Here Comes the Sun: What Senior Management Should Know About The Sunshine Act

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Today’s Topic:

CMS Open Payments
A little ‘sunshine’ to brighten your day!
Speaker Panel

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Moderator:
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Open Payments: Basics

The law requires **Applicable Manufacturers** to disclose annually to the Government:

Any payments or other transfers of value provided to or incurred on behalf of a “Covered Recipient” (i.e., physician or teaching hospital);

- Transactions < $10 do not need to be reported, except when the total amount transferred in a reporting year exceeds $100; workplace

And...

For non-public manufacturers (and group purchasing organizations (GPOs)), physician (or his/her immediate family’s) ownership in the company.
Open Payments Timeline

- **Aug. 1, 2013**: Data Collection Started
- **March 31, 2014**: Phase 1 Reports Due
- **June 30, 2014**: Phase 2 Reports Due
- **Sept. 10, 2014**: Dispute Period Ends
- **Sept. 25, 2014**: Correction Period Ends
- **Sept. 10, 2014**: Dispute Period Started
- **Sept. 11, 2014**: Correction Period Starts
- **Sept. 30, 2014**: Public Access to Data
- **Sept. 11, 2014**: Correction Period Started
- **Sept. 30, 2014**: Public Access to Data

**WHAT SENIOR MANAGEMENT SHOULD KNOW ABOUT THE SUNSHINE ACT**
Applicable Manufacturers

Manufacturers of **covered products**, or their affiliated entities, who have U.S. operations

- Also: distributors who take title to covered products

“**Covered**” **products** are drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid and CHIP

- **Excluding** OTC products or products that do not require premarket notification or approval
- **Includes** reimbursable study devices and drugs
Reporting Obligations

Manufacturers that derive less than 10% of their revenues from covered products do not have to report transfers of value with respect to non-covered products.

Manufacturers must start collecting data 180 days after one of their products first qualifies as a “covered product”
Transfers of Value

Anything of value provided directly or indirectly to a covered recipient, or to a third party at the request of a covered recipient.

Except:

Transfers of less than $10 in value, unless the aggregate annual expenditures to the covered recipient exceed $100.

*for 2014 reporting period, these values are inflation-adjusted to $10.18 and $101.75, respectively.
Covered Recipients

Physicians and Teaching Hospitals

**Doctors** of medicine and osteopathy, dentists, podiatrists, optometrists and chiropractors who are licensed in any U.S. state.

Excludes medical residents

**Hospitals** that receive direct and indirect Medicare Graduate Medical Education funds (GME, IME and psychiatric IME)

List of “teaching hospitals” posted on CMS website
Information Reported

- Name and Primary Business Address
- For Physicians: Specialty, NPI (if applicable), license number, state of license. (For teaching hospitals: EIN)
- Dates and amounts of payments
- Form of payment
  - Cash or cash equivalent
  - In-kind items or services
  - Stock or stock options
  - Dividend, profit, or return on investment
- “Nature of Payment”
- Product(s) to which payment relates (if applicable)
### Nature of Payment

- Consulting
- Compensation for services other than consulting
- Honoraria
- Gift
- Entertainment
- Food
- Travel (including destination)
- Education
- Research
- Charitable contribution
- Royalty or license
- Current or prospective ownership or investment interest
- Direct compensation for serving as faculty for a medical education program
- Grant
Research Payments

- Transfers of value related to research that are made pursuant to a **written agreement or protocol** are reported on a separate template that includes information about the clinical trial.

- If payment relates to pre-market R&D, publication can be delayed until earlier of FDA approval/clearance or 4 years.
Special Circumstances

• If a manufacturer “requires, instructs, directs, or otherwise causes” a third party to make a transfer of value to a covered recipient, the manufacturer must report the payment to the third party and identify the indirect covered recipient.

• For private companies: if payment is to a physician owner/investor (or his/her immediate family member) this must be noted in the report.
Exceptions from Reporting

• Product samples for patient use (includes coupons or vouchers)

• Evaluation products, not to exceed 90 days (i.e., 90-day supply of disposable devices, or 90-day equipment loan)

• Educational materials or items that **directly benefit patients** or are for **use with patients**

• In-kind items to be used for charity care

• Discounts and rebates

• Services and replacement items provided under a warranty or services contract

WHAT SENIOR MANAGEMENT SHOULD KNOW ABOUT THE SUNSHINE ACT
Exceptions from Reporting

• Indirect payments, if the manufacturer does not know the identity of the recipient

• Indirect payments for speaker fees, if the meeting is accredited, and the manufacturer does not select the speaker or provide a list of suggested speakers

• Buffet meals, beverages and snacks offered at “a large-scale conference or similar large-scale event.”

• Transfers of value of less than $10 each at a “large scale conference or similar large scale event” or events open to the general public
Exceptions from Reporting

- Transfers of value by manufacturers to employees who are physicians
- Transfers of value made solely in the context of a personal, non-business-related relationship
- Transfers of value to research subjects who are patients or research subjects not acting in their professional capacity
- Fees paid by a manufacturer that self-insures, for its employees’ healthcare
- Expert Witness Fees
Recent Developments

CMS has proposed to:

• eliminate the exclusion for speaker payments made in connection with an accredited CME event; and

• require the reporting of the marketed name of the related device or medical supplies (this already applies to drugs and biologics)
Who will Review the Data & Why?

**States**
- State gift ban & disclosure
- Consumer Protection
- Pricing

**CMS**
- Open Payments Violations
- Utilization

**OIG/MFCU**
- Anti-kickback
- Exclusion

**FDA**
- Disclosure of conflicts

**NIH**
- Research grants/conflicts

**IRS (and ex-spouses)**
- Undisclosed income

**Whistleblowers**

**Media**

**Hospitals**
- COI
- Med Staff By-laws
- Employed docs

**Vendor Credentialing Firms**
- New access requirement

**Health Plans**
- Participation Agreement compliance
- Utilization
- COI

**Group Practices**
- Undisclosed income / relationships

**Physicians**
- Accuracy
- Total and hourly rates

**Plaintiff Counsel**
- Product liability

**Foreign governments and trade associations / societies**

**Your competitors**
Impact of Disclosures – July 2014

• FDA announces panel for two-day meeting on use of power morcellators in hysterectomies

• WSJ reporter reviews Ethicon website, notes $100k in 2013 payments to a gynecologist appointed to panel

• Reporter asks FDA about payments

• Two days later, FDA replies that the gynecologist has resigned from panel on eve of meeting
Panel Discussion

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Parting Thought:
Be Able to Defend Your Spend

Know Your Data Before ‘They’ Do

Demonstrate compliance with applicable laws and policies
Questions?

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Thank You!

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