Physician Payment Sunshine Act

Lessons Learned in Preparation and Implementation
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• Former political consultant who founded Rockpointe, Inc. a bio-medical education company in 1995.

• Authority in changing medical education environment and economy

• Author of Policy and Medicine, the leading online coverage of the Sunshine Act, a resource informing the medical community on trends, threats and changing processes
Marc Eigner

• Heads Polaris Management Partners technology practice.

• Leading expert in HCP spend automation (Polaris works with over 80 companies), Pharma compliance technology and aggregate spend systems.

• Marc previously worked for Accenture and IBM.
Disclaimer

• The views expressed in this presentation represent our own opinions and those gleamed from discussions and work with attorneys.

• This presentation does not represent legal advice.

• We recommend you discuss many of your questions with your own attorneys.
Open Payments August 1, 2013
• The Sunshine Act requires applicable manufacturers (AM) of “covered” drugs, devices, biologics, or medical supplies to report annually to the Secretary of HHS certain payments or other transfers of value to covered recipients (CR)--physicians and teaching hospitals.

• The Sunshine Act does not “ban” any payments but simply requires reporting of payments and transfers of value
Final Rule: February 1, 2013

- Data collection begins Aug. 1, 2013
  - Report Aug through December 2013
  - Report Due to CMS by March 31, 2014
- Physicians Can Register in Open Payments – January 1, 2014
- Summer 2014 – Physicians Data Review and Ask for Corrections
- Post on CMS website by Sept. 30, 2014
Who Reports?

- Applicable manufacturers of **covered** drugs, devices, biologicals, and medical supplies
- Applicable Group Purchasing Organizations (GPOs)
  - Report only physician ownership, investment interests
  - Definition includes physician owned distributors (PODs) that purchase products for resale
- If you bill Medicare, Medicaid and SCHIP
- Excludes OTC Only Makers
Covered Recipients

• **Physician/and or group practice**
  – MD’s, DO’s, Dentists, Dental Surgeons, Podiatrists, Optometrists, or Chiropractors
  – All physicians that have a **current license**
    - Regardless of whether enrolled with CMS
    - Regardless of whether treating patients

• Does **not** include payments to **residents**

• Payments to non-CRs meant to **pass through** to physician → must report as **indirect payment**

• **Excludes** payments to non-U.S. physicians
  – Includes foreign transactions with U.S. physicians
Covered Recipients

• **Teaching hospital**
  – Any Institution receiving payments under:
    ▪ Indirect medical education (IME) (1886(d)(5)(B) SSA)
    ▪ Direct Graduate Medical Education (GME) (1886)(h))
    ▪ Psychiatric hospital IME (1886(s))
  – CMS has published a list of 1,000 hospitals
  – Does **not** include payments to non-healthcare departments at universities affiliated with hospital
  – Must report indirect payments as required
Covered Recipients

- Does **not** include nurses, NPs, PAs, Pharmacists, Nurses, other allied health professionals
  - Must comply with State laws (e.g., MA, DC, VT)
- **Not legal agents** of AM w/ MD on staff
- Does **not** include payments to physician who is a “bona fide” employee of the AM
- CMS will use **case-specific analysis** to determine
  - If (1) board members, (2) medical directors, (3) retirees, and (4) prospective employees are CRs
  - Employees who are physician investor/owners
## Civil Monetary Penalties

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
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<tbody>
<tr>
<td>Failure to Report</td>
<td>• $1,000 - $10,000/ Per Payment</td>
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<tr>
<td></td>
<td>• Maximum Penalty $150,000</td>
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<tr>
<td>Knowing Failure to Report</td>
<td>• $10,000 - $100,000 Per Payment</td>
</tr>
<tr>
<td></td>
<td>• Maximum Penalty $1,000,000</td>
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<tr>
<td>Total annual CMPs</td>
<td>• Aggregated <strong>separately</strong></td>
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<tr>
<td></td>
<td>• Maximum combined $1,150,000</td>
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<tr>
<td>Consolidated Reports</td>
<td>• CMPs apply to AM that actually submits report and signs attestation</td>
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</table>
Public Availability of Data

- CMS must publish data publicly online
  - Must be searchable and understandable
  - Must be easily aggregated and downloadable
  - Provide background on industry-physician relationships
  - Include any enforcement activities taken
- Education + outreach to stakeholders, FAQ
- Allow researchers access to basically all info
- Media/News, DOJ, Plaintiff/Qui Tam/Divorce Lawyers, IRS, Institutions
45-Day Review Period: Process

- Physicians sign into CMS secure website
  - Review data only about covered recipient
  - Initiate dispute when identified
    - Sent to AM or GPO
- Additional **15 days** to correct/resolve dispute
  - After, submit updated data & re-attest
  - Published only if dispute resolved in this period
- Can also review/submit corrections for data updated by AM’s
  - **No limit** on # of times to review/dispute transaction
- Any changes from disputes **outside** 45-day
  - Not made until “next time data is refreshed”
What information must be reported?

- Covered recipient name and business address
- NPI Number and Specialty
- State professional license #(#s) at least one State
- The amount and date of payment
- Form of Payment
  - Cash or cash equivalent
  - In-kind items or services
- Stock, stock option, ownership interest,
- Dividend, profit or other return on investment
- Nature of such payment (16 categories)
  - If payment or transfer relates to marketing, education, or research of a drug, device, biological, or medical supply, the related product must also be identified
- Product Market Name and NDC Code
- Context: 200 characters
Natures of Payment Categories

1. Travel & lodging (destination)
2. Consulting fee
3. Current or prospective ownership or investment interest
4. Research
5. Gift
6. Entertainment
7. Food & Beverage
8. Royalty or license
Natures of Payment Categories (Education)

- Education
- Honoraria
- Compensation for services other than consulting, e.g. speaking at non-CE event
- Compensation for serving as faculty or speaker at accredited/certified CE event
- Compensation for serving as faculty or speaker at unaccredited/non-certified CE
Research Payments

- All payments made in connection with an activity that meets the definition of research, and that are subject to a written agreement, contract, or research protocol, or both, are reported under “special rules.”

- Certain research payments made to a CR by an AM under a product research or development agreement may be delayed from publication on the Web site.
Payment Exclusion Categories

1. Indirect payments where AM is unaware of identity of CR
2. Payments <$10 unless annual >$100
3. Product samples, vouchers, coupons
4. Educational materials/items that directly benefit patients or intended for patient use, value of services to educate patients
5. 90 day equipment loans
6. Items/services under contract warranty
7. Physician as patient
**What is an Indirect Payment?**

**Direct Payment**
- Manufacturer pays physician or hospital **directly**

**Indirect Payment**
- Manufacturer pays a 3\(^{rd}\) party directly, the 3\(^{rd}\) party then pays a physician or Hospital
Payments on Behalf of or At the Request of

• Payments “at the request of” or “designated on behalf of” a covered recipient refers to
  • a situation in which an entity or individual receives and keeps the payment that was made on behalf of (or at the request of) the covered recipient and the covered recipient does not receive the payment or other transfer of value.
  • Rather, the covered recipient directs the payment or other transfer of value and does not receive the payment personally.

• Such payments are different than indirect
Exemption Criteria for CME Programs

The guidance released by CMS for the reporting of payments related to CME programs to covered recipients, outlines three criteria that must be met in order for a CME program to be exempt from reporting.

1. The CME program is accredited by the ACCME, AOA, AAFP, AMA, ADA CERP.

AND

2. The manufacturer does not make a payment or transfer of value directly to speakers/faculty or attendees/participants that are deemed covered recipients.

AND

3. The manufacturer does not select or influence the selection of speakers/faculty or attendees/participants.

Note: If a payment or transfer of value is made directly or indirectly to a Teaching Hospital, the payment or transfer of value must be reported, regardless of the above guidelines.
UNACCREDITED—*not-exempt*

- Meals
  - Reportable, based on rules for meals
- Travel
  - Reportable including destination
- Speaking Fees
  - Reportable
- Steering Committee
  - Reportable

ACCREDITED—*meets 3 cond.*

- Meals
  - Not Reportable
- Travel
  - Not Reportable
- Speaking Fees
  - Not Reportable
  - Identity inapplicable after grant awarded
- Steering Committee
  - Not Reportable
Attendees

UNACCREDITED—*not-exempt*

- **Meals**
  - Reportable, based on rules for meals
- **Travel**
  - Reportable including destination
- **Educational value**
  - Reportable, including slides, materials, items

ACCREDITED—*meets 3 cond.*

- **Meals**
  - Reportable, for meals where the cost is separately identifiable
- **Travel**
  - Prohibited under SCS
- **Educational value**
  - Not reportable if part of CME activity, meets conditions
Lessons Learned from Planning and Implementing Sunshine
Functional Areas

- Corporate
  - Sponsorships
  - Consulting
    - Sales
    - Marketing
    - Medical Affairs
    - Managed Markets
    - Clinical Affairs
    - Research and Development
      - Clinical Trials
      - Consulting
      - Investigator Payments
      - Organization Payments
      - Samples
      - Advisory Boards
      - Consulting
      - Publications
    - Samples, Coupons, Vouchers
    - Reprints
    - Educational Items
      - Educational Items
      - Advisory Boards
      - Continuing Medical Education
        - Entertainments, Meals, Gifts
        - Speaker Fees
        - Educational Items
        - Samples, Coupons, Vouchers
        - Market Research
        - Consulting
        - Advertising
        - Educational Items
        - Samples, Coupons, Vouchers
## Where To Start?

### Aggregate Spend Implementation Steps

<table>
<thead>
<tr>
<th>Process &amp; Project Management</th>
<th>Legal</th>
<th>Technology</th>
<th>Operations</th>
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<tbody>
<tr>
<td>• Spend Discovery and Gap Assessment</td>
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<tr>
<td>• Strategic Aggregate Spend Solution Roadmap</td>
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<tr>
<td>• Policy, Procedure and Process Map Development</td>
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<td>• Organizational Structure Advisory Services</td>
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<tr>
<td>• Legal Perspective Assessment</td>
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<tr>
<td>• State Law Data Repository</td>
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<td>• Legal Updates</td>
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<tr>
<td>• Spend Capture Systems</td>
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<td>• Semi-Automated Aggregate Spend Solution</td>
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<tr>
<td>• End – to – End Aggregate Spend Solution</td>
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<tr>
<td>• Implementation Management</td>
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<tr>
<td>• Requirements Gathering</td>
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<td>• Business Rule Configuration</td>
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<tr>
<td>• Integration with MDM and Reporting Tools</td>
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<tr>
<td>• Monitor collected information to ensure timeliness and accuracy across vendor and home office users</td>
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<tr>
<td>• Validate line item expense and profile details for each reporting state</td>
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<tr>
<td>• Work with spend capture submitters to follow up and review potential items of issue</td>
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<tr>
<td>• Run and monitor spend cap reports and thresholds</td>
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High Level Steps for Transparency Implementation

1. Spend Discovery & Solution Roadmap
2. SOP & Template Development
3. Aggregate Spend Training
4. Aggregate Spend System Implementation
5. Operations & Ongoing Support
Performing Spend Discovery Assessments: Tools

Goals

- Identify all payments to HCPs and HCOs across the organization
- Identify processes and systems which capture aggregate spend information and the level of detail captured
- Assess gaps in process, data and technology
- Create roadmap for aggregate spend solution implementation which addresses identified gaps

Benefits

- Clear picture of spend across the organization
- Understanding of gaps in processes and systems
- Understanding of the work required to meet aggregate spend requirements; likely before significant investments have been made

Discussion Board

- Clinical/R&D Involvement?
- Who's going to own this?
- What about Vendors?

Performed Validation of Aggregate Spend Reports

Performed Auditing and Monitoring Activities

Developed Ongoing Training and Communication Resource

Responded to Inquiries Regarding HCP/HCO Disclosure Disputes
### Assessment – Detailed Steps

<table>
<thead>
<tr>
<th>Phase 1: Plan</th>
<th>Phase 2: Assess and Benchmark</th>
<th>Phase 3: Recommend and Develop Roadmap</th>
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<tbody>
<tr>
<td>• Conduct kickoff meeting with key stakeholders</td>
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<td>• Meet with Core Team to finalize scope and gain baseline understanding of the existing process</td>
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<td>• Request necessary documentation, such as Policies, Procedures, SOPs, etc</td>
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<td>• Schedule interviews</td>
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<td>• Develop assessment tools</td>
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<tr>
<td>• Review policies and SOPs</td>
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<tr>
<td>• Conduct interviews to gain understanding of applicable processes, technology and all possible spend items</td>
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<tr>
<td>• Identify all spend item sources for capture and develop Spend Matrix</td>
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<tr>
<td>• Compare currently captured spend at Client to industry practices and state law requirements</td>
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<tr>
<td>• Identify gaps in reporting for state laws, aggregate spend capture, process efficiencies and system technologies</td>
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<tr>
<td>• Develop recommended action steps to address gaps</td>
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<tr>
<td>• Develop prioritized roadmap for implementation of action steps</td>
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<tr>
<td>• Develop project plan and timeline for implementing short term action steps</td>
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Indirect Payment Tracking

• What organizations are doing to track indirect payments
• Clear instructions and training vendors, hospitals, associations, CRO’s
• Providing forms templates and software for vendors
• Providing access to lists of physician NPI and State License #’s
• Vendors have Multiple Company Requirements
Training

• Important that Staff Understand the Requirements
• Integration with other training functions
• Limit the information to what is important
• Focused on Specific Areas of Application for Recipient
• Utilize existing LMS platform
• Some tracking element for future audits
• Online Training Modules
Data Accuracy

- Doctors are concerned with the accuracy of the data (AMA)
- Accuracy of data is vital
- Process for Dispute Resolution
- Company checks and balances
- Companies should consider portal or pre-notification of physicians in advance of the 45 day window provided by CMS
- Portal for Physicians
Lessons learned from initial implementation, compliance with CIA's and state reporting requirements

• SOP’s
  • Prioritization
  • Determine Simple FMV
  • Collection
  • Accuracy
  • Attestation/Audit
  • Training
  • Tools
Establishing The Scope and Internal Control Objectives or Risks

- **Completeness** – Does the company have a complete understanding of requirements?
- **Sustainability** – How does the company stay current to changes?
- **Ownership** – Has the organization established ownership of consolidation and enterprise reporting?
- **Completeness** - Are all business processes interacting with HCPs captured?
- **Consistency** – Are all processes consistently capturing relevant transactional details?
- **Timeliness** – Is the process support timely reporting?
- **Completeness** – Is the data structured in a manner that supports reporting?
- **Integrity** – Are all transaction being identified as HCP/O spend?
- **Integrity** – How is transactional data being extracted?
An Effective Plan Necessitates A Review Of The Organization, Process and Internal Control Design, And Control Operation

1- Audit Planning & Scoping
2 - Organizational Review
3 – Assess Process and Internal Control Design
4 – Evaluate Operation of the Process and Internal Controls
5 - Management Reporting & Recommendations
Factors to Be Considered When Developing The Assessment Scope

- Business Processes
- Policies & Procedures
- Technology Systems
- Organizational Structure
- Functional Stakeholders
- Legal / Regulatory Requirements
Considerations For Effective Audit Planning and Scoping

1. Understand all *of the* business processes requiring spend capture.

2. Obtain a general awareness of current state, federal and international laws and regulations.

3. Understand existing policies and procedures across functional areas.

4. Understand the stakeholders across functional areas Commercial, R&D, Medical Affairs where interactions with HCPs are taking place.

5. Understand technology applications used to enable spend capture and aggregate reporting.

6. Understand the organizational structure supporting accurate spend capture and effective reporting.
Considerations For Conducting An Effective Organizational Review

1. Inventory the departments interacting with HCPs across the enterprise including Sales, Marketing, R&D and Medical Affairs.

2. Understand how HCP/O transactions are being captured and classified?

3. Understand the key stakeholders, process owners and control owners within each functional area, including those responsible for overseeing spend capture.

4. Understand the roles and responsibilities for persons responsible for enterprise consolidation of spend capture and preparation of statutory reports.
Required Considerations For Effectively Assessing Process and Internal Control Design

1. Automation – Evaluate the level of automation within the spend capture processes. Have controls been established to ensure complete capture of Spend Data?

2. Data Completeness – Are all reportable details for each interaction captured in the source system?

3. Reporting Integration – To what extent has the spend capture processes and technology been integrated with statutory reporting systems or templates?

4. Data Integrity – How is data integrity assured when spend data is extracted from source systems or repositories and consolidated?

5. Reporting Requirements – Are the applicable reporting requirements defined in a controlled standard report or data consolidation template? To what extent do reports need to be manually generated for the various authorities?
Beyond Sunshine: Implications of Public Disclosure of Payments

- HHS OIG – Medicare Part D Data
- Implications for FCA, AKB, Stark Statutes
- International Bribery Acts
- Media
- State Examples
  - Oregon Case – Non disclosure
- Qui Tam Cases
- IRS and Other Agencies
- Employers
- Payers
- Academic Medical Centers
Open Payments Resources

- Centers for Medicare and Medicaid Services

- Policy and Medicine

- American Medical Association
  - [www.ama-assn.org/go/sunshine](http://www.ama-assn.org/go/sunshine)

- Partners for Healthy Dialogs
  - [http://www.healthydialogues.org/health-care-professionals](http://www.healthydialogues.org/health-care-professionals)

- Advamed
  - [http://advamed.org/issues/16/physician-payments-sunshine-law](http://advamed.org/issues/16/physician-payments-sunshine-law)

- CME Coalition (Including Guide and Q&A)
  - [http://cmecoalition.org/resources](http://cmecoalition.org/resources)

- Medscape (CME Accredited Web courses)
Tools

• Tracking for Companies and Physicians
• Cross Check for Physicians for Payments
• Register with CMS

Questions?
For More Information

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