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**Determining the FMV of
Thought Leader Compensation
in the Life Sciences Industry**

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Housekeeping

- The Web seminar will last about 1 hour
- Please type all questions in the Q&A tab
- Web seminar will be recorded for future playback
- Slides will be available with the recording

Guest Speaker: Ann S. Brandt, Ph.D.

Manager, HealthCare Appraisers, Inc.

- Dr. Brandt is an experienced presenter and has authored several articles on healthcare valuation topics.
- Dr. Brandt specializes in valuing compensation arrangements which may have Stark and/or Anti-Kickback implications.
- Working primarily with hospitals, pharmaceutical companies and medical device companies, Dr. Brandt leads the Firm's life sciences service line.
- She has specific expertise in valuing thought leader compensation and data acquisition arrangements as well as clinical trials and principal investigator compensation
- Dr. Brandt has more than twenty-five years of healthcare experience as a clinician, consultant, strategist, marketer and professor.
- Prior to joining HealthCare Appraisers, she served as a senior consultant specializing in healthcare information technology and process redesign at a Fortune 15 technology and consulting company.
- She has extensive experience in physician/hospital partnerships as well as in operational restructuring, information management and clinical transformation.
- In addition, she has owned and operated several healthcare-related businesses.



Guest Speaker: Scott Safriet, AVA, MBA

Principal, HealthCare Appraisers, Inc.

- Mr. Safriet is a frequent speaker and author on healthcare valuation topics.
- Mr. Safriet has over fifteen years of broad healthcare experience, the last five of which have been spent exclusively on a healthcare valuation focus, primarily addressing any type of agreement or compensation arrangement which may have Stark and/or Anti-Kickback implications.
- Prior to becoming a partner at HealthCare Appraisers, Mr. Safriet served as Vice-President of Sales and Business Development for a national in-home care services organization.
- Mr. Safriet was a senior executive with a national healthcare consulting firm whose emphasis was on strategy, business planning and acquisitions/mergers and joint ventures.



Regulatory Overview: Abridged Version

- Thou shalt not enter into compensation arrangements that are not commercially reasonable.
- Thou shalt generally heed guidance set forth in the Stark and Anti-Kickback statutes.
- Thou shalt not pay physicians at rates above FMV.



The Laws and Regulations

- Anti-Kickback Law
- Stark Law
- False-Claims Act



The Government is Watching

■ Kickbacks

- Speaker fees
- Advisory boards
- Meetings (planning, conferences, etc.)
- Training, surgical demonstrations, etc.



■ Clinical trial fraud

- Providing remuneration for clinical studies which may have no legitimate value” as a means to induce physicians to prescribe/use specific products

The Punishments

- Bayer HealthCare – \$97.5 million (2008)
- Biovail Pharmaceuticals - \$22.2 million (2008)
- Biomet, DePuy Orthopedics, Smith & Nephew, and Zimmer- \$311 million + 5 year CIA (2007)
- Schering-Plough - \$435 million (2005)
- Medtronic - \$40 million (2006)
- Lincare - \$10 million (2006)
- Pfizer (Warner-Lambert) - \$240 million (2004)



The Punishments

- In the government settlements with medical device companies concerning *payments to physician consultants (previous slide)*...
 - The settlement agreements reiterated that compensation for such arrangements must be at FMV and required the manufacturers to seek *independent third party opinions* to establish FMV anytime physician consultant compensation will exceed \$500 per hour.
- HCA's CIA required independent FMV assessment for arrangements exceeding \$150 per hour.



Establishing FMV

- Two completely acceptable approaches –
 - Internally prepared analysis/documentation (unless an agreement with the government requires independent FMV analysis above certain dollar thresholds)
 - Use of a FMV consultant
- This presentation applies equally to both approaches.

The Healthcare Valuation Risk Continuum

More Risk

- No formal valuation process
- Payment rates are based upon:
 - Market surveys
 - Physician “demands”

Less Risk

- Use of independent credentialed appraiser
- Strict compliance with FMV definition
- Formal documentation process
- Use of accepted valuation approaches
- Application market data is free from bias
- Logical, defensible, reproducible conclusions

Commercial Reasonableness

- The term “commercially reasonable” is defined as an arrangement that would make commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty, even if there were no potential business referrals between the parties.
- This definition is based on guidance provided by CMS in the preamble to the Stark II Phase II regulations at *69 Fed. Reg. 16093 (March 26, 2004)*.

Commercial Reasonableness Simplified

- The easiest way of insuring commercial reasonableness is to consider whether the compensation arrangement would be entered into with the physician assuming no possible or expected side benefit.
- Consideration can be given to whether an arrangement might be entered into by a non-healthcare company under similar circumstances.

Fair Market Value Defined

- **IRS Definition:** In Revenue Ruling 59-60 the Internal Revenue Service defines fair market value as “the amount at which property would change hands between a willing seller and a willing buyer when the former is not under any compulsion to buy and the latter is not under any compulsion to sell and when both have reasonable knowledge of the relevant facts.”
- **CMS Definition:** “...the value in arm's-length transactions, consistent with the general market value. “General market value” means the price that an asset would bring, as the result of *bona fide* bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset.” Usually, the fair market price is the price at which *bona fide* sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition.”

The Determination of FMV

- Federal regulators have historically provided little guidance on the way fair market value compensation should be calculated.
- However, a significant body of knowledge exists related to business valuations.



Valuation Approaches

- Income Approach
- Cost Approach
- Market Approach



The Income Approach

Income Cost Market

- The Income Approach is defined according to the International Glossary as “a general way of determining a value indication of a business, business ownership interest, security, or intangible asset using one or more methods that convert anticipated economic benefits into a present single amount.”
- *The use of an income approach in evaluating healthcare transactions may appear to give consideration to the value of possible referrals among the parties.*

The Cost Approach



Income Cost Market

- The Cost Approach is defined according to the International Glossary as “a general way of determining a value indication of an individual asset by quantifying the amount of money required to replace the future service capability of that asset.”
- The Cost Approach is based upon the Principle of Substitution - *i.e.*, the premise that a prudent individual will pay no more for a property than he/she would pay to acquire a substitute property with the same utility.

The Market Approach



- The Market Approach is defined according to the International Glossary as “a general way of determining a value indication of a business, business ownership interest, security, or intangible asset by using one or more methods that compare the subject to similar businesses, business ownership interests, securities, or intangible assets that have been sold.”

Potential Valuation Pitfalls

- Use of “opportunity cost”
- Reliance upon “good faith negotiations” or meeting the compensation demands of the physicians
- Reliance upon tainted market values



“Tainted” Market Data

- Generally, any market data used to establish FMV must be “arm’s-length.”
- Federal regulations dictate that “tainted” data must not be used to establish FMV.
- Therefore, industry survey data may not be a sound basis for establishing FMV.



Physician Compensation: Sources of Market Data

- Medical Group Management Association
- Sullivan, Cotter and Associates, Inc.
- Hospital & Healthcare Compensation Service
- Watson Wyatt Data Services
- *American Medical Group Association*
- Integrated Healthcare Strategies (f/k/a Clark Consulting)

Sample Compensation by Medical Specialty (MGMA)

	Median	75 th Percentile	90 th Percentile	Hourly Rate (75 th)	Hourly Rate (90 th)
Cardiology	\$368,000	\$492,000	\$613,000	\$264	\$324
Nephrology	\$292,000	\$377,000	\$466,000	\$209	\$252
Neurology	\$220,000	\$299,000	\$394,000	\$168	\$217
OB/GYN	\$271,000	\$350,000	\$451,000	\$195	\$245
Oncology	\$363,000	\$538,000	\$997,000	\$287	\$508
Psychiatry	\$186,000	\$224,000	\$267,000	\$128	\$151
Rheumatology	\$200,000	\$256,000	\$360,000	\$145	\$200

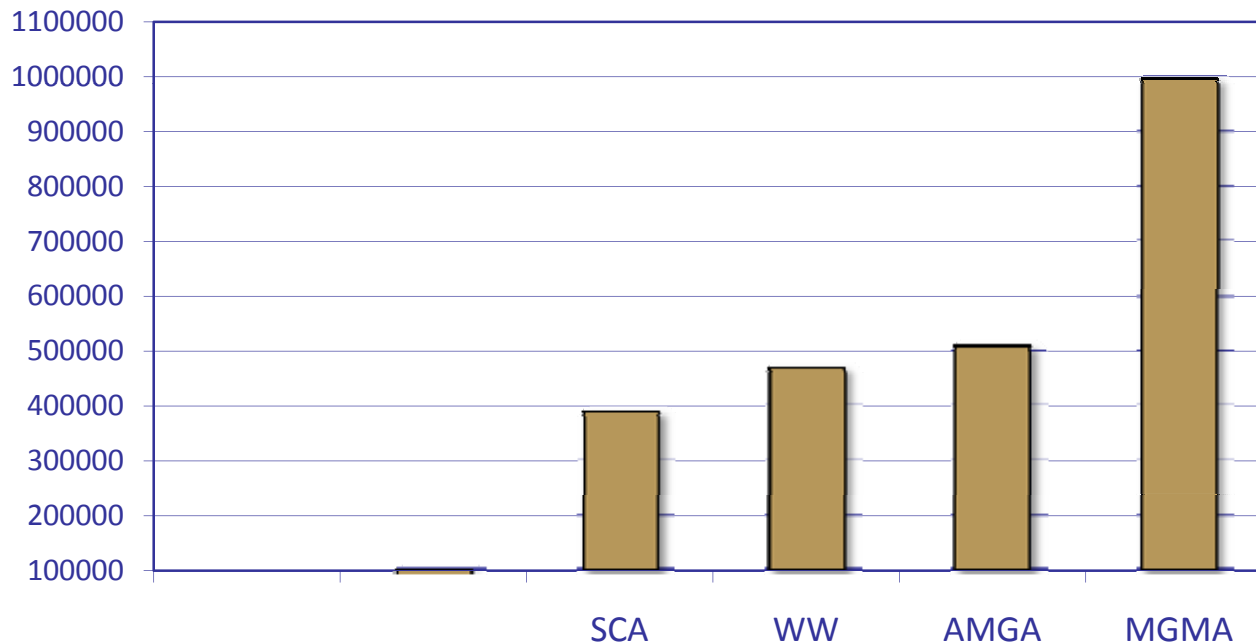
CMS “Safe Harbor” Compensation

	Hourly Rate (75 th)	Hourly Rate (90 th)	Hourly Rate CMS “Safe Harbor”
Cardiology	\$264	\$324	\$146
Nephrology	\$209	\$252	\$106
Neurology	\$168	\$217	\$ 96
OB/GYN	\$195	\$245	\$130
Oncology	\$287	\$508	\$116
Psychiatry	\$128	\$151	\$ 86
Rheumatology	\$145	\$200	\$ 92

Beware of Survey Anomalies

■ Hematology/Oncology Compensation

90th Percentile Values



Description of Subject Arrangements

- Payments to physicians for personally performed services
 - Thought Leader / Advisory Boards / Medical Director / Promotional Presentations / Educational Programs
 - Physician participation in clinical studies (*e.g.*, principal investigator, etc.)
- Other payments to physicians not covered in today's presentation...
 - Licensure / royalty payments
 - Payments involving intellectual property (*e.g.*, data)



Determining the FMV of Thought Leader Compensation

- A reliable and comprehensive valuation approach should provide the following:
 - An evaluation methodology that analyzes each parameter in an objective, consistent and repeatable way.
 - A FMV outcome that encompasses all relevant parameters.
 - A FMV outcome that can be supported via *independent* market data.



Parameters to Consider: The FMV of Thought Leader Compensation

- Extent of the services (*i.e.*, how many hours)
- The nature of the specialty
- Credentials/qualifications of the thought leader
- The specific services contemplated by the arrangement



A Cost Approach: The Thought Leader Compensation Algorithm

- Utilizes survey benchmark compensation data, by medical specialty, as the starting point.
 - Considers multi-year data.
 - Compensation data is grossed-up for benefits.
- Makes a series of adjustments to the benchmark data based on:
 - The extent of thought leader time required.
 - Specific requirements of the position.
 - The skills/experience of the specific thought leader.

Factors Based on Specific Duties and Responsibilities:

- Number of hours associated with each duty and/or responsibility
- The specific duties and responsibilities of the position
- The complexity of each duty and/or responsibility
- Level of leadership required
- Specific objectives and deliverables
- Potential impact of thought leader/consultant on organizational and/or product success



Factors Based on Thought Leader Qualifications:

- Educational credentials and specialized training
- Professional certifications
- Leadership experience
- Academic appointments
- Research experience and funding history
- Invited presentations
- Publication history
- Other professional leadership activities / recognition in the healthcare community



“Scoring” the Thought Leader Algorithm

- Establish relative weightings for the pertinent factors.
- Identify interdependencies among the factors (*e.g.*, extent of time requirement vs. qualifications of thought leader).
- Consider potential redundancy of qualifications.



A Market Approach

- Place reliance upon “non-tainted” data.
- Consider physician compensation arrangements that are free from referral bias.
- “Crosswalk” the arrangement to a non-healthcare setting.



Examples of Non-Tainted Market Data

- Fees paid to physicians who are not in a position to refer:
 - Expert witness fees
 - Physician consultants/executives
- Fees paid to comparably qualified non-physicians:
 - Consultants
 - Attorneys

In Summary

- Increased government scrutiny means there are many reasons to develop and maintain FMV assessment of arrangements with physician thought leaders.
- The methodology used to determine FMV should be reliable, comprehensive and reproducible.



Questions?



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Thank You

For more information, please contact:

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