

11TH ANNUAL MEETING OF ISMPP



**OPTIMIZING SCIENTIFIC VALUE:
SMART AND SYSTEMATIC APPROACHES
TO MEDICAL PUBLICATIONS**

April 27–29, 2015
Hyatt Regency Crystal City
Arlington, VA, USA



11TH ANNUAL MEETING OF ISMPP



SUNSHINE ACT:
EXAMINATION OF THE
OPEN PAYMENTS DATABASE

April 28, 2015
Arlington, VA



INTRODUCTIONS

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DISCLAIMER

- Information presented reflects the speaker's personal knowledge and opinions and does not necessarily represent those of her current or past employers or ISMPP.
- PLEASE NOTE: This presentation is not intended to offer legal advice regarding the Sunshine Act. For legal advice, please consult your corporate attorney.



Agenda

- The Sunshine Act
 - Overview
 - Medical Publication Support Services
 - Challenges
- Open Payments
 - In-depth review
 - How it Works
 - Benchmarking
 - Data Summary
 - Dispute & Corrections
 - Takeaways
- Questions



THE SUNSHINE ACT

Overview

Medical Publication Support Services



The Sunshine Act: Medical Publication Support Services

- Sunshine Act regulations and preamble and CMS FAQs **do**:
 - Include references to reporting the relationship with authors of “ghost-written publications”
 - Include references to payments for medical writing or publication related to a research agreement
- Sunshine Act regulations and preamble and CMS FAQs **do not**:
 - Clearly address the requirement to report the transfer of value associated with the provision of medical publication support services to a covered recipient author or entity



The Sunshine Act: Challenges

- Industry struggles to determine how to report Medical Publication Support Services:
 - Are Medical Publication Support Services reportable indirect transfers of value to a covered recipient author? If yes, then:
 - Are they reportable as part of the aggregated research payment on the federal Research report or are they a separate payment reportable on the General Payments report?
- Which Medical Publication Support Services are considered reportable?
- How are such services valued?
- How best to communicate reporting decisions internally and externally to agencies, vendors, and impacted covered recipient authors?



MEDICAL PUBLICATIONS SUPPORT



RESEARCH FAQ 8159

Question: Are payments for medical research writing and/or publication included in reporting research payments?

Answer: Under Open Payments, a payment reported as research falls within a research payment category if it is subject to either: 1) a written agreement; 2) a contract; or 3) a research protocol. Payments for medical research writing and/or publication would be included in the research payment, if the activity (here, medical research writing/publication) was included in the written agreement or research protocol and paid as a part of the research payment.



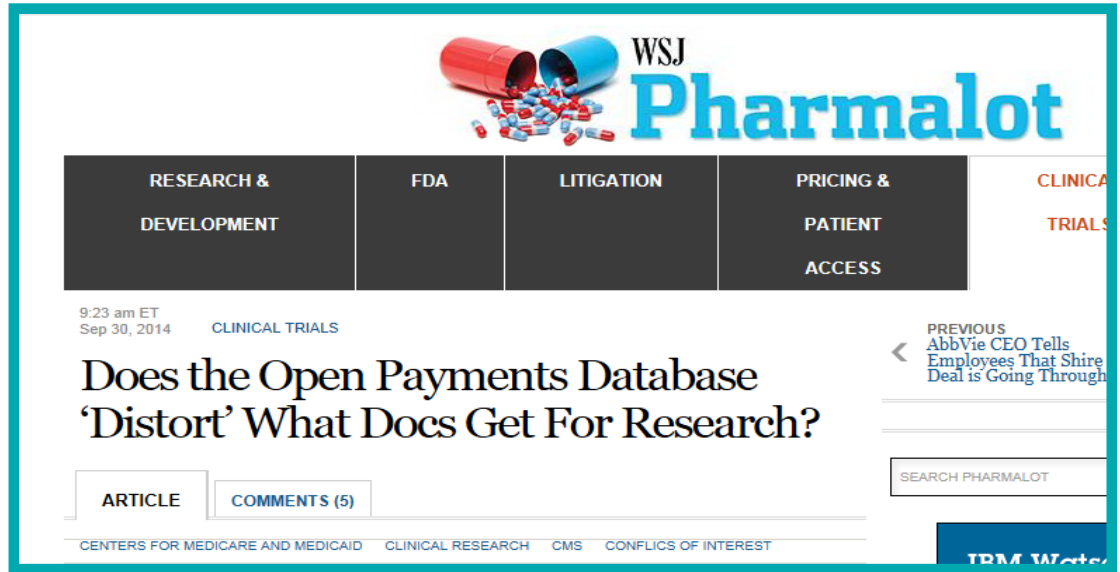
OPEN PAYMENTS

In-depth review

Open Payments

"[T]hree bioethicists and a professor of medicine and pharmacology – argue this stipulation creates a 'distorted' image of the money that doctors may receive, because it does not break out a value assigned to medicines that companies provide for the research."

"Donated drugs are intended for use by patients and do not provide direct monetary value to physician-investigators. The Physician Payment Sunshine Act rules cloud this critical distinction..."



The screenshot shows the WSJ Pharmalot website interface. At the top, there are navigation tabs for RESEARCH & DEVELOPMENT, FDA, LITIGATION, PRICING & PATIENT ACCESS, and CLINICAL TRIALS. The main article title is "Does the Open Payments Database 'Distort' What Docs Get For Research?". Below the title, there are buttons for "ARTICLE" and "COMMENTS (5)". A search bar is visible on the right side. The date and time of the article are 9:23 am ET, Sep 30, 2014.



The screenshot shows a Business Day article titled "Detailing Financial Links of Doctors and Drug Makers" by Katie Thomas, Agustin Armendariz, and Sarah Cohen, dated Sept. 30, 2014. The article text states: "Pharmaceutical and device makers paid doctors roughly \$380 million in speaking and consulting fees, with some doctors reaping over half a million dollars each, during a five-month period last year, according to an analysis of federal data released Tuesday. Other doctors made millions of dollars in royalties from products they helped develop. The data sheds new light on the often murky financial ties between physicians and the health care industry. From August to December". On the left side, there are social sharing options for Email, Share, Tweet, and Save. On the right side, there is a partial view of another article titled "REVOC" and "FULLY L & DIRE".

Open Payments

Top News Stories About the CMS Open Payments Database

"The Centers for Medicare and Medicaid Services (CMS) recently held a webinar for biopharmaceutical and medical technology companies to discuss the process behind the removal of 1.7 million records of data from the Open Payments database."



[Orphan Drugs Had A Bump 2014, Including Unprecedented Approval Rates](#) | [Main](#) | [Medtronic Subsidiary's 2 Pairs \\$1.25 Billion to Settle Litigation Related To Promethin](#)

February 23, 2015

→ Market Research and the Physician Payments Sunshine Act: Has Physician Participation Declined Due To Open Payments?



The market research space is an interesting one as far as Sunshine reporting is concerned because it implicates many of the same challenging "indirect payment" issues we have seen related to continuing medical education (CME). This article describes a number of those reporting challenges and also looks at a recent survey that sought to measure physicians' current awareness of Open Payments and to assess the impact the release of the data was having on physician participation in manufacturer sponsored market research.

Market Research and Sunshine – Indirect Payments and the Indirect Payment Exclusion

One of the most difficult aspects of compliance with the Sunshine Act is accounting for "indirect payments" that pharmaceutical and device manufacturers make to third parties—such as market research firms—that end up going to physicians (covered recipients).

Indirect payments are defined in the Sunshine regulations as transfers of value made by a manufacturer to a covered recipient through a third party, where the 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."

Dialogues +

News & Commentary about the Sunshine Act

12.16
2014

CMS Webinar: 1.7 Million Payment Records Removed from Open Payments Database

The Centers for Medicare and Medicaid Services (CMS) recently held a webinar for biopharmaceutical and medical technology companies to discuss the process behind the removal of 1.7 million records of data from the Open Payments database. The webinar was hosted by Doug Brown, Deputy Director of the Data Sharing & Partnership Group in the Center for Program Integrity at CMS.

In September, after a physician using the Open Payments database discovered that he could view payments made to a different physician with the same name, CMS took the database offline and eventually returned inconsistent data to companies for review. While this data was published in the Open Payments database on September 30, it was published as "de-identified" data. Companies are now required to correct this data and resubmit it to CMS by March 31 of next year.

The main reasons cited for data being returned to companies were related to inconsistencies with physician identification, such as a license number not matching a National Provider Identifier number, which comes from a national database of physicians, or a physician's name and addresses not matching external sources.

CMS has offered up two main solutions to these issues. First, CMS has compiled a master list of physicians with their correct information. These physicians have already been verified for use in the Open Payments system, ensuring that companies will be able to successfully submit data about these physicians to Open Payments. While this master list does not include all physicians, it does provide companies a starting point when working on future data submissions. Second, in early 2015, CMS will begin using a new series of tools to match and verify physician information.

"In implementing the Sunshine law, the Centers for Medicare and Medicaid Services (CMS) decided to create an "ongoing" awareness standard. Thus, indirect payments are only excluded if the manufacturer does not find out the identity of the covered recipient during the reporting year or by the end of the second quarter of the following reporting year." CMS specifies that manufacturers may not act in "deliberate ignorance or reckless disregard" of a physicians' identity."

Open Payments

Top News Stories About the CMS Open Payments Database

- More Than \$1B In Payments To Doctors Is Excluded From Sunshine Database, *The Wall Street Journal*, October 7, 2014
- Physician Payments Sunshine Act: Majority of Transactions in Open Payments Are Less Than \$20, *Policy and Medicine*, October 7, 2014
- So Much for Transparency: Open Payments Database Toggles the Mind, *The Wall Street Journal*, October 2, 2014
- Is Your Doctor Being Paid By Pharma? That Could Be Good., *Forbes*, October 1, 2014

10.21

2014

Top News Stories About the CMS Open Payments Database

by Partners for Healthy Dialogues

What have we learned about CMS' Open Payments database in the last three weeks? Check out the top news stories for everything you need to know about the Sunshine Act, the database release and why sufficient context is necessary to understanding the value of collaboration.

More Than \$1B In Payments To Doctors Is Excluded From Sunshine Database, *The Wall Street Journal*, October 7, 2014

What isn't in the Open Payments database? Payments related to ongoing research on medicines and medical devices that are still being developed, tested and approved and some payments that are in the process of being corrected.

Physician Payments Sunshine Act: Majority of Transactions in Open Payments Are Less Than \$20, *Policy and Medicine*, October 7, 2014

With payments ranging from clinical trials to lunch, *Policy and Medicine* took a look at the Open Payments data and found that approximately 65% of the payments reported under the Sunshine Act were for less than \$20 dollars.

So Much for Transparency: Open Payments Database Toggles the Mind, *The Wall Street Journal*, October 2, 2014

How easy can you use the Open Payments database? *The Wall Street Journal* highlights some key technical issues with the database.

Is Your Doctor Being Paid By Pharma? That Could Be Good., *Forbes*, October 1, 2014

When looking at the Open Payments database, context is key. Payments in the



Open Payments

What is it?

- Open Payments gives the public more information about the financial relationships between physicians and teaching hospitals and applicable manufacturers and GPOs. Specifically, the program:
 - Encourages transparency about these financial ties
 - Provides information on the nature and extent of the relationships
 - Helps to identify relationships that can both lead to the development of beneficial new technologies and wasteful healthcare spending
 - Helps to prevent inappropriate influence on research, education and clinical decision making

Open Payments

go.cms.gov/openpayments

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Open Payments

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View the Data

[Download Open Payments Datasets](#)
[View Open Payments Data in the Data Explorer Interface](#)
[Instructions for Searching with the Data Explorer](#)

Connect and Engage

Sign up for email updates, follow the [#openpayments](#) conversation on Twitter, and send us your feedback.
Contact the Help Desk:
1-855-326-8366

How Open Payments Works

View the complete Open Payments data collection and publication lifecycle.



Open Payments

Sometimes, doctors and hospitals have financial relationships with health care manufacturing companies. These relationships can include money for research activities, gifts, speaking fees, meals, or travel. The Social Security Act requires CMS to collect information from [applicable manufacturers and group purchasing organizations \(GPOs\)](#) in order to report information about their financial relationships with physicians and hospitals. Open Payments is the federally run program that collects the information about these financial relationships and makes it available to you. To gain a deeper understanding of data published on September 30, 2014, [view our factsheet](#).



Explore the Data

Download all Open Payments data in detail. States can [create and download](#) custom data



Open Payments Data in Context

What is a conflict of interest?
What is nature of payment? [Learn](#)



Program Participants: Access the System

Physicians, teaching hospital representatives [applicable](#)

Open Payments

How it Works

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- Resources

How Open Payments Works



The law requires CMS to collect and display information reported by [applicable manufacturers](#) and [group purchasing organizations \(GPOs\)](#) about the payments and other transfers of value these organizations have made to [physicians](#) and [teaching hospitals](#). Between when the data are collected and publically displayed, [registered physicians](#) and [teaching hospitals](#) can review and, if needed, dispute payments reported about them. Data are then displayed on the public Open Payments website.

The first reporting period covers transactions from the last 5 months of 2013. Future reports will be published every year and will include a full 12 months of payment data. Data collected for each calendar year will be published in June of the following calendar year. For example, data that is submitted by applicable manufacturers and GPOs for the 2014 calendar year will be published in June, 2015.

Reference the [Data Overview](#) page to understand what data is and is not published on September 30, 2014.

Open Payment

Open Payments

How it Works



CMS.gov

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[Dataset Downloads](#)

[Data Explorer](#)

[Reports to States](#)

[Use the Search Tool on Identified Data
\(beta\)](#)

Additional Resources

[Data Dictionary and Methodology
Document](#)

[Fact Sheet on Published Data](#)

Explore the Data

There are three distinct ways for you to search the data that will help you learn more about the financial relationships between industry and physicians—use the search tool, visualize using the Data Explorer tool, and download the complete data set (see below). Gain a better understanding of what you will and won't see in these data sets by reviewing [this overview of the Open Payments data](#).



Search

Use the [search tool](#), now released in beta, to review identified data for physicians, teaching hospitals, or companies making payments by name, city, state, and specialty.



Visualize

Explore full data sets and create visualizations with this data exploration tool. [Learn how to access](#) and [use the tool here](#).



Download

Select a dataset and download the data in .csv format. [Download the data here](#).

Open Paymer

Open Payments

How it Works



OpenPaymentsData.CMS.gov [Sign In to OpenPaymentsData.CMS.gov](#)

[Conduct a Search](#) [Data Explorer](#) [About](#) [Download the Data](#) [Open Payments Home](#)

Search for a ... [Physician](#) [Teaching Hospitals](#) [Company Making Payments](#)

First Name	Last Name
City	State ▼
ZIP	Specialty

Please be patient, search results take a few moments to load. [Search](#)

For Best Search Results

This search tool only searches **identified data**. The datasets are large and the search tool searches millions of records. For some searches the results will take some time to load, please be patient.

Disclaimer: Data is reported on this website in accordance with the statutory authority in Section 1128 G of the Social Security Act. CMS has an impartial role in the collection and reporting of data regarding payments or other transfers of value pursuant to Open Payments. The transparency display of transactions from applicable manufacturers and group purchasing organizations to physicians and teaching hospitals does not necessarily mean any of the reported financial relationships are improper.

Open Payments

How it Works

OpenPaymentsData.CMS.gov

Research Payment Data with Identifying Recipient Information – Detailed Dataset 2013 Reporting Year

All research-related payments whose identifying data about the recipients, such as names, salaries, and specialty, are included.

Research_Transaction_ID	Program_Year	Payment_Publication_Date	Submitting_Applicable_Manufacturer_or_Applicable_GPO_Name	Covered_Recipient_Type
1	21	2013 08/08/2014	Musculoskeletal Transplant Foundation Inc.	Covered Recipient Physician
2	24	2013 08/08/2014	Musculoskeletal Transplant Foundation Inc.	Covered Recipient Teaching Hospital
3	29	2013 08/08/2014	Musculoskeletal Transplant Foundation Inc.	Covered Recipient Physician
4	32	2013 08/08/2014	Musculoskeletal Transplant Foundation Inc.	Covered Recipient Teaching Hospital
5	33	2013 08/08/2014	Musculoskeletal Transplant Foundation Inc.	Covered Recipient Physician
6	34	2013 08/08/2014	Musculoskeletal Transplant Foundation Inc.	Covered Recipient Teaching Hospital
7	36	2013 08/08/2014	Musculoskeletal Transplant Foundation Inc.	Covered Recipient Physician
8	44	2013 08/08/2014	Musculoskeletal Transplant Foundation Inc.	Covered Recipient Teaching Hospital
9	46	2013 08/08/2014	Musculoskeletal Transplant Foundation Inc.	Covered Recipient Teaching Hospital
10	47	2013 08/08/2014	Musculoskeletal Transplant Foundation Inc.	Covered Recipient Physician
11	50	2013 08/08/2014	Musculoskeletal Transplant Foundation Inc.	Covered Recipient Teaching Hospital
12	51	2013 08/08/2014	Musculoskeletal Transplant Foundation Inc.	Covered Recipient Physician
13	52	2013 08/08/2014	Musculoskeletal Transplant Foundation Inc.	Covered Recipient Physician
14	61	2013 08/08/2014	Musculoskeletal Transplant Foundation Inc.	Covered Recipient Teaching Hospital
15	55	2013 08/08/2014	Musculoskeletal Transplant Foundation Inc.	Covered Recipient Physician
16	61	2013 08/08/2014	Musculoskeletal Transplant Foundation Inc.	Covered Recipient Physician
17	58	2013 08/08/2014	Musculoskeletal Transplant Foundation Inc.	Covered Recipient Physician
18	61	2013 08/08/2014	Musculoskeletal Transplant Foundation Inc.	Covered Recipient Physician
19	64	2013 08/08/2014	Musculoskeletal Transplant Foundation Inc.	Covered Recipient Physician
20	65	2013 08/08/2014	Musculoskeletal Transplant Foundation Inc.	Covered Recipient Physician



Open Payments Data Summary

OPEN PAYMENTS DATA FACT SHEET

Table 1 provides a summary of the data in Open Payments system:

Table 1 Open Payments Data	
Categories	Total
Total value published on 12/19/2014	\$3.7 billion*
Total number of records published on 12/19/2014	4.45 million*
Total number of physicians published on 12/19/2014	366,000* ⁺
Total number of teaching hospitals published on 12/19/2014	900 [^]
Total number of applicable manufacturers and applicable group purchasing organizations (GPOs) represented in the published data on 9/30/2014	1,228 (1,419 total registered)
Total number of applicable manufacturers and applicable GPOs represented in the published data on 12/19/2014	1,303

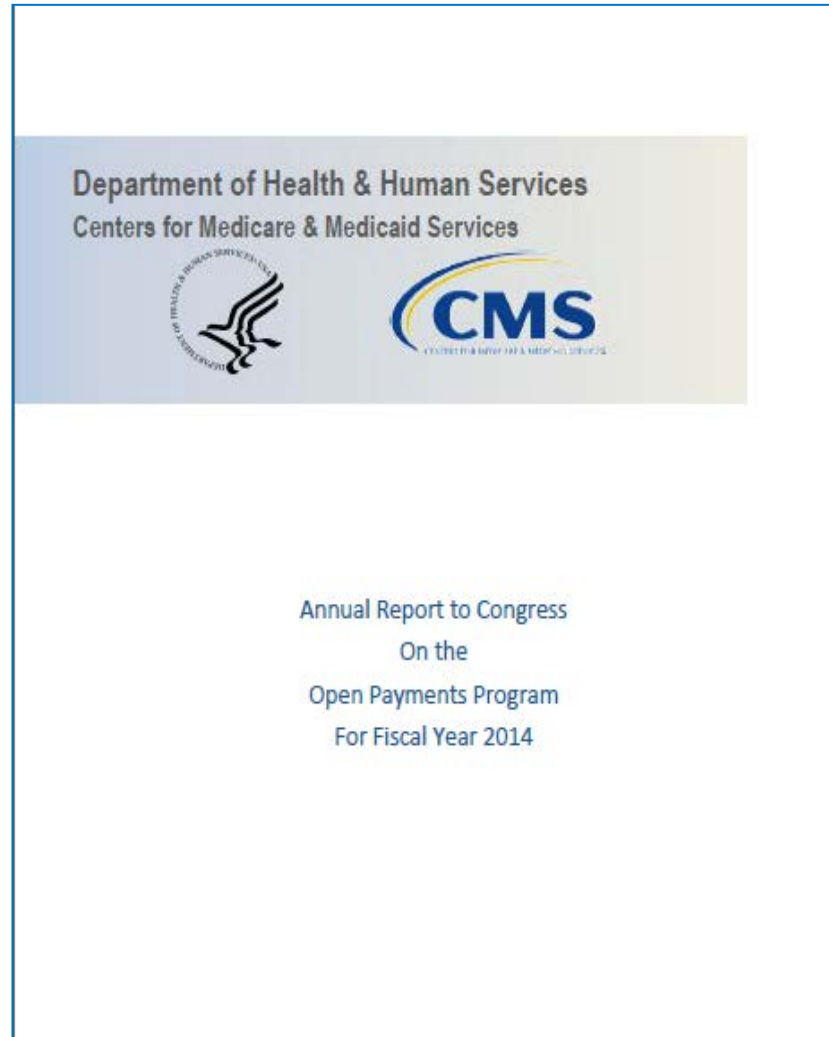
* rounded

+ up to 546,000 (rounded) based on possible physician identifier inconsistencies within de-identified data

[^] up to 1,360 (rounded) based on possible teaching hospital identifier inconsistencies within de-identified data

Open Payments

Report to Congress Released April 2015





Open Payments Delay in Publication

Table 5: Open Payments Data Not Published on 12/19/2014 (due to delay in publication requests)**

Categories	Total
Value of records	\$551 Million*
Number of records	190,000*

* rounded
** The Open Payments final rule §403.910 provides applicable manufacturers and GPOs the opportunity to request a delay in publication for a period not to exceed four calendar years after the date the payment or other transfer of value was made, or upon the approval, licensure or clearance of the covered drug, device, biological, or medical supply by the FDA. Publication of research payment records may be delayed by submitter request if the records relate to research or development of a new drug, biological, device, or medical supply; a new application of a drug, biological, device, or medical supply; or clinical investigations regarding a drug, biological, device, or medical supply.



Open Payments

Disputed and Affirmed Data

Table 6: Review and Dispute Summary

Categories	Data Published 9/30/2014
Number of physicians that registered in Open Payments system to review and dispute	26,000*
Number of teaching hospitals that registered Open Payments system to review and dispute	405
Number of records that were disputed	12,579
Number of unresolved disputes at the end of review period	9,000*
Number of records that were affirmed	17,994**
* Rounded	
** "Affirmed" indicator signifies that the covered recipient associated with the reported record has reviewed it and agreed with its accuracy.	



Open Payments

Future System Enhancements

Table 7. Summary of System Enhancements

Participant Group	System Area: Enhancement
Physicians & Teaching Hospitals (Voluntary)	<ul style="list-style-type: none"> • Registration: Physicians cannot edit first name, last name, or NPI after vetting is successful. • Registration: E-mails will now be sent to physicians regarding status of vetting process. • Review and Dispute: Principal investigators will now have the ability to review research records attributed to them and dispute their association with the reported payment. All other details such as payment amount, date, nature of payment, can only be disputed by the covered recipient.
Manufacturers & GPOs (Required)	<ul style="list-style-type: none"> • Data Submission: Validated Physician List now available, along with annually-published Teaching Hospital List. • Data Submission: Deleting records will trigger re-attestation. • Data Submission: “Unmatched” records are treated as validation errors and cannot be overridden. • Data Submission: XML is no longer an accepted bulk data file format.
All program participants (Required and Voluntary)	<ul style="list-style-type: none"> • Registration: Special characters are now allowed in physician and entity names and state license numbers. • Data Submission: Enhanced data matching for submitted records. • Review and Dispute: “Delay in Publication” status is now visible on Review Records page.

Open Payments

Example of Lookup

Figure 4. Example Company Making Payment Search: Summary Information (Search Too

For Illustrative Purposes Only



Open Payments

Sample of Data Reported to Congress

Name of Applicable Manufacturer & Applicable Group Purchasing Organization Making Payment	Dollar Amounts				Number of Transactions				Number of Physicians	Number of Teaching Hospitals
	General Identified	Research Identified	Investment Identified	Interest Identified	General Identified	Research Identified	Investment Identified	Interest Identified		
.DECIMAL	\$1,254				1				1	0
3M COMPANY	\$437,863	\$48,060			2,820	5			2,119	2
4WEB, INC.	\$4,800	\$25,000	\$524,991	\$1,403,067	24	1	4	4	22	1
AAREN SCIENTIFIC INC.	\$782				2				2	0
ABB CON-CISE OPTICAL GROUP LLC	\$20,388				648				517	0
ABBOTT LABORATORIES	\$2,830,143	\$440,573			8,922	137			4,657	85
ABBVIE, INC.	\$8,034,886	\$669,998			66,598	86			27,315	64
ABEON MEDICAL CORPORATION	\$916				1				1	0
ABIOMED	\$249,068	\$305,279			1,016	55			607	18
ABL MEDICAL, LLC	\$31,581				36				35	1
ACCEL SPINE, LLC	\$17,961				20				12	0
ACCESS CLOSURE, INC	\$13,879	\$8,439	\$3,101,323	\$1,766,962	420	5	41	41	456	0
ACCLARENT, INC	\$446,602	\$9,069			3,379	5			1,685	2
ACCURAY INCORPORATED	\$59,083	\$704,510			108	9			52	10
ACE SURGICAL SUPPLY CO., INC.	\$4,777				30				23	0
ACORDA THERAPEUTICS, INC	\$1,025,927	\$738,877			1,297	10			283	9
ACTAVIS PHARMA INC	\$820,098	\$62,431			11,094	10			5,250	7
ACTELION CLINICAL RESEARCH, INC.	\$11,788	\$520,143			9	181			53	0
ACTELION PHARMACEUTICALS US, INC.	\$801,014	\$1,180,653			6,541	80			3,776	12
ACTELION PHARMACEUTICALS, LTD	\$161,627	\$202,688			118	25			37	0

2015 Federal Reporting Timeline



1/2015
CMS Open Payments
System Down

4/3/2015
Data Submission Ends

5/2015 – 6/2015
Correction Period for
Industry

2/2/2015
Data Submission
Begins

4/6/2015 – 5/20/2015
Review and Dispute
Period (45 days)

6/30/2015
Data Publicly
Available



The Sunshine Act: Benchmarking

- How is industry handling?
 - Following release of ISMPP Suggestions document, industry evaluating scope of activities deemed reportable and the valuation of methodology to apply.
 - To date, little CMS guidance.
 - For Companies reporting publication support services:
 - Scope of activities reportable and valuation methodologies differ
 - Intend to document decision in Assumptions document
 - Capturing all publication support services
 - Available if company modifies its approach, CMS issues formal guidance, or corrections are necessary following dispute resolution period.

PTOV INTERPRETATIONS AS THEY RELATE TO MEDICAL PUBLICATIONS*

Interpretation	Proposed Rationale
<p>Yes, support for medical publications is a reportable TOV</p>	<p>There is a TOV associated with support provided by an AM to authors who are CRs for work that authors would have had to perform or secure for themselves if the AM had not provided the support</p>
<p>No, support for medical publications is not a reportable TOV</p>	<p>The value of the support provided by AMs to CR authors is to the AMs, as it helps the AMs meet their ethical obligations to publish their data in a timely manner; there is no value to be transferred to authors</p>
<p>Support for publications may be a reportable TOV, depending on the circumstance</p>	<p>Examples</p> <p>Original research: The value of the support provided by AMs to CR authors is to the AMs, as it helps the AMs meet their ethical obligations to publish their data in a timely manner; there is no value to be transferred to authors</p> <p>Reviews; author-initiated request for help: The value of the support provided by AMs to CR authors is to the CRs; the reportable TOV is for the work that authors would have had to perform or secure for themselves if the AM had not provided the support</p>

*Based on differing interpretations by industry companies, there may be other categories of interpretation that are not captured above. Content courtesy of ISMPP Sunshine Act Taskforce Update released February 21, 2014.



Individual project basis

- Total cost of publication support divided by number of authors
- Internal/company and ex-US authors included in the calculation, but TOV for these authors is not reportable

Average fair market value

- Sum of average costs by publication type divided by average number of authors on that publication type
- Could include average costs for internal or external medical writing, statistical support, congress/journal submission fees, and other costs deemed reportable by the AM
- Important to use a representative sample size



Include Work That an Author Would Most Likely Do

Time CR would spend

- Write and submit abstract or manuscript
- Develop oral or poster presentation following abstract acceptance
- Manage review process with multiple authors, incorporate comments, make revisions and create graphics

Direct cost

- Statistical analyses and support specifically for the publication
- Journal submission costs

Do Not Include the Work That an Author Most Likely Would Not Do

Time for tasks performed by AM or agency

- Develop contracts or author agreements
- Develop timelines, time tracking, general project management
- Information management (eg, publication planning database input, financial tracking, status reports)
- Status meetings
- Provide authors with information on GPP



Open Payments

Types of Reports

General Payments

- Includes payments and transfer of value given to a covered recipient (physicians, teaching hospital)
- Includes payments made to group practices, other individuals or entities on behalf of a covered recipient

Research Payments

- Includes all payments and transfers of value made in connection with an activity that meets the definition of research and that are subject to a written agreement or research protocol

Physician Ownership and Investment Interest

- Any ownership or investment interests held by a physician or immediate family member in a manufacturer or GPO
- Includes stocks, stock options, dividends, profits or other return on investment



The Sunshine Act: General or Research?

- Are companies reporting medical publication support on their General Payments or Research Payments Report?
- Research Payments
 - If part of research agreement or protocol
 - Aggregated with larger research payment if appropriate
 - Could be subject to delayed disclosure depending on nature of study
- General Payments
 - If not part of research agreement or protocol



OPEN PAYMENTS

Data Submission



Open Payments:

Data Submission

- The Open Payments System will allow:
 - Applicable manufacturers/GPOs to submit an assumptions document with their assumptions and methodologies when reporting payments or other transfers of value, or ownership or investment interests
 - Assumptions documents are voluntary
 - It will not be made available to the public, covered recipients or physician owners or investors, however, according to CMS, “we do not intend to use the assumptions document for prosecution, but acknowledge that the reporting based on the assumptions would be open to prosecution. Other HHS divisions, the Department of Justice (DOJ), or the Office of the Inspector General (OIG) could request access to the documents as part of an audit or investigation into an applicable manufacturer or applicable GPO.”
 - Provides CMS with information to help identify areas where additional guidance and clarity is needed
 - If a statement within the assumptions document pertains to a particular section of the report, applicable manufacturers should explicitly refer to that section in the assumptions document
 - Assumptions cannot be longer than 4,000 characters (including spaces).



Open Payments: Data Submission

Correcting Records

Users can edit previously submitted records as a result of a validation error, matching error, dispute, or general correction. For instructions on how to identify and correct validation and matching errors, refer to the “Open Payments System Quick Reference Guide – Identifying and Correcting Validation and Matching Errors.” Note that if a re-submitted record changes the covered recipient, the original physician or teaching hospital will no longer see the record in his or her profile; only the new physician or teaching hospital will see it.

How to Correct Records via Bulk File Upload

Users who want to correct records submitted via bulk data file upload should follow the instructions below.

1. Correct the data elements individually in the bulk data file.
 - If corrections are being done to address validation or matching errors, make sure all errors listed in the Error Report are corrected prior to re-submitting the bulk file. Refer to the “Open Payments System Quick Reference Guide – Identifying and Correcting Validation and Matching Errors” for more information on accessing and interpreting the Error Report.



OPEN PAYMENTS

Dispute & Corrections



Open Payments:

Review & Dispute Period (Began April 6, 2015)

- **45-Day Review and 15-Day Correction Period**
 - CMS will notify provide notification to manufacturers, GPOs and covered recipients when the data is ready for review.
 - Covered Recipients and Physician Owners may review data and initiate a dispute during the 45-day period.
 - If a dispute is resolved within the 45 days or the extra 15 days following the 45-day review period, CMS will publish the corrected data.
 - If a dispute in the data cannot be resolved within 15 days following the 45 day review period, CMS will post the manufacturer's data as submitted and mark it as disputed.



Open Payments:

Communication & Disputes

- **CMS Dispute Process:**

- CMS will send out a notification when data is ready for review.
- Covered recipients log into a secure website to view data attributed to them.
- Covered recipients can initiate a dispute with the applicable manufacturer or GPO via the secured website
- Disputes must be resolved between the parties. Once a resolution is reached, CMS must be notified of the corrected data.
- CMS will update the website at least once annually with corrected information.



Open Payments:

Best Practices: Pre-Submission & Post-Submission

- **Being proactive: Considerations for pre-submission communications:**
 - Who will handle; what is the message?
 - When – periodic, annually, just before submission?
 - How – in the field, via mail, fax, email?
 - What is the process to handle inquiries and complaints?
- **Being responsive: Considerations for the dispute process:**
 - Who will handle – internal personnel, outside vendor?
 - How will you respond – via phone, in writing?
 - What documentation will you provide??
 - Internal training programs?



OPEN PAYMENTS

Takeways



Open Payments

What's the Deal?

- Technical Perspective
 - Certain amounts of data not accepted
 - Failed Validation and Failed Matching Validation Errors
 - U.S. vs. United States
- User Experience
 - Log-ins expired between reporting deadlines
 - Vetting process of C-series executives
- Unreliability of CMS Information
 - Inaccurate
 - Old
 - Accurate information bounced back
 - Inconsistent



The Sunshine Act:

The Real World

- Has publication of data affected public perception
- Are investigators or authors less willing to:
 - Accept assistance
 - Write articles
- How are companies addressing
 - In agreements with investigators or authors
- Disputes about these payments

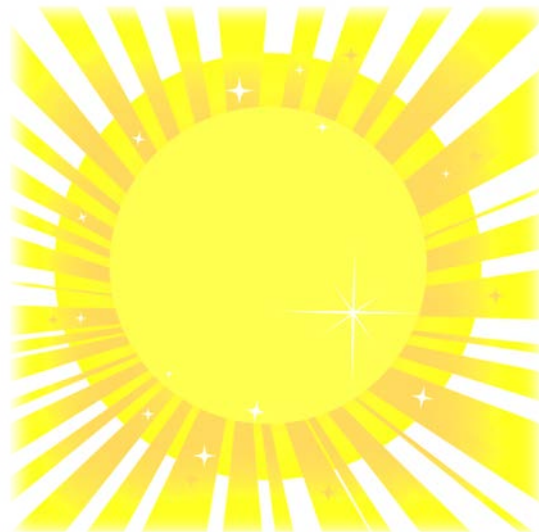


The Sunshine Act: Key Takeaways

- Identify...
 - Publication support services provided to covered recipients
- Determine...
 - Scope of publication support services deemed reportable
 - (and if such services are “included in the contract” research publication)
 - Valuation methodology to apply
- Capture...
 - All publication support services
 - (and identify the services deemed reportable)
- Communicate...
 - Reportability decision and valuation methodology internally and externally (vendors, agencies, and covered recipients)
- Develop...
 - Assumptions Document recording scope of reportable services and valuation methodology



Questions?



11TH ANNUAL MEETING OF ISMPP



**OPTIMIZING SCIENTIFIC VALUE:
SMART AND SYSTEMATIC APPROACHES
TO MEDICAL PUBLICATIONS**

April 27–29, 2015
Hyatt Regency Crystal City
Arlington, VA, USA





OPEN PAYMENTS

Background Information on Sunshine Act



The Sunshine Act: What is it?

- Subtitle A – Section 6002 – Transparency Reports and Reporting of Physician Ownership or Investment Interests (“The Sunshine Act”)
- The Sunshine Act requires applicable manufacturers and applicable Group Purchasing Organizations (GPOs) to report to CMS any direct or indirect payment or other transfer of value provided to a covered recipient or any payment provided to a third party on behalf of a covered recipient during a calendar year.



The Sunshine Act: What is it?

- **Key Term: Covered Recipient**

- Physicians

- Unless a physician is a **bona fide employee** of the applicable manufacturer reporting the payment, “Physicians” includes: (1) doctors of medicine and osteopathy, (2) dentists, (3) podiatrists, (4) optometrists, and (5) chiropractors.
- It **does not** include residents; however, it does include fellows.

- Teaching Hospitals

- Any institution that received a payment under 1886(d)(5)(B), 1886(h), or 1886(s) of the Act during the last calendar year for which such information is available.
- CMS will publish a list of teaching hospitals **90 days** prior to the start of data collection each year.



The Sunshine Act: What does it require?

- Applicable Manufacturers and GPOs must submit the following reports:
 - (1) Payment and Other Transfer of Value Report
 - Includes payments and transfer of value given to a covered recipient (physicians, teaching hospitals)
 - Includes payments made indirectly or on behalf of a covered recipient
 - Research-related payments must be reported separately
 - (2) Physician Ownership and Investment Interest Report
 - Any ownership or investment interests held by a physician, or immediate family member in a manufacturer or GPO
 - Includes stocks, stock options, dividends, profits or other return on investment



GENERAL PAYMENTS



General Payments

What is included in the report?

- **Name**
 - Middle initial required
 - From NPPES
- **Business address**
 - Primary* business address
- **Specialty**, for physicians
 - From manufacturers' internal records, using NPPES values
 - Include the taxonomy code
- **National Provider Identifier** ("NPI"), for physicians
 - From NPPES
- **State license number** and state of licensure of the recipient, for physicians
 - Up to five
- **Physician Owner or Investor Flag**
- **Amount**



General Payments

What is included in the report? (Continued)

- **Date**
 - Choose whether to report each payment as separate line item, or in the aggregate as a single line item using the first payment date as the reported date
 - Choose to report the activity date or payment date
 - Consistency within a “Nature” type
- **Form** – the method of the payment
- **Nature** – the reason for the payment
- **Recipient of payment**
 - Payment to a covered recipient as a pass through payment from a third party → report in the name of that covered recipient
 - Payment to a third party at the request of or designated on behalf of a covered recipient → report in the name of that covered recipient, and the name of the *entity* that received the payment or indicate “individual” if made to an individual
- **Product**
 - Drugs and biologicals: marketed name and the National Drug Code
 - Devices and medical supplies: marketed name, or the therapeutic area or product category
 - Also, “none” or “non-covered”
- **Contextual information** (optional)



General Payments

Nature of Payments

- Consulting fee
- Compensation for services other than consulting, including serving as faculty or a speaker at an event other than continuing education
- Honoraria
- Gift
- Entertainment
- Food and beverage
- Travel and lodging (including the City, State, Country)
- Education
- Charitable contribution
- Royalty or license
- Current or prospective ownership or investment interest
- Compensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program
- Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program
- Grant, or
- Space rental or facility fee (teaching hospitals only)



General Payments: Challenges

Indirect Payments

- Indirect payments or transfers of value are excluded where the applicable manufacturer is unaware of the identity of the covered recipient.
- If a manufacturer learns of the identity of the covered recipient during the reporting year or by the end of the second quarter of the following year, manufacturer “knows.”
- Know, Knowing or Knowingly:
 - Means that a person, with respect to information:
 - Has actual knowledge
 - Acts in deliberate ignorance of the truth or falsity of the information, or
 - Acts in reckless disregard of the truth or falsity of the information
 - Requires no proof of a specific intent to fraud

General Payments: Challenges

Indirect Payments

Reporting of Indirect Payment

Indirect Payment: The Sunshine Act defines an “**Indirect Payment**” as a payment provided to a covered recipient through an intermediary (e.g., a specialty society or research organization). The payment is considered indirect and reportable, if Applicable Manufacturers or GPOs:

- Requires, instructs, directs, or otherwise causes an intermediary to provide the payment or other transfer of value to a covered recipient.

Indirect Payment Example:




*Applicable Manufacturer or GPOs are required to identify each covered recipient who receives a payment or transfer of value, or any portion thereof, and report accordingly.



CMS FAQ8992: INDIRECT PAYMENTS

Question: Is a payment or other transfer of value considered indirect if an applicable manufacturer utilizes a market research company's services to conduct double-blinded market research with primary care physicians, which includes paying physicians for participating?

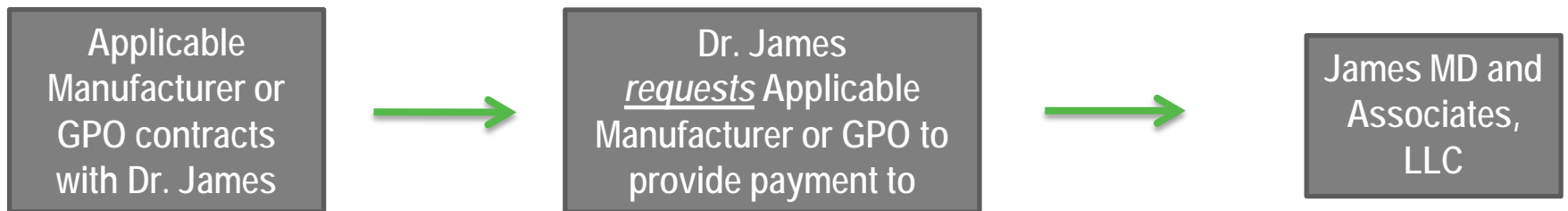
• **Answer:** No, a payment or other transfer of value provided to a market research company to conduct double-blinded market research with physicians is not considered an indirect payment. The applicable manufacturer clearly intends a portion of the payment to be provided to physicians, but given that the reason for the third party's involvement is specifically to maintain the anonymity of the respondents and sponsor, we do not intend this to be considered a reportable indirect payment or other transfer of value. Additionally, under section 1128G(e)(10)(A) of the Social Security Act, Open Payments excludes reporting of payments when an applicable manufacturer is unaware of the covered recipient, and the payment to the covered recipient is made indirectly through a third party, such as the market research company, in the above facts.



WHAT IS A THIRD-PARTY PAYMENT?

- **Third-Party Payment:** The Sunshine Act considers a payment provided to a third party at the request of or designated on behalf of a covered recipient to be a third party payment.
 - Report in the name of that covered recipient, and the name of the *entity* that received the payment or indicate "individual" if made to an individual

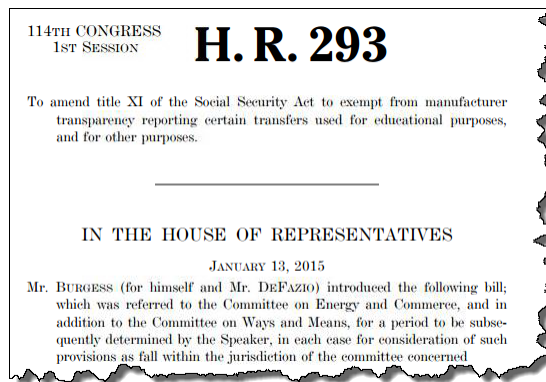
Example of Third-Party Payment:



In this example, the reporting will be made against Dr. James



BIPARTISAN BILL TO EXCLUDE EDUCATIONAL MATERIALS FROM REPORTING (CME and Medical Texts)



- Transparency Reports and Reporting of Physician Ownership or Investment Interests, Sec. 1128G. [42 U.S.C. 1320a-7h]
- (B) Exclusions.—An applicable manufacturer shall not be required to submit information under subsection (a) with respect to the following:
 - (iii) Educational materials that directly benefit patients or are intended for patient use, **including peer-reviewed journals, journal reprints, journal supplements, and medical textbooks;**
 - (xiii) **A transfer of anything of value to a covered recipient who is a physician if the thing of value is intended solely for purposes of providing continuing medical education to the physician.***

*Proposed amendments in **red** font.



RESEARCH PAYMENTS



Research Payments

Written Agreements/Research Protocols

- **The aggregated amount of any payments for services included in the written agreement/research protocol, which may include:**
 - Costs associated with patient care (e.g., diagnostics, exams, lab expenses)
 - Time spent by health care professionals treating patients and managing the study
 - Provision of study drugs, devices, biologicals, and medical supplies or other in-kind items
 - The payment amount should NOT include any payments for activities which are separate from the written agreement or research protocol or are paid through a method different than that of the research
- **Examples:**
 - Payments made directly to a physician for serving on a study steering committee or data monitoring committee that are not a part of the larger research payment should be reported separately.
 - Payments for medical research writing and/or publication would be included in the research payment, if the activity was included in the written agreement or research protocol and paid as a part of the research payment



Research Payments Reporting

- Payments or transfers of value made in connection with **research** that are subject to a written agreement **OR** research protocol are subject to special reporting requirements
- Includes payments and transfers of value related to pre-clinical, phases I through IV clinical studies, and investigator-initiated research

Research-related payments **must be reported** to **CMS** separately and include the following information:

- a. Name of the research institution, individual or entity receiving payment, and
- b. Total aggregate amount of the research payment
- c. Name of research study
- d. Name(s) of any related covered drug, devices, biological, or medical supplies and the National Drug Code(s)
- e. Indicate if eligible for delayed publication
- f. Optional: clinicaltrials.gov identifier
- g. Optional: Contextual information



Research Payments: Challenges

Delayed Publication

- Publication for research payments may be delayed in the following circumstances:
 - Payment is related to the research/development of new drug, device, biological, or medical supply, or a new application of an existing drug, device, biological, or medical supply.
 - Payment is related to a clinical investigation regarding a new product (drug, device, biological, or medical supply).
 - If the publication includes a written agreement and research protocol between manufacturer and covered recipient.
- CMS does not publicly post delayed payments until:
 - The date of FDA approval, licensure or clearance of the covered drug, device, biological, or medical supply, or
 - Four calendar years after the date of payment or other transfer of value was made.



Research Payments: Challenges

Delayed Publication

Table 4 provides a summary of data that was reported to CMS, but is not being published in the December 19, 2014 Open Payments data publication due to delay in publication requests:

Categories	Total
Value of records	\$551 Million*
Number of records	190,000*

* rounded

** The Open Payments final rule §403.910 provides applicable manufacturers and GPOs the opportunity to request a delay in publication for a period not to exceed four calendar years after the date the payment or other transfer of value was made, or upon the approval, licensure or clearance of the covered drug, device, biological, or medical supply by the FDA.



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