The Physician Open Payments Program
(or "Sunshine" Act)
-What You Need to Know-

What is Open Payments?

The Open Payments Program, which was a part of the Patient Protection and Affordable Care Act (ACA), is a national transparency program intended to highlight the financial relationships between physicians, teaching hospitals and drug and device manufacturers. Originally known as “The Sunshine Act,” the Centers for Medicare & Medicaid Services (CMS) refers to this program as the physician Open Payments Program. You can find CMS fact sheets, FAQs and additional information at the CMS Open Payments webpage.

This program requires:

1. “applicable manufacturers” of drugs, devices, biological or medical supplies to annually report to CMS certain payments and other transfers of value made to “covered recipients” (physicians or teaching hospitals)

2. “applicable manufacturers” and “applicable group purchasing organizations” (GPOs) to annually report to CMS certain ownership interests held by physicians and their immediate family members, and

3. “applicable GPOs” to report transfers of value to physician owners.

As of Aug. 1, 2013, such manufacturers offering products covered by Medicare, Medicaid or the Children’s Health Insurance (CHIP) program are required to report to CMS any payments or other transfers of value to certain physicians and teaching hospitals that are valued at more than $10 or if the aggregate value provided to a physician over the course of a year is more than $100. The first reporting period was Aug. 1 through Dec. 31, 2013. On Sept. 30, 2014 CMS made this information available to the public on a searchable and downloadable website. Beginning in 2014, the data will be collected for the full calendar year, reported to CMS and should be posted by June 30 of the following year.

Physicians and teaching hospitals have an opportunity to review and dispute erroneous data for each year before it is made publicly available. In order to review the data, CMS requires a two-step process for physician registration. First, physicians must to register in the CMS Enterprise Portal and then to review and, if necessary, dispute the data, they must register separately with the Open Payments program. More information on the registration process can be found on the CMS Open Payments Program Registration page.

What is an “applicable manufacturer”?

For the purposes of Open Payments, an applicable manufacturer is defined as any entity that manufactures a “covered” drug, device, biological or medical supply and whose products are sold or distributed in the United States. Covered items are those reimbursed by Medicare, Medicaid or CHIP. You can find more information regarding applicable manufacturers at this CMS web page.
What is an “applicable group purchasing organization” (GPO)?

For the purposes of Open Payments, an applicable GPO is defined as any entity that purchases, arranges for or negotiates for the purchase of a covered drug, device, biological or medical supply (i.e., those items reimbursed by Medicare, Medicaid or CHIP) for a group of individuals or entities, but not solely for use by the entity itself. It includes physician owned distributors of covered drugs, devices, biological or medical supplies. You can find more information regarding applicable GPOs at this CMS web page.

What is a “covered recipient”?

For the purposes of Open Payments, a covered recipient is defined as a teaching hospital (those that received payment for Medicare direct graduate medical education, IPPS indirect medical education (IME), or psychiatric hospital IME programs during the last calendar year) or any of the following types of physicians that are legally authorized to practice, regardless of whether they are Medicare, Medicaid, or CHIP providers:

- 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, but not fellows, are excluded from the definition of physicians for the purposes of this program.

What is a reportable transfer of value?

In general, transfers of value include but are not limited to entertainment, food, beverages, travel, lodging, grants, consulting fees and other items that have economic value. Transfers of value also include payments or other transfers of value provided to a third party at the request of or on behalf of a covered recipient.

Applicable manufacturers will be required to categorize the nature of all reportable payments into one of the following:

- 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 (including destination)
- Education
- Research
- Charitable contributions
- Current or prospective ownership or investment interest
- Compensation for serving as faculty or as a speaker
  - See section on compensation for speaking at CME programs
- Grants
- Space rental or facility fees (teaching hospital only)
Royalty or license

What is a reportable ownership interest?

Applicable manufacturers and GPOs are required to report certain ownership interests held by physicians and their immediate family members including but not limited to:

- Stock
- Stock option(s) (other than those received as compensation, until they are exercised*) (may be reported as a transfer of value)
- Partnership share(s)
- Limited liability company membership(s)
- Loans
- Bonds
- Other financial instruments that are secured with an entity’s property or revenue or a portion of that property or revenue

Indirect payments

Indirect transfers of value are transfers that are not made directly from a manufacturer to a physician. Instead they are made by a third party where the manufacturer requires, instructs, directs or otherwise causes the third party to make the payment to a physician. In general, these are reportable unless the manufacturer did not know or could not easily ascertain the identity of the physician during the reporting year or by the end of the second quarter of the following reporting year. For example, if a pharmaceutical company makes a grant to a medical society and requires that the grant be passed along to physicians, the grant to the physicians would be reportable.

Compensation for speaking at CME programs

To address ongoing confusion about whether speaking at CME programs should be reported, CMS made changes in the final 2015 Medicare Physician Fee Schedule which are outlined here and the agency released this FAQ:

Starting with 2016 Open Payments data collection and reporting to CMS in 2017, are payments provided by an applicable manufacturer to a continuing education organization for continuing education events reportable?

Yes, the payment is reportable if the applicable manufacturer determines that the payment meets the definition of an indirect payment, and the applicable manufacturer knows or can determine the identity of the covered recipient by the end of the second quarter of the following reporting year. An indirect payment is defined at 42 C.F.R. §403.902 as a payment or other transfer of value made by an applicable manufacturer to a covered recipient through a third party, where the applicable manufacturer requires, instructs, directs, or otherwise causes the third party to provide the payment or transfer of value, in whole or in part, to a covered recipient. In accordance with 42 C.F.R. §403.904(i)(1), indirect payments or other transfers of value do not have to be reported if the applicable manufacturer is unaware of the identity of
the covered recipient during the reporting year or by the end of the second quarter of the following reporting year.

What is excluded from reporting?

The following items are excluded from the reporting requirements:

- Payments or other transfers of value of less than $10, unless the aggregate amount over a year exceeds $100
- Payments or other transfers of value of less than $10 provided at large-scale conferences and similar large-scale events, as well as events open to the public, do not need to be included for purposes of the annual $100 aggregate
- Product samples, including coupons and vouchers that can be used by a patient to obtain samples
- Educational materials that directly benefit patients, including the value of an applicable manufacturer’s services to educate patients
- The loan of a covered device or a device under development, or the provision of a limited quantity of medical supplies for a short-term trial period, not to exceed a loan period of 90 days or a quantity of 90 days of average daily use, to permit evaluation of the device or medical supply by the covered recipient
- Discounts or rebates
- In-kind items for charity care
- Items or services provided under a contractual warranty (including service or maintenance agreements)
- Transfers of value to a physician who is a patient, research subject or participant in data collection not acting in his or her professional capacity as a physician
- A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund
- Payments for the provision of healthcare through a self-insured plan to employees of applicable manufacturers and their families
- Transfers of value solely for the non-medical professional services of a non-medical licensed covered recipient
- Payment for the services of a physician with respect to civil or criminal actions and arbitrations
- Payments made solely in the context of a personal, non-business-related relationship
- Certain indirect payments or other transfers of value, where the applicable manufacturer is unaware of the identity of the covered recipient during the reporting year or by the end of the second quarter of the following reporting year.
- Certain compensation for speakers at continuing medical education, if the payment does not meet the definition of a direct or indirect payment (see section on indirect payments)

How will reporting work?

Manufacturers must report any payment or other transfer of value made to a physician that exceeds ten dollars. This includes the common practice of drug or device representatives bringing lunch into a group practice. If a meal provided to a physician is valued at more than $10 or if the aggregate value of lunches provided to a physician over the course of a year is more than $100, the lunch will be reported. To calculate the value of a lunch, manufacturers will divide the total value of the food they bring in by the number of people who ate the lunch, but they will only report to CMS the transfer of value to physicians who ate the lunch. See table below for an example of this.

<table>
<thead>
<tr>
<th>Scenario: A drug representative brings in a pizza lunch to a 10 physician group practice</th>
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<tbody>
<tr>
<td><strong>Pizza is valued at:</strong></td>
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<tr>
<td><strong>Pizza is consumed by:</strong></td>
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<td><strong>Calculate the value of the lunch:</strong></td>
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<td><strong>Manufacturer reports:</strong></td>
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REMEMBER! Even if one lunch is valued below the $10 threshold, it could be reported if a physician has received more than $100 from the manufacturer annually. Practice professionals should track payments to physicians so they will not be surprised when the $100 annual threshold is met.

Collecting Data

As of Aug. 1, 2013, manufacturers and GPOs began collecting information on payments and transfers of value with physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their family members. Data from Aug. through Dec. 2013 was reported to CMS in the spring of 2014. Beginning with 2014, data is collected for each full calendar year. Applicable manufacturers and GPOs must report the name, date, NPI, state license number, specialty and business address of the physician or teaching hospital receiving the payment to CMS. However, a physician’s NPI and state license number will not be included on the public website. The report must also specify:

1. The amount of the payment
2. The nature of the payment (such as consulting fee, food, entertainment, travel, education, etc.)
3. The form of payment (such as cash, stock, stock option or in-kind items or services).

You can find additional details regarding data collection and submission at the CMS Open Payments Explore the Data page.

Review and Dispute

2015 Data
The review and dispute period for 2015 reporting begins April 1 through May 15, 2016.

Program Timeline for 2015 data

2014 Data
For 2014 reporting, from April 6 through May 20, 2015 physicians were able to access individual consolidated industry reports online, after completing the necessary Open Payments program registration. A consolidated report is filed by an applicable manufacturer, which includes payments or other transfers of value to covered recipients, physician owners or investment interests for the applicable manufacturer filing and applicable manufacturers under common ownership. Physicians who registered in the CMS Enterprise Portal and then registered for the Open Payments Program were able to review and, if necessary, dispute Open Payments data. Only after physicians have registered themselves in both the Enterprise Portal and with the Open Payments Program, can they designate an authorized representative, including medical practice staff, who can review and dispute data on their behalf. CMS has published several Open Payments Quick Reference Guides for physicians and authorized representatives.

Physicians had through May 20, 2015 to review their report and challenge any inaccurate information collected for 2014. Physicians may contact manufacturers or GPOs directly through the CMS web portal to dispute any inaccurate information.
If a physician and manufacturer or GPO cannot resolve the dispute during the initial review period, they are provided an additional 15 days before the report is made public to try to achieve resolution. Disputes initiated during this period that are not resolved are included on the public website, but are shown as “under dispute”. Additionally, CMS does not mediate any disputes.

**Steps to consider:**

Keep in mind that physicians are not required to report anything to CMS - that burden lies with the manufacturers and GPOs. However, in order to ensure accurate reporting and manage the reputations of physicians and practices, here are a few steps your practice can take to prepare for this new program:

1. **Have a dialogue with physicians in your practice.** Be mindful that, in addition to payments made to physicians, manufacturers and GPOs are also required to report physicians’ and immediate family members’ stock and ownership interests. It may be beneficial to have a discussion with your physicians about public reporting and whether your practice’s policies and procedures need to be modified. Consider inventorying potentially reportable relationships within your practice.

2. **Keep track of payments and transfers of value provided to physicians.** Since these reports will be made public, you will want to ensure the manufacturer’s list of transfers of value are accurate by comparing your reports to those from the manufacturer. CMS developed a mobile app that allows physicians to track payment information reported by manufacturers. Please refer to their [mobile app FAQs](#) for more information.

3. **Ask a manufacturer or GPO directly what and how much they are reporting.** Keep in mind that manufacturers face serious financial penalties for failure to report a transfer of value. As a result, they may err on the side of over-reporting. If a physician is unclear about what a manufacturer may report, ask them directly.

4. **Register with CMS.** In addition to keeping your own record/receipt, physicians can register with CMS to review Open Payments data during the review period. The first step for a physician is to register with the CMS Enterprise Portal. This is an involved registration process, and CMS created a [resource](#) to walk physicians through this. More information on Open Payments registration is available on the [CMS Open Payment Program Registration page](#).

5. **Review CMS resources.** CMS has a number of FAQs, Fact Sheets, patient brochures, and other resources. All resources can be found at [CMS’s Open Payments website](#).