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
- Excludes:
  - U.S. or U.S. territory (Puerto Rico, Virgin Islands, Guam and American Samoa) even if living abroad
- Inclusion:
  - 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 (a) made in connection with &quot;research&quot; and (b) protocol or written agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Payments</td>
<td>All other transfers of value</td>
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</tbody>
</table>

### Research Transfers of Value

- Manufacturers must track and report the following information for research transfers of value related to clinical research:
  - **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>
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<tbody>
<tr>
<td>Entertainment</td>
<td>Gifts</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

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

Pharmaceutical Company: March 2014

Pharma Company: February 2015

Settlements

Illinois Physician Pleads Guilty to Taking kickbacks from Pharmaceutical Company and Agrees to Pay $2.75 Million to Settle Civil False Claims Act Case

The Department of Justice announced today that an Illinois physician, Dr. Miller, pleaded guilty to a federal charge for receiving illegal kickbacks and benefits, totaling nearly $2 million, from two pharmaceutical companies in exchange for implicitly prescribing a second generic drug — a drug that was cheaper — to his patients. Michigan also agreed to pay the United States $2.75 million to resolve claims that it paid kickbacks to induce the physician to prescribe the drug.

Physician: February 2015
Settlements

Medical Device Manufacturer NyceVac Inc. to Pay $12.5 Million to Settle False Claims Act Allegations

California-based medical device manufacturer NyceVac Inc has agreed to pay the Federal government $12.5 million to resolve allegations that the company caused harm to patients who received faulty skin grafts, and who relied on false information to obtain federal reimbursement. The settlement, which was announced today by the Department of Justice, is the first of its kind in the medical device industry.

"This settlement demonstrates that the Department of Justice is committed to holding companies accountable for their actions," said Assistant Attorney General for the Civil Division, Washington. "It is important to note that this settlement demonstrates the importance of accurate information in the medical device industry, and that companies must take steps to ensure the safety and accuracy of their products.

The United States alleged that between 2005 and 2010, NyceVac misrepresented the use of the company's skin grafting system to surgical teams. The company sold the system to hospitals, and surgical teams used the system to perform skin grafts on patients. NyceVac represented that the system was safe and effective, but in fact, the system was not effective in the majority of cases. As a result, patients were subjected to unnecessary and painful procedures, and the federal government was forced to expend millions of dollars to cover the costs of these procedures.

The settlement includes a $12.5 million civil penalty, as well as $1.5 million in damages to the federal government. NyceVac has also agreed to implement a compliance program to ensure that it does not engage in similar misconduct in the future.

The United States is represented by the U.S. Attorney's Office for the Central District of California and the Civil Division's Antitrust Division. The case is United States v. NyceVac Inc., Case No. 1:11-cv-00001-EX,"
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 Dharapak, Anna Gonzalez, Mike Jovic, and Agnes Chang
Published December 22, 2010

Pharmaceutical and medical device companies are now required by law to disclose details of their payments to a variety of doctors and U.S. teaching hospitals for promotional aides, research and consulting, among other categories. Use this tool to search for general payments (excluding research and ownership interests) made from August 2009 to December 2010. (Detailed Story: We've Updated Dollars for Docs: Here's What's New)

How Your Doctor Received Drug or Device Company Money?

About the Dollars for Docs Data

Download the Data

The data set is available for download in the Public Data Store.

Sources

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

Archive

Dollars for Doctors

Top 10 Companies

Highest-Earning Doctors

Doctors Paid the Most Often

Yearly Payment Summary

Hospital

Payment Calendar for 2010

Types of Payments in 2010

Payments by specialty

Financial

...
COMPLIANCE CONTACTS FOR CODE CERTIFYING COMPANIES

ADVANCED MEMBER COMPANIES

Medtech, Inc.
121 Main St.
Eaton, CO 80615

Globa Labs
123 Tech Dr.
Eaton, CO 80615

MDMA
123 Tech Dr.
Eaton, CO 80615

NON-MEMBER COMPANIES

AccuMed LLC
Eaton, CO 80615

AdvaMed
123 Tech Dr.
Eaton, CO 80615

September 1, 2016

Via Overnight Mail

Etsi Streiner, Esq.
Center for Medicare & Medicaid Services
U.S. Department of Health & Human Services
345 Protection Road
Rental 123, Room 456
Rockville, MD 20851

Re: CMS-154-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. Streiner:

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 & Medicaid Services (CMS) Notice (CMS-154-P) that was published on June 16, 2016, in the Federal Register (81 FR 41430), titled "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."
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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