Professional Services Agreements: A Physician-Hospital Integration Model

Complying With Stark Law and Anti-Kickback Statute, Protecting Tax Status, and Avoiding Key Deal Breakers

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Professional Services Agreements: Emerging Hospital-Physician Integration Model

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Why PSAs?

- Market imperative to integrate and align for quality and efficiency improvement
- Need for team approach to disease and population health management
- Aversion to employment of many historically independent physicians/medical groups
- PSA preserves a modicum of practice independence and future strategic options for physicians
Types of PSAs

- Medical Director Agreements
- Coverage Agreements
- Hospital-Based Service Agreements
- Leased Employee Agreements
- Foundation Model Arrangements
- PSA Staffing/Conversion Agreements
- Co-Management Arrangements
PSA Staffing/Conversion Agreements
PSAs: Introduction

- Professional Services Agreements
  - Powerful tool
    - To staff existing hospital service or develop new hospital specialty facility
    - to convert existing group sites to hospital licensed facilities paid at hospital outpatient payment rates
    - Integrate and align hospital and group to improve quality, efficiency and operations of hospital’s specialty service line
PSAs: Introduction (cont.)

Potential economic win-win

Group paid fair market value compensation on an aggregate fixed fee or work relative value unit ("wRVU") basis

- Eliminates risk of reimbursement reductions and collection risk (free care/bad debt)
- Other: purchase of equipment, management services, employee lease?

Hospital establishes new satellite sites or facility and new book of oncology business

- Good contribution margin due to combination of hospital rates and physician office cost structure
- Potential 340B pricing opportunity

Potential economic losers

- Payors—higher rates for “same” services
- Higher patient co-pays
- Erode pharma profitability?
Hospital provides:
- License
- Provider-based status
- 340B pricing

Professional Services Agreement

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PSA Transaction

- Avoid U/A transaction—Group cannot “perform the service”
  - Hospital could take assignment of Group leases from landlords
  - Hospital could purchase Group’s FFE and inventory at fair market value
  - Hospital would need to employ nurses/techs at off-campus locations (to meet Medicare provider-based status rules)

- Group can provide all other staff
  - Physicians/NPs/PAs
  - Non-clinical staff at all sites
  - Nurses and techs at on-campus sites
PSA Transaction

- Potential Transactional Elements
  - Professional Services Agreement (PSA)
  - Asset Purchase Agreement (APA)
  - Management Services Agreement (MSA)
  - Co-Management Agreement (CMA)?
Professional Services Agreement

Hospital provides:
• License
• Provider-based status
• 340B pricing
• Space/equipment
• Nurses/techs (off-campus)

Specialty Group provides:
• Physicians/NPs/PAs
• Non-clinical staff
• Nurses/techs (on-campus)
• Administrative services?

Notes:
• FMV for assets and group retains cash and A/R
• PSA on fair market wRVU basis
• Employee lease on a fixed fee or cost plus fair market mark-up basis; or, administrative services as a percentage of collections with a FMV floor and cap
• Billing services at fair market percentage of collections or fixed fee per claim?

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Principal PSA Legal Issues

- **Stark Law**
  - Under arrangements prohibition: cannot have investment interest in entity (including own medical group) *that “performs” the DHS service*
  - Assign leaseholds/Sell equipment?
  - “Stand in the shoes”
  - Proposed regulations (2009) for quality improvement and cost savings programs never finalized
  - Personal services, fair market value or indirect comp exception: fair market value/independent appraisal advisable
    - *Tuomey* case—cannot rely on flawed appraisal that takes into account v/v of referrals
Anti-Kickback Statute

Personal services and management contracts and/or space or equipment rental safe harbor: fair market value/independent appraisal strongly advised

Some irreducible AKS risk: aggregate compensation not set in advance if wRVU based
Principal PSA Legal Issues (cont.)

- Tax Exemption Considerations
  - No inurement/private benefit
  - No excess benefit transaction
  - Rebuttable presumption of reasonable compensation process
  - Rev. Proc. 97-13 and private use of bond financed space or equipment/duration limitations (3 years/2 years out)
  - New IRS Notice 2014-67 (5 years for contracts with productivity awards based on quality if award is stated $ amount, periodic fixed fee or tiered)
Principal PSA Legal Issues (cont.)

- Provider-based Status Regulations
  - Within 35-mile radius
  - Hospital license requirements/Physical space standards
  - CON issues
  - Clinically, financially and administratively integrated
  - Hospital reporting lines
  - Hospital must directly employ mid-levels/techs at off-campus sites (other than NPs/PAs)
  - Medical group can lease non-clinical staff and NPs/PAs to Hospital
  - No off-campus joint venture with medical group
Principal PSA Legal Issues (cont.)

- **340B Drug Pricing**
  - Discount from average manufacturer price generally based on manufacturer’s best price
  - Applies only to outpatient drugs
  - Available to DSH hospitals, free-standing cancer hospitals, children’s hospitals, CAHs, RRCs, sole community hospitals, FQHCs, and certain special federal grantee programs
  - 8% DSH for RRCs and SCHs; 11.75% for others
  - Not applicable to for-profits
  - Must be within 35 miles of main hospital/meet provider-based status standards
  - Effective after first cost report filed with CMS and enrollment with HRSA/OPA—up to 16 month process
Principal PSA Legal Issues (cont.)

- HIPAA—OHCA/Business Associate
- Reassignment exception
  - Joint and several liability for refunds
  - Individual physician assignment agreements
- Antitrust
  - Sufficient clinical and/or financial integration for joint pricing?
  - Exclusivity and market power
    - New antitrust guidelines for ACOs
Key PSA Deal Maker/Breaker Issues

- Strategic Alignment
- Trust/Relative Trust
- Governance
- Financial Terms/Valuation
- Term/Duration
- Termination
- Restrictive Covenants/ROFOs
- Unwind Rights
- Addition of New Physicians
- Break-Up Fees?
- Arbitration/Dispute Resolution
PSA Conversion Model
Valuation Considerations
PSA Conversion Models
(or “Synthetic” Employment Agreements)

- Instead of traditional employment, new arrangements are gaining traction whereby physicians retain their own practice and are compensated on a productivity basis (e.g., per wRVU) for their clinical services.

- Like a traditional employment arrangement, they still must also be commercially reasonable (i.e., cannot simply enter into one simply because a physician does not want to bill and collect).

- The wRVU rate payable to the physician group is often a “grossed-up” rate that typically includes remuneration for:
  - Cash compensation
  - Taxes and benefits
  - “Retained” practice expenses (e.g., malpractice insurance, CPE costs, etc.)

- These arrangements are generally full-time (and exclusive) in nature, coupled with hospital’s ability to control the physician’s schedule.
PSA Conversion Models (cont.)
(or “Synthetic” Employment Agreements)

- FMV considerations – Generally the same as employment arrangements, with additional consideration given to the overall arrangement.

- FMV analysis should consider pre- and post-transaction compensation.
PSA Conversion Models (cont.)
(or “Synthetic” Employment Agreements)

- Employment agreements have many moving parts...the “terms and features” are critically important.

- As previously mentioned, can involve the purchase of physicians’ tangible assets and/or an employee leasing arrangement
  
  In either case, it is key that these two components are consistent with FMV as well.
PSA Conversion Agreements
Various Approaches

Market Approach
- Compares a physician/practice against available benchmark data
- Commonly seen metrics:
  - Work Relative Value Units (i.e., wRVUs)
  - Professional collections
  - Median comp per wRVU
- Through a “percentile matching technique,” align each productivity variable with the expected level of compensation.
Make a “weighting” determination based on the unique facts of the particular arrangement and credibility of data.

- For example, collections data may be incomplete or misleading; or there may be ambiguity in wRVUs (coding issues?)

Depending on the specialty and/or sources of physician data, it may be that one market indicator is more appropriate than another.
Cost and Income Approaches

- Application of these two approaches can offset and mitigate limitations of the market approach.
- Provide view into local marketplace
- Allow analysis of full array of economic factors affecting physician compensation
- Provide a reality check
PSA Conversion Agreements
Various Approaches (cont.)

- Cost Approach
  - Normalized and adjusted historical compensation
  - Realistic numbers for the cost to recruit

- Income Approach
  - *Pro forma* based on hypothetical-typical employer basis
  - Reflects future market conditions

- Earnings Available for Physician Compensation
  - (*i.e.*, Calculate applicable overhead, deduct benefits and apply a cost of capital)

- Synthesize all three approaches
Confucius Statistician say...If you torture the data long enough, it will confess to the crime it did not commit.

Data from reliable sources can be misused in a variety of ways, including:

- Cherry picking from among different tables (e.g., regional data vs. state data)
- Failure to consider ownership/ancillary profits that may be inherent in all reported percentiles of compensation
- Do regional compensation differences exist? The grass is always greener...
PSA Conversion Agreements
Caution Regarding Compensation per wRVU

Example of misuse of data, using 2013 MGMA data for General Surgery
- 90th percentile cash compensation - $607,000
- 90th percentile wRVUs – 11,021
- 90th percentile compensation per wRVU - $88.11

Where is this going?
- 90th percentile wRVUs x 90th percentile compensation per wRVU = $971,000 (i.e., 160% of 90thP compensation)
- MGMA states that there is an inverse relationship between physician compensation and compensation per wRVU
- Median compensation (per wRVU) is a misnomer; no physician wants to be below the median!
- Evaluate comp by quartile of production data; comp per wRVU declines as wRVUs increase
Providers implementing wRVU models have been observed to make errors related to:

- “Total” vs. “Work” relative value units
- GPCI adjustments
- Assistant at surgery
- Multiple procedures
- Mid-level providers (i.e., “Incident to” or “at full rate”)
- Use of “blended” rate for multiple specialties
- CMS changes in wRVUs
- New or discontinued CPT codes
PSA Conversion Agreements
Physician Non-Salary Expense

Should certain payments be passed through or fixed, rather than as a component of a wRVU rate?

- Professional liability expense
- Benefits costs such as insurance coverage for medical, dental, vision or life insurance
- Benefits costs for what is normally an employer-contributed pension or retirement plan
- Employer’s portion of taxes for FICA Medicare and FICA Social Security
- Be wary of “fixed” versus “variable” expenses.
  - Need to account for each differently
Benefit plans are becoming more robust
- Need to review and evaluate the components

Since likely “baked” into the wRVU value, it is important to determine a “cap” on benefits
- e.g., Tier out the wRVU value to accommodate the benefit ceiling

Is it commercially reasonable to have a non-exclusive arrangement? (i.e., physician gets to maintain certain aspects of the practice?)
PSA Conversion Agreements
Perils of Compensation “Stacking”

Beware of existing agreements that preceded the PSA, as well as other new terms.

- Sign-on bonus
- Productivity bonus
- Medical directorship
- Co-management agreement
- Quality bonus
- Retention bonus

- Call pay
- Tail insurance
- Excess vacation
- Relocation costs
- Excess benefits
Hybrid PSA/Service Line Co-Management Arrangements
What Is a Service Line Co-Management Arrangement?

- Co-Management Agreement is an additional independent contractor relationship
- PSA purchases professional services of physicians and clinicians
- Co-Management Agreement purchases administrative and management services from physicians and clinicians
- Engage physicians as a business and clinical partner in managing, overseeing and improving service line quality and efficiency
  - No overlap in contractual duties between PSA and Co-Management Agreement (or other agreements)
Service Line Co-Management Direct Contract Model

- **Payors**
- **Hospital**
  - Hospital-licensed services
  - Designees
  - Operating Committee
  - Designees
  - Co-Management Agreement
  - $
  - Medical Group I
  - Medical Group II
  - Other Group(s)

- **Service Line**
  - Designees
  - Two, or multi-party contract
  - Specifically enumerated services
  - Allocates effort and reward between groups

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Service Line Co-Management Joint Venture Model

- Capital Contributions
- Management Infrastructure

Payors ➔ Hospital ➔ JV Management Company ➔ Specialists/Groups

Service Line

Profit Distribution

Co-Management Agreement

$
Comparative Structural Considerations

- Simplicity and expense
- Potential securities offering for JV Model
- Physician holding company?
- JV Model better reflective of relative roles/responsibilities of hospital/MDs?
- Direct contract more remunerative?
- Participating MDs performing disproportionate services/ Compensation based on relative efforts vs. invested capital?
- Antitrust considerations (for bundled payments): JV Model more financially integrated?
Service Line Co-Management Arrangements

- Typically two levels of payment to physician managers:
  - **Base fee** – a fixed annual base fee that is consistent with the fair market value of the time and effort participating physicians dedicate to service line development, management, and oversight
  - **Bonus fee** – a series of pre-determined payment amounts, each of which is contingent on achievement of specified, mutually agreed, objectively measurable, program development, quality improvement and efficiency goals
  - Aggregate payment generally approximates 2-3.5% of service line revenues
  - Fixed, fair market value; independent appraisal advisable
Additional Legal Considerations

There are legal constraints on Service Line Co-Management Agreements (i.e., CMP, AKS and Stark):

- No stinting
- No steering
- No cherry-picking
- No gaming
- No payment for changes in volume/referrals
- No payment for quicker-sicker discharge
- No reward for changes in payor mix, case mix
- Must be FMV; independent appraisal required
Additional Legal Considerations

- Recent request (Oct. 3, 2014) by CMS for comments on proposed CMP rules for gain-sharing programs
- Some irreducible legal risk because aggregate compensation is not set in advance

Minimize legal risk by:
- Internal monitoring with compliance officer review
- Independent FMV appraisal
- Independent outside reviewer
Additional Legal Considerations: CMP Law (cont.)

- Cost savings metrics/incentives implicate Civil Monetary Penalty Law
  - Hospital cannot pay a physician to reduce or limit services to Medicare/Medicaid beneficiaries under the physician’s care.
  - Cannot pay for reduction in LOS or overall budget savings

- Can pay for cheaper not fewer items of equivalent quality?
  - Potential to incent verifiable cost-savings from standardizing supplies or reducing administrative expenses as long as quality is not adversely affected and volume/case mix changes are not rewarded
Additional Legal Considerations: Anti-Kickback Statute

- Volume/revenue-based performance measures implicate the Anti-Kickback Statute.
  - Should not reward increase in utilization, revenue, or profits of service line
  - Should not reward change in case mix
  - Should not reward change in acuity
  - Should obtain independent appraisal of FMV to help negate inference of improper intent

- Advisory Opinions indicate that the AKS could be violated if the requisite intent is present, but that OIG would otherwise not seek sanctions.
**Additional Legal Considerations:**

**Anti-Kickback Statute** (cont.)

- Co-Management contract will not meet Personal Services and Management Contracts safe harbor if “aggregate compensation” is not set in advance.
  - Maximum and minimum compensation may be set in advance, but aggregate compensation may not be.

- Joint venture probably will not meet small investment safe harbor 40/40 tests.
  - More than 40% of interests held by persons in a position to refer

- Analyze under AKS “one purpose” test; some irreducible legal risk
Co-Management Arrangements
Valuation Considerations
Typical Features of a Co-Management Arrangement

- The agreement stipulates a listing of core management/administrative services to be provided by the manager (for which the base fee is paid).

- The agreement includes pre-identified incentive metrics coupled with calculations/weightings to allow computation of an incentive payment (which can be partially or fully earned).
  - Usually tiered in terms of level of accomplishment and associated payouts.
  - Must demonstrate some level of improvement over “current state” in order to receive the “top tier” of compensation.
  - Can provide some level of compensation for maintaining current state, if at national benchmark or better.

- Compensation is directed towards accomplishments rather than hourly based services.
Valuation Process
Riskiness of Co-Management Arrangements

Among the spectrum of healthcare compensation arrangements, co-management arrangements have a relatively “high” degree of regulatory risk if FMV cannot be demonstrated.

- By design, these agreements exist between hospitals and physicians who refer patients to the hospital.
- Available valuation methodologies are limited and less objective as compared to other compensation arrangements.
- The “effective” hourly rate paid to physicians may be higher than rates which would be considered FMV for hourly based arrangements (since a significant component of compensation is at risk).
Valuation Process
Approaches to Value

☐ Available valuation approaches include:
  ■ Cost Approach
  ■ Market Approach
  ■ Income Approach

☐ In considering these valuation approaches, an income approach can likely be eliminated since the possible or expected benefits of the co-management agreement may not translate directly into measurable income.
The Cost Approach

- The Cost Approach can be used to estimate the “replacement” or “replication” cost of the management/administrative services to be provided by the manager.

- An analysis by “proxy,” or an approach that estimates the number of medical director hours required to manage the service line in the absence of a management arrangement, (which is then multiplied by an FMV hourly rate) yields one indication of value.

- However, within the framework of a joint venture management company, this approach does not consider the hospital’s contribution.

- Further, a key ideal of most co-management arrangements is to reward results rather than time-based efforts.
The Market Approach

- The Market Approach recognizes that each co-management arrangement is unique and may include and prioritize different market and operational factors.

- Therefore, within the framework of the Market Approach analysis, consideration must be given to the required management tasks.
  - Specific tasks and responsibilities of the managers must be identified.
  - On an item-by-item basis, the relative worth of each task/responsibility is “scored” relative to other comparable arrangements.
  - An indication of value of the management services is then established by comparing the “scoring” of the subject agreement to other service arrangements in the marketplace.
Valuation Synthesis

- The Cost and Market valuation methodologies should be reconciled to arrive at a final conclusion of value.
  - The Cost Approach may “underestimate” the value of the arrangement because in the case of joint ventures, the Cost Approach only considers physician participation (i.e., medical directors).
  - The Market Approach may “overestimate” the value of the arrangement because market comparables may not be exact.

- While it may be appropriate to give equal weighting to the two approaches, the valuator may conclude that one method should be weighted more heavily than the other.
  - Make an assessment regarding the split between the base fee and incentive fee components.

- The FMV of the base fee must encompass payment of any medical director fees or administrative services related to managing the service line.
What Drives Value?

- As a percentage of the service line net revenues, the total fee payable under a co-management arrangement typically ranges from 2% to 3.5% (on a calculated basis).
- The fee is fixed as a flat dollar amount, including both base and incentive components, for a period of at least one year.
  - Commonly, the base fee equals 50-70% of the total fee.
- The extent and nature of the services drive their value. Thus, the valuation assessment is the same whether the manager consists of only physicians or physicians and hospital management.
- Determinants of value include:
  - What is the scope of the hospital service line being managed?
  - How complex is the service line? (e.g., a cardiovascular service line is relatively more complex than an endoscopy service line)
  - How extensive are the duties being provided under the co-management arrangement? How many physical locations are being managed?
What Drives Value? (cont.)

- Size adjustments based on service line revenue:
  - Large programs may be subject to an “economies of scale” discount.
  - Small programs may be subject to a “minimum fee” premium.

- Consider the appropriateness of the selected incentive metrics:
  - Is the establishment of the incentive compensation reasonably objective?
  - Consider the split of base compensation and incentive compensation.

- Who is responsible for monitoring and “re-basing” the metrics?
Possible Pitfalls of Co-Management Arrangements

- The service line/revenue stream to be managed must be defined objectively, and there should be no overlap between multiple service lines which may be subject to co-management arrangements (e.g., surgery service line and orthopedic surgery service line).

- A co-management arrangement typically contemplates that no third-party manager is also providing similar services on behalf of the hospital or its service line.

- Care must be taken to ensure that employed physicians who are part of co-management arrangements are not double paid for their time.
  
  - Employment compensation based solely on wRVUs is generally self-normalizing.
Possible Pitfalls of Co-Management Arrangements (cont.)

- Medical director agreements related to the managed service line must be compensated through the base management fee.
- There can be no passive owners, active participation and significant time and effort are required by busy physicians.

- Documentation requirements
Other Key Service Line Co-Management Issues

- Performance standards and targets
  - Validation
  - Achievability
  - Reset

- Term/durability
  - Rev. Proc. 97-13 (5/3 years if 50%+ fixed)

- Dilutive effect of adding physicians due to fixed FMV fee for services rendered
Other Key Service Line
Co-Management Issues

- Cost of independent monitor, valuation, security offering (for JV)
- Some irreducible legal risk
PSA/Co-Management Lessons Learned
PSA/Co-Management Lessons Learned

- Payor pushback – site of service differential for hospitals may be temporary
  - Commercial insurance contract expiration/negotiation
  - Assault on Medicare site of service differentials

- Pharma pushback on 340B pricing
  - Advocating change in HRSA regulations for 340B pricing to apply to indigent patients of DSH hospitals rather than to all patients of DSH hospitals
PSA/Co-Management Lessons Learned

- Co-management requires active participation and **real time and effort by busy physicians**
  - Hours-based v. task-based arrangements/valuation methods
  - Documentation requirements

- **PSA exclusivity, right of first opportunity for new sites/programs**, and significant role in **governance** of service line
  - Available to larger, more dominant oncology groups; may not be available to smaller groups in competitive market
  - Large group may have footprint that aligns with multiple hospitals/systems (complementary v. competitive markets)
PSA/Co-Management Lessons Learned

- Limited opportunity to have PSAs with multiple hospitals
  - Not available to smaller groups in market with multiple groups

- Generally all service line oncologists participate in co-management arrangement because participating physicians are **responsible for performance of all oncologists**.
PSA/Co-Management Lessons Learned

- **Governance issues**
  - Board seats?
  - **Joint operating committee:** composition and authority
  - Regional councils: Group role
  - Medical directorship/sub-directorships?
  - **Reporting may be through a middle manager** (service line administrator) and not to hospital decision-makers
PSA/Co-Management Lessons Learned

- PSA operational integration issues
  - **IT integration**, interfaces and adoption; and associated **impact on productivity**
  - Disruption for **leasehold improvements** to meet hospital license requirements for physical space
  - **Split staff** (off-campus) and salary/benefit differentials
  - **Union issues**
PSA/Co-Management Lessons Learned

- PSA/wRVU issues
  - Changes in wRVU values over time v. lock-in base year wRVU values
  - Addition/deletion of CPTs/RVUs over time
  - Impact of sequestration on payments tied to Medicare Physician Fee Schedule payment methodology
  - Difference of opinion regarding how to pay for supervision of ancillary services (e.g., chemo administration)
  - Will Group get credit for NP/PA wRVUs?
  - Benefit costs and change in benefit expenses over time
  - wRVU may not cover other continuing Group overhead expenses (e.g., legal, accounting, insurance)
  - wRVUs may not be available for certain ancillary services (e.g., imaging)
  - Access to books/records to confirm wRVU count
Adding additional physicians to co-management arrangement is dilutive to existing physicians

Other PSA Compensation Issues

- Will hospital provide **base compensation guarantee** for transition period (e.g., 85% of base year compensation for 2 years, if Group provides at least 80% of wRVU productivity)?

- Will hospital provide **anti-dilution protection** to protect against internal competition? Loss of referral sources from PCPs associated with competing systems
PSA/Co-Management Lessons Learned

☐ PSA Compensation Issues (cont.)

- **New physician ramp-up/guaranteed compensation** or wRVU credits for new physicians
- **Compensation caps** for tax exempt hospitals
- **Harmonizing PSA compensation method** with new shared savings, bundled payment, capitation and risk based payments

☐ What is tipping point to trigger change in compensation methodology? Who decides?
PSA/Co-Management Lessons Learned

- Non-competes, restrictive covenants and unwind rights
  - Unwind right is key to preserving leverage and future options
  - Hospitals hate unwind rights, and will try to limit them
  - Least common denominator is unwind to private practice—not to a competing health system
  - Negotiation over unwind triggers: failure to offer FMV compensation; failure to renew; termination without cause; change of ownership; change in law; material decrease in compensation

- Generally, no unwind due to Group breach or Group non-renewal without cause
PSA/Co-Management Lessons Learned

- Unwind rights (cont.)
  - Negotiation over what Group gets back in unwind: space and TIs, assets and new or upgraded equipment, staff, medical records, data, cooperation and orderly transition
  - Hospital may try to negotiate opportunity to solicit physicians starting at notice of unwind
  - Unwind should be exception to non-competes
PSA/Co-Management Lessons Learned

- **Durability: Term/Termination**
  - **Duration of valuation opinion/periodic revaluation**
    - Revaluations have generally retained or increased wRVU rates and co-management fees
    - History may not be an accurate predictor of future.
  - **Periodic reset of performance standards and targets**
    - Continued payment for optimized standards?
  - **Rev. Proc 97-13 limits on duration of use of tax exempt bond financed space and equipment**
  - **Potential for breach, change in ownership/control, change in law, change in market and circumstances**
PSA/Co-Management Lessons Learned

- Need good dispute resolution process to focus the parties on maintaining relationship
  - Escalating dispute resolution: CEO meeting, mediation, arbitration is preferable
  - Parties should continue to perform during dispute process.

- Change in administration/leadership can change everything—can test relationship and contracts.

- Good working relationship is key to overcoming speed-bumps as they arise.
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- Requestor was a large hospital in a remote, medically underserved area.
- 16-physician cardiology group was the only provider of CC services in town and the only cardiologists on Requestor’s medical staff.
  - Requestor agreed that if other cardiologists joined medical staff it would consider extending arrangement to them.
- Requestor pays (1) a guaranteed, fixed payment, and (2) potential annual performance fees in quarterly installments.
  - Direct contract model: Payment is made to the Group, which then distributes dividends based on each shareholder’s pro rata share of ownership after payment of medical director fees.
  - Performance Fee based on (1) Requestor’s employee satisfaction (5%); (2) patient satisfaction with Requestor’s CC Labs (5%); (3) improved quality of care within the CC Labs (30%); and (4) cost reduction measures (60%).
  - Graduated targets: 50% for threshold; 75% for mid-point; 100% for target.

- OIG finds that the Fixed Fee, employee satisfaction, patient satisfaction, and quality components do not implicate the CMP Statute, but the cost savings component does.
  - Standardization of devices and supplies and limiting use of specific stents, contrast agents and medical devices, might induce physicians to alter their current medical practice and reduce or limit services.

- However, OIG will not seek sanctions because of sufficient safeguards.
  - First, Requestor certified that the arrangement has not adversely affected patient care, and that it engaged an independent reviewer to monitor both the performance of the Group under the arrangement and its implementation of the cost savings component to protect against inappropriate reduction or limitation in patient care.
  - Second, the risk that the arrangement will lead the physicians to apply a specific cost savings measure, such as the use of a standardized or bare metal stent, in medically inappropriate circumstances is low. Each of the physicians has access to the device or supply he or she determines to be most clinically appropriate for each patient.
  - Third, the Performance Fee is limited in duration and amount; it is subject to a maximum annual cap and the term of the arrangement is limited to three years.
  - Fourth, receipt of the Performance Fee is conditioned upon the physicians not: (1) stinting on care; (2) increasing referrals to Requestor; (3) cherry-picking; or (4) accelerating patient discharges.

- OIG finds low risk of AKS violation because:
  - First, Requestor certified that the compensation paid to the Group is fair market value for substantial services provided, based on an independent appraisal;
  - Second, the compensation paid to the Group does not vary with the number of patients treated, so there is no incentive to increase patient referrals to Requestor;
  - Third, because Requestor operates the only cardiac catheterization laboratories within a fifty-mile radius, and because the Group does not provide cardiac catheterization services elsewhere, the arrangement is unlikely incent the physicians to refer business to Requester from any competitor;
  - Fourth, the specificity of performance metrics helps ensure that the purpose is to improve quality, rather than reward referrals; and
  - Fifth, the agreement is limited in duration (3-year term).
Additional Legal Considerations: CMP Law

- Civil Monetary Penalty Law prohibits a hospital from making a payment, directly or indirectly, to a physician as an inducement to reduce or limit services to a Medicare or Medicaid beneficiary who is under the direct care of the physician.
  - OIG maintains that the CMP Statute prohibits reducing medically unnecessary services or substituting clinically equivalent items.
  - Section 6402 of PPACA exempts from the definition of “remuneration” “any other remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs (. . . as designated by the Secretary under regulations)”
  - Potentially broad authority, but requires regulations

- Proposed limited CMP waiver regulation issued on April 7, 2011 with respect to ACOs participating in the MSSP (76 Fed. Reg. 19655):
  - Protects distributions of ACO shared savings from a hospital to a physician if the payments are not made knowingly to induce the physician to reduce or limit *medically necessary* items or services.

- 16 favorable OIG Advisory Opinions on gainsharing—low risk of abuse.