*Davis Wright Tremaine LLP Annual Health Care Regulatory and Compliance Update*

# ALIGNING HOSPITAL AND PHYSICIAN FINANCIAL INCENTIVES: Overcoming Fraud and Abuse and Antitrust Concerns

**March 23, 2010**

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# Overview

- "Physician Alignment" Arrangements
  - Pay for Performance
  - Gainsharing
  - Other Financial Alignment (e.g., use of foundations or clinics)
- Legal Impediments / Issues
- Case Study

# Types of Arrangements

- Provider or Payor sponsored P4P programs (*payment for quality*)
- Gainsharing (payment for cost savings)
- Other Financial Alignment (e.g., use of foundations or clinics)

# Pay for Performance

- Contractual commitment providing for payment of financial incentives to physicians who are in a position to make decisions about ordering hospital services

- Government, Payor or Provider – Sponsored
  - Hospital – Physician (e.g., hospital based physician contract)
  - Hospital – Medical Group/IPA (e.g., risk-share agreement)
  - Payor – Hospital or Medical Group/IPA

# Gainsharing

Hospital program encourages changes in physician behavior

- Product substitution - routine use of less costly agents, medications, etc.
- Product standardization - routine use of specified devices and supplies, *e.g.*, stents, catheters, diagnostic devices, contrast agents, etc.
- Elimination of routine use of specified products or services ("use as needed")

Hospital pays percentage of resulting savings to physicians

# Gainsharing

## Government, Payor or Provider – Sponsored

- Hospital – Physician (e.g., hospital based physician contract)
- Hospital – Medical Group/IPA (e.g., risk-share agreement)
- Payor – Hospital or Medical Group/IPA (indirect approval; e.g., Medicare bundled payment demonstration program)

# Alignment: Goals & Key Elements

- Avoid unnecessary costs
- Improve quality (as measured by outcomes)
- Collaboration between hospital and physicians
- Voluntary -- provider (or payor) initiated
- Provide incentives to encourage changes in physician practices and more efficient use of resources

# The Dark Side

- Antitrust Law
- Physician Incentive Plan Law
- Stark Law
- Anti-Kickback Law
- Insurance Law
- Corporate Practice of Medicine

# Antitrust Law

Traditional: Sherman Act –

- Per Se illegal Competitor Agreements
- Boycotts and Coercion

Regulatory Enforcement (FTC Act § 5)

- Guidelines
- Integrated v. non risk sharing
- Multi-payer collaboration
- Common measures v. independent payment

# Physician Incentive Payment Prohibition
# Social Security Act §1128A(b)(1) (the "CMP Law")

(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
# Social Security Act § 1128B(b)

(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
# Social Security Act § 1877

The Basic Prohibition:

§ 1395nn. Limitation on certain physician referrals

(a) **Prohibition of certain referrals**

(1) **In general**

[Unless an exception applies], if a physician (or an immediate family member of such physician) has a *financial relationship* with an entity [that performs or causes the performance of a designated health service], 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, and

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

# Stark Law – Possible Exceptions

- Bona fide employment relationships
- Personal service arrangements
- Prepaid plans
- Risk sharing
  - OIG Approved?
  - Medicare Carve Out? (Spill Over?)

# 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 (flexible?), 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 "rebasing" for future years)

11. Patients are notified of Program

12. Monitor referral patterns of participating physicians

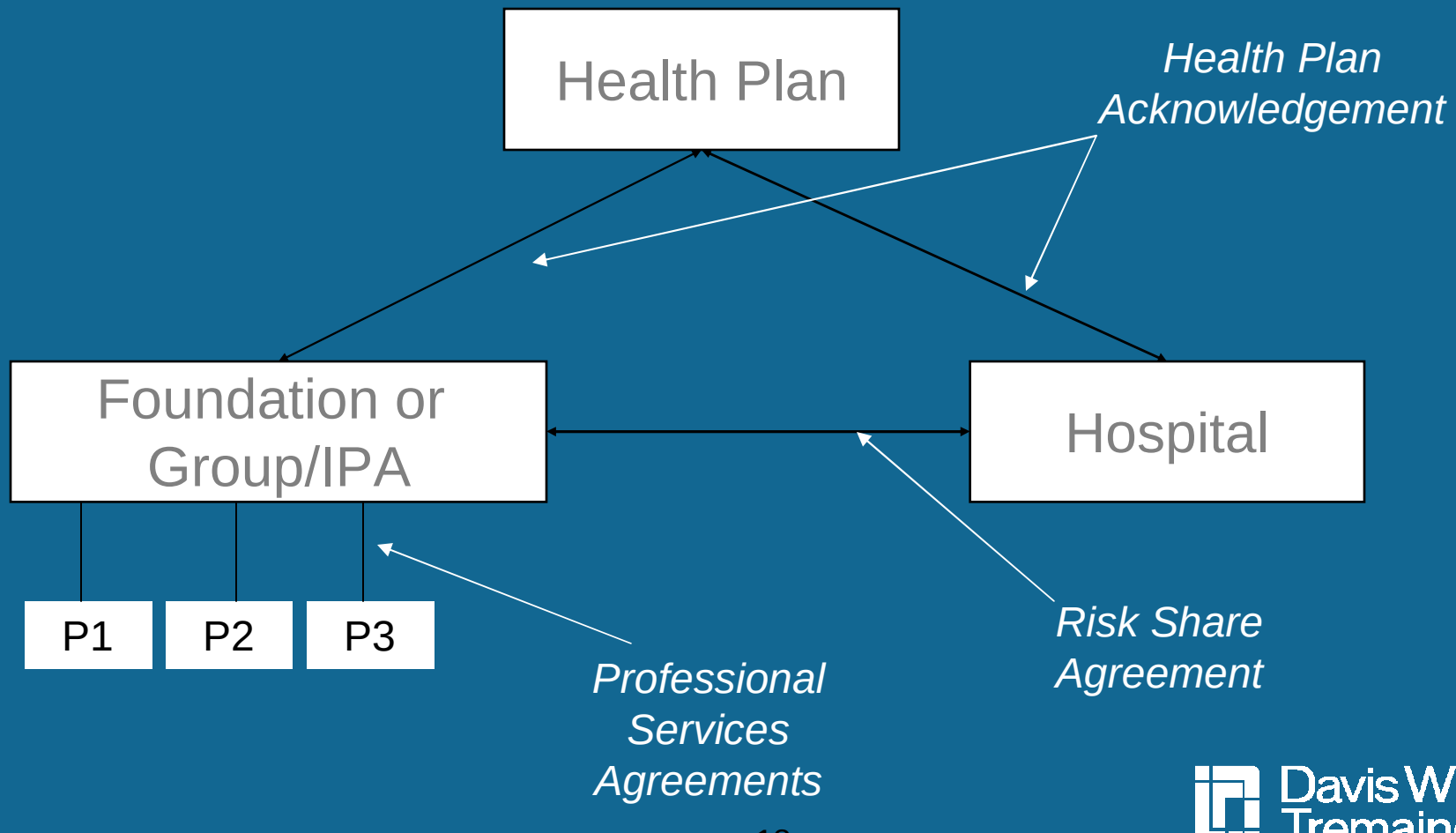
13. Records maintained and available for review by Secretary of HHS

14. Representation in submission that payments represent FMV for services provided

# CMS Action on Gainsharing/P4P – Proposed Stark Law Exception July 7, 2008

- 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"
- 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
- Proposed rule is §411.357(x). *Federal Register,* pages 38,604 – 38606
- Among comments received were objections filed by Representative Stark
- No clear signal when further action on these regulations will be taken

# Case Study: Risk Share (or Bundled Payment) Arrangement



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# Case Study: Risk Share Arrangement – Antitrust Issues

Foundation / Group physicians' negotiation of payor contracts

- Messenger Model
- Price Fixing/Boycotts
- Integration v. Independent (How much integration?)
- Enforcement issues

# Case Study: Risk Share Arrangement – Antitrust Issues

Foundation / Group physicians' negotiation of risk share agreement with hospital

- Due Diligence issues
- Integration v. Independent

# Case Study: Risk Share Arrangement – Fraud and Abuse Issues

Bonus Criteria – pass muster under CMP, Stark & AKS?

- FFS or capitated payment arrangement?
- Hospital to foundation/group or group/IPA to physician?
- Likely to induce reduction or limitation of care?
  - LOS
  - Patient satisfaction
  - All patients with pneumonia receive dosage of “Allclear”
  - Per patient discharge / per case
- Fair market value
- Health plan acknowledgement

# Case Study: Risk Share Arrangement – Antitrust Issues

- Adding physicians to the Foundation / IPA
  - Structure/Integration and Risk Issues
  - Exclusive/Non Exclusive
  - Antitrust Safety Zones
- Due Diligence
  - Merger v. Joint Venture v. Business Arrangement
  - Reasonably necessary; need to know; limited purpose
- Payor Contracting
  - Financial or Clinical Integration
  - Pricing Fixing/Boycott issues

# Questions?

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