What You *Really* Need to Know about the Sunshine Act

SLA P&HT 2015 Spring Meeting
April 21, 2015
2:00 – 3:00pm
Panel Agenda

- Introductions
- Sunshine Act Overview
- Spring Meeting Survey Review
- Survey Questions

- Panelist Commentary
- Additional Q&A
Moderator & Panelists

**Moderator:**
John Chu

**Panelists:**
Ian Palmer  Reprints Desk, Inc.
Ben Beit Zuri  Wolters Kluwer
Donna Simcoe  Medical Publication Consultant
But first...a reminder that we welcome your interaction!
Sunshine Act Primer

- OPEN PAYMENTS (Physician Payments Sunshine Act)
- Required by Section 6002 of the Affordable Care Act
- Establish a transparency program to increase public awareness of financial relationships
- Applicable manufacturers must report payments of other transfers of value made to physicians & teaching hospitals to CMS
- CMS lists SIXTEEN different payment types!
- CMS to annually collect, aggregate, publish data

- Extensive & complicated review, dispute, & correction process
- Effluvia of criticism & intense media attention

How should applicable manufacturers or applicable group purchasing organization determine the value of journal reprints provided to covered recipients?

The value of a journal reprint should reflect the cost that an applicable manufacturer or applicable group purchasing organization paid to secure the reprint from the publisher or other distributor. Applicable manufacturers and applicable group purchasing organizations may submit assumptions document describing any assumptions made to determine the value of journal reprints.

Key words: Open Payments, Sunshine Act
16287(c)
What is the Sunshine Act?

What is it?
- Signed into law in 2010 as part of the Affordable Care Act, the Physician Payment Sunshine Act requires product manufacturers to track and report transactions of value provided to healthcare professional.

Timing
- August 1, 2013: Manufacturers are required to begin collecting information about payments and transfers of value to physicians.
- September 30, 2014: 2013 data published on a public website by CMS, subsequent years will be published June 30.

Journal Reprints
- Reprints are currently classified as a transfer of value to be reported based on purchase unit cost.
- Items worth less than $10 are not reported unless the sum of all items less than $10 for a given recipient exceeds $100.

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Sunshine Act Primer (cont...)
Sunshine Act Issues

- Transfer of Value (Direct or Indirect or Other)
- Values Assessment (per unit, copyright, fair market)
- Individual & Aggregate
- Format (paper, PDF, memory stick)
- Exemptions (e.g., CME)
- Educational or Promotional
- Recipients (licensed to practice in US)
  Doctors of Medicine, Osteopathy, Dentistry, Podiatry, Optometry, Chiropractic Medicine
- Reporting Process
- Reporting Entities & Site
- Physician Disputes & Resolution (CMS WILL NOT MEDIATE)
Sunshine Act Future

- H.R 293 – Protect Continuing Physician Education & Patient Care Act (January, 2015 referred to House Subcommittee on Health)

- FDA Draft Guidance: Distributing Scientific & Medical Publications on Risk Information for Approved Prescription Drugs & Biological Products (June 2014)

- New Zealand Medical Journal March 27, 2015 Editorial “Let the sunshine in: Making industry payments to NZ doctors transparent”

- CMS MLN (Medicare Learning Network) Teleconference Presentation, April 2015
Survey Results
Demographics

Question 02: Which best describes your current job role? (Mandatory)

<table>
<thead>
<tr>
<th>Job Role</th>
<th>Answers</th>
<th>Skips</th>
</tr>
</thead>
<tbody>
<tr>
<td>Library / Information management</td>
<td>14</td>
<td>0</td>
</tr>
<tr>
<td>Medical Information / Communication</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Consultant</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>R&amp;D</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>IT</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Question 03: How many years of experience do you have within your current job role? (Mandatory)

<table>
<thead>
<tr>
<th>Experience Range</th>
<th>Answers</th>
<th>Skips</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 to 19 years</td>
<td>7</td>
<td>0</td>
</tr>
<tr>
<td>0 to 9 years</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>20+ years</td>
<td>3</td>
<td>0</td>
</tr>
</tbody>
</table>
## Implementation Status

**Question 07**
Which statement best describes the STATUS of Sunshine Act governance and compliance at your company today? *(Mandatory)*

<table>
<thead>
<tr>
<th>Status</th>
<th>Count</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implemented with widespread communication internally</td>
<td>12</td>
<td>80%</td>
</tr>
<tr>
<td>Not applicable</td>
<td>2</td>
<td>13%</td>
</tr>
<tr>
<td>In progress</td>
<td>1</td>
<td>7%</td>
</tr>
<tr>
<td>Implemented, but not widely communicated internally</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Not yet started</td>
<td>0</td>
<td>0%</td>
</tr>
</tbody>
</table>

**Answers**: 15 (100%)

**Skips**: 0 (0%)
**Workflows & Role Beliefs**

**Question 11**
Have information purchases, dissemination practices, and/or workflows inside your company changed in response to Sunshine Act regulation? *(Mandatory)*

<table>
<thead>
<tr>
<th></th>
<th>COUNT</th>
<th>PERCENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>12</td>
<td>80%</td>
</tr>
<tr>
<td>No</td>
<td>2</td>
<td>13%</td>
</tr>
<tr>
<td>Not applicable</td>
<td>1</td>
<td>7%</td>
</tr>
</tbody>
</table>

**Question 12**
Which statement best represents your belief about the role of information professionals to support Sunshine Act governance and compliance within their respective companies? *(Mandatory)*

<table>
<thead>
<tr>
<th></th>
<th>COUNT</th>
<th>PERCENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Librarians &amp; Information professionals should have a minor role</td>
<td>7</td>
<td>47%</td>
</tr>
<tr>
<td>Librarians &amp; Information professionals should have a major role</td>
<td>6</td>
<td>40%</td>
</tr>
<tr>
<td>I don't know</td>
<td>2</td>
<td>13%</td>
</tr>
<tr>
<td>Librarians &amp; Information professionals shouldn't have any role</td>
<td>0</td>
<td>0%</td>
</tr>
</tbody>
</table>
### Department Role

**Question 08**

Which best describes your DEPARTMENT's role in supporting Sunshine Act compliance within your company today? *(Mandatory)*

<table>
<thead>
<tr>
<th>Role</th>
<th>Count</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy Implementor</td>
<td>7</td>
<td>33%</td>
</tr>
<tr>
<td>Policy Influencer</td>
<td>6</td>
<td>29%</td>
</tr>
<tr>
<td>None of the above</td>
<td>3</td>
<td>14%</td>
</tr>
<tr>
<td>All of the above</td>
<td>2</td>
<td>10%</td>
</tr>
<tr>
<td>Other Option</td>
<td>1</td>
<td>5%</td>
</tr>
<tr>
<td>Not applicable</td>
<td>1</td>
<td>5%</td>
</tr>
<tr>
<td>Policy Creator</td>
<td>1</td>
<td>5%</td>
</tr>
</tbody>
</table>
### Department vs Personal Role

**Question 09**
How do you expect the role of your DEPARTMENT in supporting Sunshine Act compliance will change within the next 12 months? *(Mandatory)*

<table>
<thead>
<tr>
<th>Response</th>
<th>COUNT</th>
<th>PERCENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Same level of involvement</td>
<td>12</td>
<td>80%</td>
</tr>
<tr>
<td>Not applicable</td>
<td>2</td>
<td>13%</td>
</tr>
<tr>
<td>Lower level of involvement</td>
<td>1</td>
<td>7%</td>
</tr>
<tr>
<td>Higher level of involvement</td>
<td>0</td>
<td>0%</td>
</tr>
</tbody>
</table>

**Question 10**
How do you expect YOUR personal role in supporting Sunshine Act compliance will change within the next 12 months? *(Mandatory)*

<table>
<thead>
<tr>
<th>Response</th>
<th>COUNT</th>
<th>PERCENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Same level of involvement</td>
<td>8</td>
<td>53%</td>
</tr>
<tr>
<td>Not applicable</td>
<td>4</td>
<td>27%</td>
</tr>
<tr>
<td>Higher level of involvement</td>
<td>2</td>
<td>13%</td>
</tr>
<tr>
<td>Lower level of involvement</td>
<td>1</td>
<td>7%</td>
</tr>
</tbody>
</table>
Survey Q&A for Audience & Panel Discussion
Open Access Commercial Use Licensing Options from WK

**Included uses for OA Commercial Fee**
- OA article link posted on Product Website
- Including links in Pharma newsletters, Rep emails to HCPs, Med Affairs email
- Add on campaign usage reporting

**Excluded uses for OA Commercial Fee**
- iPad Detail for iPad Sales Reps
- Print for non iPad Sales Reps

**Topics of Interest:**
- Open Access
Topics of Interest (cont...)

• Clinical trials & POs
• Teaching hospitals

• Better identification of which ones are reportable
• Article valuation for non-bulk reprint articles
• Fair market value or exact copyright/delivery fees for reprints shared with HCPs

• Global organizations & standards (eg highest common denominator?)
• Country-specific workflows & processes (eg MedInfo)
Biggest Info Pro Challenges

- Including Info Pros BEFORE new compliance workflows are defined
- Explaining how publishing works for compliance colleagues
- Ongoing relationships with commercial, med-legal w/r/t needed info., copyright & re-use guidance.
- Staying informed of any guidance or policy or changes

- Setting a value for an article

- Providing the necessary reporting support
- How to report info. globally & train affiliates (eg licensed in US, but working in S.America)
- Wrangling reports back from non-info pros
- Details, tracking & subjective requirements
### Question 14

**How do YOU think information professionals can best support Sunshine Act compliance within their respective companies?**

<table>
<thead>
<tr>
<th>User ID</th>
<th>Date/Time</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>128.376.475</td>
<td>Yesterday, 12:37PM</td>
<td>Provide the needed background information on how we negotiate and procure the content. What our contracts state we can and cannot do. How the document delivery process works now.</td>
</tr>
<tr>
<td>122.822.208</td>
<td>Tuesday, Apr 7th 9:01AM</td>
<td>Involve early and proactively.</td>
</tr>
<tr>
<td>122.761.995</td>
<td>Monday, Apr 6th 3:26PM</td>
<td>Assisting with the tracking process by applying our process knowledge. In my case, I am supporting the team by being another person working on all the information. There are four of us on working on Sunshine year round.</td>
</tr>
<tr>
<td>121.755.067</td>
<td>Wednesday, Mar 25th 10:30AM</td>
<td>Drive workflows for approving, sharing documents, purchasing copyright permissions, and reporting compliantly.</td>
</tr>
<tr>
<td>121.070.394</td>
<td>Thursday, Mar 19th 11:28AM</td>
<td>Providing benchmarks on cost models, guidance on copyright and reuse, having tools / applications in place to make reporting and compliance part of the user’s regular workflow. Partnership with commercial, legal and medical to ensure training and compliance.</td>
</tr>
<tr>
<td>120.966.612</td>
<td>Wednesday, Mar 18th 7:43AM</td>
<td>I think we should definitely update our copyright disclaimer on the bottom of all emails, also include Sunshine Act.</td>
</tr>
</tbody>
</table>
Comments? Questions? Other Topics?
Panelist Commentary
Print Reprints

Educate Health Care Professionals about the Clinical Effectiveness of Your Product

- Provide your sales reps with a credible leave-behind with staying power.
- Deliver the clinical report, meta-analysis of data or review article for the physician to read at their convenience.
- Reps can quickly point to key passages.
- All LWW proposals and invoicing will clearly indicate the cost per unit.

Example:

<table>
<thead>
<tr>
<th>QUANTITY ORDERED</th>
<th>TOTAL PRICE</th>
<th>COST PER UNIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>10,000 Print Reprints</td>
<td>$50,000</td>
<td>$5</td>
</tr>
</tbody>
</table>
Event & Conference Reprint Solutions

Engage Health Care Professionals in Learning Mode

Conferences & Events Ruling

“We believe that at events open to the public, it will be extremely difficult for applicable manufacturer to identify physician covered recipients. Therefore, we will finalize that small incidental items that are under $10 (such as pens and note pads) that are provided at large-scale conferences and similar large-scale events will be exempted from the reporting requirements, including the need to track them for aggregation purposes."

► View Fed Reg Vol.89, No 27

- Target specialty groups at society and association meetings.
- Support your brand and conference exhibit experience with print and electronic reprints year-round.
- Display on a tablet or distribute print articles and special collections at your booth.
3rd Party Distribution Ruling

“Section 1128G(e)(10)(A) of the Act states that the exclusion of indirect payments or other transfers made through a third party is limited to situations “where the applicable manufacturer is unaware of the identity of the covered recipient.”

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Case Study: Literature Tracking

Medical Affairs approached Reprints Desk in March 2013 to create integrated process to track reprint delivery as per Sunshine Act.

**Bulk ePrints:**
- All ePrints article purchases converted to ePrint hyperlinks with Sunshine Act landing page for data capture (July 2013)

**“One-off” ePrint:**
- All ePrint one-off article purchases converted to ePrint hyperlinks with Sunshine Act landing page for data capture (November 2013)

Wish to thank Chung Lu, Medical Information Director for all of his input.
The following information is provided in response to your unsolicited inquiry requesting a reprint of the following journal article:


Please be aware that the article requires transfers of value to healthcare professionals, including journal reprints as required by applicable state and federal laws including, without limitation, in accordance with the “Sunshine Act” (Section 6002 of the Patient Protection and Affordable Care Act (PPACA)).

A copyright-secured digital form of the study is provided for your individual use and may be downloaded onto your computer at the following hyperlink:

http://Company.reprintsdesk.os.com/MyC6c6ec364aa5a5e0e5a2a25d72146135ed2894b2b9054e51cb22d861b357e24373e45

The digital rights associated with this reprint allow for only one printed copy. Once the article is downloaded onto your computer, it will remain active as a read-only file for one year.

Please note this copy is provided in response to your unsolicited request and is for your individual use only. Dissemination of the hyperlink to any other individual may constitute a violation of U.S. copyright laws.

[Image of email with link to article]
Case Study (“One-off” ePrint)
Case Study

Streamlined process

• Requester provides information
  • Saves employee time to capture Sunshine act information
• Improved turnaround time
  • Reprints Desk handles copyright issues
• Transparent education and disclosures around Sunshine Act
  • Requester provide personal licensure data
• Scalable process
  • bulk orders vs “one-offs”
• Monthly electronic data capture directly fed to Company’s Compliance department
Final Q&A / Discussion