OPEN PAYMENTS

CREATING PUBLIC TRANSPARENCY
INTO INDUSTRY-PHYSICIAN
FINANCIAL RELATIONSHIPS

An Overview
For Physicians and Teaching Hospitals

Program Overview

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This presentation was current at the time it was published or uploaded onto the web. Medicare policy changes frequently so links to the source documents have been provided within the document for your reference.

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Disclaimer

This information is a summary of the final rule implementing the Open Payments (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) 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.

Agenda

- Introduction
- Tracking Industry Data
- Registration
- Review & Dispute
- Publication
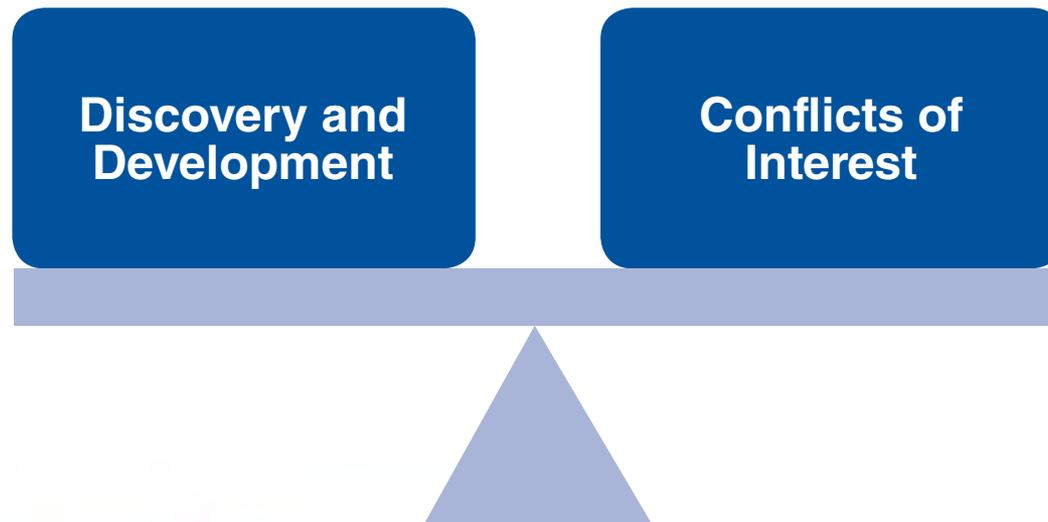- Physician Tools and Resources

Introduction

Relationships between industry and physicians are common.

- The pharmaceutical and device industries fund nearly 2/3 of registered clinical trials in the United States.

- Industry sponsors over 80% of the most frequently cited papers.[1]

- Physicians believe that they are not influenced by pharmaceutical advertising[2] but advertising[3] and other drug promotion[4] has been shown to influence prescribing.

- Only 20-40% of patients are aware of less visible gifts to physicians from industry such as books and meals.

- Between 40 - 70% of patients believe that gifts from industry influence physician prescribing.

1. Bourgeois FT, Murthy S, Mandl KD. Outcome reporting among drug trials registered in ClinicalTrials.gov. Annals of Internal Medicine 2010; 153:158-66. Patsopoulos NA, Analatos AA and Ioannidis JPA. Origin and funding of the most frequently cited papers in medicine: database analysis. BMJ 2006; 332:1061-4.

2. Norris P, Herxheimer A, Lexchin J, Mansfield P. Drug Promotion - What We Know, What We Have Yet to Learn - Reviews of Materials in the WHO/HAI Database on Drug Promotion – EDM Research Series No. 032. Journal [serial on the Internet]. 2004

3. Spiller LD and Wymer WW. Physicians' perceptions and uses of commercial drug information sources: an examination of pharmaceutical marketing to physicians. Health Marketing Quarterly 2001. 19(1):91-106.

4. Spurling GK, Mansfield PR, Montgomer BD et al. Information from Pharmaceutical Companies and the Quality, Quantity, and Cost of Physicians' Prescribing: A Systematic Review. PLoS Medicine 2010. 7(10):e1000352

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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.

Discovery and Development	Conflicts of Interest

Statute and Regulations

- <u>Statute:</u> Section 6002 of the Patient Protection Affordable Care Act

- <u>Final Rule:</u> Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests

  - Published February 8, 2013

OPEN PAYMENTS objectives

OPEN PAYMENTS is a national transparency program requiring certain manufacturers and group purchasing organizations to disclose their financial relationships with physicians and teaching hospitals
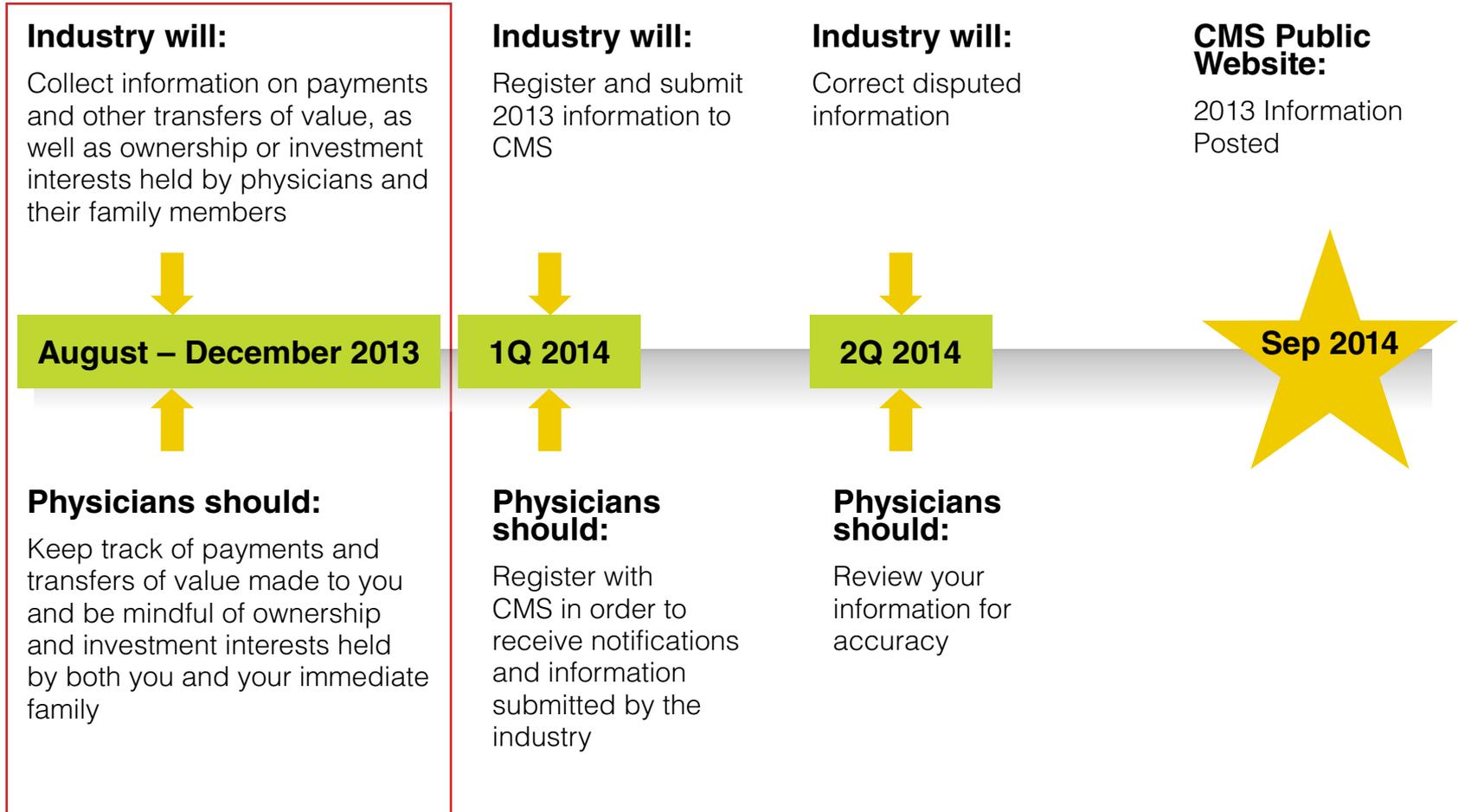
Objectives

- Make financial relationships transparent on a national scale

- 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

- Ensure reporting and disclosure are complete, accurate, and clear

2013 program cycle: Tracking Industry data

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

Industry will:

Register and submit 2013 information to CMS

Industry will:

Correct disputed information

CMS Public Website:

2013 Information Posted

August – December 2013

1Q 2014

2Q 2014

Sep 2014

Physicians should:

Keep track of payments and transfers of value made to you and be mindful of ownership and investment interests held by both you and your immediate family

Physicians should:

Register with CMS in order to receive notifications and information submitted by the industry

Physicians should:

Review your information for accuracy

Reporting Requirements for Industry

- Requires certain manufacturers to:
  - report annually to CMS
  - report payments or other transfers of value made to physicians and teaching hospitals
  - report ownership or investment interests held by physicians or their immediate family members

- Requires certain group purchasing organizations (GPOs)
  - to report annually to CMS
  - to report ownership or investment interests held by physicians & their immediate family members
  - to report payments or other transfers of value to these physicians

Three Types Of Reporting Categories

General Payments

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

Research Payments

- *Collects and reports* payments or other transfers of value made in connection with a research agreement

Ownership & Investment Interest

- *Collects and reports* ownership or investment interests

Physicians or Teaching Hospitals

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

- Teaching Hospitals
  - The hospitals that CMS has recorded as receiving a payment(s) under Medicare direct graduate medical education (GME),

  The teaching hospital list for Open Payments 2013 is NOW posted on http://go.cms.gov/openpayments

  - List posted annually by CMS

Ownership or Investment Interests

- Ownership or investment interest generally includes:
  - Stock, stock option(s) other than those received as compensation, until they are exercised.
  - Partnership share(s)
  - Limited liability company membership(s)
  - Loans, bonds, or other financial instruments that are secured with an entity's property or revenue or a portion of that property or revenue.
- May be direct or indirect and through debt, equity or other means
- *Exceptions apply (§ 403.902 Definitions).*

Physician Owners/Investors'

Immediate Family Members

- 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
  - 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

- Register to receive a preview of the data to be made public (discussed later)

- Tools and resources are available to help (discussed later)

Track and Review Your Information

Specific Physician Information Reported by Industry

- Full legal name (as appears in NPPES)
- Primary and specialty
- Primary business address
- NPI (as appears in NPPES)
- State professional license number(s)
- Email address

Track and Review Your Information

Specific Physician Information Reported by Industry

- 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
  - If designated to a third party, the name of individual or entity the physician indicated to receive the payment

Track Your Interactions With Industry

How was the payment 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

Track Your Interactions With Industry

Why did the physician or teaching hospital receive the payment? ("Nature" of Payment)

- Consulting fees
- Honoraria
- Gifts
- Entertainment
- Food & beverage
- Travel & lodging
- Education
- Research
- Charitable contribution
- Space rental or facility fees

- Royalty or license
- Current or prospective ownership or investment interest
- Grant
- Compensation for services other than consulting
- Direct compensation for serving as faculty or as a speaker for a medical education program (accredited and non-accredited)

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** • Name, address, TIN from the teaching hospital list published annually by CMS **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.	**Dr. Jane White information** • Name, business address, NPI, license number, primary and specialty type **Payment information** • Form of payment, date of payment, amount of payment, and nature of payment, drug information • Marketed name of the covered drug (SparkleRx)

Indirect Payments

- Payments or other transfer of value made by a manufacturer (or GPO) to a physician or teaching hospital **through an intermediary.**

- Manufacturer (or 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. 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.	**Information about the two dentists** • Name, address, NPI, license number, specialty ($5,000 will be attributed to each dentist that receives the award) **Payment information** • Form of payment, date of payment, and nature of payment
2. 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** • Name, address, NPI, license number, specialty ($35 will be attributed to two medical doctors that are provided the newsletter) **Payment information** • Form of payment, date of payment, and nature of payment

Note: information about the intermediary (green text) will not be reported under this prorgam

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Third Party Payments

- 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.

Example of Third Party Payments

Scenario	Reported
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.**	**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 **Drug information** • The marketed name of the covered drugs (easybreathingRx, runfreeRx)

Continuing Medical Education

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

1. The program meets the accreditation or certification requirements and standards of the ACCME, AOA, AMA, AAFP or ADA CERP.

2. The manufacturer does not directly pay the physician speaker.

3. 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.

CONTINUING MEDICAL EDUCATION
Physician-Attendees and Physician Faculty/speakers

Indirect payments associated with CME activities:	Physician-Attendees	Physician-Faculty/ Speakers	Physician-Attendees	Physician-Faculty/ Speakers
	Accredited or certified *		Non-accredited or non-certified	
Meals**	✔	X	✔	✔
Travel and Lodging	✔	X	✔	✔
Tuition Fees	X	X	✔	✔
Educational Materials included in CME Tuition Fees	X	X	✔	✔
Educational Materials not included in CME Tuition Fees	✔	X	✔	✔

*   Must meet all of the conditions in accordance with § 403.904(g)(1)

** Special rules apply in accordance with § 403.904(h)

Exclusions From Reporting: Educational Materials

- 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.

[§ 403.904 Reports of payments or other transfers of value to physician or teaching hospitals.]

Examples Of Educational Materials

Manufacturer or GPO

Transfer of value is a **textbook**

Physician or teaching hospital

The physician or teaching hospital receives a textbook from a manufacturer or GPO.

Is this reportable in OPEN PAYMENTS? Yes

Examples Of Educational Materials

Manufacturer or GPO

Transfer of value is **a wall or anatomical model**

Physician or teaching hospital

The physician or teaching hospital receives an anatomical model, which directly benefits the patient from a manufacturer or GPO.

Is this reportable in OPEN PAYMENTS? No

2013 Program Cycle: Registration

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

Industry will:

Register and submit 2013 information to CMS

Industry will:

Correct disputed information

CMS Public Website:

2013 Information Posted

| August – December 2013 | 1Q 2014 | 2Q 2014 | Sep 2014 |

Physicians should:

Keep track of payments and transfers of value made to you and be mindful of ownership and investment interests held by both you and your immediate family

Physicians should:

Register with CMS in order to receive notifications and information submitted by the industry

Physicians should:

Review your information for accuracy

Physician/Teaching Hospital Registration

- 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 for manufacturers and GPOs to review

Voluntary Registration

- Physicians and teaching hospitals can register <u>and</u> nominate an authorized representative

- Information needed to register is undergoing review and comment following the Paperwork Reduction Act (PRA) process.

- See our website for a link to the PRA action.

- Physicians, teaching hospitals and authorized representatives will be able to <u>review</u> and <u>dispute</u> information

- Registration **starts early 2014** and will remain open

NOTE: REGISTRATION will allow physicians and teaching hospitals to receive notification of information reported about them, to review information, and to initiate disputes before the data is made public.

2013 Program Cycle: Review & Dispute

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

Industry will:

Register and submit 2013 information to CMS

Industry will:

Correct disputed information

CMS Public Website:

2013 Information Posted

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Physicians should:

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Physicians should:

Register with CMS in order to receive notifications and information submitted by the industry

Physicians should:

Review your information for accuracy

Dispute and Resolution

- Physicians may initiate data disputes to correct inaccurate information anytime before the end of the calendar year in which the information was publically 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 publically but will be marked as "disputed."

- CMS will monitor the dispute and resolution process and will update the public data at least once annually.

2013 Program Cycle: Publication

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

Industry will:

Register and submit 2013 information to CMS

Industry will:

Correct disputed information

CMS Public Website:

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2Q 2014

Sep 2014

Physicians should:

Keep track of payments and transfers of value made to you and be mindful of ownership and investment interests held by both you and your immediate family

Physicians should:

Register with CMS in order to receive notifications and information submitted by the industry

Physicians should:

Review your information for accuracy

Data Publication

- CMS will make data available on a publicly accessible website.
- Any disputed data not resolved, will be marked as "disputed" but still displayed.
- Data will be organized and available for search and download.
- 2013 data will be posted in the fall of 2014.

Research Delays in Publication

- Manufacturers (or GPOs) may request a delay in publication
- Type of payments for which a delay may be requested:
  - Research on or development of new products/new product applications
  - Clinical investigations regarding a new product written research or development agreement is required
- Publication is delayed until (whichever comes first):
  - Date of FDA approval, licensure or clearance of the product
  - Four calendar years after the date the payment or other transfer of value

Physician Tools & Resources

Physician Outreach

- CMS' goals include:
  - Creating **awareness** about the OPEN PAYMENTS among physicians
  - Providing useful and easy to understand **information** about OPEN PAYMENTS to physicians
  - Providing **resources** that will support physicians

Awareness

- We are creating awareness about the Open Payments among physicians through

  ✓ Hosting National Provider Calls

  ✓ Keeping national professional associations abreast of program developments

  ✓ Leveraging national publications, Medicare Learning Network and existing CMS contractors

Information

- We are providing useful and easy to understand information about Open Payments to physicians

  ✓ Webpage dedicated to physicians
  ✓ Fact Sheets specific to physicians
  ✓ Continuing Medical Education modules (2)
  ✓ Brochure summarizing Open Payments for physicians
  ✓ Brochure summarizing Open Payments for patients

Resources

- We are providing resources that will support physicians
  - ✓ Help Desk
  - ✓ Mobile Application

Mobile Applications

- Two FREE mobile applications to aid physicians and industry in tracking data collected for Open Payments
  - Open Payments Mobile for Physicians
  - Open Payments Mobile for Industry
- Applications are available for Apple (iOS) and Android

- Benefits include:
  - Provides a tool to track payments and transfers of value in real-time.
  - Serves as a reference tool during review or information disputes
  - Allows physician to provide accurate profile information to industry
  - Minimizes the risk of data mismatches when submitted by industry
  - Allows physicians to receive event and payment or other transfer of value, and profile information from industry

Exchanging Information is Easy

Physician App

Industry App

Send Profile Information
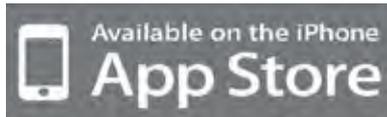
Send Profile Information

Send Payment Information

Accessing the App

Visit the iOS or Google Play Store online or on your phone and follow the steps listed below.

1. Select "Search."
2. Search for Open Payments – both apps will appear for download.
3. Select "Install" for the app you want and the app will download to your device.

Continuing Medical Education Modules

- Accessible via MedScape

- Accredited by the Accreditation Council for Continuing Medical Education

- Link to CME modules on Open Payments webpage

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 Available

- Brochures are available for physicians and patients about Open Payments
- Available for download on Open Payments webpage

Pub #11709-P: *Information Physicians Can Use on: Open Payments (Physician Payments Sunshine Act)*

Pub #11710: *Information Patients Can Use on: Open Payments*

Links are available on http://go.cms.gov/openpayments

Other Publications

- Articles on the Medicare Learning Network, MLN Matters® Number: SE1303

- Article published in the New England Journal of Medicine, Agrawal et. al., NEJM 2013; 368:2054-2057

Links are available on http://go.cms.gov/openpayments

Resources Available To Providers

Open Payments Help Desk → **Openpayments@cms.hhs.gov**

Open Payments Web Page

- General information
- Fact Sheets
- Policy Frequently Asked Questions
- Mobile App Frequently Asked Questions
- Links to Medscape CMEs
- Brochures
- Teaching Hospital List
- Data Submission File Specifications
- Links to Other Publications
- Link to Listserve

→ **http://go.cms.gov/openpayments**

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The Physicians' Role

Physicians are not required to register with or send any information under Open Payments. However, to make sure we have the right information, we do encourage you to:

- Become familiar with the information that will be reported about you.
- Download and use the Open Payments Mobile for Physicians for an easy-to-use tool to track transfers of value on your mobile phone.
- Subscribe to the listserve to receive updates regarding the program.
- Review the teaching hospital list to determine if manufacturers will be required to report transfers of value made to your hospital.
- Register with the Open Payments System (early 2014).
- Look at the information manufacturers and GPOs submitted about you (2Q 2014).
- Work with manufacturers and GPOs to make sure the information submitted about you is correct (2Q 2014).

Questions

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

THANK YOU

Question and Answer Session

Coming in Late Summer 2013 – The Medicare Administrative Contractor Satisfaction Indicator (MSI)

Attention: Medicare-Enrolled Providers and Suppliers

- Give CMS feedback about your experience with your Medicare Administrative Contractor (MAC), the contractor that processes your Medicare claims

- Your feedback will help CMS monitor performance trends, improve oversight, and increase efficiency of the Medicare program

- Only providers and suppliers who register for the MSI will be included in the random sample to rate their MAC

- For more information and to register today for the 2013 MSI, go to http://www.cms.gov/Medicare/Medicare-Contracting/MSI/

Evaluate Your Experience

- Please help us continue to improve the MLN Connects National Provider Call Program by providing your feedback about today's call.

- To complete the evaluation, visit http://npc.blhtech.com/ and select the title for today's call.

- Evaluations are anonymous, confidential, and voluntary.

- All registrants will receive a reminder email about the evaluation for this call. Please disregard the email if you have already completed the evaluation.

- We appreciate your feedback.

Thank You

- For more information about the MLN Connects National Provider Call Program, please visit http://cms.gov/Outreach-and-Education/Outreach/NPC/index.html

- For more information about the Medicare Learning Network (MLN), please visit http://cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNGenInfo/index.html