

BUILDING YOUR TOOLBOX TO MANAGE CONFLICT OF INTEREST: SUNSHINE, OPEN PAYMENTS, AND INVESTIGATIONS

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Presented by

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Agenda

- Explore the key points of the Sunshine Act
- Explain Industry's approach to "Sunshine" reporting and the Open Payments lifecycle
- Leverage your resources to conduct meaningful investigations when data doesn't match

SUNSHINE ACT

Key Points

Purpose

- Promote transparency in financial interactions between pharmaceutical and medical device companies and certain healthcare providers
- Created by the Affordable Care Act

Mandate

- Manufacturers of a drug, device, biological or medical supply covered under Medicare, Medicaid or the Children's Health Insurance Program must report most payments or other transfers of value made to a covered recipient (i.e., physicians and teaching hospitals)
- Applies only to manufacturers
- Transactions reported involve teaching hospitals and physicians

Reporting

- Manufacturers must annually register and submit reports to the Centers for Medicare & Medicaid Services (CMS) by 90 days after calendar year end
- Separate reports for general transfers of value and research transfers of value
- Annual reports cover transfers of value made in the preceding calendar year

Review Process

- Manufacturers *and* covered recipients have 45 days to review information through secure website prior to public disclosure
 - Covered recipients register to review manufacturer submissions
- Reviewers may indicate agreement/disagreement with information posted
- CMS will not arbitrate disputes between manufacturers and covered entities
- If dispute not resolved, CMS will post information as reported by manufacturer but note that information is in dispute

Penalties for Non-Compliance

- Failure to Report: Civil money penalty from \$1,000 to \$10,000 for each unreported transfer of value up to \$150,000
- Knowing Failure to Report: Civil money penalty from \$10,000 to \$100,000 for each unreported transfer of value up to \$1,000,000

Corrections

- Manufacturers must report discovered errors or omissions in information submitted immediately
- CMS notifies affected covered recipients and updates website posting annually
- CMS may undertake interim "refreshes" of data posted

Documentation

- Manufacturers must maintain all records sufficient to enable audit of compliance with reporting requirement
- Records mentioned for at least 5 years from date that transfer of value is publicly posted not date that transfer of value is reported

Covered Recipients

- Physicians
 - Licensed physician, osteopath, dentist, dental surgeon, podiatrist, optometrist, or chiropractor
 - Legally authorized to practice medicine
 - U.S. or U.S. territory (Puerto Rico, Virgin Islands, Guam and American Samoa) even if living abroad
- Excludes:
 - Employee of manufacturer
 - Residents
- Teaching Hospitals
 - Any institution receiving Medicare direct or indirect graduate medical education payments
 - CMS posts list annually on Open Payments website and manufacturers may rely on that list...or can they?

Types of Reporting Requirements

| | |
|-------------------|--|
| Research Payments | Payments or other transfers of value if (1) made in connection with "research" and (2) protocol or written agreement |
| General Payments | All other transfers of value |

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Research Transfers of Value

- Manufacturers must track and report the following information for research transfers of value related to clinical research:
 - Name of individual/entity directly receiving the transfer of value
 - Physician: Name, business and email addresses, National Provider Identifier (NPI), state license number and state, specialty (as per the taxonomy and code in National Plan and Provider Enumeration System (NPPES)) and type of medicine practiced (M.D., D.O., D.P.M., O.D., or D.C.P.)
 - Teaching Hospital: Name, business and email addresses, TIN and NPI (if applicable)
 - Other Third Party: Name and business and email addresses

Data Elements

- Total amount, date and form of research payment
- Name of research study
- Whether the product is a Covered Product, a non-Covered Product, a combination, or neither
 - Covered Product: Prescription drug or medical device if premarket approval by or premarket notification to the FDA is required and payment is available under Medicare, Medicaid or the Children's Health Insurance Program
- Name of related covered product(s)
- Information on physician principal investigators (same as for physicians above)

More Data Elements

- Manufacturers must track and report the following abbreviated information for research transfers of value related to pre-clinical research:
- Name of individual/entity receiving the transfer of value
 - Physician: Name, business and email addresses, NPI, state license number and state, specialty and type of medicine practiced
 - Teaching Hospital: Name, business and email addresses, TIN and NPI (if applicable)
 - Other Third Party: Name, business and email addresses
- Total amount, date and form of the transfer of value
- Information on physician principal investigators

Research-Related Transfers of Value

- Reported under general transfers of value
 - Protocol development consultation
 - Data monitoring committee service
 - Steering committee service
 - Meals and travel for investigators not covered in clinical trial agreement

General Transfers of Value

| | |
|------------------------------------|-------------------------|
| Consulting fees | Speaker fees |
| Honoraria | Gifts |
| Entertainment | Food & Beverage |
| Travel & Lodging | Courses & Textbooks |
| Charitable Contributions | Royalties & Licenses |
| Investment Interest (or potential) | "Grants" (non-research) |

**INDUSTRY'S APPROACH TO "SUNSHINE"
REPORTING**


THE OPEN PAYMENTS LIFECYCLE

2017 OIG Work Plan: Data Brief on Open Payments Program 




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Sunshine Data Helps Feds Uncover Fraud
Aug 26, 2016 By Jill Wechsler
The \$7.5 billion in "transfers of value" made in 2015 by pharma companies to physicians and hospitals through the federal Open Payments program has caught the attention of the Department of Justice (DoJ) and federal and state prosecutors investigating fraud throughout the health care system. Enforcement agencies see this wealth of industry data as a ready resource for uncovering unusual arrangements or heavy spending to certain providers that

2017 OIG Work Plan: Data Brief on Open Payments Program 

New: Data Brief on Financial Interests Reported Under the Open Payments Program

- ACA § 6002 requires that manufacturers disclose to CMS payments made to physicians and teaching hospitals.
- Manufacturers and group purchasing organizations must also report ownership and investment interests held by physicians.



2017 OIG Work Plan: Data Brief on Open Payments Program



OIG will also determine how much Medicare paid for drugs and DMEPOS ordered by physicians who had financial relationships with manufacturers and group purchasing organizations.



OIG will determine the volume and total dollar amount associated with drugs and DMEPOS ordered by these physicians in Medicare Parts B and D for 2015.

Settlements



JUSTICE NEWS

Department of Justice
Office of Public Affairs

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FOR IMMEDIATE RELEASE

Tuesday, March 11, 2014

Pharmaceutical Company to Pay \$27.6 Million to Settle Allegations Involving False Billings to Federal Health Care Programs

Pharmaceutical manufacturer Teva Pharmaceuticals USA Inc. and a subsidiary, IVAX LLC, have agreed to pay the government and the state of Illinois \$27.6 million for allegedly violating the False Claims Act by making payments to induce prescriptions of an anti-psychotic drug for Medicare and Medicaid beneficiaries. Teva Pharmaceuticals USA is located in North Wales, Pa., and IVAX LLC is a Florida company.

Pharma Company:
March 2014

Settlements



JUSTICE NEWS

Department of Justice
Office of Public Affairs

SHARE

FOR IMMEDIATE RELEASE

Friday, February 13, 2015

Illinois Physician Pleads Guilty to Taking Kickbacks from Pharmaceutical Company and Agrees to Pay \$3.79 Million to Settle Civil False Claims Act Case

The Department of Justice announced today that an Illinois physician, Dr. Michael J. Reinstein, pleaded guilty to a federal crime for receiving illegal kickbacks and benefits totaling nearly \$600,000 from two pharmaceutical companies in exchange for regularly prescribing an anti-psychotic drug — clozapine — to his patients. Reinstein also agreed to pay the United States and the state of Illinois \$3.79 million to settle a parallel civil lawsuit alleging that, by prescribing clozapine in exchange for kickbacks, Reinstein caused the submission of false claims to Medicare and Medicaid for the clozapine he prescribed for thousands of elderly and indigent patients in at least 30 Chicago-area nursing homes and other facilities.

Physician: February 2015

Settlements



Medical Device Manufacturer NuVasive Inc. to Pay \$13.5 Million to Settle False Claims Act Allegations

California-based medical device manufacturer NuVasive Inc. has agreed to pay the United States \$13.5 million to resolve allegations that the company caused health care providers to submit false claims to Medicare and other federal health care programs for spine surgeries by marketing the company's CoRoent System for surgical uses that were not approved by the U.S. Food and Drug Administration (FDA), the Justice Department announced today. The settlement further resolves allegations that NuVasive caused false claims by paying kickbacks to induce physicians to use the company's CoRoent System.

"The Justice Department is committed to holding medical device manufacturers accountable, which includes requiring that they follow all laws designed to ensure that medical devices are safe and effective," said Principal Deputy Assistant Attorney General Benjamin C. Mizer, head of the Justice Department's Civil Division. "It is also imperative that manufacturers not improperly influence the selection of medical devices in order to ensure that these decisions are based on the needs and interests of patients, not on a physician's own financial interests."

The United States alleged that between 2008 and 2013, NuVasive promoted the use of the CoRoent System for surgical uses that were not approved or cleared by the FDA, including for use in treating two complex spine deformities, severe scoliosis and severe spondylolisthesis. As a result of this conduct, the United States alleged that NuVasive caused physicians and hospitals to submit false claims to federal health care programs for certain spine surgeries that were not eligible for reimbursement.

The settlement agreement also resolves allegations that NuVasive knowingly offered and paid illegal remuneration to certain physicians to induce them to use the CoRoent System in spine fusion surgeries, in violation of the federal Anti-Kickback Statute. The illegal remuneration consisted of promotional speaker fees, honoraria and expenses relating to physicians' attendance at events sponsored by a group known as the Society of Latent Access Surgery (SOLAS). SOLAS was allegedly created, funded and operated solely by NuVasive, despite its outward appearance of independence.

CMS.gov Centers for Medicare & Medicaid Services

Learn about your health care services

Medicare Medicaid/CHIP Medicare/Medicaid Coordination Private Insurance Innovation Center Regulations & Guidance Research, Statistics, Data & Systems Outreach & Education

Home > Open Payments

Open Payments About Explore the Data Program Participants FAQs Contact Us

The Refreshed Data is Out!

The refreshed Open Payments data is now available. Check out the data dashboard to see an overview of the refreshed data, or dive right in and use the search tool.

Open Payments

Open Payments is a federal program, required by the Affordable Care Act, that collects information about the payments drug and device companies make to physicians and teaching hospitals for things like travel, research, gifts, speaking fees, and more. It also includes company revenues for physicians or their immediate family members in these companies. This data is then made available to the public each year on this website. [Learn more about Open Payments.](#)

Information for Program Year 2017

2017 Search, Explore List and PDF (201,000 records) available for the 2017 program year is now available.

View the Data

View Summary Data
Search the Data
Create Charts and Graphs with the Data

Search & Explore Open Payments Data

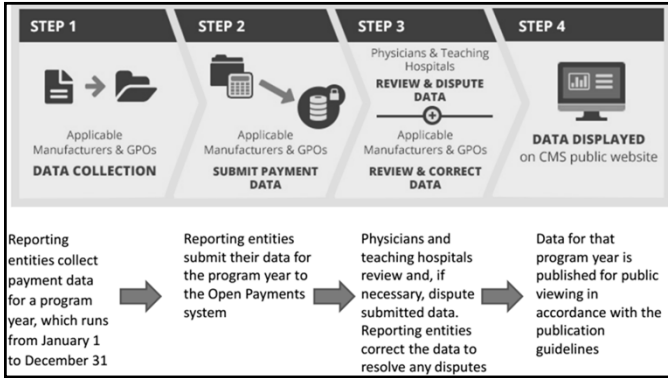
- Use the search tool to look up doctors, hospitals, or companies.

Physicians and Teaching Hospitals

- Learn how to register to review and download your managed data.

Applicable Manufacturers and Group Purchasing Organizations

- Learn how to register.
- Already registered? Login.





Payments Categories

- Consulting Fee
- Honoraria
- Gift
- Entertainment
- Food and Beverage
- Travel and Lodging
- Education
- Charitable Contribution
- Royalty or License
- Grant
- Research
- Compensation for services other than consulting, including serving as faculty or as a speaker at a venue other than a continuing education program;
- Current or prospective ownership or investment interest;
- Compensation for serving as faculty or as a speaker for a non-accredited and noncertified continuing education program;
- Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program;
- Space rental or facility fees (teaching hospital only);

Dollars for Docs

How Industry Dollars Reach Your Doctors

By Charles Ornstein, Lena Groeger, Mike Tigas, and Ryann Grochowski Jones, ProPublica. Updated December 13, 2016

Pharmaceutical and medical device companies are now required by law to release details of their payments to a variety of doctors and U.S. teaching hospitals for promotional talks, research and consulting, among other categories. Use this tool to search for general payments (excluding research and ownership interests) made from August 2013 to December 2015. | Related Story: We've Updated Dollars for Docs. Here's What's New. »

Has Your Doctor Received Drug or Device Company Money?

All States
Search

For example: Andrew Jones, Boston, 10013

\$6.25B

in disclosed payments

\$10,716

doctors

1,171

teaching hospitals

1,866

companies

Totals listed below account for all payments from August 2013 to December 2015.

About the Dollars for Docs Data
Details behind our drug company money database.

Download the Data
The entire data set is available for purchase in the ProPublica Data Store.

Source
The Centers for Medicare and Medicaid Services Open Payments data.


Archive

Totals listed below account for all payments from August 2013 to December 2015.

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Dollars for Doctors
How Industry Money Reaches Physicians



Top 50 Companies
Click on a company to see how its payments break down by drug, device or doctor. Or, see all companies »

| COMPANY | PAYMENTS |
|-----------------------------------|----------|
| GENENTECH, INC. | \$727M |
| DEPUY SYNTHES PRODUCTS LLC | \$167M |
| STRYKER CORPORATION | \$153M |
| MEDTRONIC SOFAMOR DANEK USA, INC. | \$147M |
| ASTRAZENECA PHARMACEUTICALS LP | \$145M |
| PFIZER INC. | \$128M |
| ARTHREX, INC. | \$108M |
| MEDTRONIC VASCULAR, INC. | \$106M |
| JANSSEN PHARMACEUTICALS, INC. | \$106M |
| ALLERGAN INC. | \$105M |

Highest-Earning Doctors

| NAME | PAYMENTS |
|---|----------|
| ROGER JACKSON Orthopedic Surgery of the Spine | \$54.1M |
| SUJATA NARAYAN Family Medicine | \$43.9M |
| STEPHEN BURKHART Orthopedic Surgery | \$43.4M |
| KEVIN FOLEY Neurological Surgery | \$39.8M |
| KAREN UNDERWOOD Pediatric Critical Care Medicine | \$28.5M |

Doctors Paid the Most Often

| NAME | PAYMENTS |
|---|----------|
| ANA STANKOVIC Nephrology | 2,839 |
| FARHAD JANGSINH Endocrinology, Diabetes & Metabolism | 2,433 |
| ROBERT BUSCH Endocrinology, Diabetes & Metabolism | 2,334 |


HOSPITAL

Yearly Payment Breakdown: 2015

All Payments: At a Glance

| Year | Payments | Payment Total | Companies Paid This Teaching Hospital |
|------|----------|---------------|---------------------------------------|
| 2015 | 386 | \$35,010,028 | 94 |
| 2014 | 508 | \$44,305,841 | 98 |
| 2013 | 230 | \$13,198,634 | 54 |

Payment Calendar in 2015
This hospital received a payment on 176 days in 2015. Darker blue below represents a single day during the disclosure period. A gray bar indicates no payments. The darker the color, the more payments a hospital received that day.



Types of Payments in 2015

| Category | Payments | Payment Value |
|--------------------|----------|---------------|
| ROYALTY OR LICENSE | 134 | \$32.2M |
| GRANT | 97 | \$1.1M |
| CONSULTING | 22 | \$595K |

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http://phrma-docs.phrma.org/sites/default/files/pdf/phrma_marketing_code_2008.pdf





<http://www.advamed.org/issues/code-ethics/code-ethics>

MDMA
MEDICAL DEVICE MANUFACTURERS ASSOCIATION
Innovation Today for Better Health Care Tomorrow™

http://cvmcdn.com/sites/www.medicaldevices.org/resource/resmgr/Docs/MDMA_Code_July09.pdf?hSearchTerms=%22code%22

COMPLIANCE CONTACTS FOR CODE CERTIFYING COMPANIES

| | | | |
|---|--|-----------------------------|--|
| ADVAMED MEMBER COMPANIES | | NON-MEMBER COMPANIES | |
| <p>3M Health Care Maureen Harris <small>(Infection Prevention Division and Skin & Wound Care Division)</small> mauharris@mm.com</p> <p>Abbott Laboratories Hotline: 1-855-294-4564 <small>United States Medical Products Divisions</small> <small>Website: spwslup.abbott.com</small></p> <p>ABIOMED, Inc. Hotline: 855.475.6376 <small>Stephen McEvoy</small> <small>978.646.1819 (phone)</small> <small>smcevoy@abiomed.com</small></p> <p>Acculavent, Inc. Susan Clarke</p> | <p>AccelSPINE Sheetal Patel <small>214.545.5852 (phone)</small> <small>compliance@accelspine.com</small></p> <p>AccuVein, Inc. Sue Vallejo <small>631.367.0393 (phone)</small> <small>sue@accuvein.com</small></p> <p>Accumed LLC Ed Boehmer <small>503.627.9957 x1293 (phone)</small> <small>eboehmer@accumed.net</small></p> | | |



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September 1, 2016

Via Overnight Mail

Erin Skinner, Esq.
 Centers for Medicare & Medicaid Services
 U.S. Department of Health & Human Services
 Attention: CMS-1654-P - Mail Stop C4-26-05
 7500 Security Boulevard
 Baltimore, MD 21244-1850

Re: CMS-1654-P: Medicare Program: Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Reports of Payments or Other Transfers of Value to Covered Recipients

Dear Ms. Skinner:

On behalf of the members of the Advanced Medical Technology Association ("AdvaMed"), we write in response to the Department of Health and Human Services, Centers

LEVERAGE YOUR RESOURCES TO CONDUCT MEANINGFUL INVESTIGATIONS

WHEN DATA DOESN'T MATCH

Conflict of Interest Reporting – Develop Your Program

- Appoint a Conflict Manager to oversee day-to-day monitoring plan
 - Reviewing disclosed potential conflicts
 - Conducting investigations
 - Creating management plans
- Create well-defined policies
 - Determine reporting limits
 - How much outside activity is too much?
 - Provide faculty with clear expectations and definitions
 - "What is honoraria?"

Conflict of Interest Reporting – Develop Your Program

- Determine the frequency of reporting
 - Annual? Biannual? Continuous?
 - Update existing disclosure? Provide new disclosure for each new conflict?
- Construct an effective questionnaire
 - Broad questions vs specific inquiries
 - Revise!!
- Decide on a management tool
 - Electronic vs paper
 - Databases vs spreadsheets
 - What can be simplified using the proper tool?

COI Technology Enablement

Electronic COI management systems can be used to simplify the COI reporting process – and ultimately the investigation process – for managers and researchers.

- Electronic conflict reporting options
- Centralization of management processes
- Integration with publicly reported databases

Monitoring Conflicts – Am I getting the whole story?

An effective COI management program will examine information that is reported AND look for what wasn't reported

- Conduct audits of faculty reporting no conflicts
- Check information against CMS databases
- What should raise a red flag?
 - High dollar amounts vs frequency of outside activity – what is your institution's limit?

Monitoring Conflicts – Am I getting the whole story?

Example: Dr. A reports \$10,000 in consulting fees with ABC Pharmaceuticals

- Matches what is publicly reported
- Potential conflict of interest?
- Create a management plan?
- High dollar amounts might trigger further investigation
 - Nature of the relationship between the doctor and the company?

Monitoring Conflicts – Am I getting the whole story?

Example: Dr. B reports small payments for meals and travel from several outside medical device companies

- What is the potential for conflict of interest vs conflict of commitment?
 - Impact to the institution and faculty member's institutional responsibilities
- Management plans can help provide guidelines for what is acceptable outside activity

Monitoring Conflicts – Am I getting the whole story?

Example: Dr. C reports no conflicts, but public database shows consulting and travel payments to ABC Pharmaceuticals

- Time to conduct an investigation
 - Follow up with the doctor
 - Oversight?
 - Permitted by institutional leadership?
 - Public data incorrectly reported?
- Gather information from other sources

Conducting Investigations

Sometimes the most obvious resources are the best

- Ask the Googles!
- Industry websites
 - Dr. C and ABC Pharmaceuticals
 - What do they do?
 - How does it relate to Dr. C's research or specialty?
 - Has Dr. C spoken on their behalf? Mentioned them in lectures?

Conducting Investigations

- Doctor's history, research and publications
 - What are the recurring themes and how do they relate to outside interests?
 - Who has the doctor worked with in the past? How might they be involved?
- Institutional records
 - Is there a record of the doctor being granted permission for the work they're doing?
 - Do we have other business agreements in place and how do they relate?

Reporting

- Once investigations are concluded, how do you share the information?
- Who is the audience?
- What is the frequency?
- Where at your institution does the management plan "live"?

Questions?

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