

OPEN PAYMENTS (Physician Payments Sunshine Act)

Why OPEN PAYMENTS is Important to You

Section 6002 of the Affordable Care Act requires the establishment of a transparency program, now known as OPEN PAYMENTS. The program increases public awareness of financial relationships between drug and device manufacturers and certain health care providers.

OPEN PAYMENTS requires:

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

CMS will collect the data annually, aggregate it, and publish it on a public website.

OPEN PAYMENTS:

- Speaks to public concerns about physician and industry relationships by collecting and reporting data.
- Helps to make financial relationships among industry, physicians, and teaching hospitals clear.
- Provides one place for financial interactions to be reported and monitored.
- Sets requirements so that it is easier for physicians and other stakeholder groups to make sure the information reported about them is accurate.
- Stop dishonest influence on research, education, and clinical decision-making.
- Stop conflicts of interest that can harm patients and their care.

The Intent of OPEN PAYMENTS

We view this program as a national resource for beneficiaries, consumers, and providers to know more about the relationships among physicians, teaching hospitals, and industry.

How OPEN PAYMENTS Works

Applicable manufacturers (“Reporting Entities”) will tell us every year about:

1. Payments and other transfers of value from applicable manufacturers of covered drugs, devices, biologicals, or medical supplies to physicians and teaching hospitals (“Covered Recipients”).
2. Ownerships or investments held by physicians or their immediate family in applicable manufacturers.

Registration Requirements for Applicable Manufacturers

All applicable manufacturers with data to report **must** register with CMS during the registration period each year. Additional instructions about the registration process will be released by CMS later in 2013.

Reporting Requirements for Applicable Manufacturers

Applicable manufacturers of at least **one** covered drug, device, biological, or medical supply **must** report **all** payments or other transfers of value provided to covered recipients, regardless of whether any particular payment or other transfer of value was related to a covered drug, device, biological, or medical supply. In addition to the reporting of payments and other transfers of value, applicable manufacturers must report to CMS certain ownership or investment interests held by physicians or their immediate family members.

Applicable Manufacturers:

- Operate in the United States (meaning that they have a physical location within the U.S. or otherwise conduct activities in the U.S., either directly or through a legally-authorized agent); **AND** either
- Produce, prepare, propagate, compound, or converse of at least one covered drug, device, biological, or medical supply; **OR**
- Operate under common ownership with an applicable manufacturer and provide assistance or support to the applicable manufacturer in the manufacturing, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply.

Applicable manufacturers will be required to categorize all reportable payments as falling within one of the following natures of payment:

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

Generally, applicable manufacturers are required to report all payments, whether they are related to a covered drug, device, biological, or medical supply, or not. However, there are some exceptions. For example, applicable manufacturers that had less than 10 percent gross revenue during the fiscal year preceding the reporting year from covered products are only required to report payments or other transfers of value related to covered products, not all products. In addition, certain products are excluded from the reporting requirements. For example, drug samples intended exclusively for distribution to patients are excluded from the reporting requirements (see *final rule* for a complete list of applicable exclusions).

Applicable manufacturers must also report ownership and investment interests held by physicians or their immediate family members. Please refer to the *Data Collection Templates* section of this document for more specific reporting information.

Attestation Requirements for Applicable Manufacturer

Applicable manufacturers must attest that the data they submitted are accurate and complete. In addition, applicable manufacturers with less than 10% of their gross revenues coming from covered products must attest to that fact in order to avail themselves of the special exclusion of only reporting payments related to covered products.

Reporting Covered Recipients' Data to CMS

For purposes of reporting payments to Covered Recipients, the term "Covered Recipients" refers to *physicians* (except for physicians who are bona fide employees of the applicable manufacturer reporting the payment) and *teaching hospitals*.

For the purposes of this program, a "physician" is any of the following types of professionals that are legally authorized to practice:

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

Note: Medical residents are excluded from the definition of physician for the purpose of this program.

For the purposes of this program *teaching hospitals* are defined as hospitals that received payment for Medicare direct graduate medical education (GME), inpatient hospital prospective payment system (IPPS) indirect medical education (IME), or psychiatric hospitals IME programs during the last calendar year for which such information is available to CMS.

Covered Products

A *covered product* is any drug, device, biological, or medical supply that is eligible for payment by Medicare, Medicaid, or CHIP either individually or as a part of a bundled payment (such as the inpatient prospective payment system), and requires a prescription to be dispensed (for drugs and biologicals) or requires premarket approval by, or premarket notification to, the U.S. Food and Drug Administration (FDA) (for devices, including medical supplies that are devices).

Data Collection Templates

CMS provided three data collection templates for applicable manufacturers to use:

- *General payment data collection template (non-research)*. This template should be used by applicable manufacturers to report payments and other transfers of value to physicians, teaching hospitals and physician owners or investors that are **not** made in connection with an activity that meets the definition of research.

- *Research payment data collection template.* This template should be used by applicable manufacturers to report payments and other transfers of value to physicians, teaching hospitals, and physician owners or investors made in connection with an activity that meets the definition of research.
- *Ownership and investment interest data collection template.* This template should be used by applicable manufacturers to report all ownership or investment interests that are held by physicians or their immediate family members.

The data collection templates will provide a list of the data elements that applicable manufacturers must collect and report to CMS. For each element, the template will contain the following (at a minimum):

- Data element title;
- Data element description;
- Whether the data element is required or optional;
- Data format and values; and
- Any other necessary information needed to aid the data collection process.

The 2013 reporting period data collection templates can be found on the OPEN PAYMENTS website.

Data collection templates for future reporting years will be released for applicable manufacturers and GPOs by October 1 of each year.

Teaching Hospital List

CMS has published a downloadable list (in .csv format, Microsoft Excel format and Adobe .pdf format) of all teaching hospitals subject to reporting for the 2013 reporting year. The teaching hospital list contains all hospitals that CMS has recorded as receiving a payment(s) under a Medicare direct GME, IPPS IME, or psychiatric hospital IME programs during the latest full fiscal year for which such information is available to CMS.

The list is an important resource to assist applicable manufacturers when determining if they are required to report payments or other transfers of value made to a hospital. The list includes the hospital's name, address and taxpayer identification number. The list is valid for the entire 2013 reporting period.

The teaching hospital list for future reporting years will be released for applicable manufacturers by October 1 of each year

Pre-Submission Review Process (Optional)

A pre-submission review is when the applicable manufacturer provides the physician, teaching hospital, or physician owner/investor the opportunity to review the data prior to submission to CMS.

While CMS recommends that applicable manufacturers voluntarily provide physicians and teaching hospitals the opportunity to conduct a pre-submission review, doing so is not mandatory. However, presubmission reviews could improve accuracy of the data prior to submission and reduce the frequency of disputes later on.

Note: CMS will not administer or manage a pre-submission review process.

Physicians and Teaching Hospitals' Voluntary Participation

Physicians and teaching hospitals are not required to submit any data for OPEN PAYMENTS; however, to ensure the accuracy of the data submitted, CMS encourages their participation through:

- Registering with CMS;
- Reviewing data submitted about them by applicable manufacturers; and
- Working with applicable manufacturers during the correction period to resolve any disputes.

Review, Dispute and Correction Process

Physicians, teaching hospitals, and physician owners/investors will have the opportunity to review and work together with the applicable manufacturers to make any necessary corrections to the information before we make it public.

Once the applicable manufacturer has submitted the data file to CMS, the process is as follows:

- CMS will give physicians, teaching hospitals, physician owners/investors 45 days to review and work with the applicable manufacturers to correct the information. After those 45 days, applicable manufacturers will have an additional 15 days to submit corrections based on any disputes identified by physicians, teaching hospitals, and physician owners/investors. The review and correction period starts at least 60 days before the information is made public.
- During the review and correction period, physicians, teaching hospitals and physician owners/investors can dispute information about them that they do not think is correct.
- If data is disputed, CMS will notify the applicable manufacturers that some of their data has been disputed, but will not mediate the dispute directly. Applicable manufacturers should work with physicians, teaching hospitals and physician owners/investors to correct the information.
- Once the dispute is resolved, the applicable manufacturer must send CMS a revised report for the correct data and re-attest that it is correct.
- If the applicable manufacturer cannot resolve the dispute with the physician, teaching hospital or physician owner/investor and correct the data in the initial 45 days or subsequent 15 days, the applicable manufacturer should keep trying to find a resolution.

This review, dispute and correction process will impact publication as follows:

- While the review and correction system will be open year-round, only the data corrections submitted and attested to during the 45-day review and correction period, and subsequent 15-day dispute resolution period, will be updated before publication.
- CMS will update data from the current and previous year at least once annually, in addition to the initial data publication that followed the data submission.
- In the cases when a dispute cannot be resolved, the most recent submitted and attested data by the applicable manufacturer will be published, but will be marked as disputed.

CMS will monitor the frequency of disputes reported by physicians, teaching hospitals, and physician owners or investors and the volume of disputes unresolved between physicians, teaching hospitals, and applicable manufacturers to inform the auditing process.

Data corrections made by the applicable GPO may be made at any time and the corrections will be updated with the next data refresh.

Audits and Penalties

Applicable manufacturers may be audited for compliance with the program requirements to submit timely, accurate, and complete data. Therefore, CMS requires all applicable manufacturers to keep all records related to payments and other transfers of value and/or ownership or investment interests for at least five years from the date the transaction is published on the CMS website.

Civil monetary penalties (CMPs) may be imposed for failure to report information in a timely, accurate, or complete manner. The following penalties apply to each applicable manufacturer:

Situation	CMP
Failure to report <i>each</i> payment or other transfer of value, or ownership/investment interest in a timely, accurate, and complete manner.	At least \$1,000, but no more than \$10,000, with an annual maximum of \$150,000
<i>Knowing</i> failure to report each payment or other transfer of value, or ownership/investment interest.	At least \$10,000 but no more than \$100,000, with an annual maximum of \$1,000,000
Total <i>combined</i> maximum annual penalty per reporting entity.	Maximum \$1,150,000

For applicable manufacturers that are filing consolidated reports, the applicable manufacturer submitting the consolidated report will be subject to the maximum penalties for each individual entity represented in the consolidated report.

Information CMS Will Publish

- CMS will annually publish all payments and other transfers of value and ownership and investment interest reported by the applicable manufacturer about physicians and teaching hospitals and all payments and other transfers of value to physician owners/investors made by the applicable manufacturer.
- CMS will make updates to the data at least once annually beyond the initial publication.
- CMS will post disputed data that is unresolved by the end of the 60*-day review, dispute and correction period as it was most recently submitted and attested, but will mark it as disputed.

* This reflects the initial 45-day review period plus 15-day resolution period.

Key Dates for Initial Reporting Period

- Applicable manufacturers must begin to collect the required data on August 1, 2013 and report the collected data through December 31, 2013 to CMS by March 31, 2014.
- By September 30, 2014, CMS will publish the reported data on a publicly available website.

More information and instructions will be provided on the CMS website as implementation details become available. This includes, but is not limited to, information and dates related to the registration process, and the review, dispute, and correction processes.

For More Information

Check back frequently for:

- CMS-provided information
- Registration process
- Review, dispute and correction processes

Send questions to OpenPayments@cms.hhs.gov or visit our website at <http://go.cms.gov/openpayments>

CMS is committed to publishing the most accurate data possible, and supporting applicable manufacturers, and covered recipients throughout the implementation of OPEN PAYMENTS.