Legal Issues in Pay-for-Performance Implementation

5th Annual World Congress Leadership Summit on Healthcare Quality and Pay-for-Performance

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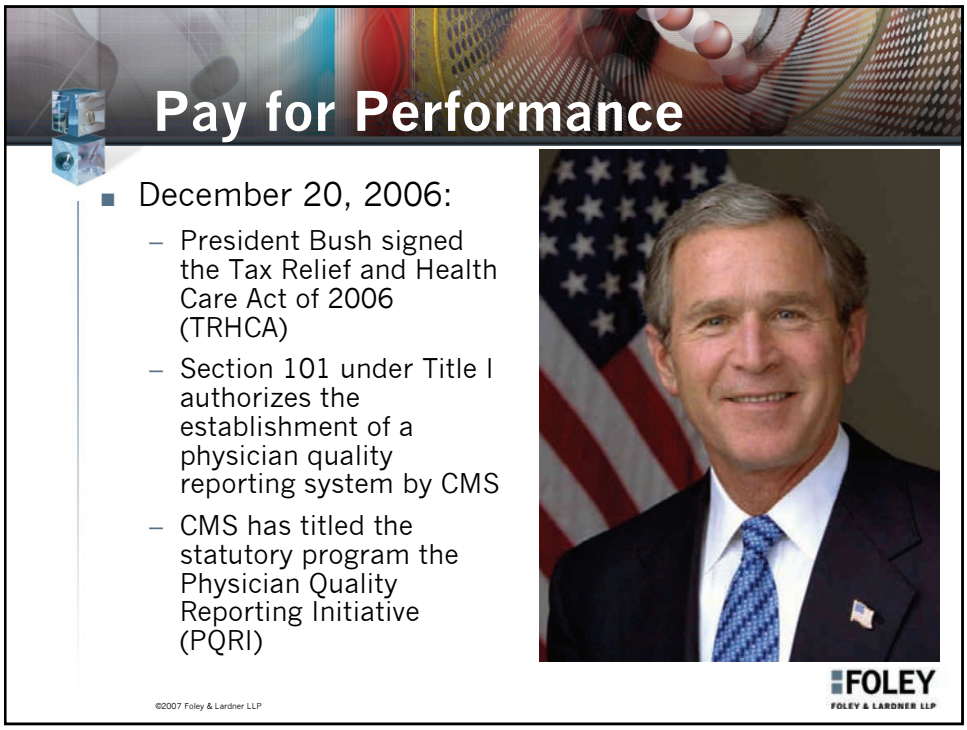

Pay for Performance

- December 20, 2006:
  - President Bush signed the Tax Relief and Health Care Act of 2006 (TRHCA)
  - Section 101 under Title I authorizes the establishment of a physician quality reporting system by CMS
  - CMS has titled the statutory program the Physician Quality Reporting Initiative (PQRI)

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News Flash

- This is nothing new...
  - Except for the federal government
- Pay for Performance (P4P) programs have been arising with increasing frequency in private insurance sector

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P4P In Private Sector

- Concept is not revolutionary
- Provide an incentive to increase a performance factor
- In general employment parlance:
  - Bonuses
  - Incentives
- In 2005, estimated 107 P4P programs in the United States

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P4P In Private Sector (cont'd)

- By 2008, estimated over 160 P4P programs to an estimated 85 million patients.
- Most P4P programs privately-funded by health plans; many work with hospitals and other large provider groups
- Employers play a large role in the development of existing P4P programs; seek to achieve cost-containment of services and improved quality of care
- Additionally, health plans have a vested financial interest in such programs; providers provide the best quality of care possible, as efficiently as possible

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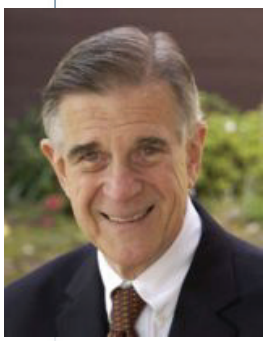
Criticism

- Rep. Pete Stark of California
  - Noted proponent of regulation of the healthcare industry
  - Physicians are supposed to provide quality care
  - Federal Government lacks the ability, understanding, training or knowledge to establish appropriate quality of care standards



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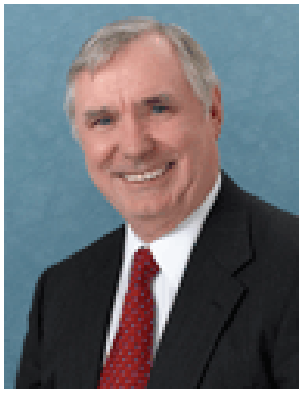
Criticism (cont'd)

- Robert E. Moffit, Ph.D. Heritage Foundation
  - "Doctors will be financially pressured to comply with government guidelines and standards. The integrity and independence of the medical profession could be compromised."



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Criticism (cont'd)

- Impact of negative attention to health care reimbursement and incentive structures

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P4P – A Definition

- Incentive programs provide monetary bonuses to participating entities that make progress in:
  - achieving or
  - attaining specific quality and/or
  - efficiency benchmarks or standards that are established by the program

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Current Efforts

- Bridges to excellence coalition reports 80 P4P efforts
- NCQA reports 100 ongoing P4P programs
- At least 12 states have implemented wide-range of P4P initiatives under Medicaid
- CMS and Premier collaboration P4P demonstration project - study of over 250 hospitals has been audited and validated by CMS

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P4P – A Definition

- This week's Leadership Summit will offer more sophisticated definitions
- For purposes of legal review, the details do matter
- For issue spotting and liability awareness, we will follow the "big picture" in P4P

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What are the Key Legal Issues?

Three categories of legal issues in P4P

1. **Regulatory and Statutory Compliance**
2. **Liability and Risk Management**
3. **Contracting**

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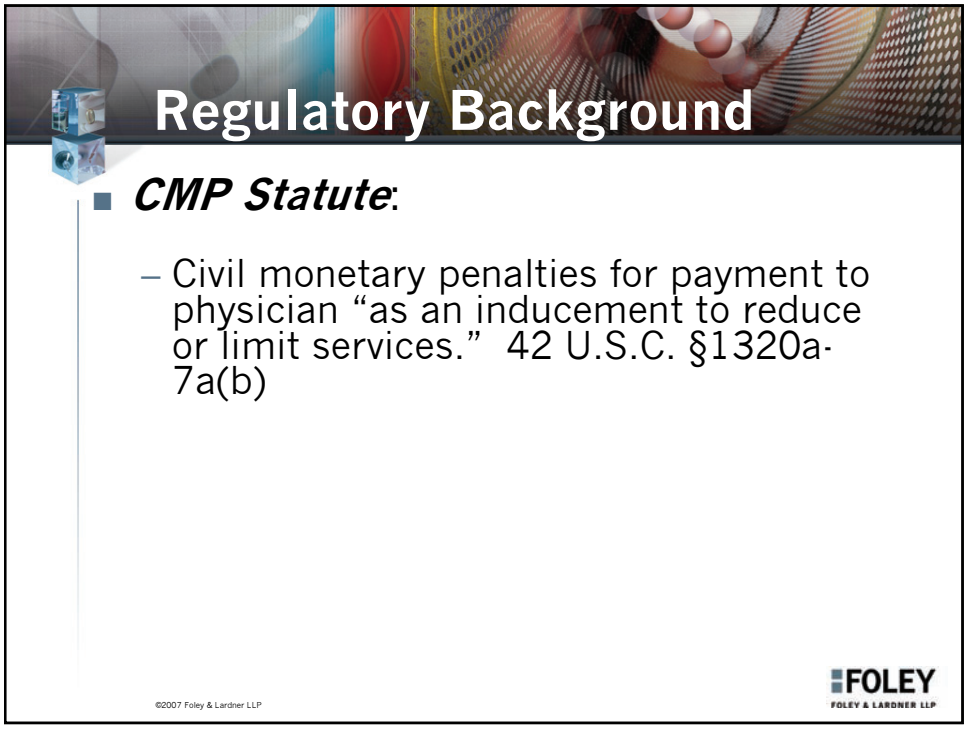

Regulatory Background (cont'd)

- ***Physician Self-Referral Statute***:
  - The "Stark law," 42 U.S.C. §1395nn, prohibits:
    - physician referrals
    - for "designated health services"
    - to an entity in which the referring physician has a financial interest, (ownership or compensation)
    - unless an exception applies

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Regulatory Background (cont'd)

- ***Anti-Kickback Statute*** (42 U.S.C. §1320a-7(b)):
  - Criminal offense:
    - knowingly and willingly
    - to offer, pay, solicit or receive remuneration
    - to induce or reward referrals of items or services reimbursable by a federal health care program.
- Criminal liability to parties on both sides
- Interpreted to cover arrangement where one purpose of remuneration was to obtain money for the referral or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert denied, 474 US 988 (1985)

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Regulatory History

- OIG Special Advisory Bulletin, July 1999
  - The OIG recognizes that hospitals have a legitimate interest in enlisting physicians in their efforts to eliminate unnecessary costs. Savings that do not affect the quality of patient care may be generated in many ways, including substituting lower cost but equally effective medical supplies, items or devices; re-engineering hospital surgical and medical procedures; reducing utilization of medically unnecessary ancillary services; and reducing unnecessary lengths of stay.

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Regulatory History (cont'd)

  - Achieving these savings may require substantial effort on the part of the participating physicians. Obviously, a reduction in health care costs that does not adversely affect the quality of the health care provided to patients is in the best interest of the nation's health care system. ***Nonetheless, the plain language of [the CMP statute] prohibits tying the physician's compensation for such services to reductions or limitations in items or services provided to patients under the physician's clinical care.***

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Regulatory History (cont'd)

- OIG Advisory Opinion ("AO") 01-01 (approved cardiac surgery program)
- OIG AO 05-01 (cardiac surgeons)
- OIG AO 05-02 (cardiac cath)
- OIG AO 05-03 (cardiac surgeons)
- OIG AO 05-04 (cardiology/cardiac cath)
- OIG AO 05-05 (cardiac cath)
- OIG AO 05-06 (cardiac surgery)

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P4P or Gainsharing?

- **Description**
  - "Gainsharing" is an arrangement where a hospital agrees to share a portion of savings from specific cost-saving behaviors with physicians who have agreed to utilize the measures in their hospital practice
  - Gainsharing is intended to incentivize physicians (who are generally paid on a fee schedule) to help reduce costs of the hospital (which Medicare generally pays on a DRG basis)

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P4P or Gainsharing (cont'd)

- **Example**
  - Hospital and group of cardiac surgeons (Surgeons) enter into gainsharing program developed by a third-party consultant (Administrator) to curb inappropriate use of operating room supplies. The Administrator identified 24 specific recommendations in four categories:
    - Opening packaged items only as needed
    - Performing blood cross matching only when patient requires a transfusion
    - Substitution of less costly items
    - Production standardization of cardiac devices where medically appropriate. The surgeons would help select vendors and devices.

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P4P or Gainsharing (cont'd)

- **Safeguards**
  - No savings below floor based on historical objective measures (30% of patients historically required cell saver)
  - Although standardization of products, the physician must make a patient by patient determination of the appropriate device
  - No payment for volume increases by physician
  - The Hospital would pay 50% of the savings determined by the Administrator to the Surgeons

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OIG Criteria

- Specific cost-saving actions and resulting savings are clearly and separately identified
- Credible medical support to demonstrate that implementation would not adversely affect patient care
- Payments based on all payors, not just Medicare
  - Procedures not disproportionately Medicare
  - Measured on actual out-of–pocket costs

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OIG Criteria (cont'd)

- Historical and clinical measures establish baseline thresholds for awards
- Same selection of products are still available per physician choice
- Financial settlements are reasonably limited in duration and amount
- Profits distributed on per-capita basis so incentive to individual physician mitigated

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P4P/Gainsharing Analysis

- Source of payment
  - Managed care plan
  - Government
  - Hospital
- Criteria design
  - Quality
  - Savings

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P4P/Gainsharing Analysis (cont'd)

- Use of criteria
  - Government
  - National
  - Health plan
  - Institution
- Decisionmaker(s) on criteria
- Relationship of participants
- Magnitude of payment

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P4P/Gainsharing Analysis (cont'd)

- CMP
  - Any limitation on care?
- Anti-Kickback
  - Any inducement to refer?
- Stark
  - Applies? If so, exception?
- Antitrust
  - Is there an agreement among competitors?

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P4P/Gainsharing Analysis (cont'd)

- Stark Law Proposed Rule, July 12, 2007:
  "we are proposing to clarify that percentage compensation arrangements: (1) May be used only for paying for personally performed physician services; and (2) must be based on the revenues directly resulting from the physician services rather than based on some other factor such as a percentage of the savings by a hospital department (which is not directly or indirectly related to the physician services provided).

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Risk Analysis

Compliance Risk

	Low						High
Sponsor	Government		Health Plan				Provider
Payor	Private Pay						Medicare Medicaid
Criteria Design	Quality						Cost Savings
Criteria Decision	Unilateral		Input				Collaborative
Payment	0 – 5%	5 – 10%	10 – 15%	15 – 20%	20 – 25%	25 – 30%	30+ %

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Other Legal Considerations

- Antitrust
- Tax-exempt entity – private inurement
- State law restrictions
- HIPAA/Confidentiality
- If P4P amounts grow – what is the provider's "actual charge"?
  - a remote risk . . . today

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Compliance Risks?

- False Claims
  - Claims submission
  - Documentation

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Liability and Risk Management

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AMA Pay-for Performance Principles and Guidelines

- P4P should comply with policy H-450.947 "Pay-for-Performance Principals and Guidelines" (Nov., 2005)
- Five principles:
  - Ensure quality of care
  - Foster the patient/physician relationship
  - Offer voluntary physician participation
  - Use accurate data and fair reporting
  - Provide fair and equitable program incentives

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AMA Pay-for Performance Principles and Guidelines (cont'd)

- Some will object to participation in P4P programs as violative of principles of medical ethics.
- Physicians are ethically required to provide care according to their sound medical judgment without influence of financial rewards.

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Liability Risks?

- Stinting on care
- Interference with medical judgment
- Consent/Notice
  - Patient notification
- What is the standard of care?

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Contract Issues

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Contract Issues

- Definitions
  - Patient pool
- Data sources
- Stop-loss protections
- Audit/review/appeal rights
- Timing for payment
- Will you get/give what you think has been negotiated?

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Contracting issues (cont'd)

- Where is the money coming from?
  - Is party promising to pay, in fact, responsible?
- Proper definitions legally enforceable
- Contractual obligation to pay
- Adverse selection

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Contracting issues (cont'd)

- The data is self-reported or comes from claims data: are we getting what we want?
- Proper establishment/identification of the base-line
- Do targets make sense for life of contract?

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Questions?

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