Evaluating and Determining Fair Market Value for KOLs

Presented by Jen Johnson, CFA
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Discussion Points

I. Introduction

II. Physician Payments – In the News

III. Guidelines to Disclosure

IV. Keys to Compliance

V. Determining Fair Market Value

VI. Helpful Compliance References
I. Introduction
Speaker Background

- VMG Health solely provides valuation advisory services in the healthcare industry
  - Founded in 1995, offices located in Dallas, Texas and Nashville, Tennessee
  - The firm performs over 600 valuations per year throughout the United States and abroad
  - Financial valuation experts who understand the regulatory guidance associated with the healthcare industry
  - Trusted third party to determine FMV between referral relationships with physicians

- Jen Johnson, CFA, Partner
  - Professional Service Agreements Division
  - Previously with KPMG’s litigation department
  - Former Finance professor from the University of North Texas
  - Published and presented multiple times related to physician compensation and fair market value
    - RX Compliance
    - Healthcare Financial Management
    - Compliance Today
    - American Health Lawyers Weekly
    - American Bar Association

- Life sciences contributions
  - Contributing author to AHLA’s life sciences new publication (in process)
  - Membership on the Fair Market Value Subcommittee for the Investigator Initiated-Sponsored Research Association (IISRA)
  - AHLA Presentation - Financial Relationships in Clinical Trials: Determining Fair Market Value
II. Physician Payments – In the News
Press – Onset of Disclosure

- **Academic Researchers Report – Bloomberg (9/1/09)**
  - Based on survey of 1,663 researchers, academic researchers get up to $110,869 from industry
  - Those involved were “substantially” more likely to report positive results

- **Pew Prescription Project - AP (9/3/09)**
  - Analysis prompted by Minnesota disclosure laws identified $750,000 paid to physicians by Forest Laboratories.
  - Speakers Fees of over $1,000 each for 62 physicians
  - Over $10,000 to 28 physicians

- **“Ghostbusting” - New York Times (9/18/09)**
  - Influential medical editors and Congress are actively investigating and punishing authors who have received extensive contributions by ghost writers
  - Zero tolerance policy, retract articles and banish authors

- **Medtronic / Dr. David Polly - Star Tribune (9/22/09)**
  - Senator Grassley’s inquiries to alliances associated with Dr. David Polly, Head of Spine Surgery at the University of Minnesota regarding Medtronic’s payment of $1.2 million from 2003 to 2007
  - Fairview Health Services asked for accounting records for devices since January 2008
  - Team Spine asked for all correspondences and bonus amounts associated with a certain sales representative.
371 new ‘whistleblower’ cases in two years (a 42.4% increase)

Penalties for only four companies over 2009-2010 total over $4.5 billion

FDA plans to pursue drug company managers for violations, not just companies
Recent Disclosure – 2010 Payments

- **Eight disclosing companies in 2010**: AstraZeneca, Cephalon, GlaxoSmithKline, Eli Lilly, Johnson & Johnson, Merck, Pfizer, and ViiV
  - Represent 36% of US market share
  - Merck is the only company voluntarily disclosing, others forced per settlement terms (Source: ProPublica)

- **GlaxoSmithKline - $85 million**
  - $56.8 million in speaking and advising fees
  - 5,331 physicians and other professionals
  - $10,600 per physician

- **Merck - $20.4 million**
  - $20.4 million in speaking fees
  - 2,000 physicians
  - $10,200 per physician

- **Pfizer - $177 million**
  - $43.3 million in speaking and advising fees
  - 4,600 physicians and other professionals
  - $9,400 per physician
  - $6,200 per physician for professional advising
  - $7,400 per physician for expert let forums

- **Royalty Payment Data** – less than 1% of payments to physicians based on a Washington University study of 1,390 respondents
## Results of Disclosure

- **Payments to physicians are dropping**
  - 50% Payment Drop - PolicyMed.com (6/17/11)
    - Pharmaceuticals & medical device companies have decreased average pay of physicians by 50% from $604 in 2006 to $299 in 2011 concurrent with onset of reporting, according to a Cutting Edge report
    - American Psychiatric Association reports over a 10% decrease in pharmaceutical industry funds for research and education.

- **Disclosed payments to physicians are prompting investigation regarding amounts and necessity, be prepared:**
  1. Build an infrastructure for compliance
  2. Understand regulatory guidelines when determining compensation
  3. Maintain documentation

### Average Physician Pay 2006 - 2011

<table>
<thead>
<tr>
<th>Year</th>
<th>Average Pay (per hour)</th>
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<tbody>
<tr>
<td>2006</td>
<td>$604</td>
</tr>
<tr>
<td>2011</td>
<td>$299</td>
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III. Guidelines to Disclosure
Governmental Guidance

- **Physician Payments Sunshine Provision**: any manufacturer of a covered drug, device, biological, or medical supply that makes a payment or another transfer of value to a physician or teaching hospital must report details of payments including
  - The transfer recipient’s name, business address
  - Amount of the payment
  - A description of the nature of the payment
  - Name of that product

- **OIG guidance for pharmaceutical manufacturers was issued in 2003.**
  - Compensation arrangements should be set out in writing in advance
  - Legitimate need for the service: quarterly or annual needs assessment suggested
  - Payments must be set at Fair Market Value
  - 5 years later 92% of drug makers stated that this guidance significantly impacted how they structure arrangements.
  - *URL link to this document is located at the back of these slides*
PhRMA Code and Advamed

Similar guidelines are supported by the PhRMA Code and Advamed Code

- Separate marketing department from consultant selection – should be R&D, medical affairs, and regulatory/legal department.
- The number of consultants engaged should not exceed what is required.
- Consultant selection based on qualifications.
- Compensation must be set at Fair Market Value.
- Payments for travel and lodging must be reasonable.
- California and Massachusetts both have referenced the PhRMA Code in their respective laws; Massachusetts also has referenced the AdvaMed code.
- Both codes provide good source when building, improving or auditing a compliance program.

*Defensible documentation for any payment to a physician is a key defense to disclosure.*
V. Keys to Compliance
Compliance Infrastructure

- Regulatory authorities have consistently considered establishing an infrastructure for compliance to be essential
  - Establish compliance policies
  - Train employees on compliance policies
  - Monitor and update compliance policies
  - Take action when necessary

- Setting Compensation
  - Demonstrate a consistent and logical methodology is applied when determining physician compensation.
  - Consider establishing internal thresholds for compensation with an internal calculator.
  - When certain arrangements deviate from an internal threshold, provide defensible documentation as to why higher compensation is justified.
Compliance Checklists

- In reviewing arrangements for compliance purposes, ask these questions:
  - Is there a legitimate need for the service?
  - Did the marketing department engage physician consultants?
  - Are there excess consultants engaged?
  - Is there documentation that services were actually provided?
  - Is the physician consultant receiving additional benefits not tied to the trial (ie: retains equipment post-trial)?
  - Was the associated publication written by the Investigator?
  - Was compensation set at Fair Market Value, as defined by the regulatory authorities?
Healthcare Compliance Association Guidelines

- **Process**
  - Is there a formal process through which payment levels are determined through pre-specified criteria?
  - Are the payments pre-set and defined or can they be variable?

- **Purpose**
  - Why is the payment necessary?
  - What is the underlying purpose?
  - Is the payment potentially duplicative?
  - Is there a potential for fraud, waste, and abuse?

- **Need**
  - Why is the service necessary from this individual or company?
  - How does it relate to the company’s commercial or clinical strategy?

- **Payment**
  - Was there a determination process to derive a “fair market value” range for the payment?
  - Is there a process to track the “totality of spend” on a particular healthcare professional?

- **Service**
  - Was the service actually performed?
  - Was there a demonstrable outcome that resulted from the payment?
IV. Determining Fair Market Value
FMV – The Basics

Why FMV matters

» Relevant regulatory guidelines state manufacturers and distributors must compensate physicians at FMV. This is because physicians are often in a position to order or recommend product sold by manufacturers or distributors.

The Business Valuation Definition

» The price, expressed in terms of cash equivalents, at which a property would change hands between a hypothetical willing and able buyer and a hypothetical willing and able seller, acting at arms length in an open and unrestricted market, when neither is under compulsion to buy nor to sell, and when both have reasonable knowledge of the relevant facts.

Regulatory Requirements

» The compensation must be set in advance and not determined in a manner that takes into account the volume or value of referrals or other business generated by the referring physician.

*FMV determination must be calculated using a reasonable and consistent methodology that considers regulatory guidance.*
Based on our understanding of previous healthcare regulatory guidance, we know the following related to determining FMV:

- Physician’s “going rate” does not constitute FMV.
  - Historical compensation does not necessarily support payments are FMV.
  - Opportunity costs should not be relied upon as the sole FMV methodology.

- The Fair Market Value of administrative services may differ from the Fair Market Value of clinical services.

- Reference to multiple, objective, independently published salary surveys remains a prudent practice for evaluating Fair Market Value.

- Look to alternative valuation methodologies when all the available comparables or market data reflect transactions between entities that are in a position to refer or generate other business.

- Whenever possible, fair market value payment rates should be analyzed and developed using multiple valuation approaches.
Guidelines: Physician Compensation

- **Identify physician needs through valid research**
  - Physician chosen based on clinical needs
  - Determine if multiple physicians are required

- **Identify services**
  - Types of services provided
    - Research
    - Design
    - Clinical trial
    - Education
  - Complexity of task – credentials required
  - Frequency of task – time required

- **Establish internal thresholds**
  - Calculators – by tier, specialty and service
  - Third party opinion on individual arrangements falling outside calculator
KOL Data Challenges

- **Cutting Edge** provides surveys related to clinical trials and KOL compensation. Key Drawbacks to the survey data include:
  - Only one survey available
  - Based on referral relationship data – “tainted”
  - Representative from Cutting Edge stated he has observed and expects continued decreases in physician compensation.
  - Lead researcher states there is little or no detail related to the “additional fees” quoted on the survey and they are beginning to see a decline in these fees.

- **Newly available data from self-disclosure and state laws**
  - Based on referral relationship data – “tainted”
  - Required details for data to be useful missing
    - Unknown time spent on services
    - Vague description of services provided
    - Requirements (credentials/experience) for position unknown
  - Same issues will be present with Sunshine Provision data

*Valuation conclusion - No perfect benchmarking data, apply several methodologies*
KOL Valuation Methodologies

- **Compensation data to consider in determining FMV**
  - Consulting Surveys
  - Clinical Surveys
  - Academic Surveys
  - Litigation Consulting Fees

- **Factors to consider in determining FMV**
  - Services being provided
    - Clinical
    - Consulting
    - Abstract/Speech
  - Therapeutic area
  - Required credentials
  - Time required from KOL

- **Understand Qualifications of KOL**
  - Number of citations and publications
  - Very specialized areas may have limited data but warrant premium
    - Migraine KOL – less citations but specialized
    - Brand new markets

- **Tier 1, 2 and 3 parameters should be identified and consistently applied**
KOL Payment Arrangements and Important Documentation

- Qualifications and services of consultant outlined in an agreement
  - Purpose of Services
  - Specialty required
  - Experience level required
  - If not an hourly agreement, estimated time required

- Maintain copy of current CV
  - Specialty/Boards
  - Consulting experience/KOL status
  - Years post-residency
  - Publications
  - Current academic positions

- Document services were provided
  - Description of services provided
  - Date
  - Time spent
  - Review and approval by appropriate department
  - Basis for FMV determination of payments
VI. Helpful Compliance References
References

- **OIG Guidance**
  - [http://oig.hhs.gov/fraud/docs/complianceguidance/042803pharmacyfifo.pngonfr.pdf](http://oig.hhs.gov/fraud/docs/complianceguidance/042803pharmacyfifo.pngonfr.pdf)

- **PhRMA Code**
  - [http://www.phrma.org/code_on_interactions_with_healthcare_professionals/](http://www.phrma.org/code_on_interactions_with_healthcare_professionals/)

- **Advamed Code**
  - [http://www.advamed.org/MemberPortal/About/code/](http://www.advamed.org/MemberPortal/About/code/)

- **IISRA: FMV Position Statement**

- **Fair Market Value and the Sunshine Act: Preparing for Mandatory Disclosure**
Questions and Discussion

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