Open Payments: Overview for Physicians

**Developed by the AAMC Forum on Conflict of Interest in Academe
Sunshine Act Working Group**

Open Payments, also known as the "Sunshine Act," began August 1, 2013. On that date applicable manufacturers and group purchasing organizations (GPOs) began collecting data about payments and other transfers of value made to physicians and teaching hospitals. "Applicable manufacturers" refers to companies that sell drugs, devices, biologicals, and medical supplies that are available for reimbursement through a federal health care program.

Open Payments is intended to increase public awareness of financial relationships between companies and certain health care providers — doctors of medicine and osteopathy, dental surgeons, dentists, licensed chiropractors, optometrists, and podiatrists. The Open Payments database will provide information about payments made by industry, but does not seek to explain or make judgments about which if any of those relationships are potentially problematic. Relationships with industry are not inherently suspect and public insight into those relationships is welcome and represents an important opportunity to begin a discussion with patients about healthcare innovation and advancing health and patient care through productive and principled partnerships with industry.

How Does It Work?

- The rule requires companies to report to the Centers for Medicare and Medicaid Services (CMS) information about payments and transfers of value to physicians and teaching hospitals.
    - Manufacturers report each payment they make to physicians or teaching hospitals and classify the payment into one of 16 categories.
    - Companies must also report physician ownership of companies (including stocks and stock options).
    - The reported payments or transfers of value do not need to be related to one of the covered drugs, devices, biologicals or medical supplies.
    - Detailed information about what will be reported is available on the Open Payments website.
- Physicians and teaching hospitals will have an opportunity to review the information before it becomes public and dispute payments they believe to be inaccurate.
- CMS will publish the data on a website in an easily searchable format that anyone can access.
    - Data for the first period, August 1 to December 31, 2013, will be published in the fall of 2014.
    - In future years, data for each full calendar year will be published the next year.
    - Historic data will continue to be available indefinitely.

What information about physicians will be reported?

- Companies are required to report all payments and transfers of value over $10 they make to physicians or teaching hospitals. The payments must be attributed to one of the following categories: consulting, services other than consulting, honoraria, gifts, entertainment, food and beverage, travel and lodging, education, research, charitable contribution, royalty or license, ownership of investment interest, compensation for serving as a speaker in an unaccredited and non-certified continuing education program, compensation for serving as a speaker in an accredited and certified continuing education program (with some exclusions), or grant.

What items are considered gifts?

- Any payment or transfer of value that does not fit into one of the other categories noted above is considered a gift (CMS did not allow an "other" category). Examples might include office supplies, journal reprints, textbooks, editorial services, and scientific posters, if they did not fit into another category.

Will my industry funded research be reported under my name?

- Industry-funded research payments and/or transfers of value will be reported under the name of the entity that receives the payment. However, the principal investigator also will be identified. These research payments or transfers of value will not, however, be published as payments or transfers of value to the physician investigators in the same way that consulting payments, for example, will be published.

What if I do not agree with a payment or transfer of value reported under my name?

- You will have a 45-day window to review data and dispute payments or transfers of value before the data is made public. If you disagree with any payment or transfer of value, you should mark the payment or transfer of value as disputed in the Open Payments system.
  - In 2014, this 45 day window runs from July 14th to August 27th.
- You must then work directly with the manufacturer to resolve the disputed payment or transfer of value. CMS will play no role in the dispute resolution process. At the end of the 45-day review period, manufacturers will have 15 additional days to resolve disputes and provide corrected data to CMS.
- Any payments or transfers of value that were disputed, but not resolved during the 45 day review period, will be reported as is but marked as "disputed."
- *If you do not review the information during the 45-day review period and dispute reports you believe to be incorrect, no changes will be made in the public database until the next year, even if you dispute the report.*

How do I register to participate in the review and dispute resolution process?

- You must register in CMS' Enterprise portal, available at https://portal.cms.gov/wps/portal/unauthportal/home/. You may then request access to the Open Payments system. Once you have completed the registration and access process, you will be able to view payments or transfers of value posted under your name. You should mark any payments or transfers of value you do not agree with and then work directly with the manufacturer to resolve the disagreement.
- In order to review their data, physicians must first register for access to the CMS Portal, and then request access to Open Payments.
  - Physicians can go to CMS (https://portal.cms.gov) to begin the registration process.
  - CMS has provided detailed information on how to register, review, and dispute data (https://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Physicians.html).
- Physicians can appoint a delegate to assist them in the process. Physicians must first complete their own registration before they can appoint a delegate and those delegates must also register and accept their role before they can review a physician's data.

How long will it take to review my data?

- You should set aside at least 2 to 3 hours to gather the information you will need to register and review payments and transfers of value posted to your name. You may need much less time to register and review the data, and you may need to allow more time if you have a significant number of relationships with industry.
- Remember that there is a short timeframe in which disputed payments can be resolved with manufacturers.

Why should I review the information before it becomes public?

- *Physicians have no reporting obligations under this regulation but should consider reviewing the reported information before it becomes public.*
- Reviewing the data before public release can increase the accuracy of the data and allow physicians to dispute inaccuracies in the reported information.
  - Disputes made during the review period have the possibility of being resolved before the data is made public.
  - Disputes made during the review period but not resolved before the data is made public will be flagged as "disputed" payments.
    - o Disputes made *after* the review period may not be flagged as "under dispute" in the published database.
- Anyone can view this information once it is published in September, including your chief or chair, institutional officials, the compliance office, patients, government representatives, colleagues, attorneys, and the media. Patients may ask you about payments or transfers of value you received. Reviewing data, before and after public release, gives you the opportunity to understand what questions you may receive.

What Should I Expect When Trying to Access the Review Information?

- This is a new system; everyone is working hard to get it right but we can expect bumps in the road.
  - o Reported data may not be accurate.
  - o The CMS website could experience slowness or other problems; the CMS help desk could get flooded with inquires and take a while to respond.
  - o The dispute process with companies may take longer than the allotted 45-day time period.
  - o The reported information may be difficult to reconcile with your own records.
  - o Physicians contacted by members of the media should contact their Public Relations or Compliance Office as directed by your institution.

Should I be worried if my name appears in Open Payments?

- No. A very large number of physicians and teaching hospitals will have information posted about them. Open Payments is focusing on transparency; simply having data posted under your name does not mean you have violated a law or any institutional policy. The most important thing is that the information posted should be as accurate as possible.
- If you have concerns about reconciling information on the Open Payments database with information you have reported to your institution or to other organizations, contact your compliance office or institutional contact for conflicts of interest.

Where can I get help or more information?

- Your compliance office or other institutional contact can offer you assistance and information about how your institution is responding to the Sunshine Act requirements.
- The Open Payments website (available here or at http://go.cms.gov/openpayments) has detailed information including official FAQs and an extensive User Guide for the Open Payments system.
  - o You can submit an email to the Help Desk at openpayments@cms.hhs.gov. Live Help Desk support is available by calling 1-855-326-8366, Monday through Friday, from 7:30 a.m. to 6:30 p.m. (CT), excluding Federal holidays.
- Finally, check the AAMC website on the Sunshine Act (available here) for further information and updates as they are available.