

# GAINSHARING & PAY FOR PERFORMANCE -- P4P

## UPDATE ON RECENT DEVELOPMENTS AND INITIATIVES

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# Types of Arrangements

- A. Gain-Sharing
- B. Provider P4P programs
- C. Government or third-party payor sponsored Pay for Performance (“P4P”) programs
- D. “Hybrid” Programs -  
Third party payor program with delegated Hospital-Physician Component



# P4P Initiatives: Environment and Context

- A. Explosion of Interest in Data Linked Improvements in Quality & Cost-Efficient Delivery of Health Services.  
([www.pfpsummit.com](http://www.pfpsummit.com))
- B. Government Initiatives toward Expanded Coverage and Cost Control in Series Demonstration Projects
- C. Development of Data, Standards, and IT Capabilities to Identify and Focus on “Best Practices” (Better Practices?)
- D. Focus on “Comparative Effectiveness” as Major Component of Obama Proposed Health Reform



# Environment and Context (*cont'd.*)

1. Dartmouth Institute Analysis and “Health Atlas”. Three decades of reports indicating significant variations in treatment modalities not clearly related to patient outcomes.  
([www.tdi.dartmouthatlas.org](http://www.tdi.dartmouthatlas.org)).
2. Results coming in from numerous CMS demonstration projects. (See CMS website for reports on 52 projects.)  
([www.cms.hhs.gov/DemoProjectsEvalRpts](http://www.cms.hhs.gov/DemoProjectsEvalRpts))
3. “Comparative Effectiveness”: Stimulus Package includes \$1.1 Billion in funding. Conceptually, administration (per Peter Orszag, budget director) sees improvements in “efficiency” as critical element to both health reform and long term budget balance. (See “Money Talks” article published in May 4, 2009 New Yorker magazine.)



# Comparative Effectiveness

1. President's campaign included proposal to establish an independent research institute to study comparative effectiveness.
2. Funding included in at least four pending bills.
3. In addition to discussion of review of drugs, devices and technology, issues regarding alignment of Hospital and Physician goals related to quality and cost have been highlighted by Congressional leadership as an issue to be addressed in reform legislation.



# Details from Stimulus Bill

The American Recovery and Reinvestment Act provides funding for Comparative Effectiveness Research:

Total of \$1.1 billion allocated as follows:

- \$400 million for the National Institutes of Health
- \$400 million for the Secretary of Health and Human Services
- \$300 million for the Agency for Healthcare Research and Quality



# Stimulus Bill *(cont'd.)*

Pursuant to Section 804 of the Act, HHS has established a “Federal Coordinating Council for Comparative Effectiveness Research”

1. 15 Members, all of whom must be Federal officers or employees
2. Half must be physicians or other persons with clinical expertise
3. Agencies Represented:
  - Agency for Healthcare Research and Quality
  - Centers for Medicare and Medicaid Services
  - National Institutes of Health
  - Office of the National Coordinator for Health Information Technology
  - Food and Drug Administration
  - Veterans Health Administration
  - Department of Defense Military Health Care System



# Goals & Key Elements

- Avoid unnecessary costs
- Improve quality (as measured by outcomes)
- Collaboration (“alignment”) between hospital and physicians vs. disconnect under Medicare payment system
- Voluntary -- Provider (or payor) initiated
- Provide incentives to encourage changes in physician practices and more efficient use of resources
  
- Perception that other cost and quality control approaches are not adequate to address perceived issues and problems.



# Federal vs. Provider/Payor Initiatives

- Mandates
- Top-Down Regulatory
- One Size Fits All
- Erodes Provider/Physician Incentives to Develop Local Initiatives
- Track Record: Mistrust, delay, complexity
- Lack of Consistency (or commitment over time)
- Compliance Issues -- likely to be burdensome and expensive



## The Dark Side

- Physician Incentive Plan Law
- Stark Law
- Anti-Kickback Law



# Physician Incentive Payment Prohibition

## 42 USC Section 1320a-7b

- (b)(1) If a hospital or a critical access hospital knowingly makes a payment, directly or indirectly, to a physician as an inducement to reduce or limit services provided with respect to individuals who—
- (A) are entitled to benefits under part A or part B of title XVIII or to medical assistance under a State plan approved under title XIX, and
  - (B) are under the direct care of the physician,

the hospital or a critical access hospital shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty of not more than \$2,000 for each such individual with respect to whom the payment is made.

- (2) Any physician who knowingly accepts receipt of a payment described in paragraph (1) shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty of not more than \$2,000 for each individual described in such paragraph with respect to whom the payment is made.



# Anti-Kickback Law; 42 USC §1320a-7b

(b)(1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.



# Anti-Kickback Law (*cont'd.*)

- (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
  - (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
  - (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both



# Stark Law; 42 USC Section 1395nn

## The Basic Prohibition:

§ 1395nn. Limitation on certain physician referrals

### (a) **Prohibition of certain referrals**

#### (1) **In general**

Except as provided in subsection (b) of this section, if a physician (or an immediate family member of such physician) has a financial relationship with an entity specified in paragraph (2), then—

(A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter, and

(B) the entity may not present or cause to be presented a claim under this subchapter or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A).



# Stark Law – Basics (*cont'd*).

## (2) Financial relationship specified

For purposes of this section, a financial relationship of a physician (or an immediate family member of such physician) with an entity specified in this paragraph is—

....

(B) except as provided in subsection (e) of this section, a compensation arrangement (as defined in subsection (h)(1) of this section) between the physician (or an immediate family member of such physician) and the entity.

## (h) Definitions and special rules

For purposes of this section:

### (1) Compensation arrangement; remuneration

(A) The term “compensation arrangement” means any arrangement involving any remuneration between a physician (or an immediate family member of such physician) and an entity other than [limited exceptions not generally relevant to gainsharing or P4P.



# Stark Law – Possible Exceptions

(2) Bona fide employment relationships *[Not generally relevant in California]*

(3) Personal service arrangements

(A) In general

Remuneration from an entity under an arrangement if—

- (I) the arrangement is set out in writing, signed by the parties, and specifies the services covered by the arrangement,
- (ii) the arrangement covers all of the services to be provided by the physician (or an immediate family member of such physician) to the entity,
- (iii) the aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement,



## Stark Law – Possible Exceptions (*cont'd.*)

- (iv) the term of the arrangement is for at least 1 year,
- (v) the compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value, and . . . is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties,
- (vi) the services to be performed under the arrangement do not involve the counseling or promotion or a business arrangement or other activity that violates any State or Federal law, and
- (vii) the arrangement meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.



# History of Regulatory Review

- A. Gainsharing was initially reviewed by the IRS with regard to permissibility for non-profit tax exempt hospital. It was approved from the tax perspective.
- B. In 1999, OIG issued a special advisory bulletin finding that gainsharing arrangements could not generally be implemented consistent with language of PIP limitations.
- C. DHHS-OIG Special Advisory Bulletin, Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries (July 1999). <http://oig.hhs.gov/fraud/docs/alertsandbulletins/gainsh.htm>

“While the OIG recognizes that appropriately structured gainsharing arrangements may offer significant benefits where there is no adverse impact on the quality of care received by patients, section 1128A(b)(1) of the Act clearly prohibits such arrangements. Moreover, regulatory relief from the CMP prohibition will require statutory authorization.”



# History of Regulatory Review (*cont'd.*)

## Three Key Points in Gainsharing Advisory

1. “[G]ainsharing arrangements pose a high risk of abuse. In order to retain or attract high-referring physicians, hospitals will be under pressure from competitors and physicians to increase the percentage of savings shared with the physicians, manipulate the hospital accounts to generate phantom savings, or otherwise game the arrangement to generate income for referring physicians. Given these pressures and the potential adverse impact on patient care from gainsharing arrangements, the OIG believes that immunizing such arrangements from sanction would be imprudent and inappropriate.”
2. “[A] critical inquiry is whether the arrangements have adequate and accurate measures of quality of care that would provide assurance that there is no adverse impact on patient care. . . . [T]he OIG has determined that any performance measures would require extensive verification through audits or review by an independent party on a continuing basis. The Office of Counsel to the Inspector General, which issues advisory opinions, has neither the resources nor the expertise to police a multitude of such arrangements on an ongoing basis. “



## History of Regulatory Review *(cont'd.)*

3. “[C]ase by case determinations by advisory opinions are an inadequate and inequitable substitute for comprehensive and uniform regulation in this area. Were the OIG to issue a favorable opinion to one provider, that provider would have a significant competitive advantage in recruiting and attracting physicians to admit patients to its facility, since the physicians would have the opportunity to earn significant additional income not available at other institutions. The consequences would be that every hospital in the country would request an advisory opinion for its own program, and many would implement their own programs in the hope that their programs were close enough.”



# History of Regulatory Review (*cont'd.*)

- D. OIG Proceeded to issue a series of Advisory Opinions which have approved a variety of gainsharing arrangements focused on specialty practices.

- Cardiac Surgery

- Anesthesiology

- Orthopedics

- 1. Programs follow a template developed by a single consultant firm and have common structure and approach.
    - 2. Designed to address potential concerns that might arise under AKL and PIP rules.

- E. No formal opinions by CMS on these programs, so potential Stark Law issues have not been addressed.



## Summary of Approved Gainsharing Programs

1. Based on recognized quality standards.
2. Payment linked to base year utilization.
3. Programs apply to all patients'
4. Developed and administered by expert independent parties.
5. Devices or therapies used prior to program implementation must continue to be available at discretion of individual physician.
6. Ongoing quality monitoring to assure no inappropriate reductions or limitations in services.
7. 1 year term, with potential for renewal/modification.



## Approved Gainsharing Programs (*cont'd.*)

8. Physicians participate on a group basis and distribute funds on a *per capita* rather than per service basis.
9. Participation limited to physicians already on staff
10. Gainsharing percentage limited to 50% of hospital savings (expect some sort of “rebased” for future years).
11. Patients are notified of Program.
12. Monitor referral patterns of participating physicians.
13. Records maintained and available for review by Secretary of HHS.
14. Representation in submission that payments represent FMV for services provided.



# Implications of OIG Advisories

1. No “safe harbor” standards.
2. Each Advisory Opinion includes assessment that program being reviewed is a potential violation of PIP and AKL restrictions.
3. Strong signal to industry that programs with adequate safeguards will be approved.
4. Implication: Any gainsharing program that has not received a specific approval from the OIG in an Advisory Opinion may be subject to significant regulatory risk.



# CMS Action on Gainsharing/P4P

## July 7, 2008 Proposed Rule

1. Action taken pursuant to statutory authority for Secretary to create exceptions to Stark Law for “any other financial relationship which the Secretary determines, and specifies in regulations, does not pose a risk of program or patient abuse.” *Section 1877(b)(4) of Social Security Act.*
2. Discussion of basis for proposed rule is at *Federal Register*, pages 38,548 - 38,558 (Vol. 73, No. 130). Includes rules covering Gainsharing and Pay for Performance as “incentive payment and shared savings programs.”
3. Discussion reflects institutional focus and historical concerns of an enforcement agency.
  - Assumption that providers may take advantage.
  - Focus on standards developed by government or government sponsored/affiliated institutions
  - Process and structure oriented with list of “bright line” parameters to facilitate regulatory review/oversight.
4. Proposed rule is §411.357(x). *Federal Register*, pages 38,604 – 38606.
5. Among comments received were objections filed by Representative Stark.
6. No clear signal when further action on these regulations will be taken.



# Key Elements of §411.357(x)

1. Performance measures must use verifiable “objective methodology” supported by “credible medical evidence” that are “individually tracked”.
2. Quality measures used must be listed in CMS Specification Manual for National Hospital Quality Measures.
3. Include baselines, targets and thresholds for determining payments to physicians.
4. Minimum 5-member physician “pools” for each performance measure.
5. Physicians must be on staff at beginning of program and not selected based on value or volume of referrals. Program must be offered to all physicians in relevant department or specialty.



## Key Elements of §411.357(x) (*cont'd.*)

6. Must include “independent medical review” that is completed prior to commencement of program and ongoing (at least annual review) with authority to implement corrective action.
  - Not affiliated with hospital.
  - Not affiliated with participating physicians or physician organizations.
  - Not participating at time of review in an incentive or shared savings program at the hospital.
7. Maintain physician access to items, services, and supplies previously available and assure decision-making autonomy on patient care decisions.
8. Physicians cannot have financial interest in use of an item, supply, or device that is linked to a hospital payment
9. Hospital may not limit availability of otherwise appropriate new technology.
10. Patients receive advance written notice of program, including identification of participating physicians and that physicians may receive financial incentives for meeting program targets.



# Key Elements of §411.357(x) *cont'd.*)

11. Written detailed contract executed by parties listing each performance measure and payments linked to it.
12. Term of between 1 and 3 years.
13. Baselines – assure that no payments made for improvements in quality or cost savings realized in prior period.
14. Limit amount and duration of payments and clearly define baseline costs for shared savings programs.
15. Payments set in advance, do not vary within term of arrangement, and not linked to value or volume of referrals or other business between parties.
16. Distributed to physician organizations or “pools” for distribution on *per capita* basis.
17. Paid directly to physicians or physician organizations.



# Key Elements of §411.357(x) *cont'd.*)

18. Payments may not take into account any increase in volume of Federal health care patient procedures or services above baseline for prior period.
19. Maintain accurate and contemporaneous documentation available for regulatory review:
  - Written Agreement
  - Basis for selecting performance measures
  - Selection and qualifications of independent medical reviewer.
  - Written findings of independent medical reviewer.
  - Corrective actions taken based on reviews.
  - Amount and calculation of payments, including documentation of cost savings.
  - Rebasement of performance measures.
  - Form of written notification provided to patients.



# Conclusions and the Future

- Is CMS proposed regulation better or worse than current status?
- Are the signals turning green or flashing yellow?
- Are there realistic, cost-effective and administratively and “politically” manageable options for individual hospitals?
- What is a realistic planning horizon?
- Other issues?

