

CMS Open Payments Expansion

Impacts to Research Conflicts of Interest

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GOALS

1

Understand the CMS Open Payments program and what has changed under recent expansion

2

Explore how CMS Open Payments data may be used by regulators to identify and investigate high-risk industry-provider relationships

3

Discuss ways to integrate review of CMS Open Payments data in research conflicts of interest processes

2

WHAT IS CMS OPEN PAYMENTS?

PROGRAM EXPANSION
Open Payments expanded in 2021 to include five new covered recipient types. Visit the [Newly Added Covered Recipients](#) page for more information.
For information about changes for [Applicable Manufacturers and Group Purchasing Organizations](#), visit the [Changes for Reporting Entities](#) page.

A national disclosure program that promotes a more transparent and accountable health care system.

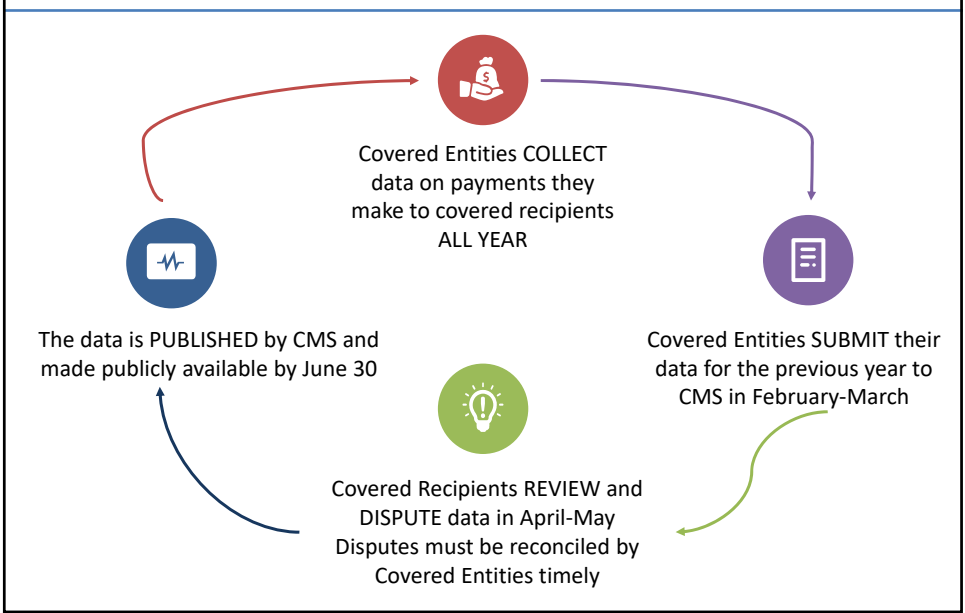
A publicly accessible database of payments made by entities such as drug and medical device companies to covered recipients like physicians

EXPANDED in 2021 to include more covered recipients and update reporting requirements!

<https://www.cms.gov/openpayments>

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HOW DOES IT WORK?



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WHO ARE “COVERED RECIPIENTS?”

BEFORE EXPANSION



US Physicians

e.g., Doctors of Medicine and Osteopathy, Dentists, Podiatrists, Optometrists, Licensed Chiropractors

AFTER EXPANSION



US Physicians PLUS

Physician Assistants, Nurse Practitioners, Clinical Nurse Specialists, Certified Registered Nurse Anesthetists & Anesthesiologist Assistants, Certified Nurse Midwives

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WHAT PAYMENTS ARE REPORTED?

PAYMENTS ARE REPORTED UNDER THREE MAJOR CATEGORIES



Research Payments



Ownership and Investment Payments



General Payments *includes* 15 SUBCATEGORIES

*Non-consulting
Consulting
Speaking for medical education program
Gifts
Long-term medical supply or device loan
Royalty or License*

*Entertainment
Food and beverage
Honoraria
Grant
Travel and lodging
Debt forgiveness*

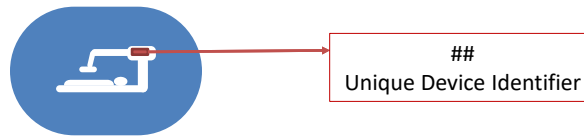
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WHAT NEW PAYMENTS ARE REPORTED?

Three NEW Nature of Payment Categories: Two Previous Categories Merged into One:



New Reporting Requirements for Medical Supplies and Devices:



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MORE ON RESEARCH PAYMENTS

Definition of Research

BEFORE EXPANSION

Research - Payments where the company making the payment has named a physician as the primary recipient

Associated Research - Payments to a research institution or entity where a physician is named as a principal investigator on the research project

<https://openpaymentsdata.cms.gov/summary>

AFTER EXPANSION

Research - Payments for different types of research activities, including the time a physician spends enrolling patients in studies for new drugs or devices. Research payments can include direct compensation to physicians, funding for research study coordination and implementation, or payments to study participants to cover expenses associated with the study.

<https://www.cms.gov/OpenPayments/Natures-of-Payment>

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WHY DOES IT MATTER?



Special Fraud Alert: Speaker Programs

November 16, 2020

I. Introduction

This Special Fraud Alert highlights the fraud and abuse risks associated with the offer, payment, solicitation, or receipt of remuneration relating to speaker programs by pharmaceutical and medical device companies. For purposes of this Special Fraud Alert, speaker programs are generally defined as company-sponsored events at which a physician or other health care professional (collectively, "HCP") makes a speech or presentation to other HCPs about a drug or device product or a disease state on behalf of the company. The company generally pays the speaker HCP an honorarium, and often pays remuneration (for example, free meals) to the attendees. In the last three years, drug and device companies have reported paying nearly \$2 billion to HCPs for speaker-related services.¹

[DHHS OIG Special Fraud Alert: Speaker Programs](#)

Department of Health and Human Services
OFFICE OF
INSPECTOR GENERAL

OPEN PAYMENTS DATA: REVIEW OF ACCURACY, PRECISION, AND CONSISTENCY IN REPORTING



Suzanne Martin
Deputy Inspector General
August 2018
OIG-43-15-0023

[OIG Review of CMS Open Payments](#)

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WHY DOES IT MATTER?

October 27, 2020

The Growing Role of Data Analytics in Healthcare Enforcement

McDermott Will & Emery

The US Department of Justice (DOJ) and US Department of Health and Human Services, Office of Inspector General (HHS-OIG) are increasingly relying on sophisticated data analytics tools to identify and investigate fraud schemes, particularly in the healthcare sector. DOJ's announcement of four new False Claims Act settlements and cases involving similar fraudulent billing schemes further demonstrates the effectiveness and importance of DOJ and HHS-OIG's data analytics programs. Healthcare companies should take steps to prepare for these data-driven enforcement actions and incorporate data analytics into their own compliance and audit programs.

DOJ and HHS-OIG's increased use of data analytics has already led to a significant rise in the number of federal FCA cases initiated directly by DOJ as opposed to via *qui tam* whistleblower complaints. DOJ initiated 100 more FCA cases in 2020 than it did in 2019, resulting in the most non-*qui-tam* FCA cases filed in almost 30 years. The number of data-driven FCA fraud investigations will likely continue to increase, particularly as the government continues to investigate potential fraud associated with the CARES Act, the Provider Relief Fund and the COVID-19 pandemic.

"The US Department of Justice (DOJ) and US Department of Health and Human Services, Office of Inspector General (HHS-OIG) are increasingly relying on sophisticated data analytics tools to identify and investigate fraud schemes, particularly in the healthcare sector."

*"DOJ initiated 100 more FCA cases in 2020 than in 2019, resulting in the most non-*qui-tam* FCA cases filed in almost 30 years"*

<https://www.jdsupra.com/legalnews/the-growing-role-of-data-analytics-in-9919389/>

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WHY DOES IT MATTER?



The screenshot shows the Excella website header with navigation links: Capabilities, Markets, Insights, Careers, About, and ATX Event Space. The main content area features the headline "Excella Awarded \$23.9M Contract to Expand Support for the HHS OIG" and a sub-headline "Excella to Expand HHS Contract to Include Combating Fraud, Waste, and Abuse Across All HHS Programs". To the right is the official seal of the U.S. Department of Health and Human Services Office of Inspector General. Below the article is a URL: <https://www.excella.com/news/excella-awarded-contract-to-expand-support-for-hhs-oig>

Excella will help integrate both internal and external data sources and support new tools for data management and data analytic processes. This includes data from the CMS Integrated Data Repository including Medicare, Medicaid and Open Payments data.

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WHY DOES IT MATTER? – STARK/ANTI-KICKBACK



The screenshot shows the header of the United States Department of Justice website, specifically the Northern District of Texas office. The navigation menu includes: HOME, ABOUT, NEWS, U.S. ATTORNEY, DIVISIONS, PROGRAMS. The breadcrumb trail reads: U.S. Attorneys » Northern District of Texas » News. The main heading is "Department of Justice U.S. Attorney's Office Northern District of Texas" with a "SHARE" button. The release is dated "FOR IMMEDIATE RELEASE Thursday, January 25, 2018". The title of the release is "Laboratory and Owner of Lab Management Services Company to Pay \$3.77 Million to Resolve Kickback and Medical Necessity Claims".

The relators alleged several kickback schemes, including a scheme where the defendants created the appearance of paying physicians to provide clinical study data for a **Primex-sponsored study related to pharmacogenetic testing** when, in fact, the physicians were being paid for referring patients for the testing.

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WHY DOES IT MATTER? – STARK/ANTI-KICKBACK

United States Department of Justice

THE UNITED STATES ATTORNEY'S OFFICE
EASTERN DISTRICT of PENNSYLVANIA

HOME ABOUT EXECUTIVE OFFICE NEWS DIVISIONS RESOURCES

U.S. Attorneys » Eastern District of Pennsylvania » News

Department of Justice
U.S. Attorney's Office
Eastern District of Pennsylvania

FOR IMMEDIATE RELEASE Wednesday, May 19, 2021

French Medical Device Manufacturer to Pay \$2 Million to Resolve Alleged Kickbacks to Physicians and Related Medicare Open Payments Program Violations

The federal settlement resolves allegations that Medtronic (which Medtronic USA Inc., recently acquired) provided items of value in the form of meals, alcoholic beverages, entertainment, and travel expenses to U.S.-based physicians at events surrounding the Scoliosis Research Society's September 2013 Congress in Lyon, France.

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WHY DOES IT MATTER? – FALSE CLAIMS ACT

THE UNITED STATES DEPARTMENT of JUSTICE

ABOUT OUR AGENCY TOPICS NEWS RESOURCES CAREERS

Home » Office of Public Affairs » News

JUSTICE NEWS

Department of Justice
Office of Public Affairs

FOR IMMEDIATE RELEASE Tuesday, February 1, 2022

Justice Department's False Claims Act Settlements and Judgments Exceed \$5.6 Billion in Fiscal Year 2021

Second Largest Amount Recorded, Largest Since 2014

"Of the more than \$5.6 billion in settlements and judgements reported by the Department of Justice this past fiscal year, over \$5 billion relates to matters that involved the health care industry..."

HEALTH CARE INDUSTRY
OVER \$5 BILLION IN
SETTLEMENTS AND
JUDGEMENTS



ALL OTHERS
Less than \$6 million in
settlements and
judgements

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WHY DOES IT MATTER? – FALSE CLAIMS ACT

JOSE M BASELGA
 Allopathic & Osteopathic Physicians | Internal Medicine | Medical Oncology
 1275 YORK AVENUE
 MEMORIAL SLOAN - KETTERING CANCER CENTER
 NEW YORK, NY 10065

Are you this physician? [Review or dispute your reported data](#)

Address shown may reflect one of the following: practice location, hospital affiliation, or third party that may be found in the [NPI Registry](#).

General Payments by Nature of Payment in 2020

What are the different natures of payment?

Nature of payment	Amount (%)	Payments
Compensation for services across the...	\$25,357.20 (100.0%)	1

Top Companies Making General Payments in 2020

Display as: [Bar Chart](#) [Table](#)
 Use the Table view to see more details.

Totals by payment type in 2020

What are the different payment types?

Payment type	Amount	Count
General payments	\$25,357.20	1 (payments)
Research payments	\$2,405.58	1 (payments)
Associated research funding	\$19,058.07	1 (payments)
Ownership and investment interest	N/A	

List of General Payments in 2020

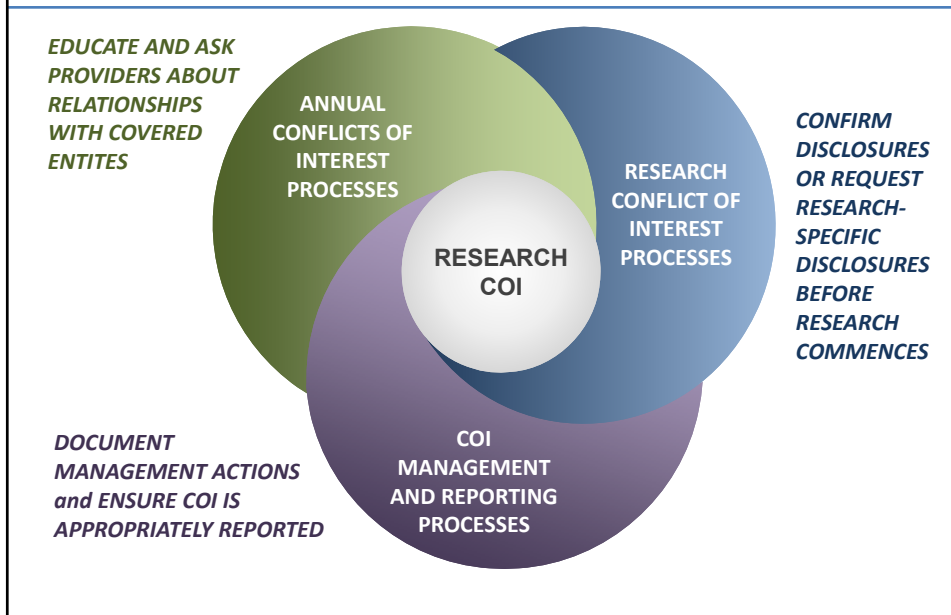
Showing 1 - 1 of 1

Company making payment	Nature of payment	Date	Total amount
Bristol Myers Squibb Company	Compensation for services other than consulting, including serving as faculty or as a speaker at a venue other than a continuing education program.	11/17/2020	\$25,357.20

<https://openpaymentsdata.cms.gov/physician/223663>

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USING CMS DATA IN RESEARCH COI PROCESSES



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ANNUAL COI PROCESSES

01
Review your COI Policies and Code of Conduct to make sure you set clear standards regarding relationships with vendors

03
Review CMS Open Payments data for covered recipients who work at your organization.



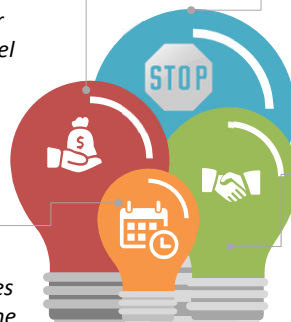
02
Explicitly ask about relationships, financial and non-financial, with start-up companies as well as drug and device companies.

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RESEARCH COI PROCESSES

03
Check CMS Open Payments data for the PI as well as for any other research personnel who are covered recipients.

01
Request updated disclosures from researchers at the time of proposal or protocol submissions.



04
Do not allow research to commence until disclosures are made, reviewed, managed and, if applicable, reported.

02
Consider a study-specific COI disclosure process which asks explicitly about relationships with the sponsor of the research (supplemental to the annual COI disclosure).

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MANAGEMENT AND REPORTING PROCESSES

DOCUMENTATION

Document how research COIs are identified, mitigated, managed, or eliminated. (e.g. COI Management Plans)

PHS REPORTING

Report identified research COI to PHS as appropriate
[42 CFR 50.605](#)
[Management and Reporting of financial conflicts of interest](#)

DISCLOSURES

Make sure expectations for disclosures in publications or presentations are documented and that researchers are appropriately trained on these.



FDA REPORTING

Ensure investigators report COI as appropriate on the [FDA 3455 Form](#)

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GENERAL GOOD PRACTICE



- 1 Do not treat conflict of interest as wrong-doing ... unless it is
- 2 Make sure organizational expectations, prohibitions, thresholds, and enforcement actions pertaining to relationships with drug and pharmaceutical companies are clearly articulated and disseminated
- 3 Include research COI and integrity, and expectations for relationships with drug and device companies (and other covered entities), in annual compliance training

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QUESTIONS?



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