

NAVIGATING THE COMPLIANCE MAZE

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Sunshine Act or Open Payments Program 2015 Data Released



In 2007, two US Senators, Charles Grassley and Herb Kohl introduced a bill that would require manufacturers of pharmaceutical drugs, medical devices and biologics to disclose compensation that they give to physicians. According to Grassley, "The bill is about letting the sun shine in so that the public can know".⁽¹⁾ The legislation was an attempt to bring transparency to an industry that appeared to be influencing physician-prescribing patterns. Initially the bill did not pass but was later included as part of the reform measures in the 2010 Patient Protection and Affordable Care Act (ACA).⁽²⁾

According to a Fact Sheet for Physicians published by the Centers for Medicare and Medicaid Services (CMS), the intent of the program is to provide a resource that beneficiaries, consumers and providers can use to learn more about the relationships between physicians, teaching hospitals and the industry.⁽³⁾

The Open Payments Program:

- ⚙ 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 ⁽⁴⁾

Types of data that manufacturers and group purchasing organizations (GPO) must report includes payments in the form of entertainment, gifts, food, travel, consulting fees, speaking fees, compensation for services, honorariums, some types of funding and grants, education or conference funding, physician ownership and investment interests, forms of equity, royalties or licenses and contributions to charity paid for by the industry.⁽⁵⁾

There are some exemptions to the reporting requirements depending on the value of the payments and other various factors. The industry must provide data on the following individuals; Doctors of Medicine, Osteopathy, Dentistry, Dental Surgery, Podiatry, Optometry and Chiropractic Medicine who are legally authorized to practice.

There are three types of payment categories:

- 1) General Payments - Payments or other transfers of value not made in connection with a research agreement or research protocol.
- 2) Research Payments - Payments or other transfers of value made in connection with a research agreement or research protocol.
- 3) Physician Ownership Information - Information about physicians or their immediate family members who have an ownership or investment interest in an applicable manufacturer or GPO.⁽⁶⁾

CMS has been given the responsibility to collect and make the data available to the public. They do not make any decisions as to whether or not the relationships are beneficial or pose a conflict of interest. However, “to ensure that the healthcare industry is compliant with Open Payments reporting requirements, CMS has the authority to impose civil monetary penalties for late, inaccurate, and incomplete reporting.”⁽⁷⁾

Physicians are encouraged to monitor the data to ensure accurate and fair reporting and to challenge any inaccurate information. Once collected, physicians have 45 days to review the data and dispute any potential errors before the information becomes public. Physicians continue to have the ability to dispute the data for up to for 2 years after the data is published. However, changes are not reflected on the website until the next regularly scheduled update. Physicians are also encouraged to answer public questions related to the Open Payments Data.



The American Medical Association (AMA) has developed a list of talking points for physicians to respond to questions and explain why certain types of financial interactions are appropriate. CMS has also developed a mobile application that can be used by physicians, manufacturers, and GPO's to track payments and other transfers in real-time.



Due to industry challenges and other various delays, CMS did not start publically reporting the data until 2014. This past June, they published 2015 data representing the second full year of data available on the program website. Previous partial year data is available for 2013.

This data can be reviewed by going to <https://openpaymentsdata.cms.gov/>. The website contains a search tool allowing the public to locate information on individual physicians, teaching hospitals, or reporting entities. Users can also download datasets or use a web-based interface to filter and sort data to create a specific report. Searching for a specific entity or physician will provide additional data such as the nature of the payment, the date of the payment, the amount of the payment and whether or not the information has been disputed.

In 2015, there were 11.90 million records related to 618,931 physicians and 1,116 teaching hospitals with accumulated payments of \$7.52 billion.⁽⁸⁾ This includes \$2.60 billion in general payments, \$3.89 billion in research payments and another \$1.03 billion of ownership or investment interests.⁽⁹⁾

CMS indicated that with the availability of more than one year of data gives them the ability to trend some of the information. For example, in the 2015 program year, they found that 2.26% of the financial transactions that were made between physicians and pharmaceutical companies related to opioid medications.⁽¹⁰⁾ They also found that the distribution of payments and that the ownership and investments categories remained consistent with some shifts in who was paid and how the money was spent.⁽¹¹⁾

Table 1: Open Payments Trending, 2014 – 2015

	2014	2015
General Payments		
Number of Records	11.18 million	11.13 million
Value	\$2.64 billion	\$2.60 billion
Research Payments		
Number of Records	672,969	764,679
Value	\$3.79 billion	\$3.89 billion
Ownership and Investment Interests		
Number of Records	5,268	4,322
Value	\$1.06 billion	\$1.03 billion
Total Open Payments Records		
Number of Records	11.86 million	11.90 million
Value	\$7.49 billion	\$7.52 billion

Centers for Medicare & Medicaid Services. (2016). CMS' Open Payments Program Posts 2015 Financial Data. Available from <https://www.cms.gov/OpenPayments/Downloads/2015-List-Serv-email.pdf>

According to Dr. Shantanu Agrawal, CMS Deputy Administrator and Director of the Agency's Center for Program Integrity, "transparency is empowering physicians to be purposeful about their financial relationships with companies, and there is a notable shift towards charitable contributions and away from other interactions such as honoraria and gifts".⁽¹²⁾

For information on the Open Payments Program, please visit <https://www.cms.gov/openpayments/>

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- (1) Grassley, C. (2007). Grassley, Kohl say public should know when pharmaceutical makers give money to doctors. Available at <http://www.grassley.senate.gov/news/news-releases/grassley-kohl-say-public-should-know-when-pharmaceutical-makers-give-money>
- (2) Mackey, T. and Liang, B. (2013). Physician Payment Disclosure under Health Care Reform. Available at http://www.medscape.com/viewarticle/803921_3
- (3) CMS Fact Sheet for Physicians; Open Payments (Physician Payments Sunshine Act) Available from <https://www.cms.gov/regulations-and-guidance/legislation/national-physician-payment-transparency-program/downloads/physician-fact-sheet.pdf>
- (4) Indem, p. 1.
- (5) Indem, p. 3.
- (6) CMS Annual Report to Congress on the Open Payments Program April 2016, p. 13. Available at <https://www.cms.gov/OpenPayments/Downloads/Open-Payments-Report-to-Congress.pdf>
- (7) Indem, p. 2
- (8) CMS' Open Payments Program Posts 2015 Financial Data. Available from <https://www.cms.gov/OpenPayments/Downloads/2015-List-Serv-email.pdf>
- (9) Ibid Ref #8
- (10) Ibid Ref #8
- (11) Ibid Ref #8
- (12) Indem, p. 5-6.

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