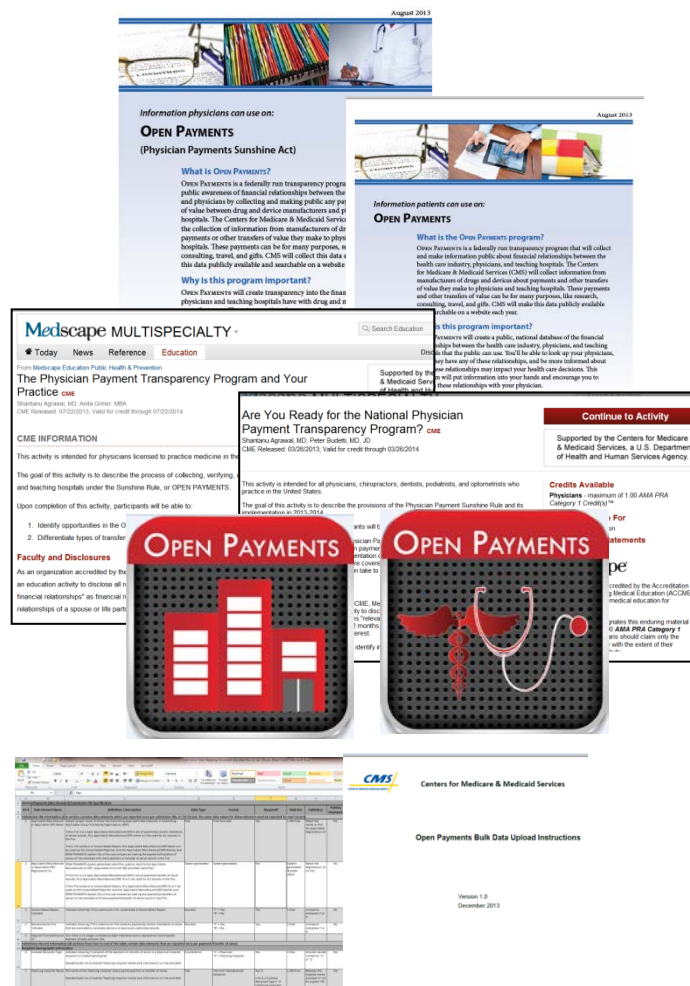
2013
Information
Posted



Tools & Resources

Multiple tools and resources have been released by CMS:

- ✓ **Webpage dedicated to stakeholders**
- ✓ **Fact Sheets & User Guide specific to stakeholders**
- ✓ **Operational tools for Industry: Guidance documents, submission specifications, teaching hospital list**
- ✓ **Recording and presentation material from past webinars**
- ✓ **Help Desk**
- ✓ **Mobile Application for Industry and Physicians**
- ✓ **QR Code guide document**
- ✓ Continuing Medical Education modules (2) for physicians
- ✓ Brochure for physicians describing Open Payments
- ✓ Brochure for patients describing Open Payments
- ✓ Publications in national professional magazines



Recent Activities

- ✓ **Released a supplement to the 2013 Teaching Hospital List**
 - Supplement includes hospital common business name in addition to legal business name
 - Supplement includes additional business address
 - Note: this list is for the 2013 data collection only
- ✓ **Posted the 2014 Teaching Hospital List with the new format**
- ✓ **Released new key reporting thresholds for the 2014 program year**
 - For the 2014 calendar year, Open Payments reporting requirements exclude payments or other transfers of value less than \$10.18 (\$10.00 for CY 2013), unless the aggregate amount of all payments or transfers of value exceeds \$101.75 (\$100.00 for CY 2013).
- ✓ **Released materials to assist reporting entities with the data submission process**
 - Submission Data Mapping Document
 - Bulk Data Upload Instructions
 - XML Schema and XML Sample Files
 - CSV Sample Files

Recent Activities

Continued

- ✓ **Enhancements to the original Open Payments mobile applications**
- ✓ **Release of how to create JSON (Java Script Object Notation) QR Codes compatible with the Open Payments mobile apps so that it can be integrate existing data collection and reporting tools with the mobile apps**
- ✓ **Technology-focused webinars geared toward applicable manufacturer and applicable GPO technology teams and focused on system details:**
 - Registration process details and system workflow
 - File schemas listing data elements, file format for xml and csv file uploads for submission
- ✓ **Presentation to local professional associations**

Upcoming Activities

- **Reorganization of FAQ site**
- **Release of additional details about Open Payments system registration, data submission and attestation via:**
 - **Upcoming technology-focused webinars**
 - **User Guide**
 - **Open Payments website**

Your Next Steps

- ❑ Bookmark the Open Payments webpage
- ❑ Register to receive email updates from CMS about the program, how it works, and the resources available
- ❑ Familiarize yourself with the tools & resources available

The screenshot shows the CMS.gov website with the URL **go.cms.gov/openpayments** circled in red at the top. The CMS.gov logo is also circled in red. On the left sidebar, the 'Open Payments' link is circled in red. In the main content area, the 'Email Updates' section is circled in red, containing a form with an 'Email Address' input field and a 'Submit' button. The page includes a navigation bar with links like Medicare, Medicaid/CHIP, and Private Insurance, and a footer with a 'Downloads' section and a 'Page last Modified' timestamp.

Questions

- For more information contact the Help Desk at openpayments@cms.hhs.gov or visit us at <http://go.cms.gov/openpayments>

THANK YOU