Shedding Some Fair Market Value Light on the Sunshine Act

Sponsored by the Life Science (LS) Practice Group

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OVERVIEW OF PRESENTATION

- PPACA Section 6002 – “Physician Payments Sunshine Act”

- Why Fair Market Value is Important

- Calculation and Process for Determining Fair Market Value

- Practical Tips and Considerations for Life Science Companies
OVERVIEW OF SECTION 6002 OF PPACA

- Section 6002 of the Patient Protection and Affordable Care Act implements the “Physician Payments Sunshine Act”
- Requires pharmaceutical and medical device manufacturers to report to the Secretary of the Department of Health and Human Services, on an annual basis, payments and other transfers of value furnished to physicians and teaching hospitals
- Predicated upon legislation first introduced by Senators Charles Grassley and Herb Kohl in 2007, and introduced annually thereafter in various forms
- Designed to encourage greater transparency in the relationships between life sciences companies and physicians
  - Allow consumers to identify potential sources of bias
  - Provides the federal government with a means of identifying potential kickbacks and other improper financial relationships
  - Deters conflicts of interest in research and education
  - Due to the enforcement risk, potentially deters manufacturers from paying remuneration in excess of fair market value to a referral source – query as to whether this will reduce the cost of healthcare...
- Regulations to be issued no later than October 2011
THE MASSACHUSETTS EXPERIENCE

- Massachusetts enacted The Pharmaceutical and Medical Device Manufacturer Code of Conduct law in August 2008.
  - Reporting of financial relationships began in 2010 for financial relationships during 2009.
  - Public database for 6 month period between July 1, 2009 and December 31, 2009 went live in 2010
  - Database available here: http://www.mass.gov/dph/pharmamed
  - Boston Globe Articles:
By March 31, 2013, each “applicable manufacturer” that provided a payment or other “transfer of value” to a “covered recipient” during calendar year 2012 must report such payment or other transfer of value to the U.S. Department of Health and Human Services.

Subsequent reports due on the 90th day of each calendar year thereafter, for transfers of value during the previous calendar year.
WHO MUST REPORT WHAT?

- **Applicable Manufacturers**
  - A manufacturer of a covered drug, device, biological or medical supply which is operating in the United States, or in a territory, possession, or commonwealth of the United States
  - A covered drug, device, biological, or medical supply is a drug, device, biological, or medical supply covered under Medicare, Medicaid, or SCHIP

- **Covered Recipient**
  - Physicians and teaching hospitals
  - Does not include nurse practitioners, physician assistants, other allied health professionals, or PhDs
  - Does not include “a physician who is an employee of the applicable manufacturer that is required to submit a report”
NATURE OF REPORTABLE PAYMENTS

A transfer of value includes:

- Consulting fees
- Compensation for services other than consulting
- Honoraria
- Gifts
- Entertainment
- Food
- Travel
- Education
- Research
- Charitable contribution
- Royalty or license
- Current or prospective ownership or investment interest
- Direct compensation for serving as faculty or speaker for medical education program
- Grant
- Any other transfer of value
EXCLUDED PAYMENTS AND TRANSFERS OF VALUE

- Transfer of anything of value less than $10, unless aggregate annual amount per covered recipient exceeds $100; for calendar years after 2012, the dollar amounts shall be increased by the same percentage as the percentage increase in the CPI for all urban consumers for the 12-month period ending with June of the previous year.
- Product samples
- Educational materials for patients’ use/benefit
- Loan of a covered device for a short-term trial period, not to exceed 90 days
- Items or services provided under a contractual warranty, including the replacement of a covered device
- Discounts
- In-kind items used for the provision of charity care
- Dividends or other profit distribution forms
- Several others related to covered recipients when not in the context of their professional capacity (e.g., as a patient, legal proceeding)
INDIRECT PAYMENTS

- In the case where an applicable manufacturer provides a payment or other transfer of value to an entity or individual at the request of or designated on behalf of a covered recipient, the applicable manufacturer shall disclose that payment or other transfer of value under the name of the covered recipient.

- Payment or other transfer of value “does not include a transfer of anything of value that is made indirectly to a covered recipient through a third party in connection with an activity or service in the case where the applicable manufacturer is unaware of the identity of the covered recipient.”

☐ Referred to as the “marketing research exclusion”
INFORMATION REQUIRED IN REPORTS

- The following information is required in the annual report, per each covered recipient:
  - Name
  - Business address
  - If the covered recipient is a physician, the NPI and specialty of the physician
  - Amount of EACH payment or transfer of value
  - Date of EACH payment provided
  - Description of form of payment (e.g., cash, in-kind items or services, stock)
  - Nature of the payment or other transfer of value
  - If the payment or transfer of value is related to marketing, education or research specific to a covered drug, device, biological or medical supply, the name of such item
  - Any other information that the Secretary of DHHS may require

- Information from the reports will be available to the public on a searchable database
PUBLICATION OF DATA

- Procedures for submission of information and public availability to be established not later than October 1, 2011 by the Secretary of the DHHS

- Public availability – i.e., internet website – by September 30, 2013 and June 30 of each calendar year beginning thereafter by the Secretary

- Website must provide the manufacturer with the opportunity to review and submit corrections “for a period of not less than 45 days prior to such information being made available to the public.”
DELAYED PUBLICATION FOR PRODUCT DEVELOPMENT AND CLINICAL INVESTIGATION PAYMENTS

- The law provides for delayed reporting of a payment made “pursuant to a product research or development agreement for services furnished in connection with research on a potential new medical technology or a new application of an existing medical technology or the development of a new drug, device, biological, or medical supply, or... in connection with a clinical investigation regarding a new drug, device, biological, or medical supply.”

- Information will be made available after the EARLIER of the following:
  - The date of approval or clearance of the product; or
  - Four calendar years after the date such payment or other transfer of value was made

- It appears that information must be reported in the year of the payment but will remain confidential (and not subject to FOIA disclosure) until it is made available as indicated above.
FEDERAL PHYSICIAN PAYMENTS SUNSHINE ACT-
RELATION TO STATE LAWS

- The Federal Physician Payments Sunshine Act preempts states laws addressing disclosures of payments by pharmaceutical and device manufacturers to physicians and teaching hospitals for payments covered under the law.

- Nonetheless, manufacturers must still consider the requirements under state disclosure laws.

- The law does not preempt any State law or regulation that requires the disclosure or reporting of information that is:
  - Not of the type required to be disclosed or reported under the federal law
  - Excluded payments except for less than $10 each or $100 in aggregate
  - By any other person or entity other than an “applicable manufacturer”
  - To any recipient other than a federal “covered recipient”

- The Federal Physician Payments Sunshine Act is limited to payments made to physicians and teaching hospitals, leaving a broad area of applicability for state laws.
CIVIL PENALTIES FOR NONCOMPLIANCE

Covered entities are subject to penalties for failure to comply with the federal reporting requirements.

<table>
<thead>
<tr>
<th></th>
<th>Minimum</th>
<th>Maximum</th>
<th>Total Annual Limitation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failure to Report</td>
<td>$1,000</td>
<td>$10,000</td>
<td>$150,000</td>
</tr>
<tr>
<td>Failure to Report, <em>Knowingly</em></td>
<td>$10,000</td>
<td>$100,000</td>
<td>$1,000,000</td>
</tr>
</tbody>
</table>

Key Dates

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>October 2011</td>
<td>Anticipated regulations</td>
</tr>
<tr>
<td>January 1, 2012</td>
<td>Begin tracking</td>
</tr>
<tr>
<td>March 31, 2013</td>
<td>First Report Due</td>
</tr>
</tbody>
</table>
SUNSHINE ACT’S IMPACT ON THOUGHT LEADERS

With the dawning of the Sunshine act identifying and engaging thought leaders will become more difficult as the regulatory environment reinforces the importance of identifying and engaging thought leaders through Qualitative means.

What is a thought leader? Today the pharmaceutical industry uses the terms "thought leader" or "key opinion leader"—KOL for short—to refer to influential physicians, often academic researchers, who are especially effective at transmitting messages to their peers. Pharmaceutical companies hire KOL's to consult for them, to give lectures, to conduct clinical trials, and occasionally to make presentations on their behalf at regulatory meetings or hearings.

Types of thought leaders:
- Expert-in-Field
- Specialist
- Subspecialist
- Surgeons
- Primary Care Physicians
- Allied Health Professionals
FMV STANDARD WITHIN THE COMPLIANCE INFRASTRUCTURE

- **Elimination of the FMV “Safe Harbor” hourly rate**
  
  - “Safe Harbor”: Under Stark II, an hourly payment for physician’s personal services is considered to be within fair market value if either (1) the hourly rate is less than or equal to the average hourly rate for emergency room physician services in the relevant physician market, or (2) the hourly rate is determined by averaging the 50th percentile for national compensation level for physicians in the same specialty in at least four of the following six surveys and dividing by 2000 hours: Sullivan Cotter & Associates, Hay Group, Hospital & Healthcare Compensation Services, MGMA, ECS Watson Wyatt, and William M. Mercer.

- **If administrative compensation does not fall under this “Safe Harbor” level, the following issues may be considered:**
  
  - High demand, high salaries for specific specialty
  
  - Unique skills, accomplishments, or status that would bring value to the company and justify higher compensation
  
  - High clinical productivity that would increase the opportunity cost of physician’s administrative services.
Current potential distinction between “Administrative” and “Clinical” services

- 72 F.R. 51016: Under Stark III
  - “We note that the fair market value of administrative services may differ from the fair market value of clinical services”
  - “may be used to compensate physicians for both administrative and clinical work, provided that the rate paid for clinical work is fair market value for the clinical work performed and the rate paid for administrative work is fair market value for the administrative work performed”
FMV FROM A COMMERCIAL PERSPECTIVE

What are the relevant relationships

↓ Transparency in the market place
↓ Doctor-patient relationships
↑ Healthcare costs

↑ Over compensation

↑ Improperly influenced medical decisions
↑ Referrals of expensive prescriptions
↑ Medical conflicts of interest
CALCULATION OF FMV COMPENSATION

Quantitative calculations of base rate(s) \( \times \) Qualitative calculation of KOL premium = Creation of FMV rate schedule
CALCULATION OF FMV COMPENSATION

- Quantitative Methodology
  - **Market Approach:** The market approach measures the value of property or services through an analysis of recent sales or offerings of comparable property. Consideration is given to differences between the market data and the subject services for attributes such as scope of services, specialty and other factors.
  - Benchmarking Market Surveys to derive compensation indications
  - Look to arrangements in markets in which professionals are paid outside of their employee compensation
    - i.e. Physician hourly rates to testify in a court of law (a non-referral relationship)
CALCULATION OF FMV COMPENSATION

- Relevant market and benchmark data:
  - American Medical Group Association;
  - Economic Research Institute;
  - Sullivan Cotter and Associates;
  - Hay Group;
  - Hospital and Healthcare Compensation Service;
  - Integrated Healthcare Strategies Survey;
  - Medical Group Management Association; and
  - Merritt Hawkins & Associates.
CALCULATION OF FMV COMPENSATION

- Qualitative Methodology

- KOL premium compensates a consultant for his or her higher level of expertise and experience in the field
  - Typical methodology involves a build-up approach of the premium

### KOL premium build-up

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early Adopter</td>
<td>X</td>
<td></td>
<td>5.0%</td>
</tr>
<tr>
<td>Led Research</td>
<td>X</td>
<td></td>
<td>5.0%</td>
</tr>
<tr>
<td>Board Certified</td>
<td></td>
<td>X</td>
<td>0.0%</td>
</tr>
<tr>
<td>KOL possible premium</td>
<td></td>
<td></td>
<td>10.0%</td>
</tr>
</tbody>
</table>
CALCULATION OF FMV COMPENSATION

- Example of hourly FMV rates for a KOL

  1. Derive annual compensation indications from your considered benchmark data
  2. Derive an annual time commitment indications from your considered benchmark data
  3. Divide annual compensation indications by time commitment indicates to calculate and hourly-base compensation rate
  4. Derive a KOL premium
  5. Potentially, adjust your hourly-base compensation by the KOL premium
### EXAMPLE OF FMV COMPENSATION CALCULATION

<table>
<thead>
<tr>
<th></th>
<th>25th Percentile</th>
<th>Median</th>
<th>75th Percentile</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>National Weighted Average Comp. and Benefits</strong></td>
<td>$415,193</td>
<td>$541,960</td>
<td>$693,880</td>
</tr>
<tr>
<td>Annual Time Adjustment</td>
<td>2.99%</td>
<td>2.99%</td>
<td>2.99%</td>
</tr>
<tr>
<td><strong>Time-Adjusted National Weighted Average Comp. and Benefits</strong></td>
<td>$440,366</td>
<td>$574,818</td>
<td>$735,948</td>
</tr>
<tr>
<td>Regional Adjustment</td>
<td>7.25%</td>
<td>7.25%</td>
<td>3.63%</td>
</tr>
<tr>
<td><strong>Time- and Region-Adjusted Weighted Average Comp. and Benefits</strong></td>
<td>$472,311</td>
<td>$616,517</td>
<td>$762,642</td>
</tr>
<tr>
<td>Annual Hours of Coverage</td>
<td>8,760</td>
<td>8,760</td>
<td>8,760</td>
</tr>
<tr>
<td><strong>Hourly Compensation Rate</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>KOL Premium</td>
<td>$53.92 $</td>
<td>70.38 $</td>
<td>87.06 $</td>
</tr>
<tr>
<td>Adjusted Hourly Compensation Rate</td>
<td>$59.31 $</td>
<td>$77.42 $</td>
<td>$95.77 $</td>
</tr>
<tr>
<td>Preparation hours</td>
<td>10 10</td>
<td></td>
<td>10</td>
</tr>
<tr>
<td>Facilitating a speaker training hours</td>
<td>10 10</td>
<td></td>
<td>10</td>
</tr>
<tr>
<td>Travel Time Hours</td>
<td>12 12</td>
<td></td>
<td>12</td>
</tr>
<tr>
<td><strong>Total Physician Consultant Cost</strong></td>
<td>$1,898 $</td>
<td>$2,477 $</td>
<td>$3,064 $</td>
</tr>
</tbody>
</table>

This example of calculation methodology is not an opinion of value.
COMMON METHODOLOGY MISTAKES

Quantitative Selection Criteria

- By Internal historical rates “tainted” market values

  - The overall industry standard of payments for consulting and speaking engagements may have been inflated over the past years
  - May not have the granularity to appropriate to an individual company’s compensation decisions

Qualitative Selection Criteria

- By Company
- By Size
- Types of Services
  - Example: Writing a manuscript vs. Writing marketing materials
FAIR MARKET VALUE TREATMENT OF ROYALTY RATES

- Establish Fair Market Value royalty percentage
  - Using a valuation firm that works on IP opinions
  - Using the market approach

- Again, In the Market Approach, value is inferred from analysis of comparable properties that are for sale (have sold) in the marketplace.

  - Applying royalty terms found in comparable patent license agreements, an estimated stream of Royalty Revenues arising from those Market
    - www.Royaltysource.com
    - www.KTmine.com
KEY ISSUES FOR CONSIDERATION AS REPORTING APPROACHES

- Reporting does not begin until 2013 for calendar year 2012. 11 Months remain to conduct internal reviews on current relationships with covered recipients.
- Start to look at all company touches with covered recipients, not just the obvious ones.
- Create a FMV tool for internal use in setting compensation.
- Have documentation of FMV on hand before reporting begins.
- FMV is not all that matters – make sure that the services paid for were actually needed and were used.
- Be aware of covered recipients other issues because your company will now be directly linked to them very publicly:
  - Licensure issues/DEA issues
  - Patient care and malpractice problems
- Be prepared for your very own “Boston Globe” type article
QUESTION AND ANSWER SESSION
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