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

2017 HCCA Compliance Institute, National Harbor, MD

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
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

<table>
<thead>
<tr>
<th>Research Payments</th>
<th>Payments or other transfers of value if (1) made in connection with “research” and (2) protocol or written agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Payments</td>
<td>All other transfers of value</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Consulting fees</th>
<th>Speaker fees</th>
</tr>
</thead>
<tbody>
<tr>
<td>Honoraria</td>
<td>Gifts</td>
</tr>
<tr>
<td>Entertainment</td>
<td>Food &amp; Beverage</td>
</tr>
<tr>
<td>Travel &amp; Lodging</td>
<td>Courses &amp; Textbooks</td>
</tr>
<tr>
<td>Charitable Contributions</td>
<td>Royalties &amp; Licenses</td>
</tr>
<tr>
<td>Investment Interest (or potential)</td>
<td>“Grants” (non-research)</td>
</tr>
</tbody>
</table>
INDUSTRY’S APPROACH TO “SUNSHINE” REPORTING

THE OPEN PAYMENTS LIFECYCLE

2017 OIG Work Plan: Data Brief on Open Payments Program
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

FOR IMMEDIATE RELEASE

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

FOR IMMEDIATE RELEASE

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

Forest Laboratories and Forest Pharmaceuticals to Pay $38 million to Resolve Kickback Allegations Under the False Claims Act

Forest Laboratories LLC, located in New York, New York, and its subsidiary, Forest Pharmaceuticals Inc., have agreed to pay $38 million to resolve allegations that they violated the False Claims Act by paying kickbacks to induce physicians to prescribe the drugs Bextra® (valdecoxib), Celebrex®, and Namenda®, the Department of Justice announced today.

“Kickback schemes undermine the integrity of medical decisions and increase the costs of health care for everyone,” said Principal Deputy Assistant Attorney General Benjamin C. Mizer, head of the Justice Department’s Civil Division. “Such schemes are contrary to the laws that are designed to influence these recommendations, and the Department of Justice will not tolerate them.”

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 Lateral Access Surgery (SOLAS). SOLAS was allegedly created, funded and operated solely by NuVasive, despite its outward appearance of independence.
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 meals. It also includes ownership interests that physicians or their immediate family members have 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 Teaching Hospital List and Key the minimum Thresholds for the 2017 program year is now available.

View the Data

Search & Explore
Open Payments Data

Physicians and Teaching Hospitals

• Use the search tool to look up doctors, hospitals, or companies.
• Learn how to register to review (and dispute) your financial data.

Applicable Manufacturers and Group Purchasing Organizations

• Learn How to register.
• Already registered? Login.

STEP 1
Applicable Manufacturers & GPOs
DATA COLLECTION

STEP 2
Applicable Manufacturers & GPOs
SUBMIT PAYMENT DATA

STEP 3
Physicians & Teaching Hospitals
REVIEW & DISPUTE DATA

STEP 4
Applicable Manufacturers & GPOs
REVIEW & CORRECT DATA

DATA DISPLAYED
on CMS public website

Reporting entities collect payment data for a program year, which runs from January 1 to December 31

Reporting entities submit their data for the program year to the Open Payments system

Physicians and teaching hospitals review and, if necessary, dispute submitted data. Reporting entities correct the data to resolve any disputes

Data for that program year is published for public viewing in accordance with the publication guidelines
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 Tigar, and Iyann 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?

| $6.25B in disclosed payments | 810,716 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

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## Top 50 Companies

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

<table>
<thead>
<tr>
<th>COMPANY</th>
<th>PAYMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>GENENTECH, INC.</td>
<td>$727M</td>
</tr>
<tr>
<td>DEPUY SYNTHES PRODUCTS LLC</td>
<td>$167M</td>
</tr>
<tr>
<td>stryker corporation</td>
<td>$153M</td>
</tr>
<tr>
<td>MEDTRONIC SOFAMOR DANEK USA, INC.</td>
<td>$147M</td>
</tr>
<tr>
<td>ASTRAZENECA PHARMACEUTICALS LP</td>
<td>$145M</td>
</tr>
<tr>
<td>PFIZER INC.</td>
<td>$128M</td>
</tr>
<tr>
<td>ARTHREX, INC.</td>
<td>$108M</td>
</tr>
<tr>
<td>MEDTRONIC VASCULAR, INC.</td>
<td>$106M</td>
</tr>
<tr>
<td>JANSSEN PHARMACEUTICALS, INC.</td>
<td>$106M</td>
</tr>
<tr>
<td>ALLERGAN INC.</td>
<td>$105M</td>
</tr>
</tbody>
</table>

## Highest-Earning Doctors

<table>
<thead>
<tr>
<th>NAME</th>
<th>PAYMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>ROGER JACKSON</td>
<td>$541M</td>
</tr>
<tr>
<td>SUJATA NARAYAN</td>
<td>$432M</td>
</tr>
<tr>
<td>STEPHEN BURKHART</td>
<td>$432M</td>
</tr>
<tr>
<td>KEVIN FOLEY</td>
<td>$399M</td>
</tr>
<tr>
<td>KAREN UNDERWOOD</td>
<td>$285M</td>
</tr>
</tbody>
</table>

## Doctors Paid the Most Often

<table>
<thead>
<tr>
<th>NAME</th>
<th>PAYMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANA STANKOVIC</td>
<td>2,839</td>
</tr>
<tr>
<td>FARHAD ZANGENEH</td>
<td>2,433</td>
</tr>
<tr>
<td>ROBERT BUSCH</td>
<td>2,334</td>
</tr>
</tbody>
</table>
### Yearly Payment Breakdown

**All Payments: At a Glance**

<table>
<thead>
<tr>
<th>Year</th>
<th>Payments</th>
<th>Payment Total</th>
<th>Companies Paid This Teaching Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>386</td>
<td>$35,010,028</td>
<td>94</td>
</tr>
<tr>
<td>2014</td>
<td>508</td>
<td>$44,305,841</td>
<td>98</td>
</tr>
<tr>
<td>2013</td>
<td>230</td>
<td>$13,198,634</td>
<td>54</td>
</tr>
</tbody>
</table>

**Payment Calendar in 2015**

This hospital received a payment on 176 days in 2015. Each box below represents a single day during the disclosure period. A grey box indicates no payments. The darker the color, the more payments a hospital received that day.

<table>
<thead>
<tr>
<th>Jan</th>
<th>Feb</th>
<th>Mar</th>
<th>Apr</th>
<th>May</th>
<th>Jun</th>
<th>Jul</th>
<th>Aug</th>
<th>Sep</th>
<th>Oct</th>
<th>Nov</th>
<th>Dec</th>
</tr>
</thead>
</table>

**Types of Payments in 2015**

<table>
<thead>
<tr>
<th>Category</th>
<th>Payments</th>
<th>Payment Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Royalty or License</td>
<td>134</td>
<td>$32,204</td>
</tr>
<tr>
<td>Grant</td>
<td>97</td>
<td>$111,111</td>
</tr>
<tr>
<td>Consulting</td>
<td>22</td>
<td>$59,595</td>
</tr>
<tr>
<td>Goods and Services</td>
<td>69</td>
<td>$1,234,567</td>
</tr>
</tbody>
</table>

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**PhRMA**

[PhRMA Research, Progress, Hope](http://phrma-docs.phrma.org/sites/default/files/pdf/phrma_marketing_code_2008.pdf)

**AdvaMed**

[Advanced Medical Technology Association](http://www.advamed.org/issues/code-ethics/code-ethics)

**MDMA**

COMPLIANCE CONTACTS FOR CODE CERTIFYING COMPANIES

ADVAMED MEMBER COMPANIES

3M Health Care
(Infusion Prevention Division
and Skin & Wound Care
Division)
Maureen Horne
651.733.4879 (phone)
mahorne@mmm.com

Abbott Laboratories
United States Medical
Products Divisions
Hotline: 1-855-294-4584
Website: speakup.abbott.com

ABIOMED, Inc.
Hotline: 888.475.0376
Stephen McEvoy
978.646.1819 (phone)
smcevoy@abiomed.com

Acclarent, Inc.
Susan Clarke

NON-MEMBER COMPANIES

AccelSPINE
Sheetal Patel
214.545.5852 (phone)
compliance@accelspine.com

Accu/Vein, Inc.
Sue Vallejo
631.367.0303 (phone)
sue@acouvain.com

Acumed LLC
Ed Boehmke
503.627.9957 x1293 (phone)
eboehmke@acumed.net

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
for Medicare and Medicaid Services, 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.

Advamed is the national trade association for the medical technology industry. Advamed represents the full spectrum of medical technology companies. Advamed advocates for policies and regulations that support innovation, investment, and the delivery of high-quality care.

Advamed is deeply concerned about the potential impact of the proposed changes to Part B payments and the reporting requirements. The segment of the medical technology industry that provides off-the-shelf components (such as the manufacturers of medical supplies, devices, instruments, and biomaterials) will likely see a significant impact on their ability to invest in research and development, and on their ability to provide high-quality, innovative products to patients.

Advamed respectfully requests that the Department of Health and Human Services carefully consider the potential negative impact of these proposals on the medical technology industry and its ability to meet the needs of the nation’s healthcare system.
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?

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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