

OPEN PAYMENTS (Physician Payment 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 GPOs (“Reporting Entities”) will tell us every year about:

1. Ownerships or investments held by physicians or their immediate family in applicable GPOs.
2. Payments and other transfers of value from an applicable GPO to a physician holding an ownership or investment interest in the applicable GPO.

Registration Requirements for Applicable GPOs

All applicable GPOs 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 GPOs

Applicable GPOs **must** report information on ownership and investment interests held by physicians and their immediate family members, as well as any 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.

Applicable GPOs:

- 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**
- Purchase, arrange for purchase, or negotiate the purchase of a covered drug, device, biological, or medical supply for a group of individuals or organizations that is not solely for use by the purchasing entity itself.

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 U.S. Food and Drug Administration (FDA) (for devices, including medical supplies that are devices).

Data Collection Template

CMS provided the *Ownership and Investment Interest Data Collection Template* for applicable GPOs to capture all ownership or investment interests in the applicable GPO that are held by a physician or their immediate family member.

The data collection template provides a list of the data elements that applicable GPOs 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 to aid the data collection entities.

In instances where applicable GPOs have provided payments or other transfers of value to physician owners or investors, applicable GPOs should use one of the following additional templates:

- *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.

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

Pre-Submission Review Process (Optional)

A pre-submission review is when the applicable GPO provides the physician owners/investors the opportunity to review the data prior to submission to CMS.

While CMS recommends that applicable GPOs voluntarily provide physicians the opportunity to conduct a pre-submission review, doing so is not mandatory. However, pre-submission 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' Voluntary Participation

Physician owners/investors 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 GPOs; and
- Working with applicable GPOs during the correction period to resolve any disputes.

Attestation Requirements for Applicable GPOs

Applicable GPOs must attest that the data they submitted are accurate and complete.

Review, Dispute and Correction Process

Applicable GPOs and physician owners/investors will have an opportunity to review and work together to make any necessary corrections to the information before we make it public.

Once the applicable GPO has submitted the data file to CMS, the process will be as follows:

- CMS will give physician owners/investors 45 days to review and work with the applicable GPOs to correct the information. After those 45 days the applicable GPOs will have an additional 15 days to submit corrections based on any disputes identified by the 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, physician owners/investors can dispute information about them that they do not think is correct.
- If data is disputed, CMS will notify the applicable GPO that some of their data has been disputed, but will not mediate the dispute directly. Applicable GPOs should work with physician owners/investors to correct the information.
- Once the dispute is resolved the applicable GPO must send CMS a revised report for the correct data and re-attest that it is correct.
- If the applicable GPO cannot resolve the dispute with the physician owners/investors and correct the data in the initial 45 days or subsequent 15 days, the applicable GPO 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 GPO will be published, but will be marked as disputed.

CMS will monitor the frequency of disputes reported by physician owners/investors, and the volume of disputes unresolved between physician owners/investors and applicable GPOs.

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 GPOs may be audited for compliance with the program requirements to submit timely, accurate, and complete data. Therefore, CMS requires all applicable GPOs to keep all records related to 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 may apply to applicable GPOs:

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 <i>each</i> 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

Information CMS Will Publish

- CMS will annually publish all payments and other transfers of value, and ownership and investment interest reported by the applicable GPOs about physician owners/investors.
- 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 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 GPOs 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 data collection template, registration process, and 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 GPOs, and physician owners/investors throughout the implementation of OPEN PAYMENTS.