

compliance

Sunshine or Stormy Weather?

BY CINDY PARMAN, CPC, CPC-H, RCC

The Sunshine Act appears as Section 6002 of the Patient Protection and Affordable Care Act (PPACA or ACA) and requires manufacturers to report to the Centers for Medicare & Medicaid Services (CMS) virtually all payments and gifts made to physicians and teaching hospitals. The Final Rule for the ACA's Open Payments program (the government's updated name for the Sunshine Act) was issued in February 2013 and will soon result in publicly distributed financial information.

According to CMS in a public presentation on Aug. 8, 2013, the objectives of the Open Payments program include making financial relationships transparent on a national scale and providing consumers with the information needed to ask questions and make informed decisions about their healthcare professionals. The CMS role in this program is to ensure that reports and disclosures are complete, accurate, and clear, while remaining neutral when presenting the data on a public website.

According to the CMS Open Payments webpage:¹

Collaboration among physicians, teaching hospitals, and industry manufacturers can contribute to the design and delivery of life-saving drugs and devices. However, while some collaboration is beneficial, payments from manufacturers to physicians and teaching hospitals can also introduce conflicts of interests.

While financial ties alone do not signify an inappropriate relationship, Open Payments is necessary to:

- Encourage transparency of reporting

financial ties;

- Reveal the nature and extent of relationships;
- Prevent inappropriate influence on research, education, and clinical decision-making;
- Avoid conflicts of interest that can compromise clinical integrity and patient care; and
- Minimize risk of increased health care costs.

More than 90 percent of physicians report having some type of business relationship; about 80 percent report receiving food or beverages in the workplace from industry sources.² According to an April 26, 2010 article published by Kaiser Health News:³

Research suggests that those details matter to some patients. Kevin P. Weinfurt, an associate professor of psychology and neuroscience at Duke University, has studied how patients participating in clinical trials react to physician disclosures. He found that patients were particularly troubled when doctors owned stock in the companies that were managing the clinical trials. "They felt somehow that this physician could do something in the trial that could make the company a lot of money, which would then make him a lot of money," Weinfurt says.

According to Dr. Shantanu Agrawal, director of the CMS data-sharing and partnership group, "Pharmaceutical companies spent \$15.7 billion in 2011 on face-to-face sales and promotional activities."²

As part of a separate agreement with the government, Amgen Inc., a biotechnol-

ogy manufacturing company, recently released records of physician payments made during the first quarter of 2013.⁴ Although the majority of payments to physicians were for less than \$100 in food costs, at least ten individual physicians received more than \$20,000 in payments and other transfers of value during this three-month period.

What Providers are Affected?

For the purposes of Open Payments, a "physician" is any of the following types of professionals that are legally authorized to practice—regardless of whether they are Medicare, Medicaid, or Children's Health Insurance Program (CHIP) providers. (Medical residents are currently excluded from the definition of physicians for the purpose of this program.)

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

Open Payments will not initially apply to midlevel providers, such as nurse practitioners and physician assistants.

For the purposes of Open Payments, "teaching hospitals" are hospitals that received payment for Medicare direct graduate medical education (GME), inpatient prospective payment system (IPPS) indirect medical education (IME), or psychiatric hospital IME programs during the last calendar year for which such

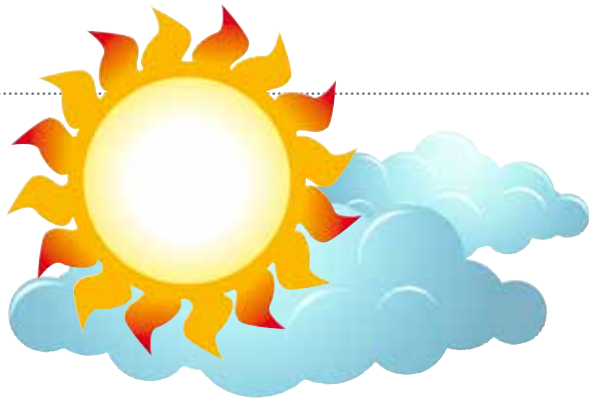


Table 1. 2013 Open Payments Program Cycle

<p>Industry Will: Collect information on payments and other transfers of value, as well as ownership or investment interests held by physicians and their family members.</p>	<p>Industry Will: Register and submit 2013 information to CMS.</p>	<p>Industry Will: Correct disputed information.</p>	<p>CMS Public Website: 2013 information posted.</p>
<p>August – December 2013</p>	<p>1st Quarter 2013</p>	<p>2nd Quarter 2013</p>	<p>September 2014</p>
<p>Physicians Should: Keep track of payments and transfers of value made and be mindful of ownership and investment interests held by both the physician and their immediate family.</p>	<p>Physicians Should: Register with CMS in order to receive notifications and information submitted by the industry.</p>	<p>Physicians Should: Review information for accuracy.</p>	

information is available. CMS has posted a list of these teaching hospitals on the Open Payments program webpage and this list will be updated annually.

Who is an Applicable Manufacturer or GPO?

Open Payments defines applicable manufacturers as those that:

- 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, or

compound 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 of at least one covered product must report to CMS all payments and other transfers of value made to physicians and teaching hospitals. CMS defines a “covered product” as 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 IPPS) and that requires a prescription to be dispensed (for drugs and biologicals) or requires pre-market approval by or pre-market notification to the U.S. Food and Drug Administration (for devices, including medical supplies that are devices).

Open Payments defines applicable GPOs as those that:

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- 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 entities, but not solely for use by the purchasing entity itself.

Applicable GPOs must report information on ownership and investment interest held by physicians and their immediate family members, as well as any payments or other transfers of value made to physician owners or investors.

What Payments Are Included?

“Nature of payment” categories must be used to describe why a payment or other transfer of value was made. The categories are:

- 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
- Direct compensation for serving as faculty or as a speaker for a medical education program (unaccredited or non-accredited)
- Grants
- Space rental or facility fees (teaching hospital only).

CMS has also clarified that in addition to direct payments to physicians and teaching hospitals, the manufacturers and GPOs must also report indirect payments and payments that are transferred to a third party. For example, if the manufacturer contracts with an agency to distribute funds to physicians who endorse a certain product, these payments would be reported under the Open Payments program.

In another scenario, if the physician scheduled to receive a payment for serving as a speaker directs the company to forward his compensation to a charity, this action must still be reported as a payment to the physician.

There are, however, limited exceptions for compensation for speaking at a continuing education program when all published criteria are met. But even if the compensation is exempt from the reporting requirements, it is possible that the manufacturer will have to report the costs of meals, travel, lodging, and educational materials for these continuing education events.

Excluded from the reporting requirements are items that directly benefit patients or are intended to be used by patients, including the value of a manufacturer’s services to educate patients regarding a covered drug, device, biological, or medical supply. For example, if the transfer of value consists of a wall chart or anatomical model, these costs are not reportable. That said, CMS has clearly stated that the provision of a textbook by a manufacturer or GPO is reportable under the Open Payments Program.

The data collected under the Open Payments program will become part of a database that the FDA’s Office of Criminal Investigations (OCI) is building to detect potentially fraudulent activity, such as off-label marketing violations.

What Information Will Be Reported?

CMS states that the standard reporting categories include:

- General Payments: payments or other

transfers of value not made in connection with a research agreement

- Research Payments: payments or other transfers of value made in connection with a research agreement
- Ownership & Investment Interests.

From coffee and doughnuts to investigator grant permits, any payment or transfer must be reported under the provisions of the Open Payments program. Section 6002 provides the following limited exception:⁵

Small payments or other transfers of value, which the statute defines as payments or other transfers of value less than \$10, do not need to be reported, except when the total annual value of payments or other transfers of value provided to a covered recipient exceeds \$100.

Specific information reported by industry manufacturers and GPOs includes the physician’s full legal name, primary specialty, primary business address, national provider identifier (NPI), state professional license number(s), and email address. In addition, there will be data relating to the name of the drug, device, biological, or medical supply and the amount, date, number, and nature of the payment(s) or other transfer(s) of value. Last, the interactions will be categorized as cash (or cash equivalent), “in kind” items or services, stock (including stock options or other ownership interest), or dividend, profit, or other return on investment.

Applicable manufacturers and GPOs will report the data for August through December of 2013 to CMS by March 31, 2014; CMS will release the data publicly by September 30, 2014. After that, a full year’s worth of data will be published the following June; for example, the data from January through December 2014 will be

published in June 2015. In addition, manufacturers and other reporting entities will be required to register on a CMS website, and will submit data using templates.

According to a CMS official speaking at the annual meeting of the American Medical Association (AMA) House of Delegates in Chicago, Ill. on June 17, 2013, once data has been collected and processed, providers will have 45 days to dispute and correct manufacturer's reports.⁶ After that, the data will be made public. If a discrepancy is not brought to the manufacturer's attention during the 45-day period, resolutions could take months.

If providers believe that reported data is false or misleading, they must document the disputed data elements in writing to CMS, and then work out the dispute directly with the manufacturer. The data will be flagged as "disputed" on the website, but will not be removed until the manufacturer withdraws the information. In addition, CMS will not mediate the dispute; if it is not resolved in a year, the manufacturer's data will be reported to the public.

To ensure data accuracy, CMS is required to conduct audits of the data submitted and levy civil monetary penalties against manufacturers and GPOs for failing to submit data or submitting inaccurate data. CMS can impose \$10,000 fines on manufacturers for failing to report gifts, but this penalty may climb to \$100,000 should a manufacturer be found to have deliberately omitted payment information.

What Should You Do?

There are industry concerns that this type of public database will be a target for industry critics, the press, the Internal Revenue Service (IRS), and even attorneys seeking to sue physicians or facilities. As a result, industry sources must make reporting accuracy the first priority.

Physicians, hospitals, and cancer programs should track their data. In

addition, they should monitor the Open Payments website for an opportunity to register for online access to reports and dispute documents. Further, CMS recommends that physicians and teaching hospitals:

- Become familiar with the information that will be reported about physicians or teaching hospitals
- Keep records of all payments and other transfers of value received from manufacturers or GPOs
- Register with CMS and subscribe to the listserve to receive updates regarding the program
- Review the information manufacturers and GPOs submit on a physician's or hospital's behalf
- Work with manufacturers and GPOs to make sure the information submitted is correct.

Physicians and teaching facilities can register with CMS starting Jan. 1, 2014 to receive a report on their activities each June before the public report is released. CMS is also promoting its smartphone app, called "Open Payments Mobile for Physicians" that tracks payments and other value transfers from manufacturers. The physician app will work in tandem with the "Open Payments for Industry" app that allows the manufacturer to exchange information with the physician on a dynamic basis, but the apps will not be used to transmit information to CMS.

In an effort to ensure that physicians understand the details of the Open Payments Program, AMA has developed a Tool Kit, including a free archived webinar and frequently asked questions, which is available at: www.ama-assn.org/ama/pub/advocacy/topics/sunshine-act-and-physician-financial-transparency-reports.page.

Last, physicians and hospitals that will be impacted by the Open Payments program should be prepared to respond to questions from patients and other consumers once the payment results are

published. This response could include disclosing the information on the provider's website, publishing frequently asked questions, and training staff to respond appropriately to questions about industry payments received during a patient encounter.

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References

1. CMS. Open Payments. www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/index.html. Last accessed Sept. 26, 2013.
2. Robeznieks A. Docs Fear Sunshine Act Data May be Misread. www.ModernPhysician.com. Available online at www.modernphysician.com/article/20130620/MODERNPHYSICIAN/306209969#. Last accessed Oct. 29, 2013.
3. Weintraub A. New health law will require industry to disclose payments to physicians. *Kaiser Health News*. Available online at www.kaiserhealthnews.org/Stories/2010/April/26/physician-payment-disclosures.aspx. Last accessed Sept. 26, 2013.
4. Amgen, Inc. Physician Payment Report 01/01/2013 to 03/31/2013. Available online at http://clearlyamgen.amgen.com/cia/pdf/Corporate_Integrity_Agreement_Physician_Payment_Report_Q1_2013.pdf. Last accessed Sept. 26, 2013.
5. HHS. *Federal Register*. 78(27):9485. Available online at www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Downloads/Final-Rule.pdf. Last accessed Sept. 26, 2013.
6. Ault A. Sunshine Act: tracking of gifts, payments starts in August. *The Oncology Report*. Available online at www.oncologypractice.com/oncologyreport/single-view/sunshine-act-tracking-of-gifts-payments-starts-in-august/39ce25c0f722d7863824588e591c466.html?tx_ttnews%5BsViewPointer%5D=1. Last accessed Sept. 26, 2013.