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FMV for Relationships between Providers and Manufacturers, Distributors, or Payors (but not Hospitals)

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Agenda

- Introduction (McCormick)
- Significance of FMV (Sanders)
 - Laws
 - Challenges
- Prosecutor's Perspective (Wawzenski)
- Approaches for Determining FMV (Silver)
 - Cost
 - Market
 - Income
- Policies & Procedures and Documentation (McCormick)
- Common Problems and Solutions (Panel)
- Case Studies (Silver + Panel + Audience)

Introduction (McCormick)

- Reason
 - Law Enforcement Focus on Consultant Relationships
 - Medtronic settlement
 - Ortho settlements
 - Cardiac DoJ and OIG subpoenas
 - Difficult and Complex
- Goals
 - Provide useful background information and possible solutions
 - Audience Participation
 - Ask questions
 - Give ideas
 - Discuss experiences
 - Participate in case studies

The Significance of FMV (Sanders)

- Manufacturers and distributors purchase items, services or IP from providers.
- Providers are often in a position to order or recommend product sold by manufacturers or distributors.



The Significance of FMV

- Above FMV payments to potential referral sources might imply that the payment is for something other than the items, services or IP, such as a referral.
- Below FMV charges to a referral source may suggest that the seller is making a hidden payment to the buyer for something (only an issue if the buyer can deliver business to the seller).
 - OIG is suspicious of:
 - Discounts below seller's fully loaded costs
 - Discounts made available to a buyer with business to swap, but not to one without such business



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The Significance of FMV

- Failure to be able to demonstrate that payments are at FMV may mean:
 - Can't take advantage of AKL safe harbors (e.g., personal services, equipment rental, etc., all contingent on payment being at FMV)
 - Relationships outside of a safe harbor may be viewed as abusive, thereby making them susceptible to prosecution under the AKL (unable to demonstrate appropriate intent)
 - May make you vulnerable to attack not only under the AKL but also state AKL and commercial bribery statutes
 - You may overpay! (might create fiduciary duty and IRS issues)

The Significance of FMV

- To be useful, your FMV determination must be:
 - demonstrable
 - calculated using a reasonable methodology

Challenges

- Lots of examples of people getting in trouble for a failure to pay/charge only at FMV; examples of reported cases include:
 - Above FMV payments for services, by hospital to medical director
 - Above FMV payments for services, by specialists to referral sources
 - Above FMV payments for services, by hospital to physicians group
 - Above FMV payments by manufacturer to one subsidiary of an organization to obtain favorable formulary placement by another subsidiary
 - Above FMV payments for consulting services, by device manufacturers to physicians

Challenges

- Sources of Guidance
 - OIG will not opine, except very broadly, on FMV issues
 - IRS and OIG use different standards
 - Stark physician compensation test withdrawn in last round of amendments to the regulations
 - No perfect benchmarking data



Prosecutor's Perspective (Wawzenski)

- Identifying Suspect Relationships
 - Clear cases of violation
 - Make a fact-specific inquiry
 - Go beyond form to substance of the relationship
 - Find indicia of intent or knowledge
 - Impact on Federal programs



Prosecutor's Perspective



- Research Grants
 - Initiated by marketing department/physician
 - Requires continued (exclusive?) use of manufacturer's products
 - Data collected of little or no use
 - Provides equipment/services used for non-grant purposes

Prosecutor's Perspective

- Physician Relationship Red Flags
 - PSAs with questionable/overlapping duties
 - Excessive payments for professional services
 - No documentation of performance or payments
 - Failure to collect on leases/loans



Widely Accepted Definition of Fair Market Value

In the context of fee for service arrangements, fair market payment rate is often defined as:

...the price at which the items or services would be exchanged between a willing buyer and a willing seller, neither being under any compulsion to buy or sell and both having reasonable knowledge of the relevant facts, and without consideration of either party's position to make or influence referrals, to furnish items or services to, or otherwise generate business for the other party as of the Date of Valuation.

PPNPS – 5 Critical Elements to Documentation

- 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?

Approaches for Determining FMV

- In applying the **COST** approach to services, a “cost build-up” approach is often utilized. Under the cost build-up approach, actual or expected costs incurred are analyzed and an assumed profit level is estimated to derive an indication of the fair market value of the services.
- In applying the **MARKET** approach we are looking for arrangements or transactions involving the sale or exchange of similar services. Market data is generally adjusted for significant differences. Based on types of services provided, the complexity of the service, and the competitive demand, the value can be greatly impacted and lead to adjustments.
- In applying the **INCOME** approach to services, analyses of various rates of return provide corroboration for estimated fair market values.

Assessing Fair Market Value

The HHS OIG has identified payments to healthcare professionals as compliance risk areas; however, they do not establish fair market value payment rates nor define a procedure or calculation to derive this value.

- Develop ranges of Fair Market Value payment rates to be used as a guideline in the establishment of service fee agreements.
- Regulatory agencies provide little guidance – specific facts and circumstances dictate appropriate approach and methodologies.
- Typically, the cost and market approaches are used to value service agreements, with income approach utilized as corroboration.
- Whenever possible, fair market value payment rates should be analyzed and developed using multiple valuation approaches.

Performing Valuation Analysis

- Valuation theory provides three broad approaches to developing data and analysis pertinent to the goods or services that are being valued (Cost, Income, and Market).
- However, valuation analysis itself is very specific to the facts and circumstances that are presented.
- In general, a customized approach is developed to meet the specific valuation need.
- In most cases, one approach tends to emerge as the most appropriate methodology for the valuation analysis. In such cases, the other two approaches, when feasible are used to corroborate the analysis.
- Development of an appropriate fair market value payment rate generally considers the following:
 - Understanding the nature of the contracted services, the competitive landscape of the marketplace, and analogous goods and services provided within the industry and from other industries;
 - Gather and analyze Company data;
 - Gather and analyze market data; and
 - Consider general knowledge of industry best practices.

Policies & Procedures (McCormick)

- General policy to pay FMV
 - Details by Relationship Type
 - Consulting
 - Typically time based
 - Research
 - Time
 - Staff (i.e., investigator and coordinator)
 - IRB expenses
 - Equipment and software
 - Overhead/Benefits
 - Medical care/procedures
 - Patient expenses/stipend
 - Other???
 - Inventions (Intellectual Property)
 - Commercial value
 - Exception process
 - Key consultant will not accept standard daily/hourly consulting fees
 - Additional payment based on evaluations
 - Expensive, but excellent and reliable research sites
 - Essential IP



Policies & Procedures

- Documentation
 - Consultants -- Qualifications & Time-Based FMV
 - Standard Per Day/Hour
 - Maintain copy of then-current CV
 - Likely Factors for Documentation (See sample checklist)
 - » Specialty/Boards
 - » Consulting experience
 - » Years post-residency
 - » Publications
 - » Current academic positions
 - » Luminary/KOL status
 - Reconsideration and/or exception process
- Activity/Event Fixed Fees
 - Likely Factors for Documentation
 - » Typical specialty and experience level (middle-of-the-road or averaging)
 - » Estimated standard preparation time
 - » Estimated activity/event time
 - » Estimated travel time
 - Document assumptions
 - Annually Review
 - » Compare assumptions to actual experience
 - » Adjust accordingly

Policies & Procedures

- Documentation
 - Consultants -- Qualifications & Time-Based FMV (cont)
 - Services Provided
 - Service Reports from Health Care Professional (See sample quarterly report)
 - » Regular requirement, i.e., quarterly
 - » Description of services provided
 - » Date
 - » Time spent
 - » Review and approval by appropriate business staff
 - Activity/Event Fixed Fee
 - » Confirmation of services by appropriate staff



Policies & Procedures

- Documentation (cont)
 - Research
 - Time Only Fixed Fee (e.g., post-market survey/registry)
 - Likely factors for Documentation
 - » Typical specialty and experience level
 - » Estimated activity time per activity/event
 - Multiple Factors (e.g., clinical studies)
 - Physician/staff time
 - » Estimated time for each activity, i.e., forms completed, data compilation, investigator meetings
 - » Salary based vs. independent qualifications based FMV determination
 - » Billable services
 - IRB expenses
 - Overhead
 - » Ability to negotiate
 - Equipment and software
 - » Use for other purposes
 - Medical care/procedures and patient stipends

- Services Provided
 - Maintain log
 - » Activities performed and events attended and related payment per agreement terms
 - » Milestone payments
 - » Other???



Policies & Procedures

- Documentation (cont)
 - Inventions/Intellectual Property
 - Likely Factors/Considerations for Documentation
 - Purpose/Use
 - » Essential
 - » Enhancement/Improvement
 - » Meeting competition
 - Anticipated Market
 - » % market share
 - » # sales/year
 - Contribution
 - » Inventor/Patent Holder
 - » Contributor
 - » Value of Contribution
 - Valuation Method
 - Payments
 - » Time based
 - » Royalties



Common Problems and Solutions (Panel)

- Common Issues with available data:
 - Tainted data
 - OIG suspicious of internal or industry data
 - Failure to take into account entire compensation package
 - Multiple separate contracts
 - Hidden compensation
 - Lack of comparables
 - Qualifications different
 - Services different
 - Salary v. Billings

Common Problems and Solutions (Panel)

- Failure to demonstrate arm's length bargaining
 - Buyer cautious about engendering ill will – seller seeks to use referral clout as negotiating leverage
 - Can tainted record ever be redeemed?
 - Preventative measures
 - Evidence of hard bargaining is helpful
 - Ensuring that party doing the bargaining is insulated from sales concerns and incentives
- Failure to document FMV assessment process
- Failure to require that seller adhere to terms of contract in order to get paid
- Failure to document need for purchased items or services
- Should valuation be done under privilege?

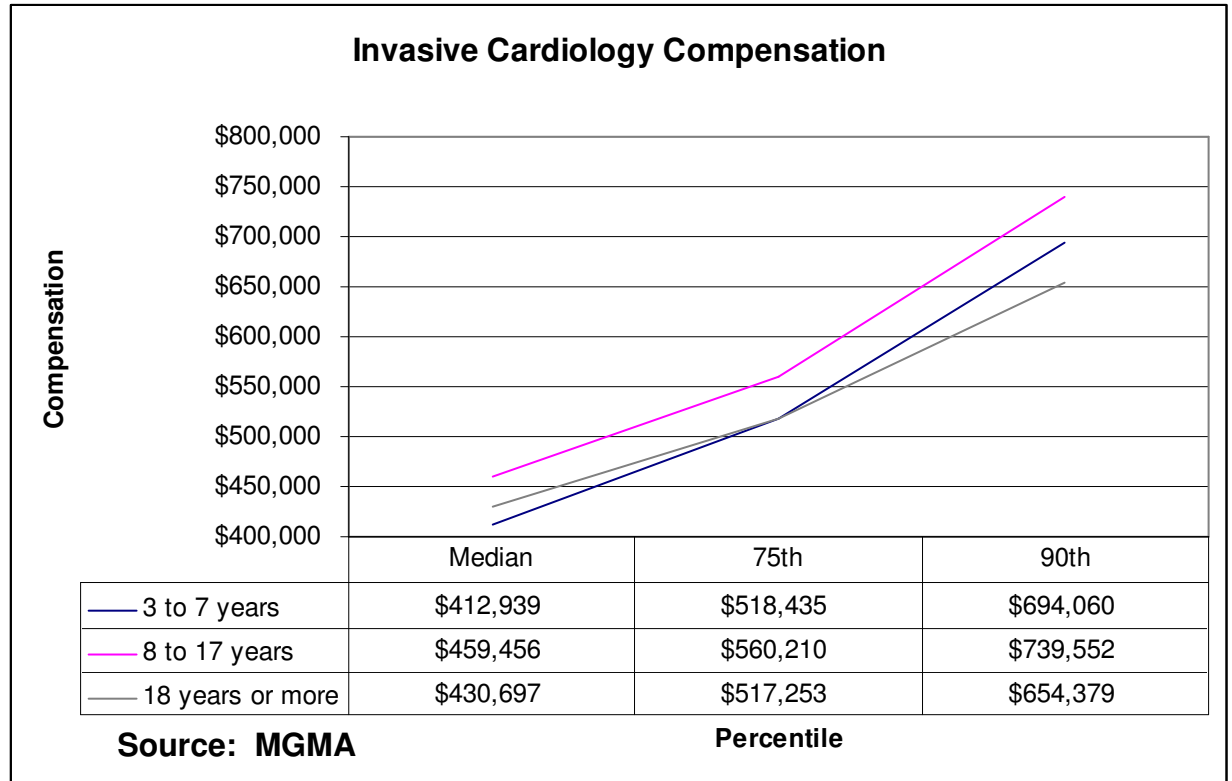
Case Study #1: Advisory Board Compensation

- Strong Heart Inc. needs to conduct a physician advisory board to gain insights on developing a commercial strategy in support of new clinical data.
- The advisory board will have 11 attendees who are the preeminent invasive cardiologists in the U.S. and the Chief of Cardiology from Mass General will chair the meeting.
- The attendees are from nationally renowned institutions around the country and they will be traveling to New Orleans for the meeting.
- Plans are for all attendees are to arrive on Thursday evening and participate in an all day meeting on Friday with attendees leaving for the airport at 4:00 PM.

Case Study #1 – Analytical Framework

Key Analytical Points:

1. Experience and compensation are positively correlated in some age segments.
2. The dispersion of the data is significant at the upper-end of the distribution.
3. A premium may be necessary to compensate physicians for lost opportunity cost or leisure time.
4. Competitive market conditions may need to be considered for highly sought after physicians.
5. Additional considerations may include referral network, increase in sphere of influence, etc.



Basic Principles for FMV Calculation:

$$(\text{Base Rate}) \times (\text{Physician's Level of Effort}) = \text{FMV Range or Payment Limit}$$

Case Study #1: Group Discussion Points

- What kinds of data are available to use and how do we use it to establish FMV?
- How do we adjust that data to use for purposes of calculating FMV?
- What kind of factors should we consider in establishing a base compensation rate?
 - Qualitative (e.g., level of influence, luminary status, etc.)
 - Quantitative (e.g., experience, specialty, geography, etc.)
- What kind of factors should we consider in establishing base metrics for level of effort?
 - Time commitment
 - Complexity of task
 - Frequency of task

Case Study #2: Catheter Training

- Bayou Medical College Hospital has a well known cardiac center in the New Orleans area and is the site where the upside down albumen-ablation catheter was tested and FDA approved with the assistance of Dr. Strong Heart, Chair of Cardiology.
- The revolutionary catheter used by Dr. Heart was developed by Cathy Catheters, Inc., an early stage New Orleans based device manufacturer with a long standing relationship with Bayou Medical.
- The technique may revolutionize cardiac catheterization and more physicians would like to be trained on the product and the procedure. Moreover, Dr. Heart would like to gain international recognition and would like to promote more widespread use of the procedure in the U.S. and internationally.
- Cathy Catheters, Inc. would like to develop a training program with Bayou Medical, under the direction of Dr. Heart, and utilize the various facilities at Bayou Medical including the cardiac catheter and cadaver labs.
- Concerned about the current enforcement climate and Bayou Medical Hospital's status as a safety net provider, Cathy Catheters needs to conduct a comprehensive FMV analysis for this initiative.

Case Study #2 – Analytical Framework

Key Analytical and Discussion Points:

1. Basic labor and non-labor cost considerations for Bayou Medical to accommodate the training program in both the cardiac catheterization and cadaver labs.
2. Direct compensation costs for Dr. Heart and other allied health professionals in the department to support and oversee the training.
3. Additional cost considerations for Bayou Medical to conduct the sessions including: meals, transportation, lodging, etc.
4. Analysis of other locations in the U.S. or ex-U.S. that may serve as potential sites or benchmarks for data.