Co-Management Arrangements in Healthcare: Complying with Regulatory Requirements in Structuring Hospital-Physician Arrangements

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Road Map to the Presentation

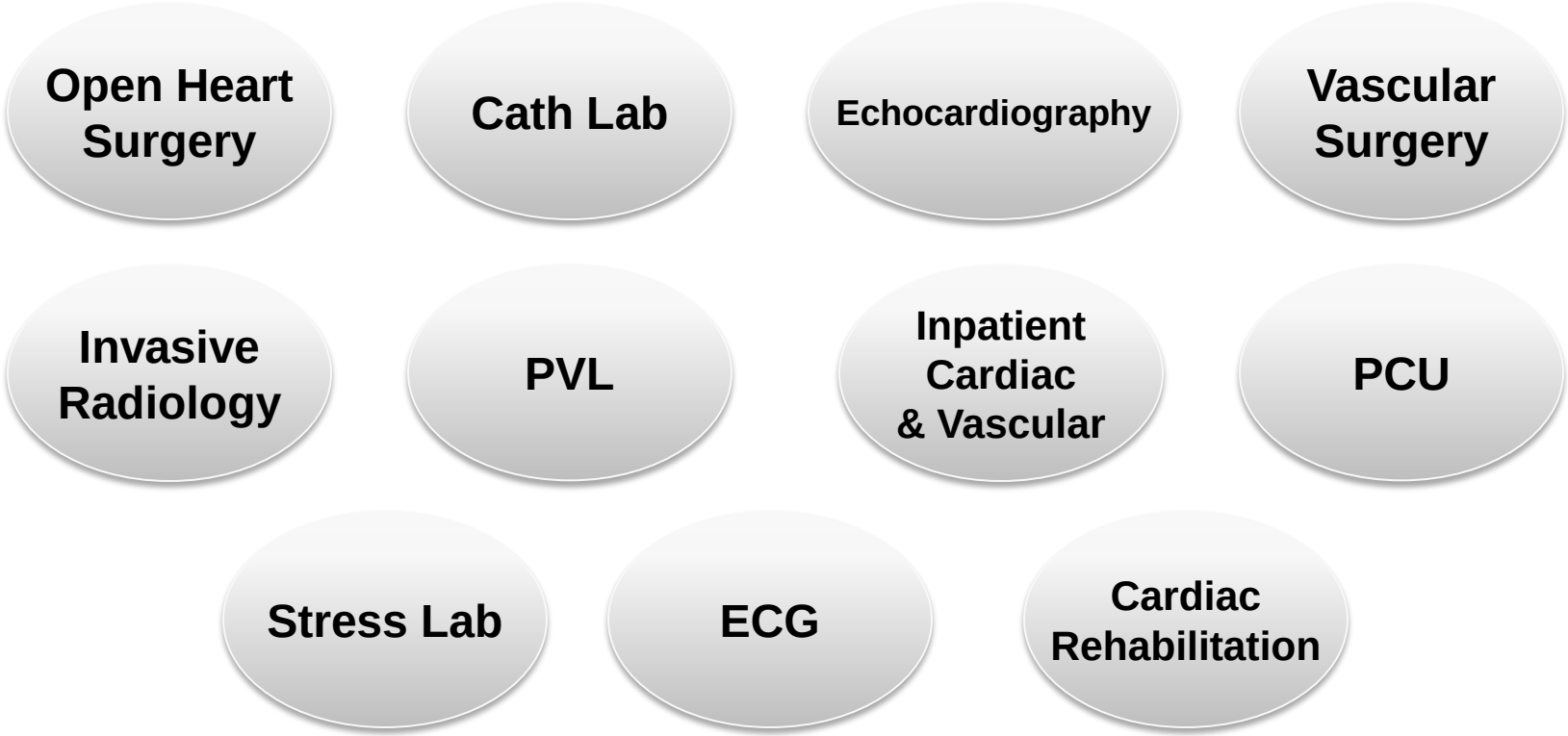
- Definition and Description of a Co-Management Arrangement
- Discussion of Key Regulatory Concerns
- Review of FMV Considerations and Structural Guidance
- Questions & Answers

Service Line Co-Management Arrangements

- The purpose of the arrangement is to recognize and appropriately reward participating medical groups/physicians for their efforts in developing, managing and improving quality and efficiency of a particular hospital service line.
- Scope of service – The arrangement may cover inpatient, outpatient, ancillary and/or multi-site services.

Service Line Co-Management Arrangements

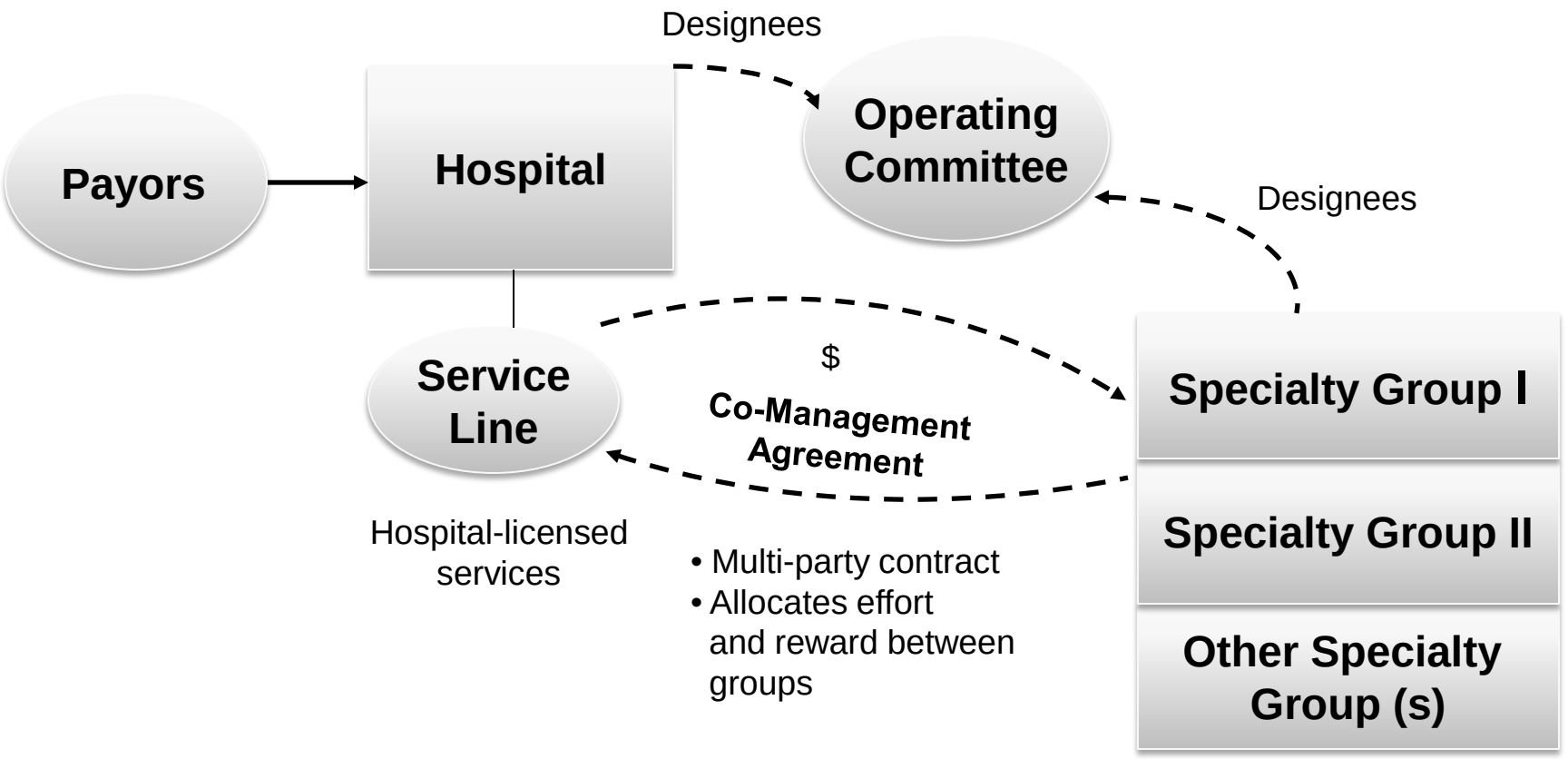
Example: Potential Scope of Cardiology Service Line



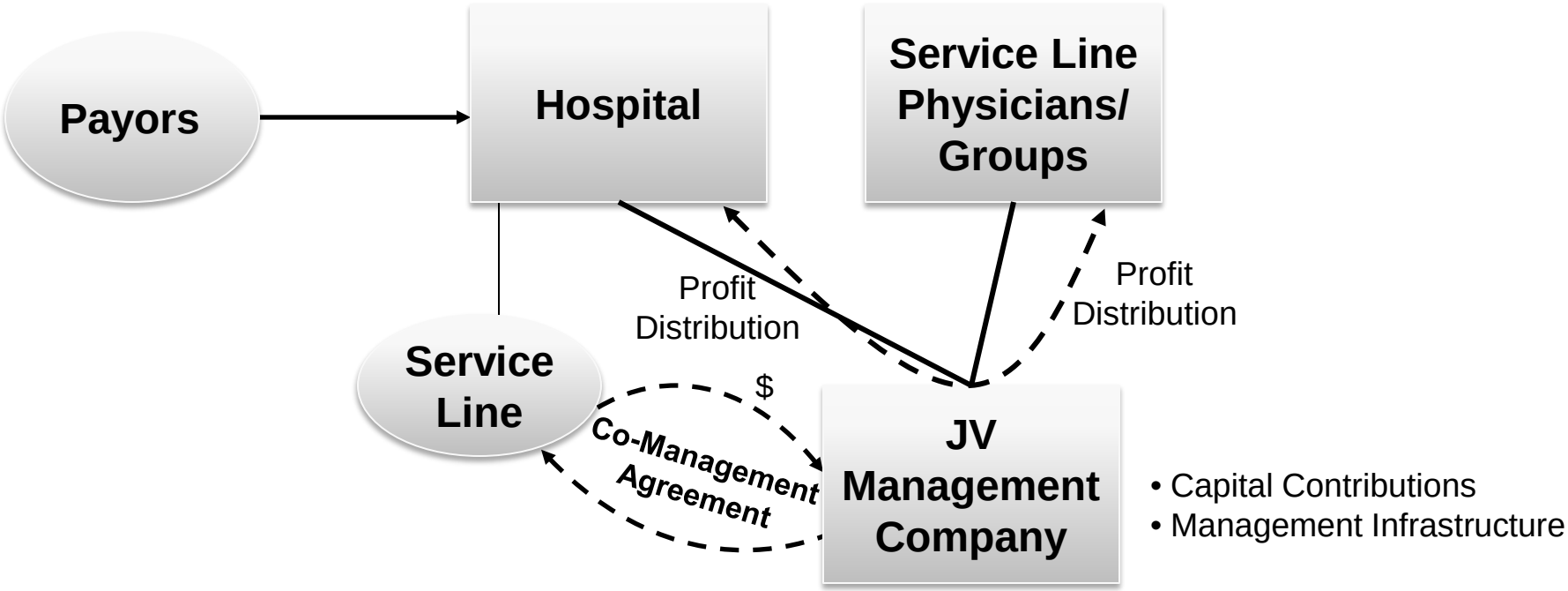
Service Line Co-Management Arrangements

- The contract may be either with one or more physician(s) / medical group(s) (or faculty practice plan(s)) or with a joint-venture entity owned by the hospital and participating physician(s) / medical group(s).

Service Line Co-Management Arrangements
Direct Contract Model



Service Line Co-Management Arrangements
Joint Venture Model



Service Line Co-Management Arrangements

- There are typically two levels of payment under the service line contract:
  - Base fee – a fixed annual base fee that is consistent with the fair market value of the time and efforts participating physicians dedicate to the service line development, management, and oversight process
  - Bonus fee – a series of pre-determined payment amounts contingent on achievement of specified, mutually agreed, objectively measurable, program development, quality improvement and efficiency goals
  - Must be fixed, fair market value arrangement; independent appraisal strongly advised

Service Line Co-Management Arrangements

- Sample Co-Management Services (Select)
  - Development of Service Line
  - Medical Director services
  - Budget process
  - Strategic/business planning process
  - Community relations and education
  - Patient, physician and staff satisfaction surveys
  - Development of clinical protocols and performance standards

Service Line Co-Management Arrangements

- Sample Co-Management Services (Cont.)
  - Ongoing assessment of clinical environment and work flow processes
  - Physician staffing
  - Patient scheduling
  - Staff scheduling and supervision
  - Human resource management

Service Line Co-Management Arrangements

- Sample Co-Management Services (Cont.)
  - Case management activities (*e.g.,* discharge planning, arranging follow-up services and supplies, call back processes)
  - Materials management
  - Medical Staff related activities and committee participation
  - Credentialing assistance
  - Coordination with and reporting to hospital

Sample Surgical Performance Metrics

Incentive	Priority	Allocation	Upper Payment Limit (a)	Current Performance	Performance Target		
					Measurement	Year 1	Year 2
Operational Efficiencies Incentive Compensation (OEIC)							
Supply Cost per Case	1	13.2%	$ 120,000	$5,670	% of Budget	95.0%	95.0%
Turn Around Time (c)	2	8.2%	$ 75,000	2.56	# Hours	</=1.00	</=1.00
On-Time Starts (1st Case of Day)	2	8.2%	$ 75,000	20%	Improvement On Target	>/= 95%	>/= 95%
Room Utilization	1	13.2%	$ 120,000	76%	# Hours	>/= 85%	>/= 85%
Quality of Service Incentive Compensation (QSIC)							
Infection Rate: Antibiotics Within 30 Minutes Prior to Incision	1	13.2%	$ 120,000	89%	% Compliance	>/=95%	>/=98%
Infection Rate: Insulin Drip for Patients with Blood Sugar Level > 150	2	8.2%	$ 75,000	0%	% Compliance	>/=50%	>/=75%
Return to OR for Post-Op Bleeding	2	8.2%	$ 75,000	2.9%	% Rate of Return to OR	</=2.7%	</=2.5%
Mortality Rate	1	13.2%	$ 120,000	(d)	O/E Rate (b)	</=1.00	</=0.95
Patient Satisfaction	3	7.1%	$ 65,000		Peer Group Percentile	>/=80	>/=85
Peer / Employee Evaluations	3	7.1%	$ 65,000		360° Feedback Scores	Survey Development / Administration	TBD
Total Incentives			**$ 910,000**				
Quality of Service Threshold							
Mortality Rate (e)	Quality Threshold would be required to be met in order for any of the above incentives to be paid out.			2.98%	Gross Mortality % and/or O/E Rate (TBD) (e)	2.98%	Conversion to O/E Rate

(a) Based on maximum total incentives payout of $910,000 **(Subject to Fair Market Value and Legal Approval)**

(b) O/E = Observed v. Expected rate

(c) Turn Around Time Defined as time of incision closure to time of next incision

(d) O/E mortality rate is currently not measured

(e) Assumes Quality of Service Threshold will change from gross mortality % to an O/E rate once available.

For Illustrative Purposes Only

*Prepared by PricewaterhouseCoopers

Principal Regulatory Considerations

- Civil Monetary Penalty Statute
- Anti-Kickback Statute
- Physician Self-Referral Statute (Stark)
- False Claims Act
- Tax Exemption/Intermediate Sanctions
- Provider-Based Status Rules

CMP Statute, Section 1128A(b) of the SS Act, 42 USC 1320a-7a(b)

- Prohibits a hospital (or CAH) from knowingly 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
  - Note that paying a physician to design a plan or to oversee its implementation would not violate the CMP statute if the physician is not directly providing care to Medicare or Medicaid beneficiaries
- CMP of not more than $2,000 for each such individual with respect to whom the payment is made
- A physician who knowingly accepts payment subject to a CMP of not more than $2,000 for each individual with respect to whom the payment is made
- Potential for exclusion from Federal and State Healthcare programs (see 1128(b)(7) of the SS Act)

OIG's Implementation CMP Statute

- No regulations – proposed rule issued but never finalized
- Primary guidance document is July 1999 Special Advisory Bulletin, available at: http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/gainsh.htm
- OIG has consistently maintained that the CMP Statute must be read as prohibiting even payments to physicians for reducing medically unnecessary services or for using device A or supply A instead of clinically equivalent device B or supply B
  - Questionable whether conclusion is compelled by text and supported by legislative history
- OIG initially hostile to idea of issuing advisory opinions on proposed gainsharing arrangements, but began issuing favorable advisory opinions in 2001 and has issued 15 favorable opinions to date, including 4 in 2008 and 1 in 2009

CMP Statute - GainsharingAdvisory Opinions

- In the typical arrangement covered by AO, OIG will conclude that some or all aspects of the arrangement would constitute an improper payment under the CMP statute but that it would not seek sanctions.
  - Product substitutions are found to implicate the CMP Statute. Occasionally, some minor aspects of the arrangement may have no appreciable clinical significance, such as paying physicians to use reusable supplies.

CMP Statute – Gainsharing Advisory Opinions

- Actual verifiable cost savings tied to specific protocol/cost lowering activity. Measure cost savings on basis of existing volume (avoid incentives to change volume).
- Ensure quality is measured and maintained.
- Monitor change in case mix (protection against steering away sicker/more costly patients).
- Disclose to patients.
- Reasonable compensation (based on independent appraisal).

Bottom-line: 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

CMP Statute - OIG Says a Change in Law is Needed . . .

- "Properly structured, gainsharing arrangements may offer opportunities for hospitals to reduce costs without causing inappropriate reductions in medical services or rewarding referrals of Federal health care program patients. In a number of specific cases, OIG has concluded that the arrangement presents a low risk of abuse and, therefore, exercised its prosecutorial discretion not to impose sanctions. However, absent a change in law, it is not currently possible for gainsharing arrangements to be structured without implicating the fraud and abuse laws." – *Lewis Morris, Chief Counsel OIG, 2005 Testimony before House Ways and Means Committee, Subcommittee on Health*

CMP Statute - OIG Says a Change in Law is Needed . . .

- "We are keenly aware of the need for innovation in business arrangements to fully implement the ACO provisions in the Affordable Care Act. To that end, let me say this. The fraud and abuse rules enforced by our office should not stand in the way of improving quality and reducing costs through ACOs. As the Medicare and Medicaid programs incorporate and test new payment and delivery models, there is a need for fresh thinking about program integrity and the types of risks faced by our programs and beneficiaries." – *Dan Levinson, Inspector General, October 5, 2010 remarks on Workshop held at CMS on Accountable Care Organizations*

CMP Statute – . . . And Congress Changes the Law

- 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)"
  - Broad authority, but requires regulations
  - Amends section 1128A(i)(6), which is applicable to the entire CMP Statute, so not just limited to the beneficiary inducement provisions of the CMP Statute
- Will the OIG issue regulations to address shared savings programs and other arrangements, or does it read this section (incorrectly) as pertaining only to the beneficiary inducement provisions of the CMP Statute?

Anti-Kickback Statute, Section 1128B(b) of SS Act, 42 USC 1320a7-b(b)

- Criminal statute - requires intent of an illegal inducement
- Prohibits the knowing and willful offer, solicitation, payment or receipt of anything of value that is intended to induce the referral of an individual for which a service may be made by Medicare and Medicaid or certain other federal and state healthcare programs or to induce the ordering, purchasing, leasing or arranging for, or recommending the purchase, lease or order of, any service or item for which payment may be made by such federal healthcare programs (collectively referred to as an illegal inducement)
- Covers referrals for any item or service that might be paid for by Medicare or any other federal health care program
- Ascribes criminal liability to both sides of an impermissible “kickback” transaction, and has been interpreted to apply to any arrangement where even one purpose of the remuneration offered, paid, received, etc., is to obtain money in exchange for referrals or to induce referrals

Anti-Kickback Statute

- 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.
  - OIG's position is that percentage compensation is not "set in advance".
- 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.

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 state that the AKS could be violated if the requisite intent were present but that OIG would not seek sanctions.

Physician Self-Referral (Stark)
Section 1877 of SS Act, 42 USC 1395nn

- Prohibits a physician from making referrals for certain "designated health services" (or DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless an exception applies
- Prohibits the entity from submitting a claim (or causing a claim to be submitted) to Medicare
- "Financial relationships" include both ownership and compensation relationships.
- Strict liability statute – no intent to violate necessary for claims to be denied, but enhanced penalties available for knowing violations (CMPs/assessments, exclusion, and False Claims Act liability)

Stark Implications of IP/SS Plans

- Incentive payments to physicians, or payments to physicians under an incentive payment or shared savings plan constitute a compensation arrangement, and therefore an exception is needed.
  - Need direct compensation exception for service line co-management agreement with participating individual physicians, and medical group owners that “stand in the shoes” of their “physician organization”
  - Indirect compensation analysis for joint venture model and other physician entities (*e.g.,* faculty practice plans)
    - Outside of Stark if aggregate compensation to referring physician does not vary with or reflect volume or value of DHS referrals
    - Otherwise, need to rely on indirect compensation arrangements exception (411.357(p))
      - Fair market value requirement

Proposed Stark Exception for IP/SS Plans

- In CY 2009 PFS proposed rule, CMS proposed a stand-alone exception for IP/SS plans.
  - Invoked authority under section 1877(b)(4) of the Act, which allows Secretary to promulgate new exceptions provided there is no risk of program or patient abuse
- The proposed exception would permit remuneration by a hospital to physicians on its medical staff.

Proposed Stark Exception for IP/SS Plans

- Aimed at permitting appropriate quality improvements and cost-savings programs while guarding against:
  - Stinting
  - Steering
  - Cherry-picking
  - Gaming
  - Paying for referrals/volume increase
  - Quicker-sicker discharges

Proposed Stark Exception for IP/SS Plans

Scope of the proposed exception

- Incentive Payment Programs
  - P4P
  - Quality improvement payments
  - Do not involve cost sharing
- Shared Savings Programs
  - Includes traditional gainsharing
  - “Hybrid models” combining cost sharing measures and quality improvement

Proposed Stark Exception for IP/SS Plans

- 16 detailed standards -- Many conditions mirrored those found important by OIG in the favorable advisory opinions it had issued to date for gainsharing programs.
- Key Constraints of proposed IP/SS Exception
  - Quality measures must be listed on CMS' Specification Manual for National Hospital Quality Measures – too limited?
  - Applies to "cost savings resulting from reduction in waste or changes in physician or clinical practices"
    - Efficiency gains (*e.g.,* turn-around times, on-time starts) that reduce unit cost, but not overall costs?
  - Performance measures to be judged against Hospital's baseline historic and clinical data – Hospital may not have baseline information for some key measures

Proposed Stark Exception for IP/SS Plans

- Key Constraints of proposed IP/SS Exception (Cont.)
  - Targets developed by comparing to national/regional performance norms – may not be available benchmarks
  - At least 5 physicians must participate in each performance measure – service line may have less than 5 physicians.
  - Independent medical review prior to commencement and annually thereafter
  - Physicians must have access to same selection of items as before commencement of program – implications for standardization initiatives.

Proposed Stark Exception for IP/SS Plans

- Key Constraints of proposed IP/SS Exception (Cont.)
  - Term of no less than 1 nor more than 3 years – implications for attractiveness, durability and continuous quality improvement
  - Re-basing – cannot periodically rebase standards or pay for "maintenance" of quality/efficiency gains
  - Remuneration set in advance and cannot change during term – no opportunity to set new performance standards and reappraise during multi-year agreement

Proposed Stark Exception for IP/SS Plans

- Proposed exception not finalized
- CMS received comments critical of the proposed exception as not guarding against program or patient abuse, as required for new exception.
- On the other hand, CMS received comments that exception was not particularly helpful.
- CY 2009 PFS Final Rule reopened the comment period and solicited comments on 55 specific areas.
  - No exception anytime soon?

Proposed Stark Exception for IP/SS Plans

BUT…Is a stand-alone exception even necessary?

- We know that arrangements are taking place in the sunshine, including the arrangements that received favorable AOs from the OIG and have reported data from the arrangements, so some must believe that arrangements can fit into one or more existing.
- What existing Stark exceptions can be used?
  - Personal service arrangements (411.357(d))
  - Fair market value (411.357(l)

Proposed Stark Exception for IP/SS Plans

- Both the PSA and FMV exceptions contain requirement that compensation be FMV and "set in advance" and not vary with volume/value of referrals.
  - "Set in advance" permits a specific formula that is set in advance, can be objectively verified and does not vary with volume/value of business generated (*e.g.,* fixed payment for objective quality metrics) – percentage comp can "be set in advance".

Proposed Stark Exception for IP/SS Plans

- Both the PSA and FMV exceptions contain the requirement that *"The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates a Federal or State law."*
  - What does this mean? Does it apply just to hawking questionable arrangements, or does it also apply to having an arrangement that violates the AKS and/or CMP? If the latter, is obtaining a favorable AO enough to satisfy the requirement? Does it apply to designing or overseeing implementation of a IP/SS plan that otherwise violates the CMP Statute?

Proposed Stark Exception for IP/SS Plans

- **BUT**…Only the FMV exception has the requirement that *"The arrangement does not violate the Anti-Kickback Statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission."*
- Does this argue in favor of using the PSA exception instead of the FMV exception? Is the CMP statute a Federal . . . law . . . governing billing or claims submission"?

False Claims Act 31 U.S.C. 3729-3731

- As amended by the Fraud Enforcement and Recovery Act of 2009 (FERA), liability under the False Claims Act occurs when a person or entity:

  (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

  (2) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; or

  (3) conspires to commit a violation of any of certain provisions of the False Claims Act (including the two listed above).

  - Violations are punished by penalties of not less than $5,500 and not more than $11,000 per claim, plus treble damages for the amount of damages the Government sustains.
  - Whistleblower (qui tam) suits are allowed.
  - Reverse false claims provision now may reach self-discovered overpayments.
- FCA actions can be based on Anti-kickback Statute and/or Stark Law violation.

IRC 501(c)(3)

- Tax Exemption Rules
  - No inurement, private benefit or excess benefits
  - Reasonable compensation (base fee, each component of bonus fee, and in aggregate)
    - Not based on service-line net earnings

IRC 501(c)(3)

- Tax Exemption Rules (Cont.)
  - Follow steps for rebuttable presumption of reasonable compensation under intermediate sanctions regulations (IRC 4958; 26 C.F.R. 53.4958 – IT *et. seq*.)
    - Board/committee obtains appropriate comparability data.
    - Members of Board/committee have no personal interest in the arrangement.
    - Board/committee approves the arrangement in advance w/o participation by any person with a conflict of interest.
    - Document basis for decision, approval date, members present, comparability data, and members recused.
    - Board reviews/approves documentation as being reasonable, accurate and complete.

IRC 501(c)(3)

- Tax Exemption Rules (Cont.)
  - Rev. Proc. 97-13 durational limits, if agreement involves private use of tax-exempt bond-financed space

Provider-Based Status Rules
42 C.F.R. 413.65

- Hospital-licensed service on-campus or at hospital satellite
- If off-campus, must be within 35 miles of hospital campus and under financial, administrative and clinical control of hospital
  - Management contract limitations apply (413.65(h)): clinical staff directly employed by hospital, except for practitioners who can bill independently under Medicare fee schedule (*e.g.,* MDs, NPs)

Antritrust Considerations

- Sherman Act, 1 prohibits contracts, combinations and conspiracies in restraint of trade
- Price fixing is per se illegal
- Does Service Line Co-Management Agreement provide sufficient financial and/or clinical integration to permit joint pricing (e.g., global payment)?
  - Bonus payments at risk
  - Common clinical protocols and standards
  - Investment in co-management company

Service Line Co-Management Arrangements

- Business Considerations:
  - Requires active participation and real time and effort by busy physicians
    - Documentation requirements
  - Durability: need to periodically adjust performance standards and targets?
    - Will the parties reach agreement/dispute resolution?
  - Dilution by adding physicians
  - Physicians may not share in reward from growth of service line

Service Line Co-Management Arrangements

- Physician entity to organize participating physicians and allocate payments?
- Cost of independent appraisal (and clinical monitor)
- Legal costs
- Some irreducible legal risk

Valuing Co-Management Arrangements
Understanding the Arrangement

- For purposes of our discussion, a co-management arrangement is deemed to have certain common elements.

Typical Features of a Co-Management Arrangement

- As indicated earlier in our presentation, compensation for the manager's services is typically comprised of a *base fee* and an *incentive fee*.
  - However, for smaller services lines or in unique instances (*e.g.,* sleep lab), there may only be a base fee.
- The co-management arrangement may or may not involve the creation of a new entity, which may or may not be owned in part by the hospital.
  - Thus, the "manager" may consist of physicians only, or physicians and hospital management collectively.
- The co-management agreement will replace any existing medical director agreements, *except* for certain agreements that are purposefully kept in place in coordination with the co-management arrangement. However, the medical directors will be paid from the *base fee* management fee.

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).
- 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.
  - Physicians are not being compensated under the traditional "hours worked and logged" approach.
  - 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

- As one approach to value, the Cost Approach can be used to estimate the “replacement” or “replication” cost of the services to be provided by the manager.
- An estimate of the number of medical director hours required to manage the service line multiplied by an FMV hourly rate yields one indication of value.
  - However, the exact number of required work hours cannot reasonably be determined in advance.
  - Further, a key ideal of most co-management arrangements is to reward ***results*** rather than time-based efforts.

The Market Approach

- A Market Approach recognizes that each co-management arrangement is unique and considers specific market and operational factors related to the subject arrangement.
  - The specific services of the co-management agreement can be itemized.
  - On an item-by-item basis, the relative worth of each task/objective can be “scored” relative to other comparable arrangements.
  - An indication of value of the management services can then be established by comparing the “scoring” of the subject agreement to other service arrangements in the marketplace.

Valuation Synthesis

- The Cost and Market valuation methodologies must be reconciled to arrive at a final conclusion of value.
- 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.
- Once the FMV of the *total management fee* is established, an assessment must be made 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 6% (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; multiple hospital campuses)
  - How extensive are the duties being provided under the co-management arrangement?

What Drives Value?

- 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.
  - Addressing poor payor mix
- 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.
- Occasionally, certain other services (*e.g.,* call coverage) may be included among the co-management duties. (Some hospitals prefer to embed call coverage in the co-management fee to avoid a separate compensation arrangement with the physicians.)

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 services lines which may be subject to co-management arrangements.
  - Inpatient vs. outpatient; sub service lines carved out, etc.
  - High poor payor mix; possible adjustments
- A co-management arrangement typically contemplates that no third-party manager is also providing similar services on behalf of the hospital service line.
  - Service line administrators
- Medical director agreements that relate to the service line should be appropriately accounted for.