

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



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- ["Health Care Professional Frequently Used Web Pages,"](#) Educational Tool, ICN 908466, Downloadable only. (Posted June 2013)

MLN Matters® Number: SE1330

Related Change Request (CR) #: Not Applicable (N/A)

Related CR Release Date: N/A

Effective Date: N/A

Related CR Transmittal #: N/A

Implementation Date: N/A

OPEN PAYMENTS: An Overview for Physicians and Teaching Hospitals

Provider Types Affected

This MLN Matters® Special Edition article is intended for physicians and teaching hospitals submitting claims to Medicare contractors (Fiscal Intermediaries (FIs), carriers, and A/B Medicare Administrative Contractors (MACs)) for services to Medicare beneficiaries.

What You Need to Know

The Centers for Medicare & Medicaid Services (CMS) conducted an MLN Connects™ National Provider Call on August 8, 2013, for physicians and teaching hospitals to give an update on the OPEN PAYMENTS program policy, with a focus on third party payments and indirect payments as well as the Physician Resource Toolkit. This article gives you an overview of the key points discussed.

OPEN PAYMENTS (Physician Payments Sunshine Act) requires manufacturers of pharmaceuticals or medical devices to publicly report payments made to physicians and teaching hospitals.

- OPEN PAYMENTS data collection began on August 1, 2013.
- Physicians and teaching hospitals may voluntarily enroll in the OPEN PAYMENTS program in order to monitor their data reported by industry.

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Background

This article provides an overview of the OPEN PAYMENTS program for physicians and teaching hospitals. This information is a summary of the final rule implementing the OPEN PAYMENTS program (Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests (CMS-5060-F), codified at 42 Code of Federal Regulations (CFR) Parts 402 and 403). This summary is not intended to override or take the place of the final rule, which is the official source for requirements and information on the program.

Relationships Between Industry and Physicians are Common

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. However, financial relationships may also influence professional judgment and conflicts of interest can potentially arise.

Section 6002 of the Affordable Care Act requires the establishment of a transparency program, known as OPEN PAYMENTS, which requires manufacturers of pharmaceuticals or medical devices to publicly report payments made to physicians and teaching hospitals, creating greater transparency around the financial relationships that occur among them.

The Final Rule, entitled "Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests," was published February 8, 2013. This rule requires manufacturers of drugs, devices, biologicals, or medical supplies covered by Medicare, Medicaid or the Children's Health Insurance Program (CHIP) to report annually to the Centers for Medicare and Medicaid Services (CMS) payments or transfers of value provided to physicians or teaching hospitals. In addition, manufacturers and Group Purchasing Organizations (GPOs) are required to report annually physician ownership or investment interests. CMS will publish manufacturers' and GPOs' submitted payment and ownership information on a public website.

Manufacturers and group purchasing organizations began to collect the required data on August 1, 2013, and will report the data to CMS by March 31, 2014.

OPEN PAYMENTS Objectives and Roles

The objectives of the program are to:

- Make financial relationships transparent on a national scale; and
- Give consumers the information needed to ask questions and make more informed decisions about their healthcare professionals.

CMS' Role

- Remain neutral and present the data on a public website; and
- Ensure reporting and disclosures are complete, accurate, and clear.

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Industry's Role

- Collect information on payments and other transfers of value, as well as ownership or investment interests held by physicians and their immediate family members.
- Register and submit 2013 data to CMS in the first Quarter of 2014.
- Report required annually to CMS;
- Correct disputed information.

Physicians' Role

- Voluntarily keep track of payments and transfers of value made to them and be mindful of ownership and investment interests held by themselves or immediate family.
- Voluntarily register with CMS in order to receive notifications and information submitted by industry.
- Voluntarily review information for accuracy prior to public posting and dispute potentially inaccurate data.

Impact on Physicians or Teaching Hospitals

Under the OPEN PAYMENTS program, a “physician” is any of the following types of professionals that are legally authorized by the State to practice, regardless of whether they are Medicare, Medicaid, or Children's Health Insurance Program (CHIP) providers:

- Doctor of Medicine;
- Doctor of Osteopathy;
- Doctor of Dentistry;
- Doctor of Dental Surgery;
- Doctor of Podiatry;
- Doctor of Optometry; or
- Doctor of Chiropractic Medicine.

Note: Medical residents are excluded from the definition of physicians for the purpose of this program, but Fellows are not excluded.

Under the OPEN PAYMENTS program, “teaching hospitals” are hospitals that received payment for Medicare direct Graduate Medical Education (GME), Inpatient Prospective Payment System (IPPS) Indirect Medical Education (IME), or psychiatric hospital IME programs during the last calendar year for which this information is available and on the list posted annually by CMS. The teaching hospital list for OPEN PAYMENTS 2013 is posted at <http://go.cms.gov/openpayments> and will be updated annually.

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As mentioned, industry will submit to CMS information on payments and other transfers of value, as well as ownership or investment interests held by physicians and their immediate family members. Ownership or investment interest generally includes: stock, stock options other than those received as compensation, until they are exercised; partnership shares; limited liability company memberships; and loans, bonds, or other financial instruments that are secured with an entity's property or revenue or a portion of that property or revenue.

The ownership or investment interest may be direct or indirect and through debt, equity, or other means. Certain exceptions apply (See Section 403.902 Definitions in the Final Rule.).

Ownership or investment interests of an immediate family member of a physician can also trigger reporting. Immediate family member of a physician is a 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; or spouse of a grandparent or grandchild.

Track and Review Your Information

Physicians should track all interactions they have with industry involving payments or transfers of value to ensure accuracy. Physicians and teaching hospitals are not required to register with the program. However, voluntary registration will allow physicians and teaching hospitals to review their data prior to public release. They will also be able to dispute any data thought to be incorrect.

Physicians and teaching hospitals can register and nominate an authorized representative. The information needed to register is undergoing public review and comment through the Paperwork Reduction Act (PRA) process. The information will be finalized and officially released after completion of the PRA process.

Physicians, teaching hospitals, and authorized representatives will be able to review and dispute information. Registration starts early 2014 and will remain open.

Physicians may initiate data disputes to correct inaccurate information any time before the end of the calendar year in which the information was publicly available. If the manufacturer or GPO can't resolve the dispute with the physician or teaching hospital and correct the data in the initial 45-day or subsequent 15-day period, the manufacturer or GPO and physician or teaching hospital should continue to seek a resolution. Corrections from disputes initiated after 45 days may not be reflected in the initial public data. Data from unresolved disputes will still be posted publicly but will be marked as "disputed." CMS will monitor the dispute and resolution process and will update the public data at least once annually.

Here is the specific physician information that is reported by the industry:

- Full legal name (as it appears in National Plan and Provider Enumeration System (NPPES));
- Primary practice and specialty;
- Primary business address;
- National Provider Identifier (NPI) as it appears in NPPES;
- State professional license number(s);

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- E-mail address;
- Information about the covered product: name(s) of the related covered drug, device, biological, or medical supply;
- Information about the payment: amount, date, form, and nature of payment or other transfer of value; number of payments; and, if designated or assigned to a third party, the name of individual or entity the physician assigns the payment to; and
- How the payment was made ("Form of Payment"): Cash or cash equivalent; in kind items or services; stock or stock options or any other ownership interest; dividend, profit or other return on investment indicated to receive the payment.

In addition, the industry must report why the physician or teaching hospital received the payment ("Nature of Payment"), e.g.:

- Charitable contribution;
- Compensation for services other than consulting;
- Consulting fees;
- Current or prospective ownership or investment interest
- Direct compensation for serving as faculty or as a speaker for a medical education program (accredited and non-accredited programs);
- Education;
- Entertainment;
- Food and beverage;
- Gifts;
- Grant;
- Honoraria;
- Research;
- Royalty or license;
- Space rental or facility fees; and/or
- Travel and lodging.

Types of Payments in the Open Payment Program

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"); and

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- Payments designated by physicians or teaching hospitals to be paid to another party (known as Third Party Payments)

Direct payments are 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. Here are examples of direct payments:

1. University Teaching Hospital accepts a \$10,000 grant paid by check from ABC drug manufacturer on August 5, 2013. The manufacturer reports:
 - University Teaching Hospital name, address, and TIN from the teaching hospital list published annually by CMS; and
 - Payment information: 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 5th 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. The manufacturer reports:
 - Dr. Jane White information: name, business address, NPI, license number, primary and specialty type; and
 - Payment information: Form of payment, date of payment, amount of payment, nature of payment, drug information, and marketed name of the covered drug (SparkleRx).

Indirect payments are those payments or other transfers of value made by a manufacturer (or GPO) to a physician or teaching hospital through an intermediary. The manufacturer (or GPO) requires, instructs, directs, or otherwise causes the third party to provide the payment to a physician or teaching hospital. Information about the intermediary will not be reported under this program. Here are examples of indirect payments:

1. Root Canal Specialty, LLC, provides \$10,000 to a dental specialty society on October 12, 2013, requesting the award to be split between the two dentists, chosen by the dental specialty society. The manufacturer reports the following information about the two dentists:
 - Name, address, NPI, license number, specialty (\$5,000 will be attributed to each dentist that receives the award); and
 - Payment information: form of payment, date of payment, and nature of payment.
2. Asthma Relief, LLC, contracts with an advertisement agency to create a 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.

The manufacturer reports the following information about top prescribers:

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- Name, address, NPI, license number, specialty (\$35 will be attributed to two medical doctors that are provided the newsletter); and
- Payment information: Form of payment, date of payment, and nature of payment.

Third Party Payments are payments or other transfer of value provided to a third party at the request of or designated on behalf of a physician or teaching hospital. Here is an example of a third party payment:

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. The manufacturer reports the following information about the doctor:

- Dr. Henry Jones information: name, address, NPI, license number, specialty (\$500 will be attributed Dr. Henry Jones);
- Payment information: 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; and
- Drug information: the marketed name of the covered drugs (easybreathingRx, runfreeRx).

Compensation for speaking at a CME program is not required to be reported, if all of the following conditions are met:

- The program meets the accreditation or certification requirements and standards of the Accreditation Council for Continuing Medical Education (ACCME), the American Academy of Family Physicians (AAFP), the American Dental Association's Continuing Education Recognition Program (ADA CERP), the American Medical Association (AMA), or the American Osteopathic Association (AOA);
- The manufacturer does not directly pay the physician speaker; and
- The manufacturer does not select the physician speaker nor does it provide the third party vendor with a distinct, identifiable set of individuals to be considered as speakers for the accredited or certified continuing education program.

Other Indirect Payments associated with CME programs include meals, travel and lodging, tuition fees, educational materials included in CME tuition fees, and educational materials not included in CME tuition fees.

For Certified or Accredited programs:

- For Physician-attendees: report meals, travel and lodging, and educational materials not included in CME tuition fees. Do not report tuition fees and educational materials included in CME tuition fees.

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- For physician-faculty/speakers: do not report meals, travel and lodging, tuition fees, educational materials included in CME tuition fees, and educational materials not included in CME tuition fees.

For non-accredited or non-certified programs:

For physician-attendees and for physician-faculty/speakers: report meals, travel and lodging, tuition fees, educational materials included in CME tuition fees, and educational materials not included in CME tuition fees.

Items that directly benefit patients or are intended to be used by or with patients, including the value of a manufacturer's services to educate patients regarding a covered drug, device, biological, or medical supply, are not required to be reported. (See Section 403.904 Reports of payments or other transfers of value to physician or teaching hospitals of the Final Rule.) Here are two examples of educational materials:

- A manufacturer or GPO transfers a textbook to a physician or teaching hospital. This is reportable in the OPEN PAYMENTS program because it does not directly benefit patients.
- Manufacturer or GPO transfers a wall model or anatomical model to a physician or teaching hospital. This is not reportable in the OPEN PAYMENTS program because it directly benefits patients.

Physician Tools & Resources

CMS' goals include creating awareness about the OPEN PAYMENTS program among physicians, providing useful and easy to understand information about OPEN PAYMENTS and providing resources that will support physicians.

CMS is creating awareness about the OPEN PAYMENTS through:

- Hosting National Provider Calls – see the schedule of calls at <http://www.cms.gov/Outreach-and-Education/Outreach/NPC/National-Provider-Calls-and-Events.html> on the CMS website;
- Keeping national professional associations abreast of program developments; and
- Leveraging national publications, the Medicare Learning Network® and existing CMS contractors educational and outreach efforts.

Mobile Applications (Apps)

Two free mobile applications (Apps) to aid physicians and industry in tracking data collected for OPEN PAYMENTS are available for Apple (iOS) and Android:

- OPEN PAYMENTS Mobile for Physicians
- OPEN PAYMENTS Mobile for Industry

See MLN Matters® Special Edition Article, SE1329, for details on these Apps. SE 1329 is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1329.pdf> on the CMS website.

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CME Modules

CME modules are accessible via MedScape. They are accredited by the Accreditation Council for Continuing Medical Education. A link to CME modules is available at

<http://go.cms.gov/openpayments> on the CMS website.

CME Activity #1: Are You Ready for the National Physician Payment Transparency Program?

CME Activity #2: The Physician Payment Transparency Program and Your Practice.

Educational Brochures

Brochures are available for physicians and patients about OPEN PAYMENTS. They are available on the OPEN PAYMENTS webpage at <http://go.cms.gov/openpayments>.

- Pub #11709-P: Information Physicians Can Use on: OPEN PAYMENTS (Physician Payments Sunshine Act)
- Pub #11710: Information Patients Can Use on: OPEN PAYMENTS

Other Publications

- MLN Matters® SE1303 "Information on the National Physician Payment Transparency Program: Open Payments," is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1303.pdf> on the CMS website.
- "The Sunshine Act — Effects on Physicians," Agrawal, et. al., New England Journal of Medicine, NEJM 2013; 368:2054-2057, is available at <http://www.nejm.org/doi/full/10.1056/NEJMp1303523> on the Internet.

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

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