



OPEN PAYMENTS Program

An Explanation of Section 6002 of the Affordable Care Act

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

**C R E A T I N G P U B L I C T R A N S P A R E N C Y
O F I N D U S T R Y - P H Y S I C I A N
F I N A N C I A L R E L A T I O N S H I P S**

Center for Program Integrity

June 2013

CMS Disclaimer: 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.

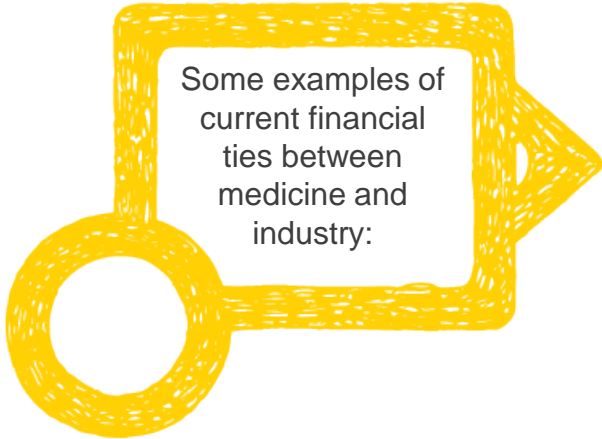
BACKGROUND/PURPOSE

OPEN PAYMENTS Defined

- Section 6002 of the Affordable Care Act, or the “**Sunshine Act**”, finalized in February 2013
- Creates a **national transparency program** for payments made to physicians or teaching hospitals from manufacturers and group purchasing organizations
- CMS will collect and post the information on a **public website**

Current Physician and Industry Relationships

Collaborations between physicians and the medical manufacturing industry are common



Some examples of current financial ties between medicine and industry:

94% of physicians have some type of relationship with industry¹

83% of physicians report receiving food and beverages in the workplace¹

\$15.7B spent by pharmaceutical industry in 2011 on face-to-face sales and promotional activities²

¹ <http://www.nejm.org/doi/full/10.1056/NEJMp078141>

² <http://www.pewhealth.org/other-resource/persuading-the-prescribers-pharmaceutical-industry-marketing-and-its-influence-on-physicians-and-patients-85899439814>

Downstream Impacts

Physicians reporting industry relationships have important interactions which further increase the impact of these relationships:

- 60% were involved in medical education
- 40% were involved in creating clinical practice guidelines

Impact of Industry-Physician Interactions

- Cooperation promotes discovery and development of new technologies that improve health
- Conflicts of interest can potentially arise because of financial ties between medicine and industry
- CMS must remain neutral when presenting financial ties



Transparency Today

- Several **states** have existing transparency programs and publish similar information on public websites
- Several dozen pharmaceutical companies have active **Corporate Integrity Agreements (CIAs)**
 - Some require publishing payments to physicians publically on their websites
- Some other pharmaceutical companies have voluntarily opted to disclose their payments to physicians on their **websites**

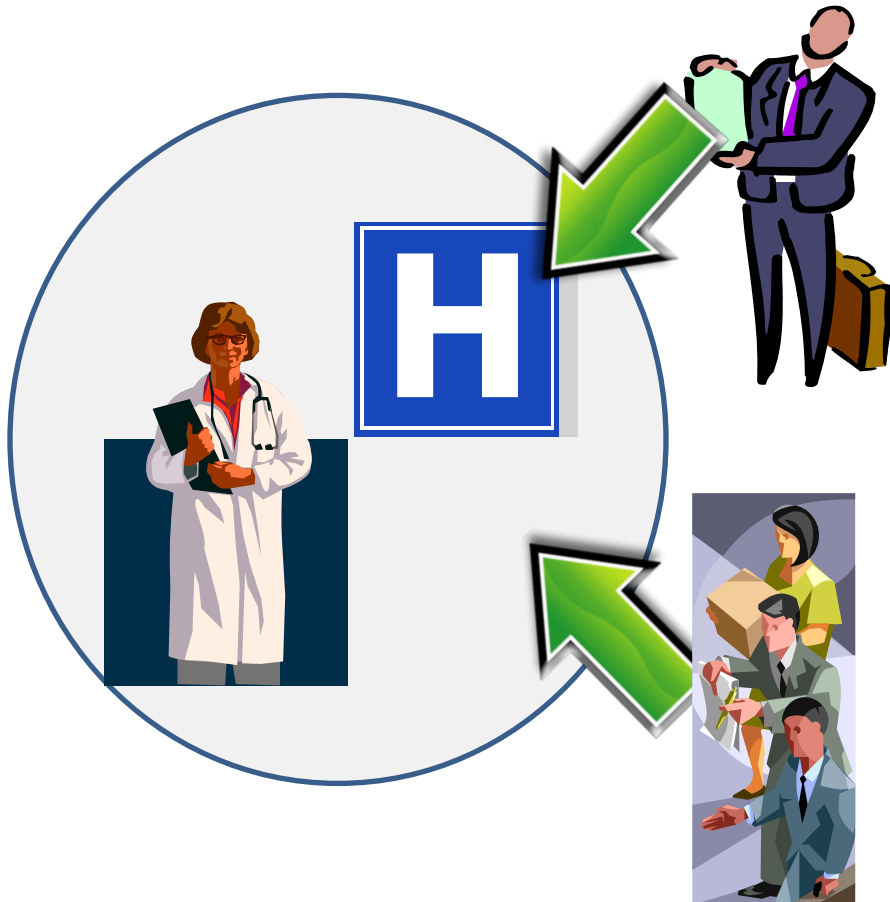
POLICY OVERVIEW

Overall Objectives of the Rule

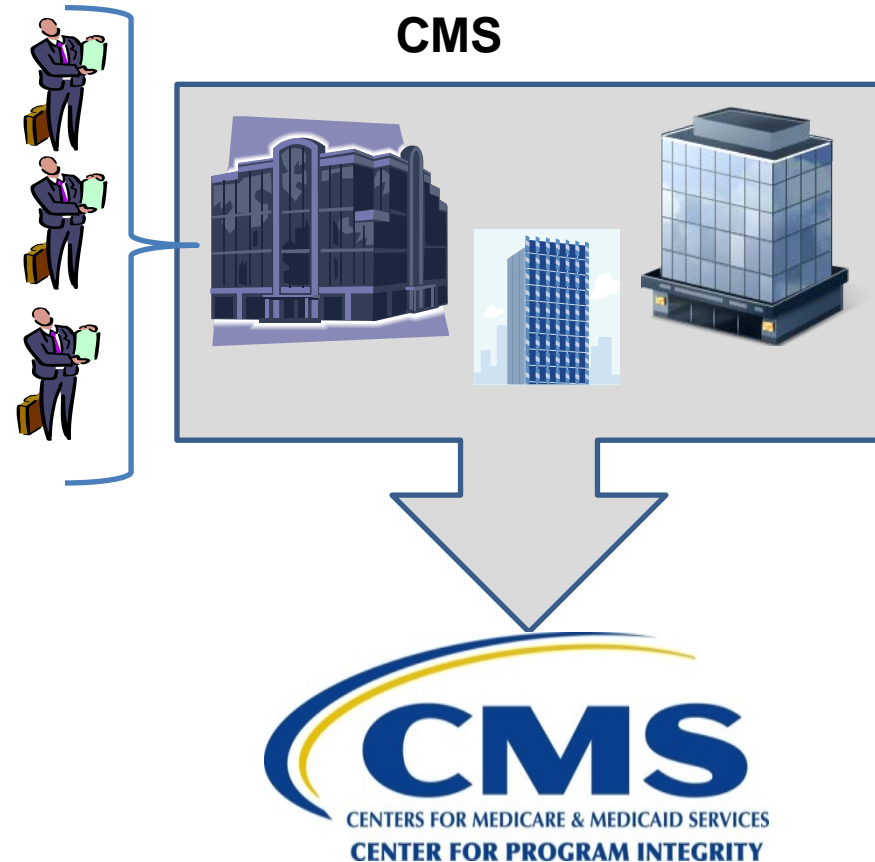
- Annual reporting of payments or other transfers of value from applicable manufacturers to physicians and teaching hospitals
- Reporting of physician and immediate family ownership and investment interests in applicable group purchasing organizations (GPOs) and applicable manufacturers
- Reporting of payments or other transfers of value from applicable GPOs to physicians with ownership interest
- Display of reported data on a public website each year

How It Works

Industry payments and other transfers of value are made to physicians and teaching hospitals




Companies collect information about payments and other transfers of value and submit to CMS



Who Will Report

Applicable Manufacturers



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 with applicable manufacturers

- Certain entities under common ownership (5% ownership interest) with an applicable manufacturer must also report
- Some limitations on reporting by certain manufacturers (such as manufacturers that had less than 10% gross revenue for covered products, not all products)

Who Will Report

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

- Includes physician owned distributors that purchase products for resale
- Investment interest is broadly defined and includes close family member investment interest

What are Covered Products

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 or require **administration or authorization** by a physician

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).

Examples of Transfers of Value (TOVs)


- Consulting fees
- Compensation for services other than consulting, including serving as faculty or speaker at an event other than CE program
- Honoraria
- Gifts
- Entertainment
- Food and beverages
- Travel and lodging
- Education
- Research
- Charitable Contributions
- Royalty or license
- Current or prospective ownership or investment interest
- Compensation for serving as faculty or speaker for an unaccredited and non-certified CE program
- Compensation for serving as faculty or speaker for an accredited or certified CE program
- Grants
- Space rental or facility fees (teaching hospital only)

TOVs That are NOT Reported

- Transfer of value less than \$10 unless the total aggregates to over \$100
- Product samples
- Educational materials directly benefits patients
- Loan of covered device to recipient, not to exceed 90 days
- Items or services provided under contractual warranty
- Discounts (including rebates)
- In-kind items used for charity care
- Dividend or other profit distribution
- Payments for employees in self-insured plan
- Transfer of value to non-physicians
- Transfer of anything of value to patients

Who is Reported About

Covered Recipients: Physicians

- 
- Doctor of Medicine
 - Doctor of Osteopathy
 - Doctor of Dentistry
 - Doctor of Dental Surgery
 - Doctor of Podiatry
 - Doctor of Optometry
 - Doctor of Chiropractic Medicine

 - **Physicians do not need to be enrolled in Medicare, Medicaid, or CHIP or bill these programs to be included**

 - **Excludes residents**
 - **Excludes physicians employed by applicable manufacturers**
 - **Other exclusions apply**


Who is Reported About

Covered Recipients: Teaching Hospitals

- Teaching hospital is defined as any institution that received payment(s) under a Medicare:
 - Direct graduate medical education (GME)
 - Inpatient hospital prospective payment system (IPPS) indirect medical education (IME), or
 - Psychiatric hospital IME programs
- Includes the most recent calendar year for which such information is available
- **CMS posted the list of teaching hospitals for the 2013 reporting year; the 2014 list will be posted by Oct. 1, 2013**

Reporting Examples

Reporting of any **TOV** from **applicable manufacturers** to **covered recipients**.



Example

Dr. Smith attends lunch hosted by an applicable manufacturer with her clinical team to discuss a new drug. She's impressed by it, and spends 12 months traveling and speaking to promote it, with expenses and honoraria paid by the manufacturer.

Note: Items underlined are reportable payments or transfer of values

Reporting Examples

Reporting of any **TOV** from **applicable manufacturers** to **covered recipients**.



Example

ABC University Teaching Hospital receives \$10,000 from a drug manufacturer as a research grant.

Note: Items underlined are reportable payments or transfer of values

Reporting Examples



Reporting of physician or family ownership and investment interests in **applicable GPOs** and **applicable manufacturers**.

Example

Dr. Smith's sister has an ownership interest in a major medical device manufacturer.



Reporting of any **TOV** from **applicable GPOs** to physicians with ownership interests.

Example

To speak at a conference financed by the applicable GPO in which she is an owner, Dr. Jones receives an honorarium from the same applicable GPO.

PHYSICIAN-SPECIFIC ISSUES

Continuing Medical Education (CME)

An educational event itself (*tuition/educational materials*) is considered exempted from reporting for the speaker and attendees if all three of these 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 applicable manufacturer does not select the covered recipient 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; AND
- (3) The applicable manufacturer does not directly pay the covered recipient speaker.

Other TOVs Related to CME

For CME which meet the three requirements:

- **For speakers:** all transfers of value for exempted CMEs are not reportable
- **For attendees:** tuition and educational materials are not reported, but other TOVs are reportable (e.g., travel support)

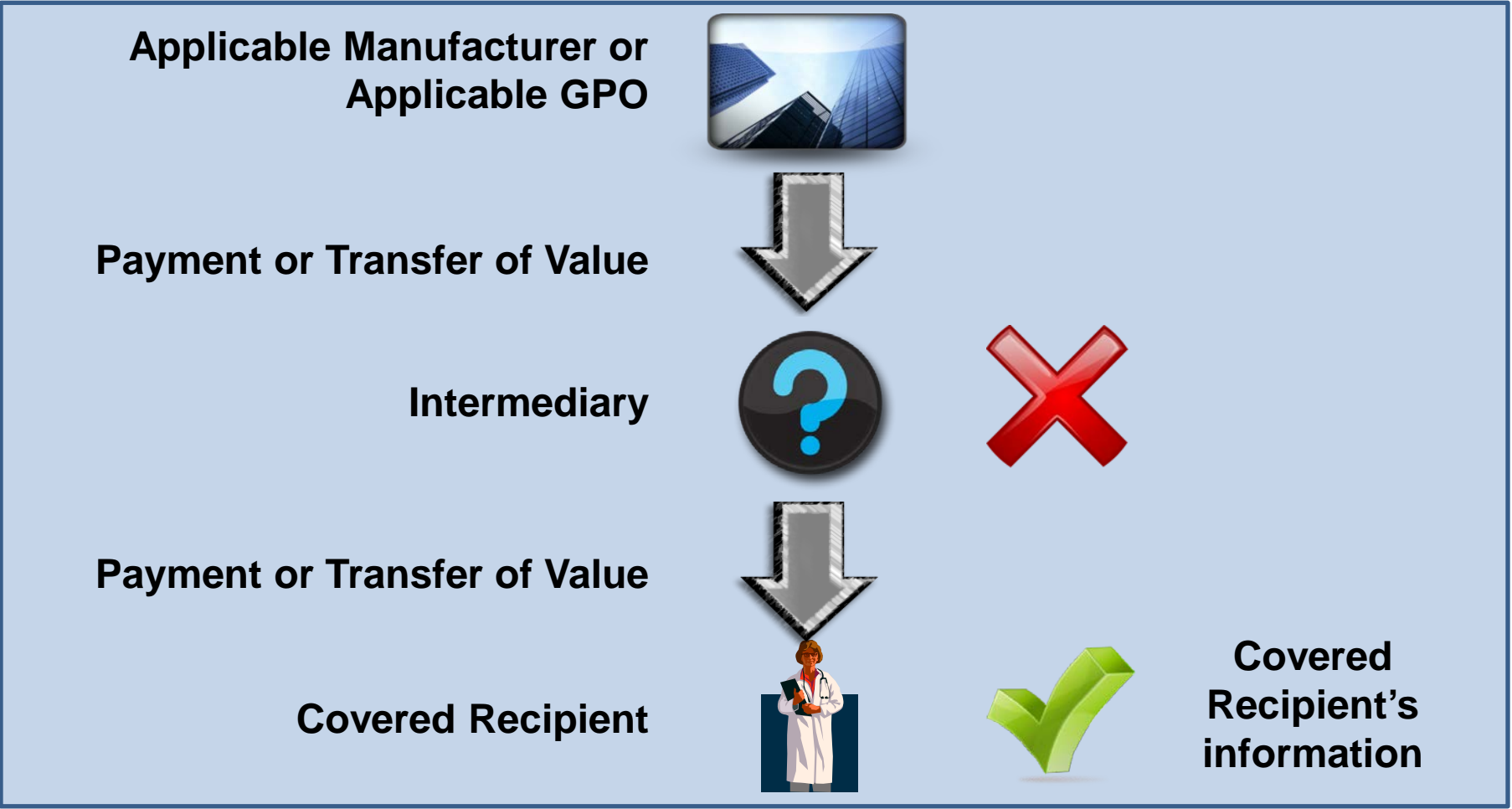
For other educational events which do not meet the three conditions outlined for accredited CME, all transfers of value are reportable

Indirect Payments

- An indirect payment goes from a manufacturer to a physician or teaching hospital **through an intermediary** – for example a specialty society or research organization
- A payment is considered indirect, and reportable, if an applicable manufacturer or GPO **requires, instructs, directs, or causes an intermediary** to provide the payment or other transfer of value to a physician or teaching hospital
- Applicable manufacturers are required to identify each physician who received a payment or transfer of value and report appropriately

Indirect Payments: Payments Directed by Manufacturers to Covered Recipients Through Intermediaries

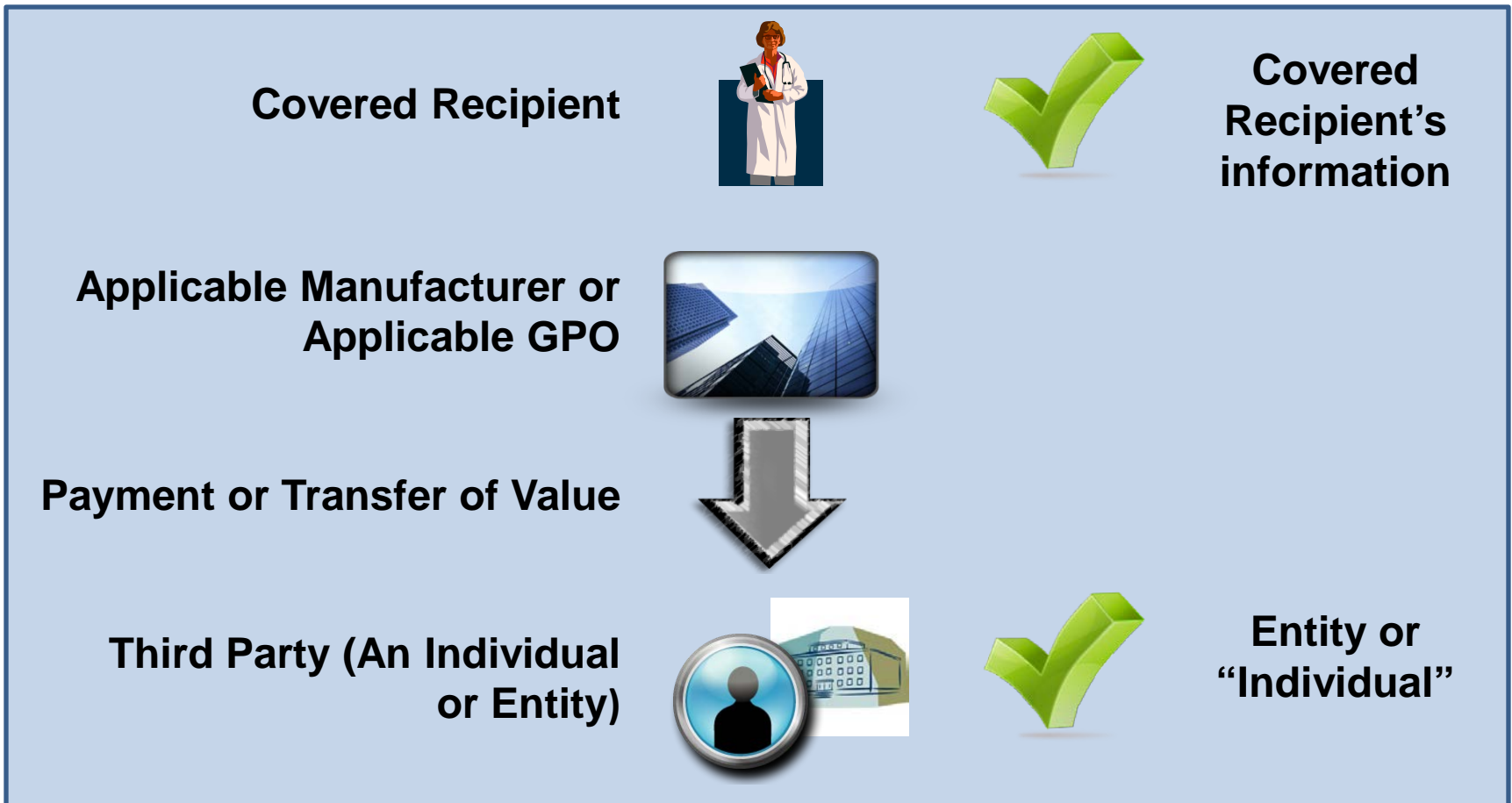
What is publically reported by CMS?



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Third Party Payments: Payments Directed by Physicians to Other Individuals or Entities

What is publically reported by CMS?



Treating Research Payments Differently

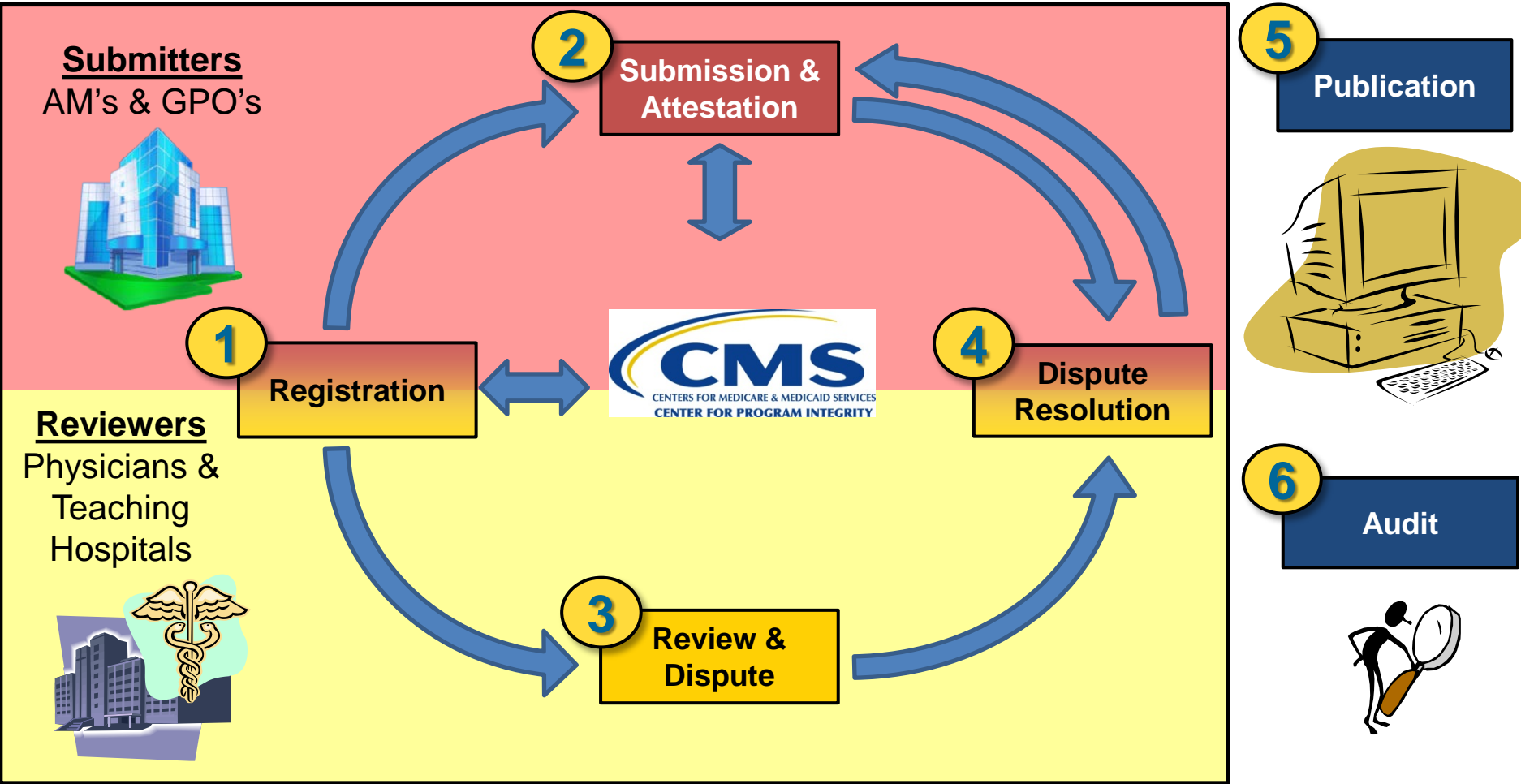
- Providing a balance between transparency and innovation is very important for this program
- Applicable manufactures and applicable GPOs will report the total amount of the research payment included in a research protocol or agreement provided to a teaching hospital, physician, or non-covered recipient entity
- Additionally, applicable manufacturer or applicable GPOs will report the names of physician principal investigators involved in the research study

Delay in Publication and Displaying Research Differently

- If they meet certain criteria, manufacturers can indicate that they wish to delay the publication of payments or other TOV related to research for up to **four years** or until the drug, device or biological under investigation **achieves FDA approval, whichever comes first**
- TOV related to research will also be **displayed separately** from other payments or other transfers of value on the public website

OPERATIONS

Program Functions



2013 Program Cycle

- Collection Period (*8/1/2013 – 12/31/2013*)
- Registration Period (*early 2014*)
- Data Submission Period (*by March 31, 2014*)
- Data Review and Dispute Period (*2nd Quarter in 2014*)
- Correction Period (*2nd Quarter in 2014*)
- Publication (*September 30, 2014*)

2014 and Beyond Program Cycle

- **Collection Period (1/1/2014 – 12/31/2014)**
- Registration Period (*early 2015*)
- Data Submission Period (*by March 31, 2015*)
- Data Review and Dispute Period (*2nd Quarter in 2015*)
- Correction Period (*2nd Quarter in 2015*)
- **Publication (June 30, 2015)**

Data Collection Requirements

| Row # | Data Element Name | Definition / Description | Values | Required? | Data Element Size | Publicly Displayed |
|--|---|--|-----------------------|--|-------------------|--------------------|
| General | | | | | | |
| 1 | Applicable Manufacturer or Applicable GPO Name Submitting File | Textual proper name of either the Submitting Applicable Manufacturer (AM) or Submitting Applicable GPO (GPO). If this file contains a single AM/GPO's set of payment(s) and/or transfer(s) of value records, this AM/GPO name will be used for all records in the file. If this file contains a Consolidated Report, this AM/GPO Name will be used as the Consolidated Reporter and the AM/GPO Names and NPPTP IDs of the sub-companies making the payment of value will be recorded with every payment or transfer of value record in the file. | Text | Yes | 100 Char | Yes |
| 2 | Applicable Manufacturer or Applicable GPO Registration ID Submitting File | NPPTP generated alphanumeric identifier used to identify the Applicable Manufacturer (populated only with CMS provided identifier). If this file contains a single AM/GPO's set of payment/transfer of value records, this AM/GPO ID will be used for all records in the file. | Text | Yes | 10 Char | Yes |
| 3 | Consolidated Report Indicator | Indicator showing if this submission file constitutes a Consolidated Report. | "Y" = Yes "N" = No | Yes | 1 Char | No |
| 4 | Resubmission File Indicator | Indicator showing if this submission file contains ownership/investment interest records that are amended or corrected versions of previously submitted records. | "Y" = Yes "N" = No | Yes | 1 Char | No |
| 5 | Original File Submission ID | Generated alphanumeric identifier used to identify the original file submission. This data will be reported to the submitter after a successful submission and should only be reported back in a resubmission for file identification purposes. | Alphanumeric | Yes if Resubmission File Indicator = "Y" | 15 Char | No |
| Physician Ownership | | | | | | |
| Research | | | | | | |
| Submission Record Information | | | | | | |
| Recipient Demographic Information | | | | | | |

A link to the data collection specifications for the 2013 OPEN PAYMENTS program cycle is **NOW** posted on <http://go.cms.gov/openpayments>

Data Templates Identify the Key Data Points for Reporting

- Identity of the applicable manufacturer or applicable GPO
- Identifiers for the covered recipient
 - Physicians: name, business address, specialty, NPI, state license information
 - Teaching Hospital: name, address, TIN (all provided in the teaching hospital list)
- Information about the payment or transfer of value
 - Date of payment
 - Amount
 - Form of payment
 - Nature of Payment
- Ownership or investment interests held by physicians and their immediate family members are collected in a second template.
- Research payments must be included in a separate report which includes the name of the institution receiving the payments and identities of principal investigators.

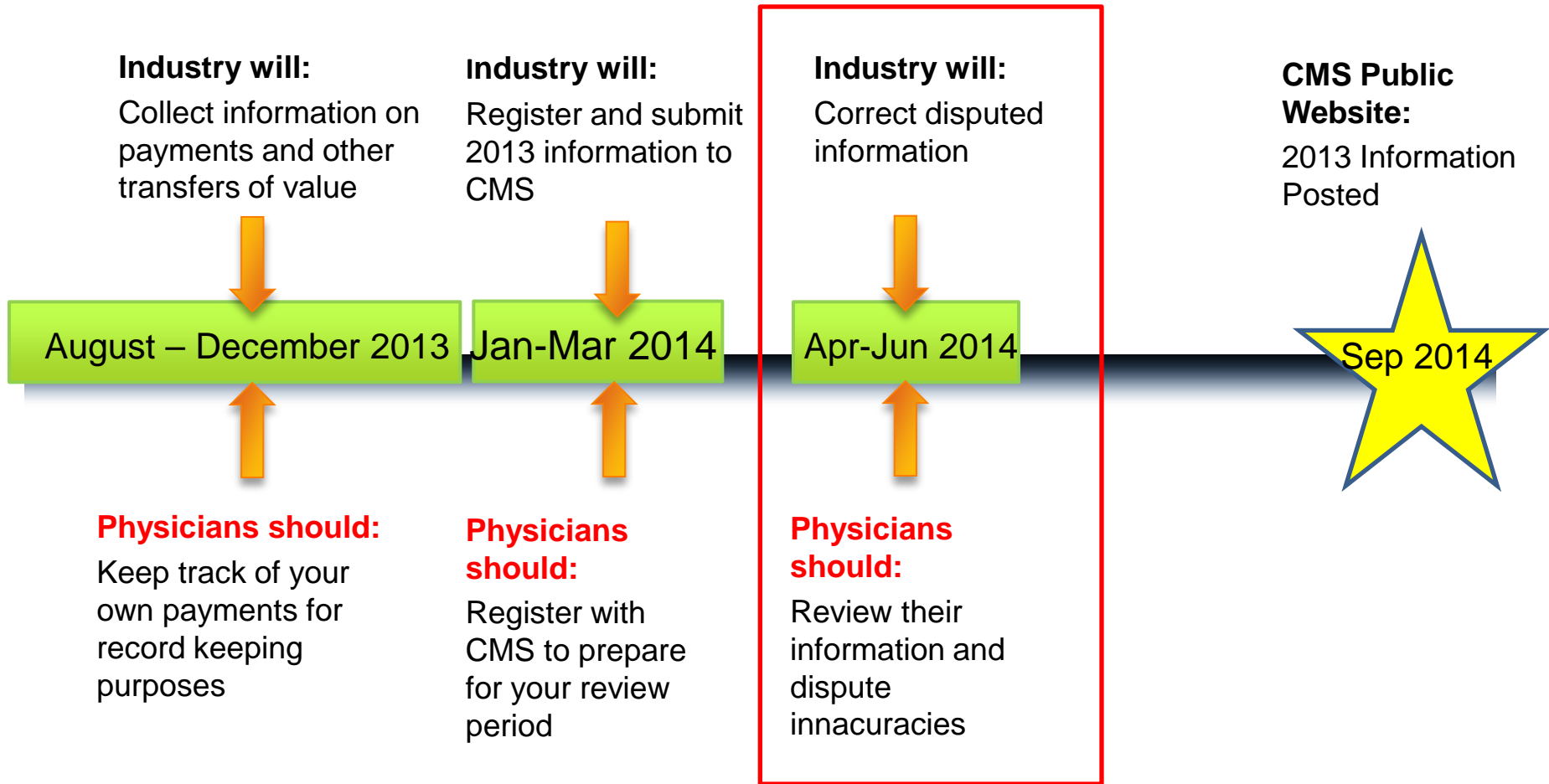
The Operations: TODAY

CMS is actively:

- Finalizing the **data collection specifications** that applicable manufacturers and applicable GPOs can use
- Developing **tools** that can be used by physicians to track transfers of values
- Launching **educational modules** explaining the rule
- Developing a **technology solution** that will collect, aggregate and report the data submitted

PHYSICIAN ROLE & RESOURCES

2013 OPEN PAYMENTS Cycle Voluntary Physician Actions



Tracking Your Payments

- It is important that physicians and teaching hospitals track their own payments and other transfers of value throughout the year
- This will provide **accurate information** to compare against what the industry reports about you to CMS
- CMS is developing **tracking tools** that you may use (discussed later)

Registering with CMS

- Registration is **voluntary** for physicians and teaching hospitals
- Physicians and teaching hospitals should register with CMS so that they will be able to **dispute** inaccurate information
- A primary and backup can register with CMS (*note: for physician registrants, the physician must be the first to register and then approve their backup*)

Reviewing Your Information

- Registered users will be able to review the information submitted by industry about them **prior** to public posting (45 day period)
- Physicians and teaching hospitals should review their information and **dispute** any inaccuracies
 - The primary or backup user can review and dispute information
- Disputes will be routed to the company who submitted the information for them to correct the information

Correcting Information

- Corrections to disputed information must be made by the manufacturer or GPO
 - Physicians should work with industry to ensure corrections are made properly
- Any disputes issued during the **45-day period** should be resolved by the applicable manufacturer or applicable GPO,
- Corrections made during these periods **will be** reflected on the public website
- Corrections not made during this period may not be reflected in the public data, but will be marked as “disputed”

Resources for Physicians

AVAILABLE NOW

- ✓ Webpage dedicated to Physicians
- ✓ Fact Sheet specific to Physicians
- ✓ CME Modules (through Medscape)
- ✓ NEJM article
- ✓ Medicare Learning Network Information including National Provider Calls

COMING SOON

- Mobile Application to track transfers of value
- File for tracking payments
- List of questions to ask Industry prior to interaction
- List of questions & answers when interacting with patients

Support Resources

CMS Program Website: Fact Sheets, Frequently Asked Questions, Links

<http://go.cms.gov/openpayments>

The screenshot displays the CMS.gov website interface. At the top, the CMS.gov logo is visible, along with navigation links for Home, About CMS, Newsroom Center, FAQs, Archive, Share, Help, Email, and Print. A search bar is located below the navigation. The main content area features a navigation menu with categories such as Medicare, Medicaid/CHIP, Medicare-Medicaid Coordination, Insurance Oversight, Innovation Center, Regulations and Guidance, Research, Statistics, Data and Systems, and Outreach and Education. The current page is titled "National Physician Payment Transparency Program: OPEN PAYMENTS" and includes a sidebar with links to "Applicable Manufacturers", "Applicable Group Purchasing Organizations", "Physicians", "Teaching Hospitals", "Definitions and Acronyms", and "Frequently Asked Questions". The main content area provides an overview of the program, stating that it creates greater transparency around the financial relationships of manufacturers, physicians, and teaching hospitals. It also lists the information required to be reported annually to CMS, including applicable manufacturers of covered drugs, devices, biologicals, and medical supplies; applicable manufacturers and applicable group purchasing organizations (GPOs) to report to CMS certain ownership or investment interests held by physicians or their immediate family members; and applicable GPOs to 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. The page concludes with a statement that CMS will collect this data, aggregate it, and publish it on a public website. A footer note indicates "Trusted sites | Protected M".



OPEN PAYMENTS

Physician Tracking Mobile Application

- CMS is developing a mobile application that physicians can use to track their own transfers of value
- Anticipated release in July 2013, in time for data tracking
- Will help you have your own list of information to compare what the industry submits about you to CMS
- Available for free, iOS and Android
- Optional tool for physicians, will not be used to send information to CMS or any other required activity





OPEN PAYMENTS



OPEN PAYMENTS

Apps Exchange Info: Easier, More Accurate Data Collection

Physician App



Send Profile Information



Industry App



Send Profile Information



Send TOV Information



Questions and Contacts

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