Proposed New Stark Regulations: Implications for Service Line, Gainsharing and P4P Arrangements

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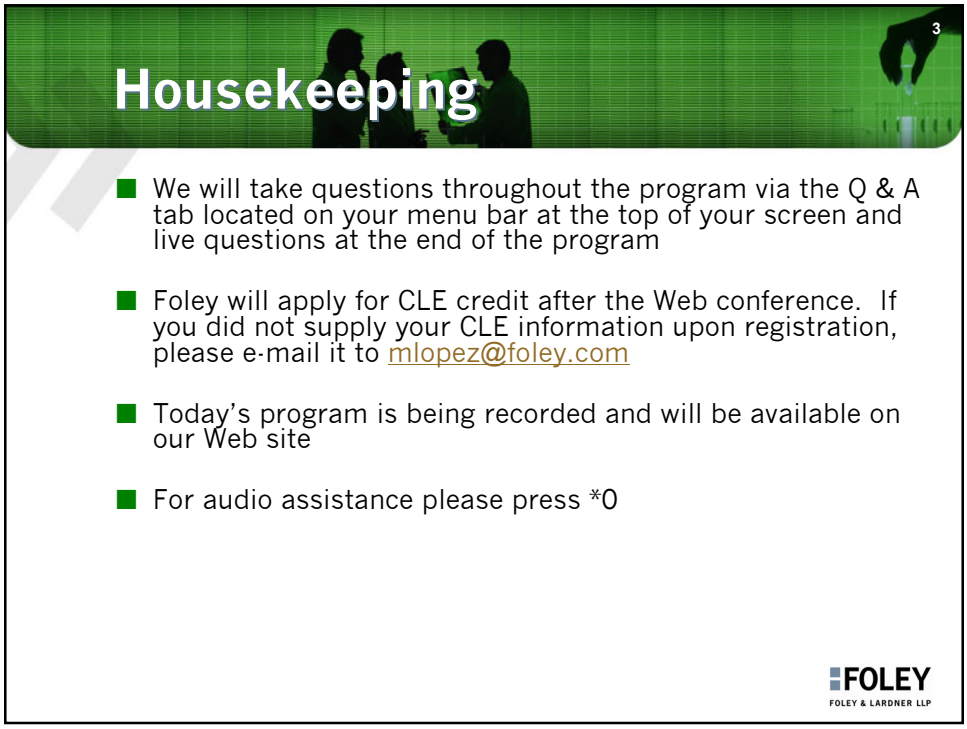
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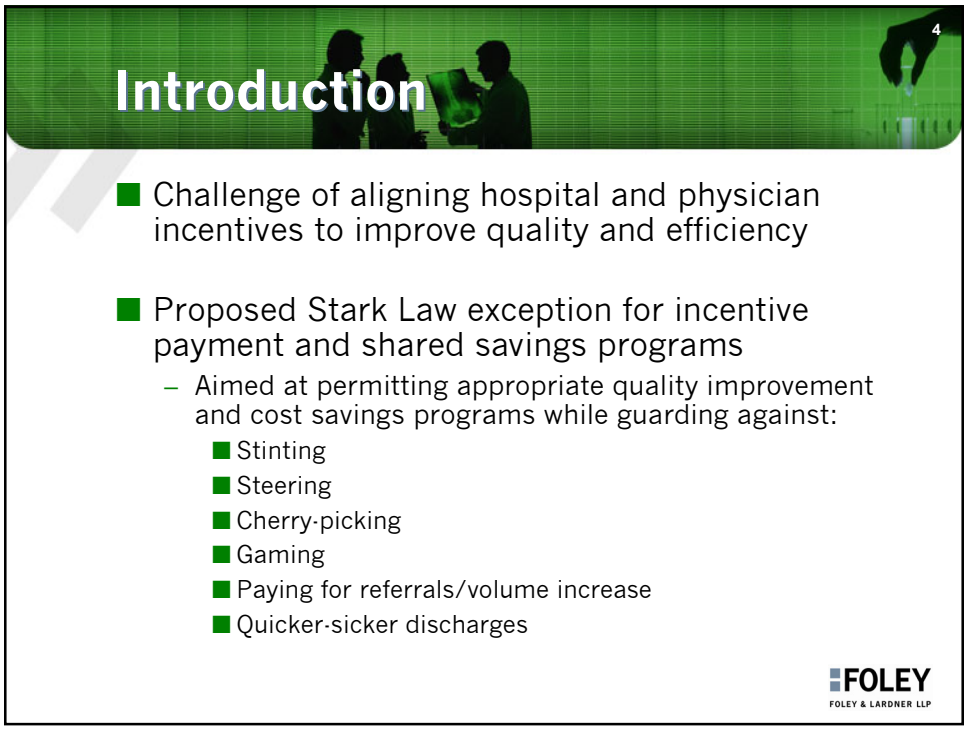
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Introduction
Challenge of aligning hospital and physician incentives to improve quality and efficiency
Proposed Stark Law exception for incentive payment and shared savings programs
– Aimed at permitting appropriate quality improvement and cost savings programs while guarding against:
Stinting
Steering
Cherry-picking
Gaming
Paying for referrals/volume increase
Quicker-sicker discharges
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Introduction (cont'd)

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- Proposed Exception For Incentive Payment and Shared Savings Programs
  - 16 detailed standards
  - Open issues/comment period
  - Positive development, but limited utility?
  - Continued reliance on other exceptions?
    - Fair Market Value Compensation
    - Personal Service Arrangements
    - Indirect Compensation Arrangements
- Insight into CMS thinking about Anti-Kickback Statute and Civil Monetary Penalty Law implications

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Introduction (cont'd)

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- The New Proposed Exception – Charles B. Oppenheim
- Implications for Service Line Co-Management Arrangements – Michael L. Blau
- Implications for Pay-For-Performance and Gainsharing Arrangements – Janice A. Anderson

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The New Proposed Exception

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The New Proposed Exception

- Remuneration from a documented "incentive payment" or "shared savings" program to:
  - Improve quality; or
  - Reduce costs (with no adverse impact on quality)

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The New Proposed Exception (cont'd)

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- The program uses performance measures that:
  - Are objective, verifiable, supported by medical evidence, and individually tracked
  - Relate to the hospital's (or comparable hospitals') practices and patients
  - Are listed in CMS' Specification Manual for National Hospital Quality Measures (for patient care quality measures); and

    [Website link: http://www.qualitynet.org/dcs/ContentServer?cid=1141662756099&pagename=QnetPublic%2FPage%2FQnetTier2&c=Page]

    [Question: Is this too narrow?]
  - Are monitored to prevent inappropriate reductions or limitations on patient care

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The New Proposed Exception (cont'd)

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- The Program establishes:
  - Baseline levels for performance measures using the hospital's historical and clinical data **[Question: What if the service is new, or data is limited?]**
  - Target levels for performance measures developed by comparing the hospital's historical data to national or regional data for comparable hospitals; and
  - Thresholds above or below which no payments are earned

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The New Proposed Exception (cont'd)

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- At least five physicians must participate in each performance measure, and they must be on the medical staff from the start; may not be selected based on referrals or business generated between the parties; a hospital may include only physicians in a particular department or specialty, if the opportunity is offered to all physicians in the department or specialty; only individual physicians and "physician organizations" where all physicians who participate can qualify
  [Questions: What about new physicians? What if there aren't 5 physicians? Why can't special purpose entities be formed?

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The New Proposed Exception (cont'd)

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- Independent medical review of the program's impact on patient care quality is required, and corrective action if indicated in that review; the independent medical review must be completed before the program starts (as to the ***potential*** impact on quality), and at least annually thereafter
  [Question: Is this necessary?]

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The New Proposed Exception (cont'd)

- Under the Program:
  - Physicians must have "access" to the same selection of items, supplies or devices as available before, and must not be restricted in their ability to make medically appropriate decisions, including as to tests, treatments, procedures, services, supplies or discharge
    [Note: It's ok not to pay if physicians use non-preferred items, but you can't prohibit it.]
  - Payments may not be made for using an item, supply or device if the physician or physician organization has a financial relationship with the manufacturer, distributor or GPO that sells the item, supply or device; and
  - The hospital may not limit access to new technology that (i) is linked to improved outcomes and is clinically appropriate for a particular patient; and (ii) meets the same Federal regulatory standards as technology under the program

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The New Proposed Exception (cont'd)

- The hospital provides written notice to patients that: identifies the participating physician; (ii) discloses that they receive payments for meeting performance measures; and (iii) describes the performance measures
  [Note: CMS asks if patients should have "opt out" rights.]
- The arrangement is set out in writing, signed by the parties, specifies the remuneration to be paid and the specifics of the program, the applicable baseline measures, and the targets for performance; each specific performance measure and the resulting payment must be clearly and separately identified

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The New Proposed Exception (cont'd)

- The performance measures may not involve the counseling or promotion of any unlawful arrangement or activity, and must (in the aggregate) be "reasonable and necessary" for the legitimate business purposes of the arrangement
  [Question: How is "reasonable and necessary" determined?]

- The term of the program must be for at least one year, and be no more than three years

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The New Proposed Exception (cont'd)

- Payments must take into account prior performance payments to ensure that no payments are made for measures that were achieved during a prior period; no payment may be made for cost savings that diminish quality of care
  [Question: If you can't pay, will there be backsliding?]

- Payments must be limited in duration and amount. Cost savings must be measured by comparing the actual acquisition costs to the baseline costs for the same items, supplies or services during the one year period immediately preceding the program's start

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The New Proposed Exception (cont'd)

- The remuneration paid over the term of the program (or the formula for the remuneration) is:
  - Set in advance, without regard to the volume or value of referrals or other business generated between the parties **[Question: Will percentage compensation work under "set in advance" requirement?]**
  - Not based on a reduction in the length of stay for a particular patient or the whole hospital; and
  - Distributed to the participating physicians on a per capita basis for each performance measure.

[Note: Fair market value is not required.]

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The New Proposed Exception (cont'd)

- Remuneration cannot take into account any increase in volume of Federal health care patient procedures or services compared to the prior period

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The New Proposed Exception (cont'd)

- The hospital maintains at least the following documentation and makes it available to the Secretary upon request:
  - The written agreement between the parties
  - The basis for selecting the performance measures
  - The selection and qualifications of the independent medical reviewer
  - The written findings of the independent medical reviewer
  - Corrective actions taken based on the independent medical review
  - The amount and calculation of payments made, including projected and actual acquisition costs, as relevant
  - The re-basing of performance measures; and
  - The written notification provided to hospital patients

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The New Proposed Exception (cont'd)

- The Program does not violate the Anti-Kickback Statute or any Federal or State law or regulation governing billing or claims submission

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Implications For Service Line Co-Management Arrangements

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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 hospital service line (e.g., orthopedics, cardiovascular, general surgery)

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Service Line Co-Management Arrangements

- The arrangement is contractual in nature
- There are typically two levels of payment under the 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

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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)							
Standardization of Supplies of Equivalent Quality	1	13.2%	$ 120,000	40%	Order of Specified Item	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

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Regulatory Considerations

- Preamble to proposed exception addresses regulatory compliance with:
  - Stark Law (42 USC § 1395nn)
  - Civil Monetary Penalty Law (42 U.S.C. § 1320a-7a)
  - Anti-Kickback Statute (42 U.S.C. § 1320a-7b)

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Regulatory Considerations (cont'd)

- Cost savings metrics/incentives implicate Civil Monetary Penalty Law[1]
  - 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
- 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?
  - Independently assess in relation to baseline cost, volume and case mix and other safeguards?

[1] See OIG Special Advisory Bulletin on Gainsharing (July 8, 1999) and Clarification Letter (Aug. 19, 1999); See also OIG Adv. Ops. 01-1, 05-01-5, 06-22, 07-21, 07-22

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Regulatory Considerations (cont'd)

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- Volume/revenue based performance measures implicate the Anti-Kickback Statute and Stark law
  - No AKS safe harbor protection
    - Maximum and minimum, but not "aggregate", compensation is set in advance
  - Cannot reward increase in utilization, revenue, profits (or change in acuity)

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Stark Law Considerations

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- Key Constraints of Proposed Exception on Service Line Co-Management Agreements
  - 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
  - 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

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Stark Law Considerations (cont'd)

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- All physicians in the department must be given opportunity to participate on same terms – can chief/medical director be paid disproportionate base fee?
- 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
- Term of no less than 1 nor more than 3 years – implications for attractiveness, durability and continuous quality improvement
- Re-basing – cannot 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

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Stark Law Considerations (cont'd)

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- How useful is the proposed exception?
  - Other potentially available exceptions provide greater flexibility
    - Fair Market Value Compensation
    - Personal Services
    - Indirect Compensation
  - Does not propose that more specific new exception "trump" more general existing exceptions
  - Greater assurance of AKS/CMP compliance?

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Regulatory Considerations

- Stark Law
  - If Agreement is with a medical group (or other physician organization), then "stand in shoes" rule and "direct compensation" analysis applies
  - If Agreement is with individual physicians, "direct compensation" analysis applies
  - Direct compensation exceptions that may apply:
    - Fair Market Value Compensation Exception – individual physician or group
    - Personal Service Arrangements Exception – individual physician or group
    - Proposed Incentive Payment and Shared Savings Program Exception

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Regulatory Considerations (cont'd)

- Stark Law
  - If Agreement is with a physician holding company or management company (and not a "physician organization"), then "indirect compensation" analysis applies
    - Outside of Stark if no "indirect compensation", i.e., payments do not vary with or otherwise reflect volume or value of referrals or other business generated by the referring physician
    - Otherwise Indirect Compensation Arrangement Exception may cover the program

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Regulatory Considerations (cont'd)

- Direct/Indirect Compensation Exception Common Elements
  - In writing, signed by parties
  - Specifies "services"
  - Legitimate business purpose
  - Set in advance (except Indirect)
  - Fair market value – independent appraisal
  - Does not vary with volume or value of referrals
    - Permits set in advance, objectively measured performance standards that do not vary with volume/value or business generated
  - Duration
  - Compliance with AKS and other laws

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Implications for Gainsharing and P4P Incentive Programs

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Gainsharing Programs

- An arrangement in which a hospital pays physicians a share of cost savings attributable in part to the physician's efforts
- The purpose of gainsharing arrangements is to align the physicians' incentives with those of the hospital to reduce costs
- The OIG has issued 10 favorable Advisory Opinions for gainsharing programs to date, all of which are structured by the same consultant

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The Government's View of Gainsharing Programs

- The OIG historically has been very wary of gainsharing programs as they implicate the Civil Money Penalty and Anti-kickback Law
- The OIG has interpreted the Civil Money Penalty Law to preclude any payment by a hospital to a physician to induce the reduction of services (even unnecessary services)
- Gainsharing also implicates the Anti-Kickback law by encouraging "cherry picking" or by inducing referrals
- Proposed Stark exception gives CMS' insight into gainsharing arrangements

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Permissible Gainsharing Arrangements

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- Focus on product standardization, product substitution, "open as needed", or limiting use of certain drugs or supplies
- Safeguards are present:
  - Transparency (not a "black box" program)
  - Quality controls (Independent review of measures to ensure quality of care. Measures have "floor" based on objective quality data beneath which no savings are shared)
  - Limits on ability to change referral patterns (1 year program only, limited to existing active staff members, distributions to physicians on per capita basis, volume is limited to base year)
  - Other safeguards such as disclosure to patients, not rewarding changes to case mix, etc.

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P4P Incentive Programs

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- P4P programs are payment programs that incent quality care
- Most to date are payer programs that provide financial incentives for:
  - Adhering to recommended tasks or processes
  - Adopting desired tools or infrastructure
  - Meeting or improving measured outcomes
  - Sometimes includes cost savings or efficiency targets (aka “gainsharing”)

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P4P Incentive Programs (cont'd)

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- The number of private payer P4P programs is increasing exponentially
- Blue Cross of California expanded its P4P programs into California market in March, 2008
- Wellpoint has hospital P4P programs in 12 states (California, Colorado, Connecticut, Georgia, Indiana, Kentucky, Maine, Missouri, New Hampshire, New York, Ohio and Virginia). In Spring, 2008, Wellpoint standardized its core quality indicators, including safety measures such as staffing ratios in intensive care units, the use of computerized physician order entry, and disease-specific standards such as the use of ACE inhibitors and angiotensin receptor blocker (ARB) medications in heart-attack patients

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P4P Incentive Programs (cont'd)

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- Medicare Value Based Purchase Plan
  - Hospitals are now reporting quality data to CMS under RHQDAPU program
  - As required by DRA, CMS is developing a Value Based Purchasing plan to be implemented by CMS in 2009
  - CMS issued final report to Congress on November 21, 2007
  - The VBP will build on the RHQDAPU program

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P4P Incentive Programs (cont'd)

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- Payer based programs may not implicate Stark, Civil Money Penalty or Anti-kickback laws, however those laws directly apply when hospitals seek to reward physicians for meeting quality targets
- Quality targets may not implicate Civil Money Penalty law
- Preamble to new proposed Stark exception recognizes benefits to be achieved for hospitals through physician quality incentive program

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The Government's View of P4P Incentive Programs

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- No Advisory Opinions to date on hospital based P4P Incentive Program, but one is pending and soon to be released
- Two demonstration projects are pending to evaluate quality and cost gainsharing programs (with a waiver of the application of the Civil Money Penalty, Anti-Kickback and Stark laws for participants). Another demonstration project addresses the use of bundled physician/hospital payments

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Potential New Construct – "Pay for Quality"

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- Rationale for New Structure
  - National mandates for safety/quality are difficult to meet without standardizing clinical practice
  - "Carrot vs. Stick" approach
  - Pay-for-Performance ties reimbursement to achievement of quality outcomes
  - Consumer access to quality data likely will lead to more patient choice (See Hospital Compare www.hospitalcompare.hhs.gov)
  - Manage legal risk (liability for failing to comply with evidence based guidelines, corporate liability; false claims liability for poor quality or unnecessary care, negligent credentialing)

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Potential New Construct – "Pay for Quality" (cont'd)

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- Elements of New Structure
  - Hospitals pay physicians to meet quality targets. Includes a broad array of services necessary to achieve compliance
  - Pay-for-Performance dollars may provide funding source
  - Payments made based on achievement of targets (core measures, CMS hospital quality indicators) set annually. Payments distributed to physicians on a per capita basis

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Potential New Construct – "Pay for Quality" (cont'd)

- Likely will require the establishment of a legal structure with which Hospital can contract to allow payments to be made and distributed to physicians
- Differs from Service Line Co-Management model
- Anti-Kickback/Stark CMP laws implications– would require safeguards as in gainsharing arrangements
- Advisory Opinion is pending

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Questions & Answers

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