The Physician Payment Sunshine Act: The Who, What & When

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June 27, 2013
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Physician Payment Sunshine Act
- February 8, 2013 Final Rule
- CMS website ("Open Payments")
- Interaction with Conflicts of Interest
- Practical implications
Sunshine Act

**High-Level** Review of “Final Rule” for Physician Payment Sunshine Act (the “Sunshine Act”)

1. Who reports?
2. Who is covered by the reports?
3. Process for reporting
4. What is reported
5. Special rules for reporting research funding
6. Penalties
Sunshine Act Origins & Goals

- Background

- Adopted as part of the Affordable Care Act of 2010
  - 42 USC 1302
  - 42 USC 1395hh

- Final Rule issued February 8, 2013
  - 42 CFR 403.900-910
Sunshine Act Origins & Goals

- **Key Dates:**
  - Transfers and ownerships beginning August 1, 2013
  - Reports to CMS due March 31, 2014
  - First publication by CMS by September 30, 2014

- **Note:** Final Rule is “definition heavy”
  - 23 significant definitions
Policy Goal:

“You should know when your doctor has a financial relationship with the companies that manufacture or supply the medicines or medical devices you may need. Disclosure of these relationships allow patients to have more informed discussions with their doctors.”

Peter Budetti, MD – CMS Deputy Administrator for Program Integrity
General Purpose

“These regulations apply to applicable manufacturers and applicable group purchasing organizations and describe the requirements and procedures for applicable manufacturers to report payments or other transfers of value provided to covered recipients...

...as well as for applicable manufacturers and applicable group purchasing organizations to report ownership or investment interests held by physicians or immediate family members of physicians in such entities.”

42 CFR 403.900
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42 CFR 403.900
1. **Applicable Manufacturers**
   - Produces, prepares, compounds...drug, device, biologic or supply that is reimbursable under Medicare or Medicaid; and
   - Is not being used by itself for its own patients

2. **Applicable Group Purchase Organizations**
   - Purchase, arranges, negotiates a covered drug, device, biologic or supply reimbursable under Medicare or Medicaid; and
   - Not used by the GOP itself.

Note: Check detailed definitions and exceptions
1. **For Transfers of Value:**
   “Covered Recipients”
   - Physicians
   - Teaching Hospitals

   Note: Includes transfers made to Third Parties but intended for benefit of a covered recipient

2. **For Ownership or Investment Interests:**
   - Physicians
   - Immediate Family Members
Process of Reporting

- Applicable Manufacturer or Applicable GPO submits report to CMS by March 31 for preceding calendar year
  - Note: Reports are due by March 30 in leap-years!

- CMS must provide the reporting entities, physicians and teaching hospitals opportunity to review material for at least 45 days before posting on CMS website
  - First posting: By September 30, 2014
  - Thereafter: By June 30 of each year

- Physician may certify accuracy or register a dispute
“National Physician Payment Transparency Program: OPEN PAYMENTS”

Applicable manufacturers and applicable GPOs can begin reporting financial relationship data on August 1, 2013. Applicable manufacturers and applicable GPOs will report the data for August through December of 2013 to CMS by March 31, 2014 and CMS will release the data publicly by September 30, 2014. Beginning in 2014, they will be required to register on a CMS website, and will submit data using templates.

In 2014, physicians and teaching hospitals will be able to:

• Register to access their data prior to public posting;
• Initiate data disputes; and
• Work with applicable manufacturers and applicable GPOs on dispute resolution.

To ensure data accuracy, CMS is required to conduct audits of the data submitted and levy civil monetary penalties against applicable manufacturers and applicable GPOs for failing to submit data or submitting inaccurate data.
What is reported?

- **Transfers of Value:**
  - Anything over $10
  - Under $10 if aggregate is over $100
  - *Very broad*
  - “Form” and “nature” of payment or transfer needs to be disclosed

- **Exclusion:**
  - Speaking fees at accredited education events if not paid directly to the physician by a reporting entity
Special Rules on Reporting Research Funds

- **Research funds must be reported if provided to:**
  - Physician;
  - Teaching hospital; or
  - Third Party for the benefit of the physician or teaching hospital

- **To be reported includes (but not limited to)**
  - Study name
  - Amount of funding

- **Delay in publication allowed if requested by sponsor under certain circumstances**
  - Delay can be no longer than 4 years
Penalties

- **Strict Liability:** $1000-$10,000 per failure to report; aggregate cap of $150,000

- **Level of Knowledge** (parallels False Claims Act): $10,000-$100,000; aggregate cap of $1M

- **Note:** Penalties are on the reporting entity
Compliance & Operational Considerations

- **Biggest Issue:** Everyone will know!
  - Patient will know
  - Other physicians will know

- **Physician certification of accuracy**
  - Penalties in Rule do not apply to physicians or teaching hospitals but pay attention to what the certification says and whether it is subject to perjury penalties (likely)
Compliance & Operational Considerations

- **45 Day response time to review**
  - Who will coordinate?

- **Research funding and projects will be public**
  - Specific to study
  - Will budgets be scrutinized?
Interaction with Conflicts of Interest

- What is the physician required to report at your organization?
- Does it match the Sunshine reports?
- Some payments exempt from Sunshine reporting but may be required by your COI policy
- Are you a State entity and the physician’s COI disclosure is public?
  - Watchdog groups will likely be matching up reports
Practical Points to Consider

- Will physicians (personally) have responsibility for reviewing “response time” reports?
- Will a central office at your organization coordinate with the physician?
- Will you check reports against COI disclosures to identify differences?
If your organization has multiple sites and there is no common contracting process, how will you handle reports of research funds for the same study which may be different for different PI/sites?

Prepare public relations office for handling press inquiries when reports are made public.
- Questions/Discussion