

Open Payments: Overview for Media Relations Offices

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

“Open Payments” is a federal program intended to promote transparency into financial relationships between the medical industry and healthcare providers by publishing all payments made to physicians and teaching hospitals by manufacturers of drugs, devices, biologicals and medical supplies on a publicly accessible website. The Centers for Medicare and Medicaid Services (CMS) plans to make the information accessible to the public on a website starting on September 30, 2014. The types of payments or transfers of value that must be reported include consulting fees, honoraria, gifts, entertainment, food, travel, education, charitable contributions, grants, and payments for research.

Transparency about relationships between healthcare providers and industry is an essential component in maintaining public trust in our healthcare delivery and biomedical research.

- Relationships with industry are not inherently problematic, and can serve to improve health by facilitating biomedical research and advancing discovery.
- Providing insight into those relationships can improve and maintain public trust and can prompt productive conversations between patients and their physicians or research subjects and investigators.
- When specific relationships with industry pose potential conflicts of interest for physicians or researchers, institutions are engaged in the review, management, and oversight of those interactions.

The Open Payments database is not a listing of physicians or teaching hospitals who have done anything wrong; it lacks the context to assess the nature of any single reported payment.

- The Open Payments database is a compilation of reports from manufacturers of all payments made, not a listing of conflicts of interest or prohibited relationships.
- There is insufficient detail and context in the listing of payments to determine if any one payment represents a conflict of interest. Academic medical centers and teaching hospitals have policies to review certain individual financial interests and manage potential conflicts of interest.
- The regulations require manufacturers to report each payment in one of 16 categories, but these category names alone may not provide information about the purpose of the payment or the nature of the relationship.

The information included on the public database may be inaccurate, incomplete, or misleading.

- The Open Payments rollout has been very frustrating for physicians and teaching hospital administrators. The process has been marked by delays, system failures, incorrect or

misattributed data, and unannounced shut downs. These problems have shaken confidence in the readiness of this data for public release.

- A process to allow physicians and teaching hospitals to review the information specific to them in advance of the public release of data was interrupted several times and was preceded by a multi-step registration process that took some physicians and teaching hospital representatives hours to complete.
- In mid-August, partway through the 45-day process to review payments, the entire system was shut down for 12 days. When it was reopened, CMS announced that about a third of the payment information submitted by manufacturers was incorrect and removed and will not be available when the information is released to the public.
- Although the database included a mechanism for physicians and teaching hospitals to mark incorrect or unknown payments as “disputed,” many of the reported payments were not reviewed in advance of the public release because of system-wide delays, partial data removal and system access failures that made it difficult or impossible for physicians and teaching hospital representatives to access their records. The public should not assume that each payment not marked as disputed has been reviewed and determined to be accurate by the reported recipient.

Information on the Open Payments database may differ from other publicly available sources of information about financial relationships between healthcare providers and industry.

- There are many other sources of information about industry relationships, including institutional websites and individual disclosures specific to manuscripts or educational activities. Differences between these sources may be a result of differences in reporting timeframes, thresholds, or required reporting categories.
 - *For example: A physician who goes to a scientific advisory board may report to her institution the amount of the honorarium paid to her, but the Open Payments website would report any “transfer of value,” related to that event, including travel, lodging, and food. The physician’s disclosure would appear much smaller than the manufacturer’s reported payment.*
- The information on Open Payments is not a “real time” listing of current relationships and payments, but an annual compilation of reports from the previous calendar year. In the current public database, information available in September 2014 concerns payments made between 9 and 14 months *before* the database was published.
- The removal of one-third of the data by CMS and the fact that the manufacturer reporting period didn’t begin until August 2013 means that the database will only include up to two-thirds of the data from the last five months in 2013.

Reports about research payments may be inaccurate or misleading, and may not reflect how research is funded.

- An individual who leads a research project is called the principal investigator. This person, who may be a physician, does not personally receive the payment and his or her salary does not increase by the amount of research funding received.
- The amount reported often includes items budgeted within the research agreement, (i.e., salaries and benefits, equipment, services used in the research, administrative and

facilities overhead and IRB fees) rather than payments to individuals made directly by the manufacturer.

- In some cases, the information on the Open Payments database attributes research payments to a teaching hospital or physician who are not involved in the research or not the direct recipients of the research payment.
 - *For example: A single tax ID number may be shared by teaching hospital(s) and the affiliated academic institution. Payments made to the non-healthcare departments of the university (such as an Office of Sponsored Programs or other centralized office that administers, receives and manages payments for research) may incorrectly be reported as payments to the affiliated teaching hospital. Despite commentary from CMS that “payments to non-healthcare departments of universities affiliated with teaching hospitals should not be included in the reporting requirements” (78 Fed. Reg. 9468), manufacturers have indicated that all payments to an entity with the same tax ID number have been reported as payments to that teaching hospital.*

INFORMATION TO PREPARE FOR MEDIA CALLS OR PUBLIC INQUIRIES

- **Contact Person:** Identify the appropriate office or person to contact or where external inquiries should be directed

- **Responding to Open Payments**
 - What was the institutional experience with the registration and review and dispute process, and what information was provided to faculty?
 - Is the institution systematically reviewing any faculty physician data?
 - Has the teaching hospital(s) data been reviewed by the institution?
 - Were any records disputed? If so, on what basis? What was the resolution?

- **Handling Conflicts of Interest**
 - Describe your institution's policies to identify and manage potential conflicts of interest and applicable state laws, such as state ethics laws
 - Decide whether you will verify compliance with these policies for individuals based on the nature of the records reported/data submitted about the individual

- **Understanding Reported Research Payments**
 - How does your institution receive and handle research payments?
 - How much funding does your institution receive from industry for research? Consider giving a representative example of the type of research, understanding that confidentiality agreements may preclude providing the name of the study drug or title of the study.

ADDITIONAL BACKGROUND INFORMATION ON OPEN PAYMENTS

1. What is the Physician Payments Sunshine Act or Sunshine Law about?

This law was passed as part of the Affordable Care Act. It requires certain drug, device and equipment manufacturers (“applicable manufacturers”) to report payments made to physicians (and certain other clinicians) and teaching hospitals for consulting, teaching, honoraria, travel, gifts, entertainment and other activities. The law is intended to make publically available the financial relationships between industry and physicians and the potential conflicts of interest created by these relationships. Congress wanted this information available to the public so that patients can determine for themselves whether their physician has a relationship with a device or drug company, and whether that relationship may impact decisions about treatment or care they may receive.

2. When is data being collected and reported?

Data was collected for payments made between August 1, 2013 and December 31, 2013 and submitted to CMS (Centers for Medicare and Medicaid Services). CMS will make this information available to the public in a searchable database starting on September 30, 2014. Data will be collected on a full calendar year basis going forward and submitted to CMS in March of each year. The Sunshine Act reporting period is not necessarily consistent with other federal and state mandated reporting periods and other financial disclosures required of University researchers.

3. What have academic institutions heard from manufacturers?

Some applicable manufacturers have inconsistently characterized or categorized payments and some have placed the obligation to provide detailed information about a payment on the recipient. CMS has stated that the recipient does not have any obligation to track or report data. Manufacturers have also expressed concern about the imposition of fines or penalties for failing to report or for under-reporting, which may lead to over-reporting. There is also variation among manufacturers for the same item, such as travel expenses.

4. What were physicians and teaching hospitals required to do to register with Open Payments?

CMS used a two-phase registration process. In phase 1, physicians and teaching hospitals established their log-in credentials (User ID and password) and then requested access to Open Payments. Phase 1 began on June 1, 2014.

In Phase 2, which was announced on July 11, 2014 and started on July 14, 2014, the first day of the “review and dispute” process, physicians and teaching hospitals were able to register for the Open Payments system. Successful registration in both the Enterprise Identity Management System and requested access to the Open Payments systems must be done prior to initiating registration in the Open Payments system.

5. Are physicians and teaching hospitals required to register?

No, registration is not required under the Sunshine Act. However, in order to view, review and dispute records prior to their being made available to the public, registration is required.

6. How does the review and dispute process work?

Having registered, the physician or teaching hospital representative must go to the Open Payments system, select the record they wish to dispute, state a reason for the dispute and send it to the reporting entity by e-mail. After CMS adjusted the closing date by two weeks for the system shut down, physicians and teaching hospitals had until September 11, 2014 to initiate a dispute. The disputer received an e-mail acknowledging receipt of the dispute. Some reporting entities contacted the physician or teaching hospital representative by phone or e-mail to attempt to resolve the dispute. Reporting entities had 15 days to resolve the dispute. Reporting entities may unilaterally decide to change the information or keep it the same and will consider the dispute resolved. If the physician or teaching hospital disagrees with this result, they may re-initiate a dispute. Any changes made during this dispute period will be included in the September 2014 publication. If the dispute is not resolved before publication, the record will appear as disputed.

7. Will CMS provide assistance to resolve the dispute?

No. CMS will not mediate the dispute resolution process. Physicians and teaching hospitals must work directly with the reporting entity to resolve the dispute.

8. Can a physician or teaching hospital initiate a dispute after the data is made public?

Yes. Disputes may be initiated after the data is made public. The deadline to initiate a dispute regarding the data for 2013 is December 31, 2014. If a covered recipient waits until after the data has been made public to initiate a dispute, the data will not be marked as disputed and any correction will not appear until CMS updates the information, which could be six months to a year later or with the next year's publication.

9. What about the payments that were made in 2013 and CMS removed from the Open Payments system?

Removed payments will be returned to the reporting entities and will be asked to re-submit them with their 2014 reports. This means that the removed payments from this year will show up in the review and dispute process for next year.

10. How accurate is the data being reported?

Based on the documented reporting errors, system difficulties, reporting variations and inconsistencies in interpretation of the regulation, there are concerns about the accuracy of the data. There are also many physicians who have not registered and participated in the review and dispute process.

11. Why did CMS suspend access to the Open Payments system during the review and dispute process?

One physician was able to see the reports of payments made to another physician with the same name. When reviewing the root cause of this error, CMS found that a single reported payment had included the NPI of one physician and the medical license of another physician with the same name. This caused the two profiles to be linked and appear as one profile, with either physician having access to all the records for both. CMS decided to review all the reported data and, using a cross check with other databases it has access to, remove from the Open Payments system any reported payment that could not be unambiguously linked to a single physician or teaching hospital.

12. How are research payments being reported?

Payments will be reported for the institution receiving the payment as well as for physicians who are investigators for research supported by manufacturers. CMS has indicated there will be a separate research reporting section of the website.

RESOURCES

- CMS Open Payments website: <http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/index.html>
- AAMC Sunshine Act Resources: www.sunshine.org/sunshinerule
- Other Resources:
 - AMA, Toolkit for Physician Financial Transparency Reports (Sunshine Act): <http://www.ama-assn.org/ama/pub/advocacy/topics/sunshine-act-and-physician-financial-transparency-reports.page>
 - Johns Hopkins Medicine, Physician Payments Sunshine Act: http://www.hopkinsmedicine.org/Research/OPC/Policies_Regulations/SunshineAct

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