

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.

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 payments and other transfers of value from an applicable manufacturer of covered drugs, devices, biologicals, or medical supplies to teaching hospitals (“Covered Recipients”).

Teaching Hospitals’ Voluntary Participation

Teaching hospitals are not required to register with or send any information to OPEN PAYMENTS. However, to make sure CMS has the right information, we do encourage teaching hospitals to:

- Become familiar with the information that will be reported about teaching hospitals.
- Keep records of all payments and other transfers of value received from applicable manufacturers.
- Register with CMS and subscribe to the listserve to receive updates regarding the program.
- Look at the information applicable manufacturers submitted on behalf of teaching hospitals.
- Work with applicable manufacturers to make sure the information submitted about teaching hospitals is correct.

CMS will provide additional information about registration later in 2013.

Covered Recipients

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, teaching hospitals are defined as hospitals that received a 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 during the most recent calendar year for which such information is available.

Applicable Manufacturer Entities Reporting Data to CMS:

- 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.

Covered Product

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 required premarket approval by or premarket notification to the Food and Drug Administration (for devices, including medical supplies that are devices).

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 will include the hospital's name, address and taxpayer identification number. The list will be 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.

Applicable Manufacturers are Required to Report to CMS

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.

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 limitations. For example, applicable manufacturers that had less than 10 percent gross revenue during the previous fiscal year coming 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).

Pre-submission Review Process

The applicable manufacturer can give the teaching hospital the chance to see their information before sending it to CMS. This process is voluntary. CMS will not oversee pre-submission reviews.

If the teaching hospital asks for a pre-submission review, there is a better chance that the information sent to us about the teaching hospital will be accurate and complete.

Review, Dispute, and Correction Process

Teaching hospitals will have an opportunity to review and work with the applicable manufacturers to make any necessary corrections to the information before we make it public.

Once the applicable manufacturers have submitted the data file to CMS the process is as follows:

- CMS will give teaching hospitals 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 the teaching hospitals. The review and correction period starts at least 60 days before the information is made public.

- During the review and correction period, teaching hospitals 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 teaching hospital to correct the information.
- Once the dispute is resolved, the applicable manufacturers 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 teaching hospital and correct the data in the initial 45 days or subsequent 15 days, they should continue 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 noted 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 teaching hospitals and the volume of disputes unresolved by applicable manufacturers.

Data corrections made by the applicable GPOs 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.

Information CMS Will Publish

- CMS will annually publish all payments and transfers of value reported by applicable manufacturers about teaching hospitals.
- 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 manufacturer must begin to collect the required data on August 1, 2013 and report the collected data through December 31 to CMS by March 31, 2014.
- By September 30, 2014, CMS will publish the reported data on a publicly available website.

More Information is Available

We will give more information and instructions about OPEN PAYMENTS and Section 6002 of the Affordable Care Act on cms.gov. Check back frequently for:

- Teaching hospital list
- 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 teaching hospitals throughout the implementation of OPEN PAYMENTS.