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Establishing and Documenting Fair Market Value Compensation

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Regulatory Overview: Abridged Version

- Physician compensation arrangements must be commercially reasonable.
- The arrangements must be in compliance with applicable federal (and state) regulations.
- Compensation paid to physicians must not exceed FMV.



The Laws and Regulations

- Anti-Kickback Law
- Stark Law
- False-Claims Act
- Prescription Drug Marketing Act



Approaches to Establish and Document
Fair Market Value Compensation

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Suspect Arrangements

■ Kickbacks

- Meetings (advisory, training, planning, conferences)
- Speaker fees
- Physician investment/ joint venture relationships (medical device industry)

■ Clinical Trial Fraud

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



The Settlements

- Between 2001 and the end of 2008, more than \$4 billion has been recovered from drug manufacturers as a result of cases brought by whistleblowers:
 - TAP - \$875 million settlement (2001)
 - Abbott Labs - \$622 million (2003)
 - Warner-Lambert (Pfizer) – \$430 million (2004)
 - Eli Lilly - \$36 million (2005)
 - Cephalon - \$425 million (2008)



The Settlements

- In a recent series of government settlements with medical device companies concerning *payments to physician consultants*, the companies involved were required to pay a total of \$311 million dollars.
- 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 acceptable *sources* for FMV analysis/documentation:
 - Internally prepared analysis/documentation (unless an agreement with the government requires independent FMV analysis under certain circumstances)
 - Use of an independent FMV consultant
- This presentation applies equally to both sources.

Establishing FMV

- Two acceptable *approaches* for FMV analysis/documentation:
 - “Global” or “blanket studies,” internal “safe harbors” and other similar approaches
 - Specific analysis related to certain physicians and/or certain types of services
- This presentation addresses 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 means 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.

Does the Government Really Mean FMV?

- FMV is a term of art.
- The IRS really means FMV. Opposing experts regularly battle over valuation theory.
- Do healthcare regulators really mean FMV, or does the arrangement just have to be “fair”?
- Federal healthcare regulators are more likely to defer to reasonable methodologies and good intentions than would the IRS.

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.”

Implications of the FMV Standard

- FMV involves a *hypothetical* scenario.
- FMV is distinctly different from *investment value* (which considers synergies among the parties).
- FMV is not *necessarily* established through...
 - Earnest negotiations
 - An amount that is requested
 - Opportunity cost
- CMS has noted that the value may be different for physician clinical vs. administrative services.

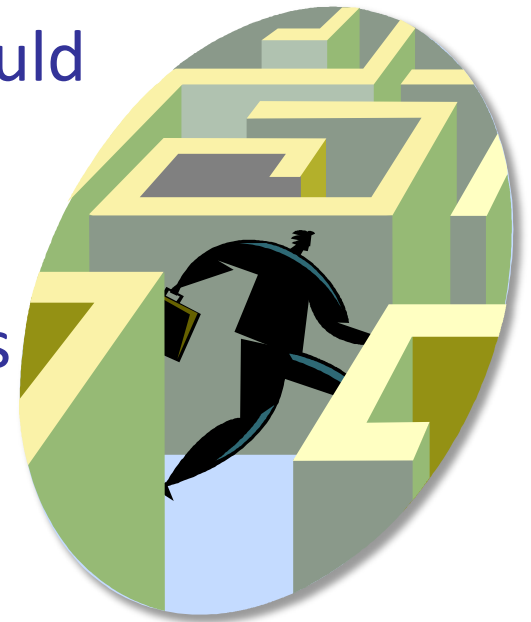
US Court of Appeals opinion in the case of *U.S. ex rel. Ted D. Kosenske, M.D. v. Carlisle HMA*

The Court of Appeals held that,

“...as a legal matter, a negotiated agreement between interested parties does not “by definition” reflect fair market value. To the contrary, the Stark Act is predicated on the recognition that, where one party is in a position to generate business for the other, negotiated agreements between such parties are often designed to disguise the payment of non-fair-market-value compensation.”

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



Why does the “Approach” Matter?

- Whether the valuation process is prepared by someone with valuation training/experience or not, each valuation approach should be founded in a rational methodology, generally mirroring the widely recognized valuation approaches.

Examples include:

- “We valued the services based upon our market research.”
- “We valued the services from a ‘make vs. buy’ standpoint.”

Income Approach



- The Income Approach is defined by 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.*

Cost Approach



- 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.

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.”

Most Widely Used Approaches

- Frequently used - Market Approach
 - How does the market value these services (on an arms' length basis)? (*e.g.*, home values, employment arrangements, restaurant meals)
- Occasionally used - Cost Approach
 - What would it cost to replicate the same service?
 - Sometimes, a Market Approach and a Cost Approach may be synonymous.
- Rarely used – Income Approach

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 “arms-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 (Diag)	\$411,000	\$511,000	\$641,000	\$274	\$337
Nephrology	\$299,000	\$355,000	\$447,000	\$198	\$243
Neurology	\$229,000	\$295,000	\$412,000	\$166	\$225
OB/GYN	\$283,000	\$360,000	\$450,000	\$200	\$244
Oncology	\$363,000	\$516,000	\$778,000	\$276	\$403
Psychiatry	\$206,000	\$251,000	\$278,000	\$142	\$157
Rheumatology	\$219,000	\$274,000	\$365,000	\$154	\$202

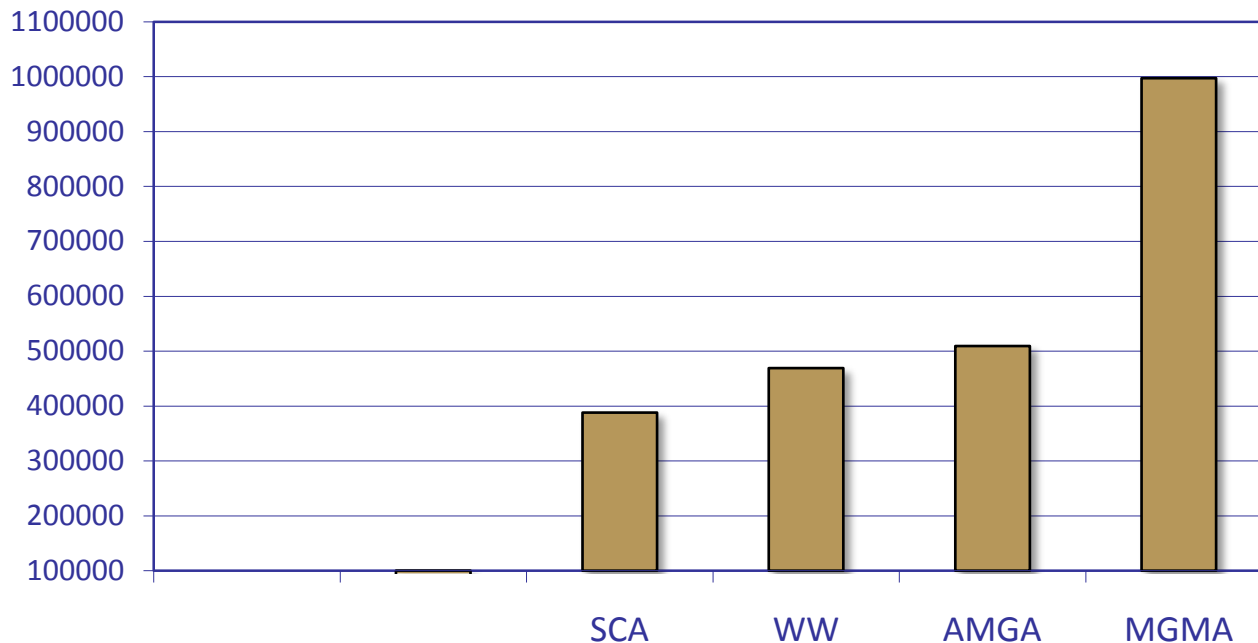
CMS “Safe Harbor” Compensation

	Hourly Rate (75 th)	Hourly Rate (90 th)	Hourly Rate CMS “Safe Harbor”
Cardiology	\$274	\$337	\$163
Nephrology	\$198	\$243	\$109
Neurology	\$166	\$225	\$ 101
OB/GYN	\$200	\$244	\$120
Oncology	\$276	\$403	\$141
Psychiatry	\$142	\$157	\$ 89
Rheumatology	\$154	\$202	\$ 93

Beware of Survey Anomalies

■ Hematology/Oncology Compensation

90th Percentile Values



Description of Subject Arrangements

- Payments to physicians for personally performed services
 - Thought Leader / 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



In-Direct Market Approach: Thought Leader Compensation “Buildup”

- Utilize survey benchmark compensation data, by medical specialty, as the starting point.
 - Consider multi-year data.
 - “Gross up” for taxes/benefits.
 - Be cautious with cost of living adjustments.
- 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 “Buildup”

- 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.



Supporting a Concluded Value

- Ensure that the concluded value corresponds to the nature of the services (*i.e.*, clinical vs. administrative time).
- This may present a challenge even if the proposed compensation falls within the 90th percentile of the compensation surveys. If the proposed compensation is above the 90th percentile, a particularly compelling case must be made.

Direct 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

Reconcile the Approaches

- Are the results of a compensation buildup “buildup” (*i.e.*, the indirect Market Approach) similar to the results of a direct Market Approach?
- If not, how should the findings be reconciled? What is the final (supportable) conclusion?

National Compensation Data

Hematology / Oncology

	<i>n</i> =	Mean	25th Percentile	Median	75th Percentile	90th Percentile
MGMA	460	\$450,000	\$292,000	\$363,000	\$516,000	\$778,000
SCA	305	\$309,000	\$234,000	\$299,000	\$359,000	\$455,000
HCS	345	\$248,000	\$184,000	\$202,000	\$277,000	N/A
AMGA	662	\$344,000	\$244,000	\$302,000	\$400,000	\$510,000
WW	146	\$305,000	\$206,000	\$296,000	\$351,000	\$507,000
Low		\$248,000	\$184,000	\$202,000	\$277,000	\$455,000
Median		\$309,000	\$234,000	\$299,000	\$359,000	\$509,000
High	1,918	\$450,000	\$292,000	\$363,000	\$516,000	\$778,000

Approaches to Establish and Document Fair
Market Value Compensation


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MGMA Regional Compensation Data

Hematology / Oncology

	<i>n=</i>	Mean	25th Percentile	Median	75th Percentile	90th Percentile
Eastern	102	\$422,256	\$250,798	\$373,300	\$539,370	\$694,308
Midwest	108	\$487,617	\$309,122	\$413,974	\$531,371	\$946,838
Southern	113	\$503,148	\$320,124	\$429,790	\$544,880	\$964,628
Western	137	\$395,551	\$297,070	\$324,000	\$387,745	\$578,739

MGMA Sub-Regional Compensation Data

Hematology / Oncology

	<i>n=</i>	Mean	25th Percentile	Median	75th Percentile	90th Percentile
Northeast	30	\$364,275	\$228,975	\$255,253	\$521,059	\$700,329
North Atlantic	53	\$424,723	\$259,232	\$355,349	\$549,527	\$689,446
Rocky Mountain	23	\$644,749	\$301,800	\$301,800	\$937,434	\$1,539,176
Northwest	40	\$355,360	\$300,798	\$334,593	\$410,778	\$457,038
Southeast	55	\$558,985	\$319,592	\$396,687	\$796,130	\$1,068,544
Eastern Midwest	61	\$554,059	\$304,387	\$435,296	\$722,057	\$1,038,803
Upper Midwest	55	\$382,873	\$290,526	\$363,136	\$471,333	\$529,674
Lower Midwest	59	\$490,237	\$331,250	\$495,183	\$550,459	\$750,190
California, Alaska, Hawaii	74	\$339,822	\$290,948	\$317,114	\$359,137	\$441,168

Approaches to Establish and Document Fair
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MGMA State Compensation Data

Hematology / Oncology

	<i>n</i> =	Mean	25th Percentile	Median	75th Percentile	90th Percentile
California	71	\$339,617	\$288,392	\$316,787	\$357,482	\$444,711
Florida	35	\$578,643	\$325,000	\$385,696	\$796,130	\$1,279,657
Illinois	16	\$705,095	\$452,770	\$722,057	\$939,658	\$1,080,838
Indiana	20	\$717,768	\$417,825	\$635,442	\$982,397	\$1,350,115
Iowa	11	\$411,834	\$335,194	\$427,162	\$506,947	\$520,352
Kansas	33	\$451,225	\$426,382	\$500,945	\$532,798	\$554,228
Massachusetts	18	\$297,173	\$227,725	\$243,339	\$396,468	\$525,607
Minnesota	19	\$368,382	\$315,888	\$379,555	\$418,523	\$492,321
New York	17	\$649,836	\$543,168	\$657,129	\$693,394	\$913,389
North Dakota	14	\$355,469	\$279,431	\$317,584	\$474,829	\$555,648
Ohio	13	\$334,844	\$275,000	\$300,000	\$415,656	\$479,443
Oregon	11	\$414,723	\$338,497	\$412,408	\$450,293	\$721,080
Pennsylvania	36	\$318,419	\$250,555	\$296,990	\$356,700	\$491,980
Texas	11	\$553,295	\$325,000	\$468,730	\$688,200	\$1,185,593
Washington	27	\$333,425	\$300,000	\$320,821	\$383,919	\$439,246

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MGMA Compensation Data Grossed Up for Benefits

Data	Survey Data		Grossed Up	
	75 th Percentile	90 th Percentile	75 th Percentile	90 th Percentile
National Data	\$ 516,000	\$ 788,000	\$ 575,000	\$ 849,000
Eastern Region	\$ 539,000	\$ 634,000	\$ 598,000	\$ 694,000
Southern Region	\$ 545,000	\$ 965,000	\$ 605,000	\$ 1,025,000
Northeast	\$ 521,000	\$ 700,000	\$ 580,000	\$ 760,000
Southeast	\$ 796,000	\$ 1,069,000	\$ 856,000	\$ 1,129,000
New York	\$ 693,000	\$ 913,000	\$ 753,000	\$ 973,000
Massachusetts	\$ 396,000	\$ 526,000	\$ 453,000	\$ 585,000
Florida	\$ 796,000	\$ 1,280,000	\$ 856,000	\$ 1,340,000

Approaches to Establish and Document Fair
Market Value Compensation

Hourly Rates

Data	Hourly Rate*	
	75 th Percentile	90 th Percentile
National Data	\$ 275	\$ 410
Eastern Region	\$ 290	\$ 335
Southern Region	\$ 290	\$ 495
Northeast	\$ 280	\$ 365
Southeast	\$ 410	\$ 545
New York	\$ 360	\$ 470
Massachusetts	\$ 220	\$ 280
Florida	\$ 410	\$ 645

* Based on 2,080 hours and rounded to nearest \$ 5

Examples of Hourly Compensation Physician & Non-Physician Thought Leaders

Category of Thought Leader	Maximum Hourly Compensation
Non-Physician Consultants	\$ 750
Physician Consultants Working in Non-Medical Industries	\$ 750
Attorneys	\$ 600
Physician Expert Witnesses (Consultations)	\$700
Physician Expert Witness (Court Testimony)	\$ 1,200

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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