INTRODUCTION
Cardinal Health Specialty Solutions is a division of Cardinal Health Inc. (NYSE:CAH) and provides clinical, reimbursement, technology and distribution services that help health care professionals, payers and pharmaceutical and biotech companies improve the quality and cost-effectiveness of caring for patients who are managing complex diseases. Cardinal Health Specialty Solutions helps customers alleviate day-to-day administrative burdens, optimize business functions and partner to implement new innovations that move their businesses forward. To learn more, visit www.cardinalhealth.com/specialtysolutions.
Michael D. Untiet

- Counsel for Cardinal Health Inc. Supporting the Specialty Solutions Division.

- Primary Legal support to the Cardinal Health Specialty Solution business that provide products and services to pharmaceutical and biotech manufactures.

- Previously with The Johns Hopkins University, School of Medicine focusing on clinical trial contracting issues.

- The views and opinions expressed here are my own and do not necessarily reflect those of Cardinal Health Inc.
VMG Health

- VMG Health solely provides transaction advisory and valuation services in the healthcare industry.
  - Been in business since 1995, offices in Dallas and Nashville.
  - 70 professionals.
  - Perform over 1,200 valuation per year.

- VMG is structured in teams.
  - Professional Services Valuations (Contracts) – Today’s Topic*.
  - Business Valuation.
  - Transaction Advisory Services / JV Relationship Development.
  - Equipment Appraisals.
  - Real Estate Appraisals.
Jen Johnson, CFA

- Partner at VMG Health.
- Leads 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.

[HFMA logo]

[HFMA healthcare financial management association]

[ABA logo]

[Defending Liberty Pursuing Justice]

[ACC logo]
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OVERVIEW

Presentation Overview

- Physician Alignment Trends
- Regulatory Guidelines
- Determining FMV
- Practical Considerations / Compliance Tips
PHYSICIAN ALIGNMENT TRENDS
Physician Alignment Trends

Hot Topics for the PSA Division
Any payment between physician and referring entity must be FMV

- Quality Payments
- Cost Savings
- Bundled Payments
- Compensation Calculators
- Life Sciences
- Commercially Reasonable
Physician Alignment Trends

Reasons for Growth in Physician Alignment

Hospitals and life sciences companies need physicians and physicians need them now more than ever.

Non-economic Reasons

- Quality of Life – older and younger physicians, on average, working less hours.
- Vertical integration strategies.
- Growth in innovation within life sciences segment.

Economic Reasons

- Increased compensation: post employment or contracted arrangement.
- Better hospital-based reimbursement.
- Replace potential loss of ancillary earnings.
- Investment requirements for information technology.
- Participate in risk based contracting, ACOs, quality initiatives.
Physician Alignment Trends

Physician Service Agreements ("PSA")

May be a result of joint ventures, acquisitions, employment or independent contractor arrangements.

*May have a P4P component.

It is now likely a combination of several valuations will be required for one agreement, choose the right data/analysis to reflect each of the services.
PHYSICIAN ALIGNMENT TRENDS

P4P In the News

- HQID (CMS/Premier Hospital Quality Incentive Demonstration).
  - Raised their overall quality by an average of 18.6 percent over six years.
  - Incentive payments of almost $12 million in the final year 6 to 211 providers for top performance, as well as top improvement.

- UnitedHealth Group – largest US health insurer by sales.
  - Currently paying 21 different specialties based on quality.
  - Expect to save twice as much than the quality payments due to healthier patients.

- WellPoint – largest US health insurer by membership.
  - Will increase primary care physician pay by 10%.
  - Additional cost savings bonus of 20% to 30% of savings achieved.
  - Total P4P increase could be as much as 50%.

- Aetna – 30% of its primary care physicians are already eligible for P4P.
  - New payments expected to increase physician reimbursement by 15%.
  - Program spreading quickly.
Tennessee Surgical Quality Collaborative.
- 10 hospitals experienced significant improved surgical outcomes.
- Millions in cost savings - $2.2 million per 10,000 surgery cases.

Ohio’s Medicaid Program – P4P component will be included when it rebids contracts for 2013.

February 2012 Committee on Ways and Means.
- UnitedHealth Group discusses results of its Premium Designation Program (PD).
- Results show over 50% decrease in some complication rates and 14% in savings for PD physicians.
PHYSICIAN ALIGNMENT TRENDS

P4P Quality / Shared Savings Payments Overview

- Massive surge in reporting initiatives.
- Congress authorized value-based purchasing (VBP) program to replace the RHQDAPU program.
  - Performance Incentives would be based on improving historical performance or attaining superior outcomes compared with national benchmarks.
  - Proposed ACOs include similar guidelines.

- Numerous third party payors provide quality payments to hospitals and physicians.
- C-Level executives’ compensation may be subject to a hospital’s quality outcomes.
- Physicians assist in lowering cost of care and/or improve efficiencies.

- Quality Driven Expense Reductions.
- Direct expense reductions.
- Patient population shared cost savings.
**PHYSICIAN ALIGNMENT TRENDS**

*Life Sciences - 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.
Life Sciences—Disclosure Findings

- 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).

- 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 led forums.

- 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.

Royalty Payment Data – less than 1% of payments to physicians based on a Washington University study of 1,390 respondents.
Payments to physicians are dropping.
  • 50% Payment Drop - PolicyMed.com (6/17/11).

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

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.
  • major catalyst to the transparency and disclosure movement in the life sciences industry; the government continues to increase its scrutiny of physician compensation arrangements.
Physician Alignment Trends

Life Sciences – Payment Trends and Solutions

- **GlaxoSmithKline - $3 billion.**
  - Settled July 2, 2012 for a total of $3 billion (largest health care fraud settlement in US History).
  - Cited for paying kickbacks to physicians for prescribing its drugs.

- **Sanofi - $109 million.**
  - Settled December 19, 2012 for a total of $109 million.
  - Cited for paying kickbacks to physicians in the form of excessive free drug samples.

- **Merck Serono - $44 million.**
  - Settled May 4, 2011 to pay a total of $44 million.
  - Serono cited for paying kickbacks to physicians in the form of speaker training fees and resort stays before and after its acquisition by Merck.

- **Orthofix - $42 million.**
  - Originally agreed in June of 2012 to pay a total of $42 million.
  - Cited for paying kickbacks to physicians.
  - Judge has rejected the offer, stating “extreme unease of treating corporate criminal conduct like a civil case.

- **Victory Pharma - $11.4 million.**
  - Settled December 27, 2012 for a total of $11.4 million.
  - Cited for paying kickbacks to physicians in the form of tickets to professional and collegiate sporting events; tickets to concerts and plays; spa outings; golf and ski outings; dinners at expensive restaurants; and numerous other out-of-office events.
Commercially Reasonable – whose responsibility is it?
• Facility needs – check for overlap of services (numerous medical directors needed).
• Operational assessment (quality metrics relevant for patient population).
• Financial alternatives.
• Understand total hours (reasonable).
• Needs assessment.

Agreement terms must be understood and are sometimes unclear at valuation stage, define:
• What services will be provided?
• How parties will be compensated?
• Valuation should match the agreement – may require several valuations for one agreement.
Compensation amounts paid to potential referral sources must follow guidance set forth by applicable healthcare regulations and guidance documents. For example:

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

Legal Counsel should determine which federal and/or state statutes may be applicable under various circumstances.

Compensation arrangements with healthcare professionals must be commercially reasonable and the amounts must not exceed fair market value.
Federal regulators have historically provided little guidance on the way FMV compensation should be calculated (and they are prohibited from providing any opinions regarding FMV). However, some Guidance under stark Law and the IRS RULES.

**Fair Market Value**

**IRS Definition:** The price at which property or the right to use property would change hands between a willing buyer and a willing seller, neither being under any compulsion to buy, sell or transfer property or the right to use property, and both having reasonable knowledge of relevant facts (IRS Rev. Rul. 59-60).

**CMS Definition:** The value in arms length transactions, consistent with the “general market value.” “General market value” means the price of an asset or service resulting from bona fide bargaining between well informed parties who are not otherwise in a position to generate business for each other, on the date of acquisition of the asset or at the time of the services agreement. 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, or the compensation that has been included in bona fide service agreements with comparable terms at the time of the agreement where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals. **42. C.F.R. § 411.351**

**Commercial Reasonableness**= 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. **69 FED. REG. 16093 (MARCH 26, 2004).**
Prohibits any individual or entity from:

- Offering, paying, soliciting or receiving any remuneration (anything of value, including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind).

To induce:

- The purchase, lease, order, arranging for or recommending the purchase of any item or service payable whole or in part under a Federal health care program (Medicare, Medicaid, VA, and TRICARE).

6 Statutory exceptions and regulatory safe harbors that, if all conditions are met, will immunize an arrangement from prosecution.

Failure to meet all the elements of an exception or safe harbor does not mean the transaction is illegal.

The courts turn to the fundamental issue, which lies with the combined impact of the “one purpose” test and the safe harbor. That is it may be a violation of the AKS if one purpose of the offer of remuneration is to influence the recipients reason or judgment relating to referring, ordering, recommending or arranging for items or services that may be covered under a federal or state health care program.

VIOLATION OF THE AKS MAY RESULT IN SIGNIFICANT MONETARY AND CRIMINAL PENALTIES.
Requires:

- Written, signed agreement.

- Agreement must cover all of the services to be provided over agreement term and must specify exact services to be provided.

- If agreement is for part-time or periodic services, must specify exact schedule, precise length, and the exact charge for services.

- Term of the agreement must not be for not less than one year.
- Services performed under agreement must not involve an activity that violates any state or federal law.

- Aggregate services must be reasonably necessary to accomplish the commercially reasonable business purpose of the services.

- Aggregate compensation paid over term of the agreement must be set in advance, consistent with FMV, and not take into account the volume or value of any referrals or business.
Prohibits healthcare organizations and physicians from improperly filing false claims to any federal healthcare program (Medicare and Medicaid).

Department of Justice can sue to recover monies improperly paid by Federal payers, together with civil penalties (up to 3x the damages plus penalties).

Amended on March 23, 2010 by Patient Protection and Affordable Care Act.

- Easier to argue that a kickback = a false claim = $\$. Items or services resulting from a violation of the AKS are actionable under the FCA.
Stark Law

- Stark (federal physician self-referral law) prohibits financial relationships between physicians and other providers to which the physicians make referrals for “designated health services” unless the financial relationship fully satisfies an “Exception.”

- Strict liability statute and does not require a showing of intent to violate its terms.

- Implicated based on referrals unless there is an applicable exception:
  - Isolated transaction exception.
  - Personal services arrangement.
  - Bona-fide employment relationships.

- For example with the bona-fide employment relationships exception:
  - the employment must be for “identifiable services.”
  - the amount of the remuneration cannot be determined in any manner that takes into account the volume or value of referrals by the referring physician.
  - the compensation must be “commercially reasonable” even if no referrals were made between the physician and the organization.
  - The amount of remuneration must be consistent with FMV
Examples of the Consequences for Violating FMV pursuant to FCA and AKS

- **DPAs/NPA.**
  - Must annually complete a needs assessment for all consulting services and include a budget for all consultant payments, protocols for authorizing consultant agreements, and the type and amount of services needed (e.g., the number of consultants, consultant qualifications, and the consultant’s FMV).
  - The FMV rate for consultant services shall be no more than $500 per hour. To increase the hourly rate, an FMV analysis from an entity approved by the monitor must be obtained.

- **2010 Corporate Integrity Agreements (“CIA”).**
  - Requires payments to consultants, researchers, authors according to a centrally managed, pre-set rate structure determined on an FMV analysis conducted by the company.
  - AstraZeneca and Ortho-McNeil Janssen were the first, followed by Forest Laboratories.
  - Now standard for all CIAs.
Qui tam action alleging that the compensation Hospital paid under part-time employment agreements with 19 specialists exceeded FMV, was not commercially reasonable and took into account the volume or value of referrals

Jury verdict found Tuomey Hospital violated Stark Law but had not violated the False Claims Act (“FCA”).

District court set aside jury verdict and ordered a new trial on the FCA claim

Fourth Circuit Court of Appeals (3/20/12) concluded that District Court’s judgment in favor of the U.S. violated Tuomey’s 7th Amendment right to a jury trial because verdict had been set aside and motion for new trial granted.
FACTS:

- Hospital conducted study focusing on percentage of cases and revenue likely to be lost over an extended period if physicians redirected surgeries to their own ASC.

- 4 law firms had looked at the proposal; 2 commented negatively, including relator’s law firm.

- Compensation methodology with 3 components: base salary subject to adjustment based on net collections for outpatient procedures; production bonus of 80% of net collections; incentive bonus of up to 7% of production bonus

- Compensation designed to pay 131% of professional collections (reasonable compensation ranges were in the 49%-63% range).

- 10-year term plus 2-year post-termination covenant not to compete.

- Exclusivity to perform all outpatient procedures at Tuomey and physicians were penalized if they did not refer to Tuomey.
WHICH ELEMENTS CONCERED THE FEDERAL GOVERNMENT?

- **Compensation**: Compensation was in excess of 130% of the physicians’ net collections (reasonable compensation ranges were in the 49% to 63% range).

- **Commercially Reasonable**: The government also contended that even if the compensation was fair market value, compensating physicians at a level greater than collections would never be commercially reasonable. If a proposed arrangement appears to have been developed in response to the threat or fear of losing a referral stream, the government may look closely at issues of commercial reasonableness and at a party’s intent in entering into the transaction.

- **Exclusivity**: The physicians were penalized if they did not refer to Tuomey for services.

- **Non-Compete Clauses**: These provisions prevented the physicians from providing outpatient surgeries within a 30-mile radius of Tuomey during the agreement and for two years after the agreement’s termination.

- **Drop in Revenue**: Perhaps one of the more problematic facts of the case was that the hospital’s interest in the physicians arose only after the approval of the competing ASC and a financial analysis by the hospital showed an appreciable revenue drop if certain services were performed at the ASC versus at the hospital.

- **4th Circuit addressed Stark issues likely to recur on retrial**:
  - Concluded that the facility component of the services performed by the physicians pursuant to the contracts, for which Tuomey billed a facility fee to Medicare, constituted a “referral” within the meaning of Stark
  - Concluded that, based on the Stark definition of “fair market value,” fixed compensation that is not based solely on the value of the services the physician is expected to perform, but that also takes into account additional revenues the hospital anticipates will result from the physician’s “referrals,” by necessity takes into account the volume or value of such referrals.
GUIDELINES FOR DETERMINING FAIR MARKET VALUE
GUIDELINES FOR DETERMINING FAIR MARKET VALUE

Importance of Valuation - Tuomey Case Take-Aways

- Hospital is at risk for relying on unsupportable valuations.

- Valuation methodology is as important as total compensation.

- Creative arrangements need to be carefully constructed, the government suggests getting an OIG Opinion.

- No opinion shopping, carefully choose your valuation firm.

- Logic Test – Tuomey examples:
  - Do not pay fulltime benefits/malpractice premiums for part-time services
  - Physicians paid above the 75th percentile of market data should demonstrate productivity consistent with other physicians in this percentile
  - Understand arrangements where the provider is not making money
  - Compensation for administrative duties should be based on significant duties
  - Compensation must be set at Fair Market Value
Select a valuation expert with care – does the valuation expert have:

- Credentials from recognized organizations (AICPA, ASA, CFA, NACVA)?
- Experience with healthcare industry regulations and guidance?
- Expertise on the impact of the regulations on a valuation?
- Knowledge of relevant market survey data and its limitations?

There are no published standards for valuing physician services and compensation.

- Stark law indicates that fair market value is based on the facts and circumstances and reasonable methodologies should be used.
- Most valuators start with traditional business valuation approaches (Cost, Market, and Income Approaches)
Based on the anti kickback statute, and other healthcare regulations and guidelines, any transaction between hospitals and physicians must be at Fair Market Value.

IRS definition - “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.”

Provides a conclusion which should not reflect consideration for value or volume of referrals.

- Offer equal opportunities to all providers.
- Do not tie compensation to expected referrals (volume or technical revenues).
- Data should not reflect referral relationships - Competing Hospitals: Extra Caution.
- Do you need the service and is it commercially reasonable – serve a legitimate business purpose (absent referrals)?
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.
Cost and Market Approaches (blended Cost-Market Approach):
- Cost to employ/contract with a physician based on market data.
- Most commonly utilized method among valuators.
- Simple to understand.
- Benchmarking analysis that aligns compensation and productivity.

Compensation and productivity data are obtained from independent, published surveys:
- MGMA Physician Compensation and Production Survey.
- AMGA Medical Group Compensation and Financial Survey.
- SCA Physician Compensation and Productivity Survey.

Common productivity metrics include:
- Work RVUs.
- Total RVUs.
- Professional collections.
- Gross charges.
- Patient encounters.

Note: MGMA = Medical Group Management Association, AMGA = American Medical Group Association, and SCA = Sullivan, Cotter and Associates, Inc.
Common benchmarking mistakes include:
• Including mid-level provider productivity.
• Benchmarking total RVUs to reported work RVUs.
• Benchmarking total collections to reported professional collections.
• Miscalculation of patient encounters (read the data definition of each survey!).

Understand who bills and collects, employed, independent contractor, etc...

Common mistakes in using the reported compensation per work RVU:
• Per MGMA, an inverse relationship exists between work RVU volume and compensation per work RVU.
• Paying a highly productive physician the 75th to 90th percentile compensation per work RVU may result in compensation outside of FMV.
• See illustration on the following page.
Guidelines for Determining Fair Market Value

Clinical Services - Valuation

- Misuse of reported compensation per work RVU data.
  - Solo practitioner specialized in general orthopedic surgery.
  - No in-office ancillaries or mid-level providers.
  - 2011 annual work RVU volume of 13,867.
  - Hospital employer proposed MGMA 90th percentile compensation per work RVU.

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<th>Compensation per Work RVU - Orthopedic Surgery: General</th>
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<th>Median</th>
<th>75th</th>
<th>90th</th>
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<td>$60.39</td>
<td>$77.39</td>
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<td>Times: Physician's Annual Work RVU Volume (equal to MGMA 90th)</td>
<td>13,867</td>
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<td></td>
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<tr>
<td>Equals: Annual Physician Compensation</td>
<td></td>
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<td>$1,324,021</td>
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<th>Physician Compensation - Orthopedic Surgery: General</th>
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**Annual Physician Compensation is more than 160% of the 90th percentile!!!**

**$1,324,021**

Takeaway: *Always* test productivity models to ensure the selected metric and expected productivity result in FMV compensation.
Historically, physicians provided call coverage to Hospital emergency departments on an uncompensated basis.

- Sometimes a condition of medical staff membership.
- Sometimes granting/renewal of clinical privileges.

Not anymore . . . . Why not?

- Increasing number of uninsured patients.
- Aging active physician staff.
- Increasing cost of malpractice insurance and declining reimbursement.
- Perceived increase in risk of lawsuits.
As noted previously, no published standards exist for valuing call coverage services.

Regulatory guidance – OIG Advisory Opinion no. 07-10.

• Issued on September 20, 2007.
• OIG agreed not to prosecute a hospital for paying for call coverage services.
• OIG found the arrangement to be at low risk for fraud and abuse and noted the following:
  o Independent analysis was conducted to ensure compensation was FMV.
  o The per diem rate was designed to compensate based on the burden of call.
  o On-call physicians were obligated to provide care to ED patients regardless of the patient’s ability to pay.
  o Physicians in each specialty received the same per diem rate.
  o The medical center had a legitimate need for the coverage services.

Takeaway: The development of a reasonable and FMV rate for call coverage services must consider the specific burden of call.
Cost Approach – Beeper Rate Method:
- Determines call compensation as a percentage of base compensation.
- Base compensation rates are based on multiple, published surveys:
  - MGMA Physician Compensation and Production Survey.
  - AMGA Medical Group Compensation and Financial Survey.
  - SCA Physician Compensation and Productivity Survey.
- Percentage of base ranges (or beeper rates) are based on market observations and call coverage pay rates of non-referring physicians.
- Base rate may need to be adjusted for independent contractor relationship.

Factors to consider in determining a Beeper Rate:
- Volume of calls.
  - Phone calls.
  - In-person.
- Response time requirements.
- Ability to bill/collect.
- Payor mix of patients served.
- Restricted versus unrestricted coverage.

Note: MGMA = Medical Group Management Association, AMGA = American Medical Group Association, and SCA = Sullivan, Cotter and Associates, Inc.
Guidelines for Determining Fair Market Value

Call Coverage Services – Valuation

➢ Market Approach:
  • Considers available market survey data for call coverage services.
  • Currently, there are two prevalent market surveys:
    o MGMA Medical Directorship and On-Call Compensation Survey.
    o SCA Physician On-Call Pay Survey.
  • Compensation data within the surveys is reported as an hourly rate or daily stipend.

➢ Limitations of the survey data:
  • Based on referral relationships (physician-hospital).
  • Limited number of respondents.
  • Can be large variances in the fees reported.
  • Important factors such as call volume payor mix are unknown.
  • Details such as whether the physician bills/collects are unknown.

Takeaway: The shortfalls of the Market Approach often limit its use to a reasonableness check to the results of the Cost Approach.

Note: MGMA = Medical Group Management Association, AMGA = American Medical Group Association, and SCA = Sullivan, Cotter and Associates, Inc.
As with call coverage, historically it was not unusual for physicians to volunteer their time to hospitals for medical director duties.

Due to the increase in duties and demand of services, physicians require reasonable payment for their time and services.

According to Integrated Healthcare Strategies Medical Director Survey, medical directors commonly provide the following services:

- Act as a liaison between the medical staff and hospital management.
- Participate in the JCAHO accreditation process.
- Physician credentialing and peer review.
- Utilization review and quality improvement.
- Establish and implement clinical pathways.
- New program development and implementation.
GUIDELINES FOR DETERMINING FAIR MARKET VALUE

Medical Director Services – Valuation

- Preliminary questions to ask prior to valuation:
  - Are the services needed (i.e., how many hours? How many other directors?)?
  - Do the services require a physician? A specific specialty?

- Cost Approach.
  - Considers the cost of the physician’s time based on clinical compensation.
  - Considers multiple, published compensation surveys:
    - MGMA Physician Compensation and Production Survey.
    - AMGA Medical Group Compensation and Financial Survey.
    - SCA Physician Compensation and Productivity Survey.
  - Careful with “opportunity cost.”

- Limitations of the Cost Approach
  - Compensation does not match the services provided.
  - Stark indicates that clinical compensation may not be FMV for administrative services.

**Takeaway: Limited reliance is usually placed on the Cost Approach.**

Note: MGMA = Medical Group Management Association, AMGA = American Medical Group Association, and SCA = Sullivan, Cotter and Associates, Inc.
**GUIDELINES FOR DETERMINING FAIR MARKET VALUE**

*Medical Director Services – Valuation*

(summary)

- **Market Approach.**
  - Considers compensation data for similar services.
  - Considers multiple, published medical director compensation surveys:
    - IHS Medical Director Survey.
    - MGMA Medical Directorship and On-Call Compensation Survey.
    - SCA Physician Compensation and Productivity Survey.
  - Annual hours set at 2,000 based on Stark guidance.

- **Limitations of the Market Approach.**
  - Limited number of respondents.
  - Some conservative parties argue the data is “tainted” with referral relationships.

- **Other Considerations.**
  - Productivity data is not applicable to medical director survey data.
  - Percentiles above the median are often selected based on qualitative factors.

**Takeaway:** The Market Approach matches compensation and services and is generally relied upon to determine FMV medical director compensation.

*Note: MGMA = Medical Group Management Association, AMGA = American Medical Group Association, and SCA = Sullivan, Cotter and Associates, Inc.*
Hospital and physicians enter into an agreement where physicians are jointly responsible with hospital for managing a defined service line.

Various arrangement types exist in the market.
- Joint Ventures.
- Contractual arrangements.

Payments contained in the agreement.
- Fixed: physician time to work on quality committees.
- Variable: based on quality outcomes.
- Payments will vary based on services outlined.
- Should be linked to actual services and/or outcomes.

Several other types of arrangements contain quality and costs savings payments.
Quality measures should be clearly and separately identified.
Quality measures should utilize an objective methodology verifiable by credible medical evidence.
Quality measures should be reasonably related to the hospital’s practice and consider patient population.
Do not consider the value or volume of referrals. Consider an incentive program offered to all applicable providers.
Thresholds should exist where no payment will accrue and should be updated annually based on new baseline data.
Hospitals should monitor the incentive program to protect against the increase in patient fees and the reduction in patient care.
Incentive payments should consider the hospital’s historical baseline data and target levels developed by national benchmarks.
Incentive payments should be set at FMV.
Stick to regulatory guidance – benchmark.
Governmental programs and third party payors are good market comparables.
Each member of the physician group should have medical staff privileges.
The arrangement should be administered by a program administrator, whose compensation was not tied in any way to the incentive compensation.
• A program administrator should identify cost-savings metrics after reviewing historical practices and understanding its medical appropriateness.
• The savings targets should be “re-based” at the end of each year in multi-year arrangements.
• The hospital should calculate the cost savings separately for each group and for each cost savings recommendation.
Engage an independent reviewer or auditor to review the program prior to commencement and at least once per year.
The arrangement should include objective measures to monitor quality (i.e., CMS Specification Manual for National Hospital Quality Measures).
Incentive payments should be set at FMV.
Lack of strong guidance on determining FMV for these payments.
• OIG opinions – 50%.
• Demonstration Projects – Capped at 25% of Part B payments.
Identify services

- Types of services provided:
  - Research.
  - Design.
  - Clinical trial.
  - Education.
- Complexity of task – credentials required.
- Frequency of task – time required.
Identify physician needs through valid research.
  • Physician chosen based on clinical needs.
    o Determine if multiple physicians are required.

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.
  • 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.
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 (i.e., 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?
Great tool for call coverage and administrative services and thought leaders.

Internal Compensation Calculators are based on systematic and unbiased overall guidelines which eliminate the user’s ability to include its results.

- Each indication of value considers the specialty and reflects the service provided by the physician.
- Utilizes multiple, objective national surveys reflecting compensation data by specialty.
- Each indication delineates between employed and independent contractor agreements.
- More robust models consider the burden of call for on-call payments and experience of the physician for administrative positions.

Stacked, clinical and P4P services – valuations more complicated.

Compliance Infrastructure Tip

Establish Internal Thresholds

1. Calculators by specialty type and service.
2. Third party opinion on individual arrangements falling outside calculator.
PRACTICAL CONSIDERATIONS
### PRACTICAL CONSIDERATIONS

**Compliance Infrastructure**

<table>
<thead>
<tr>
<th>Practical Considerations</th>
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<tr>
<td>Intent is important</td>
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<td>Establish, monitor, and enforce compliance program</td>
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<tr>
<td>Educate business development personnel on importance of FMV</td>
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<td>Avoid opinion shopping</td>
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<tr>
<td>Utilize internal calculators to show systematic and consistent approach</td>
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<td>Do not consider referral volume or technical revenue in making decisions</td>
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Practical Considerations

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.
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.
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.
- *URL link to this document is located at the back of these slides*

*Defensible documentation for any payment to a physician is a key defense to disclosure.*
Communicating with Physicians throughout Engagement

- **Starting Engagement.**
  - Introducing counsel and reason for process.
  - Represent valuation firm as credible third party.

- **Data Submission.**
  - Transparent Communications or NDA?
  - Ideally, data approved by both before issuing conclusions.

- **Preliminary Conclusions.**
  - “Draft” / “For Discussion Purposes.”
  - Opportunity to consider new data or facts.
  - Read Qualifying Assumptions carefully.

- **Final FMV Opinion.**
  - Avoid opinion shopping.
  - Presenting to physicians.
HELPFUL COMPLIANCE REFERENCES

- **Anti-Kickback Statute and Safe Harbor Provisions**: 42 U.S.C 1320a-7b(b)2 and 42 CFR 1001.952
- **False Claims Act**: 31 U.S.C § 3729
- **Stark Law and regulations, including CMS definition of fair market value**: 42 USC 1395 and 42 CFR 411.350
- **Recommended Preliminary Questions and Supplementary Information for Addressing Requests for OIG Advisory Opinion**: In Accordance With Section 1128D of the Social Security Act and 42 CFR Part 10208
- **OIG Guidance** [https://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf](https://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.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/)
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