Exploring Gainsharing and ACO Compensation Trends

Legal and Operational Considerations

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Joseph Wolfe is a partner with Hall Render, the largest health care focused law firm in the country, now with offices nationwide. He provides advice and counsel to some of the nation’s largest health systems, hospitals and medical groups on a broad range of regulatory, operational and strategic matters. He regularly counsels clients on a national basis regarding compliance-focused physician compensation strategies. He is a frequent speaker on issues related to the physician self-referral statute (Stark Law), hospital-physician transactions, physician compensation and health care fair market value issues. Before attending law school at the University of Wisconsin, he served as a combat engineer in the United States Army.

Upcoming and recent presentations specific to quality, cost savings, and other physician group strategies and compensation trends include:

- Maintaining Compliance While Compensating Physicians for Quality and Cost Savings; HFMA, National Payment Innovation Summit (February 12, 2016) Memphis, TN.
- Strategies for Developing Compliant Physician Compensation Plans; AMGA Compensation Conference (November 12, 2015) New York, NY.
- Implementing Value-Based Physician Compensation Models: Tackling the Regulatory Complexities; Clear Law Institute (July 29, 2015).
- The $10,000 Question: Tackling the Complexities of Value-Based Physician Compensation; AHLA Annual Meeting (June 29, 2015) Washington, D.C.
Session Overview

• Part I: Introductory Concepts
  – Health Care Reform Trends
  – Innovation Models
  – The Current Enforcement Environment

• Part II: Overview of the Regulatory Standards
  – Anti-Kickback, Stark Law, Tax Exemption and Anti-Trust Considerations
  – New Stark Rules

• Part III: Value-based Compensation, ACOs and Gainsharing Models

• Part IV: Compensation-Focused Compliance

• Part V: Question and Answer
Part I: Introductory Concepts
Health Care Reform – A *Road to Value*?

- Reimbursement Focused on Value
- Alternative Payment Models
- Innovative Delivery Models
- Population Health
- Prevention and Wellness
- Bundled Payments
- Medicaid Expansion
- Health Exchanges
- Accountability and Shared Risk
- Market Consolidation
- Gainsharing

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Health Care Reform – Innovation Models

- Accountable Care
- Episode-based Payment Initiatives
- Primary Care Transformation
- Initiatives Focused on the Medicaid and CHIP Population
- Initiatives Focused on the Medicare-Medicaid Enrollees
- Initiatives to Accelerate the Development and Testing of New Payment and Service Delivery Models
- Comprehensive Care for Joint Replacement Model
- Initiatives to Speed the Adoption of Best Practices
Core Quality Measure Development

• Designed by CMS and America’s Health Insurance Plans
  — Designed to aid in promotion of measurement that is evidence-based and generates valuable information for quality improvement, consumer decision-making, value-based payment and purchasing, reduction in the variability in measure selection, and decreased provider’s collection burden and cost.

• 7 Core Measure Sets:
  — Accountable Care Organizations (ACOs), Patient Centered Medical Homes (PCMH), and Primary Care
  — Cardiology
  — Gastroenterology
  — HIV and Hepatitis C
  — Medical Oncology
  — Obstetrics and Gynecology
  — Orthopedics
The Road to Compliance

• **The Current Climate:**
  – More integration and financial relationships with physicians
  – More health care delivery and payment reform
  – Still stuck with a rigid and technical regulatory framework, but getting better
  – Enforcement + disproportionate penalties = *Astronomical Damages and Enterprise Risk*

• **Considerations for Managing Risk:**
  – Value-based models must be **defensible** under the all applicable health care laws
  – Focus on demonstrating the **3 Tenets of Defensibility:** *Fair market value ("FMV"), commercial reasonableness ("CR") and not taking into account ("TIA") referrals*
  – **Documentation** and **governance** processes (e.g., business planning, valuation, etc.) should support defensibility
  – For gainsharing models, also focus on building in **safeguards** to ensure gainsharing models do not incentivize reductions in medically necessary services
  – For CMS Innovation Models (e.g., ACOs, BPCI, CCJR, etc.) focus on meeting the applicable technical requirements and the fraud and abuse waiver requirements

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Focus on the 3 Tenets of Defensibility

- **The Toumey Case**
  - FMV
  - CR
  - TIA

- **The Halifax Case**
  - FMV
  - CR
  - TIA

a. entered into compensation arrangements with physicians in violation of the Stark Statute, specifically by paying the physicians (who referred designated health services) under contracts that exceeded fair market value, were not commercially reasonable and which took into account the volume or value of the referrals or other business generated between the physician and Toumey;

a. entered into compensation arrangements with physicians in violation of the Stark Statute, specifically by paying the physicians (who referred designated health services) under contracts that exceeded fair market value, were not commercially reasonable, and/or took into account the volume or value of the referrals or other business generated between the physician and Halifax; and
Focus on Defensible Business Planning

67. On April 28, 2008, for example, the Finance Committee of the Board met to approve the purchase of EMA and employment of Drs. Bradley, Corse, and Gaskin. Sharon Bell and Hart Williford, a former Chief Operating Officer and Senior Vice President of the Parent Company, prepared a PowerPoint Presentation to the Finance Committee in support of the addition of EMA (the “April 28 PowerPoint”), which was attached to the minutes of the meeting.

a. On a slide titled “Background Information,” the April 28 PowerPoint notes that Drs. Bradley, Corse, and Gaskin are the “three busiest members of the Candler Medical Group” and EMA is a “high-volume practice with large numbers of hospital admission and referrals to specialists.”

b. The next slide, also titled “Background Information,” stated that “estimated gross revenues (including downstream revenues from referrals) to St J/C” are for

2006: “$57 million + $3.4 million radiology”
2007: “$63 million + $3.7 million radiology”

c. The slide indicated that the information was “reported by physician,” and that these figures “account[] for almost 6% of St J/C total volume.”
In his Report, Mr. Day notes that the Board of BRMC wanted a covenant not to compete associated with the sublease in order to protect “three revenue streams”: CT and MRI revenues, inpatient net revenues, and outpatient net revenues (not including CT and MRI revenues). (Day Report, at 14.) In his appraisal of the covenant not to compete, Mr. Day created a table to show the expected revenues BRMC would receive with the non-competition agreement in place, and compared those revenues to how much BRMC would pay under the non-compete agreement. (Id. at 17.) Mr. Day explained that his table is “based on the assumption that the Physicians would likely refer this business to the Hospital in the absence of a financial interest in their own facilities or services, although they are not required to do so by virtue of any of the covenants contained in the Agreements or otherwise.” (Id.)

Therefore, the Report itself indicates that the analysis of whether the non-competition agreement represents a fair market value is based, in part, on anticipated referrals from the doctors. BRMC affirmed that the Report evaluated expected revenues based on the assumption that Defendants would likely refer the business to BRMC. (Leonhardt Dep. at 56.)
Cases and Settlements from 2014

**Enforcement Actions:**
- New York Heart Center $1.33 million
- Infirmary Health System $24.5 million
- All Children’s Health System $7 million
- Halifax Hospital $85 million
- King’s Daughters Medical Center $40.9 million

**Recurring Issues:**
- Executive, physician and compliance department whistleblowers
- Allegations based on the Key Tenets of Defensibility: Fair Market Value, Commercial Reasonableness and not TIA DHS Referrals
- Testing of Internal Group Practice Requirements
- Application of Stark to Medicaid
- DHS Pooling Issues
Cases and Settlements from 2015

- **Enforcement Actions:**
  - Memorial Health $9.8 million
  - Tuomey Healthcare System $72.4 million
  - Adventist Health System $115 million
  - North Broward Hospital District $69.5 million
  - Columbus Regional Health $35 million
  - Dr. Andrew Pippas $425 thousand
  - Westchester Medical Center $18.8 million
  - Citizens Medical Center $21.8 million

- **Recurring Issues:**
  - Executive, physician and compliance department whistleblowers
  - Allegations based on the Key Tenets of Defensibility: Fair Market Value, Commercial Reasonableness and not TIA DHS Referrals
  - Systematic Practice Losses and DHS “Referral Tracking” Processes
  - Allegations involving up-coding, billing issues and overlapping duties
  - Enforcement against physicians
Part II: Overview of the Regulatory Standards
Regulatory Framework

• Federal Health Care Programs
  ― Anti-Kickback Statute
  ― Federal Stark Law
  ― False Claims Act
  ― Civil Monetary Penalties Law

• Tax Exemption Issues
  ― Private Benefit, Inurement and Intermediate Sanctions

• Antitrust Compliance
  ― Clayton Act

• State Law Issues
  ― Corporate practice of medicine, employment, etc.
Anti-Kickback Statute Framework

• **Criminal Statute** -
  – Prohibits paying remuneration to induce items or services payable under federal health care programs
  – Intent is required (case law allows for inference of intent)
  – Broad and subjective statute

• **Safe Harbors** -
  – Protection requires strict compliance with all conditions of the applicable safe harbor
  – Safe harbor compliance is *voluntary*
  – Failure to comply with a safe harbor does *not* mean an arrangement is illegal
  – Arrangements that do not fit in a safe harbor must be evaluated on a case-by-case basis
Stark Law Framework

• If Physician + Financial Relationship + Entity:
  — Physician **may not make a Referral** to that Entity for the furnishing of Designated Health Services ("DHS") for which payment may be made under Medicare; and
  — The entity **may not bill Medicare**, an individual or another payor for the DHS performed pursuant to the prohibited Referral...

  *... unless the arrangement fits squarely within a Stark exception*

• **Threshold Compliance Statute**
  — Strict liability – no intent required. Civil (non-criminal statute)
  — Triggered by “technical” violations, inadvertence and error
  — Your regulatory “Litmus Test”
  — 11 Categories of DHS (e.g., clinical lab services, radiology and certain other imaging services, radiation therapy and supplies, outpatient prescription drugs, inpatient and outpatient hospital services, etc.)
Common Stark Exceptions

- **Common Stark Exceptions:**
  - Rental of Office Space or Equipment
  - Physician Recruitment
  - Personal Service and FMV Exceptions
  - Isolated Transactions
  - Bona Fide Employment
  - In-Office Ancillary Services
  - *New in 2016 - Assistance to Compensation an NPP*
  - *New in 2016 - Time Share Arrangements*

- **Common Elements of the Stark Exceptions:**
  - The arrangement must be set out in writing and signed by the parties
  - The arrangement must be *commercially reasonable*, and compensation must be consistent with *fair market value*
  - Compensation must be *set in advance* and not *take into account* the volume or value of referrals generated between the parties
The New 2016 Stark Rules

• New Exceptions
  – Assistance to Compensate an NPP – 411.357(x)
  – Time-Share Arrangements – 411.357(y)

• Reducing Burdens on Health Care Organizations
  – Writing requirement
  – Term Requirement
  – Holdover Requirement

• Clarifications/Corrections
  – Remuneration
  – Stand-in The Shoes
  – Temporary Noncompliance
  – Takes into Account
Flexibility for Stark Group Practices*

- **Single Legal Entity Test.** Must be a “single legal entity” operated primarily for the purpose of being a group practice (e.g., a hospital cannot be a group practice, etc.)
- **Physicians.** Two (2) physicians must be owners or employees of the group practice (i.e., not independent contractors)
- **Unified Business Test.** A body representative of the group practice must maintain “effective control” over its assets and liabilities
- **Distributions of Income and Expenses.** Methods of distribution must be determined by the group practice prospectively before the receipt of payment for services
- **Range of Care.** Each physician must furnish substantially his or her full range of patient care services through the group practice
- **“Substantially All” Test.** At least 75% of the aggregate total patient care services of the group practice members must be furnished and billed through the group
- **Physician-Patient Encounters.** Members of the group (i.e., not independent contractors), in the aggregate, must personally conduct no less than 75% of the physician-patient encounters of the group practice
- **Volume/Value Compensation Test.** Shares of overall profits and productivity bonuses cannot be determined in a manner that directly relates to the volume or value of a physician’s referrals of DHS

*Not all detailed requirements are listed.
Tax Exemption Framework

• **Private Benefit**
  — A tax exempt organization cannot provide more than incidental benefits to individuals
  — If it does, it is no longer organized and operated exclusively for exempt purposes

• **Private Inurement**
  — A tax exempt organization’s net earnings may not inure to the benefit of an “insider”
  — Compensation to “insiders” is compliant if “reasonable” (i.e., consistent with FMV)

• **Excess Benefit**
  — Occurs if excessive compensation is paid to a “disqualified person”
  — A “disqualified person” is a person in a position to influence an exempt organization (e.g., Board Members, Management and family members of disqualified persons, etc.)
  — Compensation to disqualified members is compliant if “reasonable” (i.e., FMV)

• **3 Part Rebuttable Presumption of Reasonableness Test**
  — Approved in advance by a disinterested body (e.g., board or committee);
  — The disinterested body relied upon appropriate data as to comparability; and
  — The decision was documented appropriately in the organizations’ minutes
Antitrust Framework

• **Key Antitrust Concepts**
  – Transactions that create or enhance market power may raise anti-competitive concerns
  – Horizontal mergers are higher risk than vertical mergers
  – Antitrust analysis is a highly fact-specific, economics-based analysis
  – Antitrust laws are enforced by the FTC, DOJ, state AGs, but private actions are also available

• **Key Statute: Section 7 of the Clayton Act**
  – Prohibits transactions whose effect substantially lessen competition
  – Requires premerger (HSR) reporting and waiting periods for transactions meeting certain financial thresholds

• **Horizontal Merger Guidelines (FTC/DOJ)**
  – Key question: Will the merger likely result in anti-competitive effects?
  – Actual effects of consummated mergers
  – Market shares and concentration
  – Intensity of head-to-head competition
Part III: Value-Based Compensation, ACOs and Gainsharing Models
CMS Support for Value-Based Compensation

- **Stark Phase I (915)** - Stark does not preclude basing compensation on quality measures unrelated to the volume or value of referrals or other business generated by the physician.

- **Stark Phase II (16088)**
  - Stark does not bar payments based on quality measures as long as the overall compensation is FMV, does not TIA referrals and the other conditions of the exception are satisfied.
  - Stark does not prohibit payments based on achieving certain benchmarks related to the provision of appropriate preventative health care services or patient satisfaction.
  - Payments to reduce or limit services could violate the CMP.

- **2009 PFS (38551)** - Incentive payments and shared savings programs can be structured to fit within existing Stark exceptions.
CMS Fraud and Abuse Waivers

• **Current Issued Waivers**
  – Pioneer Accountable Care Organization (ACO) Model
  – Bundled Payment for Care Improvement (BPCI) Models
  – Health Care Innovation Awards (HCIA) Round Two
  – Comprehensive ESRD Care (CEC) Model
  – Comprehensive Care for Joint Replacement (CJR) Model
  – Next Generation ACO Model
  – Medicare Shared Savings Program

• **Caution from CMS**
  – **Eligibility** - Individuals or entities seeking waiver protection should keep in mind that a waiver will apply to their arrangement(s) only if the are eligible to use the waiver and all conditions of the waiver are met.
  – **Legal Counsel** - We encourage all parties to consult with legal counsel as necessary to ensure that waivers are available to them and that arrangements for which they seek waiver protection meet all required conditions.
ACOs – Have Additional Flexibility

• **Scope of Waivers.** The scope of the Accountable Care Organization (“ACO”) waivers is limited to compliance with the Stark Law and Anti-Kickback Statute. The waiver no longer applies to the gainsharing CMP.

• **Uniform Application.** The ACO waivers apply uniformly to all ACOs, ACO participants and ACO provider/suppliers.

• **Automatic Application.** The ACO waivers apply automatically if the conditions are satisfied. There is no need (or process) for participants to apply for an individualized waiver.

• **Joint Issuance.** CMS and the OIG jointly established the ACO waivers and have stated their intent to monitor and limit the scope of the waivers over time.
ACOs – Applicable Waivers

- **ACO Pre-participation Waiver**
  - Protects ACO-related start-up arrangements.

- **ACO Participation Waiver**
  - Applies when an ACO is actively participating in the Medicare Shared Savings Program.

- **Shared Savings Distribution Waiver**
  - Protects disbursements of shared savings.

- **Compliance with Stark Law Waiver**
  - Applies when an arrangement fits in a Stark Law exception.

- **Patient Incentive Waiver**
  - Allows in-kind incentives to beneficiaries to encourage preventive care and compliance with treatment regimens.
The CMP Law - Gainsharing Arrangements

• **The CMP Law Prohibits:**
  
  — A hospital or critical access hospitals from
  — knowingly making payments, directly or indirectly,
  — to a physician
  — as an inducement to reduce medically necessary services
  — provided to Medicare (Parts A or B) or Medicaid beneficiaries
  — under the direct care of the physician.

• **Penalties**
  
  — CMP of $2,000 per patient covered by the arrangement.
  — Both the hospital and the physician receiving payment are subject to liability.

• **Blending of Co-Management / Gainsharing Standards**
Regulatory Support for Co-Management

- **OIG Statement (10/3/14):** OIG would be unlikely to bring a case against a hospital or physician for a gainsharing arrangement that included patient and program safeguards such as those identified in our advisory opinions.”

- **Example Safeguards from OIG Advisory Opinion 12-22:**
  - Cost savings measures based on evidence & clinical outcomes.
  - An external valuation regarding the FMV of the fixed and performance based components of compensation.
  - An independent third party review of performance fee factors and clinical outcomes.
  - Performance fee structures with safeguards that addressed historic concerns: Conditioned on the physician not: (i) stinting on care; (ii) increasing referrals to the hospital; (iii) cherry picking patients or those with desirable insurance; or (iv) accelerating patient discharges.
Regulatory Support for Gainsharing

- **April 16, 2015 -** Medicare Access and CHIP Reauthorization Act ("MACRA")
  - **Game changer** for structuring future gainsharing arrangements.
  - Limited the scope of the gainsharing CMP to payments to reduce or limit *medically necessary* services.
  - Likely that OIG will issue new regulations that will interpret *reduce or limit* and *medically necessary*.

- **2016 Report:** Congress directed HHS and OIG to issue a report that identifies potential exceptions, safe harbors and/or statutory changes that will further define gainsharing arrangements.

- More activity to come – an area to watch.
Part IV: Compensation Focused Compliance
Transitioning to Value-Based Models

• Cultural Assessment
  – Are value-based compensation models needed to facilitate change?

• Evaluation of Electronic Medical Record Capabilities
  – Are timely and reliable metrics available?
  – Does the organization have the capabilities for the necessary modeling/shadowing?

• Development of Metrics
  – Patient Experience
  – Outcomes
  – Process
  – Operational Efficiency
  – Provider Engagement/Citizenship

• Regulatory Considerations:
  – Maintain focus on FMV, CR and the prohibition on TIA referrals.
  – Should not incentivize reductions in medically necessary services.
  – Should be based on documented evidence and clinical outcomes.
  – Should contain appropriate safeguards.
Value-Based Model Governance

• Initial Governance Considerations
  – Integration of Value-Based Models with Compliance Program
  – Engagement of Legal Counsel and Third-Party Valuation Consultant

• Regulatory/ Compliance Training and Education

• Update Oversight, Review, Auditing Processes to Monitor Quality

• Obtain Approval(s) and Update Documentation
  – Physician and Management Involvement in Metric Development
  – Obtain Board/ Compensation Committee Approval
  – Update Applicable Compensation Plan
  – Updated Impacted Physician Compensation Policies

• Documenting Regulatory Compliance
  – Legal Analysis (Stark, AKS, CMP, etc.)
  – Valuation Analysis (FMV and CR)
Practical Takeaways

• Value-based models must be defensible under the all applicable health care laws (e.g., Anti-Kickback, Stark Law, CMP)
• Focus on demonstrating the 3 Tenets of Defensibility: Fair market value, commercial reasonableness and not taking into account referrals
• Documentation and governance processes (e.g., business planning, valuation, etc.) should support defensibility
• For gainsharing models, also focus on safeguards that ensure gainsharing models do not incentivize reductions in medically necessary services
• For CMS Innovation Models (e.g., ACOs, BPCI, CCJR, etc.) focus on meeting the applicable technical and fraud and abuse waiver requirements
• Compensation arrangements should align with evolving models of reimbursement
• Critical to monitor the evolving enforcement environment
Please visit the Hall Render Blog at [http://blogs.hallrender.com](http://blogs.hallrender.com) for more information on topics related to health care law.

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