



Co-Management Arrangements: Legal, Structural and FMV Implications

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Practice Groups

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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
- Physician Perspectives regarding Co-Management Arrangements
- Questions & Answers

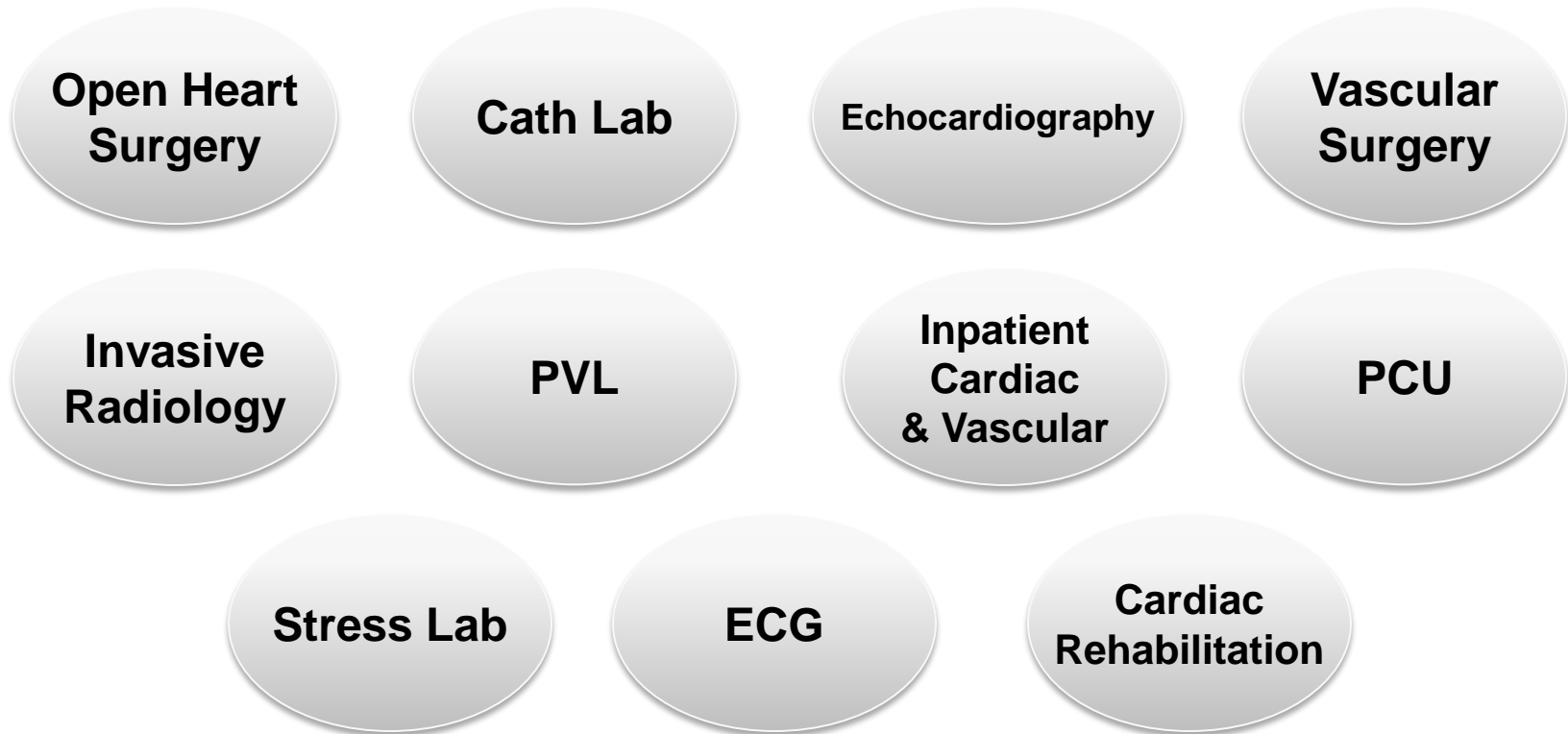
Service Line Co-Management Arrangements



- 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

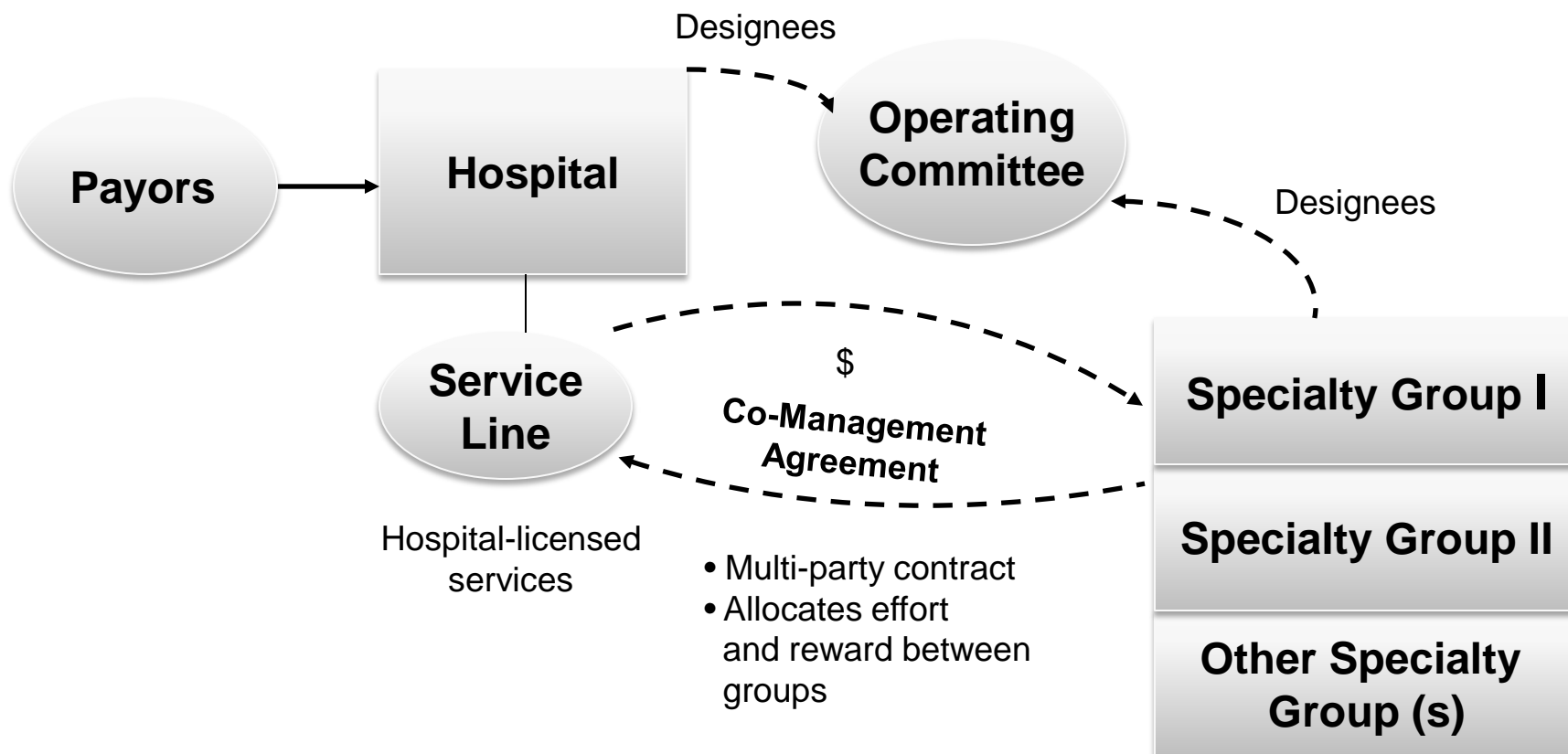


Service Line Co-Management Arrangements

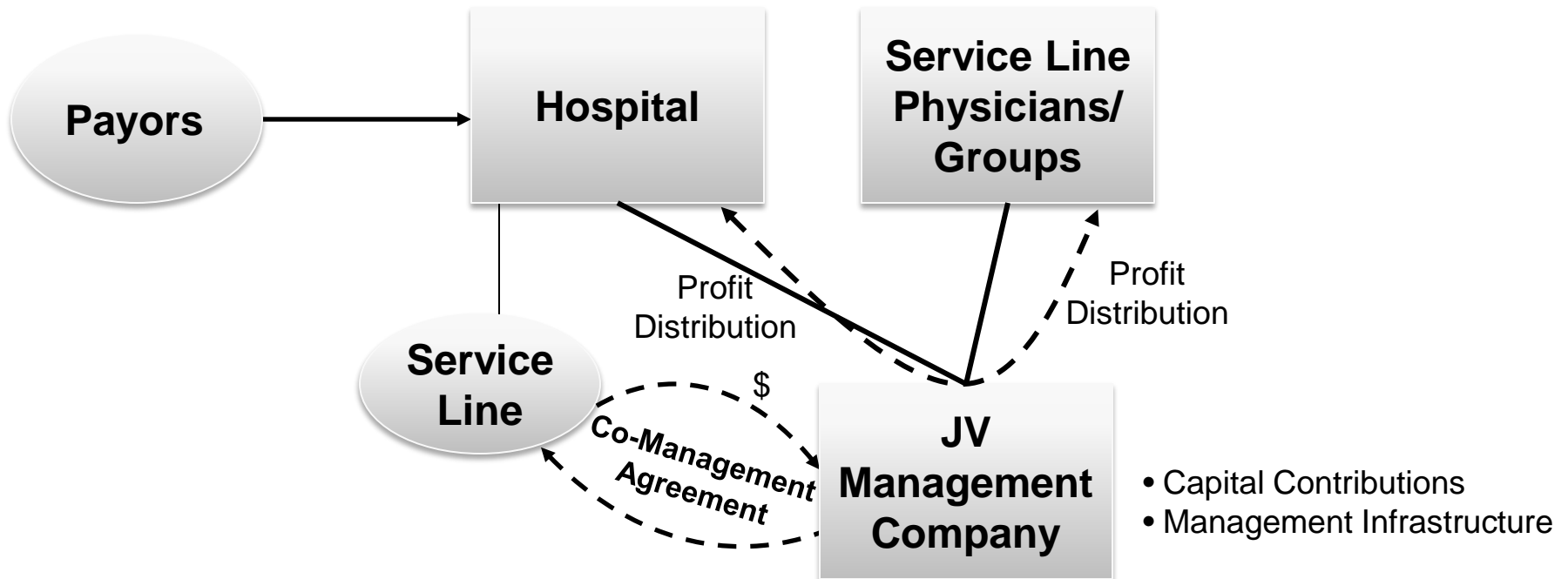


- The contract may be either with one or more physician(s) / medical group(s) (or faculty practice plan(s)) or with a joint-venture entity owned by the hospital and participating physician(s) / medical group(s).

Service Line Co-Management Direct Contract Model



Service Line Co-Management 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
- PPACA Makes Significant Change –
- CMP Statute is amended to except from definition of remuneration any other remuneration which promotes access to care and poses a low risk of harm to patients (sec. 6402 of PPACA (new 1128J of SS Act))

CMP Statute Gainsharing Advisory Opinions



- 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
- 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).
- Assure 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

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 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.

Anti-Kickback Statute

- PPACA provisions on the Anti-Kickback Statute
 - Section 6402 -- AKS violation per se a false claim for purposes of the False Claims Act
 - Section 6402 -- Specific intent standard of *Hanlester Network* rejected (“with respect to violations of [AKS and 18 USC 1347], a person need not have actual knowledge of this section or specific intent to commit a violation of this section”)

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.

False Claims Act

31 U.S.C. 3729-3731

- PPACA amendments to False Claims Act
 - Public disclosure bar now relates only to Federal administrative proceedings and Federal reports – fraud discovered in State administrative proceedings or State reports is fair game for a relator in a *qui tam* action.
 - “Original source” broadened to include someone who has knowledge that is “independent of and materially adds to the publicly disclosed allegations or transactions and who voluntarily provided the information to the Government” before filing suit.
 - Public disclosure bar now not jurisdictional – where fraud was disclosed in a Federal criminal, civil or administrative proceeding in which the government was a party, or in a Federal report, hearing, audit or investigation, or in the news media, and relator is not an original source, the suit will not be dismissed for lack of jurisdiction – rather, the suit will be dismissed unless DOJ objects.

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)

Fair Market Value Considerations

- Valuation of Service Line Co-Management Agreement
 - Independent valuation by qualified appraiser
 - Value of Base Fee for administrative/management services
 - Value of Bonus Fees for meeting performance standards
 - Relationship to other agreements:
 - Clinical staffing agreements
 - Call/coverage agreements
 - Medical directorship agreements
 - Department/division chair agreements
 - Physician lease/lease-back agreements
 - Allocation of value among participating physicians/medical groups
 - Engagement of valuator by counsel to obtain benefit of attorney-client privilege?

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

Physician Perspective of Co-Management Agreements

Business and Legal Considerations

- Use of Physician Organizations
- Selection of Performance Measures
- Physician Choice of Treatment
- Independent Medical Review
- Selection of Physicians
- Pooling Requirement
- FMV Considerations
- Baseline Performance Levels and New Participants
- Other Issues of Concern to Physicians

Use of Physician Organizations

- Proposed exception allows hospital to contract with “Qualified Physician Organizations”.
 - New legal entity (*e.g.*, LLC)
 - Comprised entirely of physicians participating in the same incentive payment or shared savings program
 - Eligible physicians may be allowed to own even though not participating in each incentive
 - QPO signs written agreement with hospital
- Another option is for hospital to contract with individual physicians and use advisory committee to help establish and oversee performance.
- CMS considering allowing other entities to serve as pass-through entities (*e.g.*, existing medical group).
 - Concerns over internal distributions that reflect referrals
 - Would permit income tax and possibly retirement plan withholding

Advantages/Disadvantages of Different Structural Options From the Physician Perspective



- QPOs allow multiple physicians/groups to participate
- May help address inertia (e.g., hospital might form QPO and issue ownership via private placement memorandum)
- Provides legal entity for capital and contracting
- Creates governance structure to negotiate and oversee performance
- Limited liability

Other Advantages and Disadvantages

- Costs of formation and operation of QPO
- Individual contracts simpler, but may not encourage physicians to participate as a group
- Use of existing groups likely favored by physicians
 - Established structure, governance, insurance
 - Might sub-contract with smaller groups/individual
 - Issue will be how to structure pass-through

Selection of Performance Measures

- Proposed exception allows patient care quality or shared savings incentives or both.
- Measures must not be a sham or reflect payments for referrals.
- Shared savings measures vs. quality measures
 - Shared savings measures may provide more flexibility in program design (quality measures may need to be listed in CMS Specifications Manual for National Hospital Quality Measures).
 - Yet creates uncertainty (will measure inappropriately reduce patient services?)
 - May also have limits with shared savings measures (e.g., CMS proposal to limit payment to 50% of savings over base year, and/or restrictions on amount of savings paid per year in multi-year contracts)

Selection of Performance Measures

- Performance measures must be supported by “credible medical evidence”.
- Payment may not be based on reduction in hospital stays.
- Role of third-party payor important (*e.g.*, payor may establish quality incentive under hospital payor agreement that cannot be achieved without assistance of medical staff)

Physician Choice of Treatment

- Program may not limit physicians' ability to make medically appropriate patient decisions (e.g., decisions about what tests, treatments, supplies, and services to provide).
- Program may condition payment on a certain physician choice, but hospital must allow access to same supplies and devices as available before.
- Physicians must be able to use new technology that meets same FDA and Medicare coverage decisions as items/supplies included in program.
- Physicians should not receive payments involving a product with respect to which the physician has an investment interest or consulting contract .
 - Will encourage conflict of interest disclosures

Independent Medical Review

- Independent review before program begins and at least annually to ensure program not adversely impacting quality of care
- Who will conduct the review?
- Physician concerns if corrective action required:
 - Termination of entire program (may be overly broad)
 - Termination of a performance measure (Will there be a new one to replace it? CMS concern that a program may not be designed to make up a lost bonus next year or under another measure)
 - Removal of bonus payment or expulsion from program (will it apply to all MDs or only those specifically affected?)
 - Who decides the type of corrective action - hospital, third party, independent reviewer?

Selection of Physicians

- May not select physicians based on the volume/value of referrals
- Potential physician concerns over selection process:
 - May limit participation to a specialty or department (but if all will participate, some physicians may benefit from efforts of others)
 - CMS: Not use program to induce physicians from other hospitals to join staff – must be a member of medical staff at onset of program (What about new physician members or practice growth?)

Pooling Requirement

- Minimum number of participating physicians at beginning of program (CMS proposes a minimum of five)
- Payments shared among members per capita
 - May have departments/specialty with fewer than five physicians
 - What criteria/requirements will there be for sharing per capita?
- Base compensation (e.g., hourly compensation at FMV rates) may be a part of the program to compensate physicians for time spent in the development and oversight of the program.
 - May help recognize individual efforts

FMV Considerations for Base Compensation

- Will base compensation (e.g., hourly compensation) be consistent with FMV?
- Are the services duplicative of services required/expected already (e.g., medical director services)?
- Are the services contracted for reasonable and necessary?
- Will the base and incentive compensation under the program push total compensation over other compensation limits (e.g., for MDs employed by tax-exempt organizations)?

Baseline Performance Levels and New Participants



- Proposed exception would not cover payment that takes into account increases in volume of services/procedures.
- Baseline volume of services/procedures of participants determined during period prior to program (e.g., costs of supplies for all patients during one-year period preceding commencement of program)
- Physicians may have concerns regarding volume increases due to growth in their practice (e.g., employment of new MDs)

Other Issues of Concern to Physicians

- Written program agreement that clearly describes each measure and formula for payment
- Term of agreement (e.g., 1 to 3 year maximum)
- Rebasing provisions (hospital may not pay for improvements achieved in previous periods)
- Scaling provisions (hospital decreases the amount of cost savings available for payment each year)
- Target and ceiling provisions

Other Issues of Concern to Physicians

- Mechanics of patient pre-admission disclosure requirements and patient opt-out provisions
- Termination
 - Of individual participants due to adverse impact on quality of patient care
 - Of particular measure
- Insurance and indemnification
- Exclusivity
- Dispute resolution

Questions?

Thank you for your kind attention!

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