The Fifth National Pay for Performance Summit

MAKING IT REAL:
PROVIDER FINANCIAL REALIGNMENTS – CRITICAL LEGAL ISSUES & STRUCTURING OPTIONS

March 9, 2010

Robert Girard & Jill Gordon

Anchorage
Bellevue
Los Angeles
New York
Portland
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Seattle
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Washington, D.C.

Overview

- Types of “Physician Alignment” Arrangements
- Legal Impediments / Issues
- Case Studies

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Types of Arrangements

- Provider P4P programs
- Government or third-party payor sponsored P4P programs
- Gainsharing
- “Hybrid” Programs –
  Third party payor program with delegated Hospital-Physician Component

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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

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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

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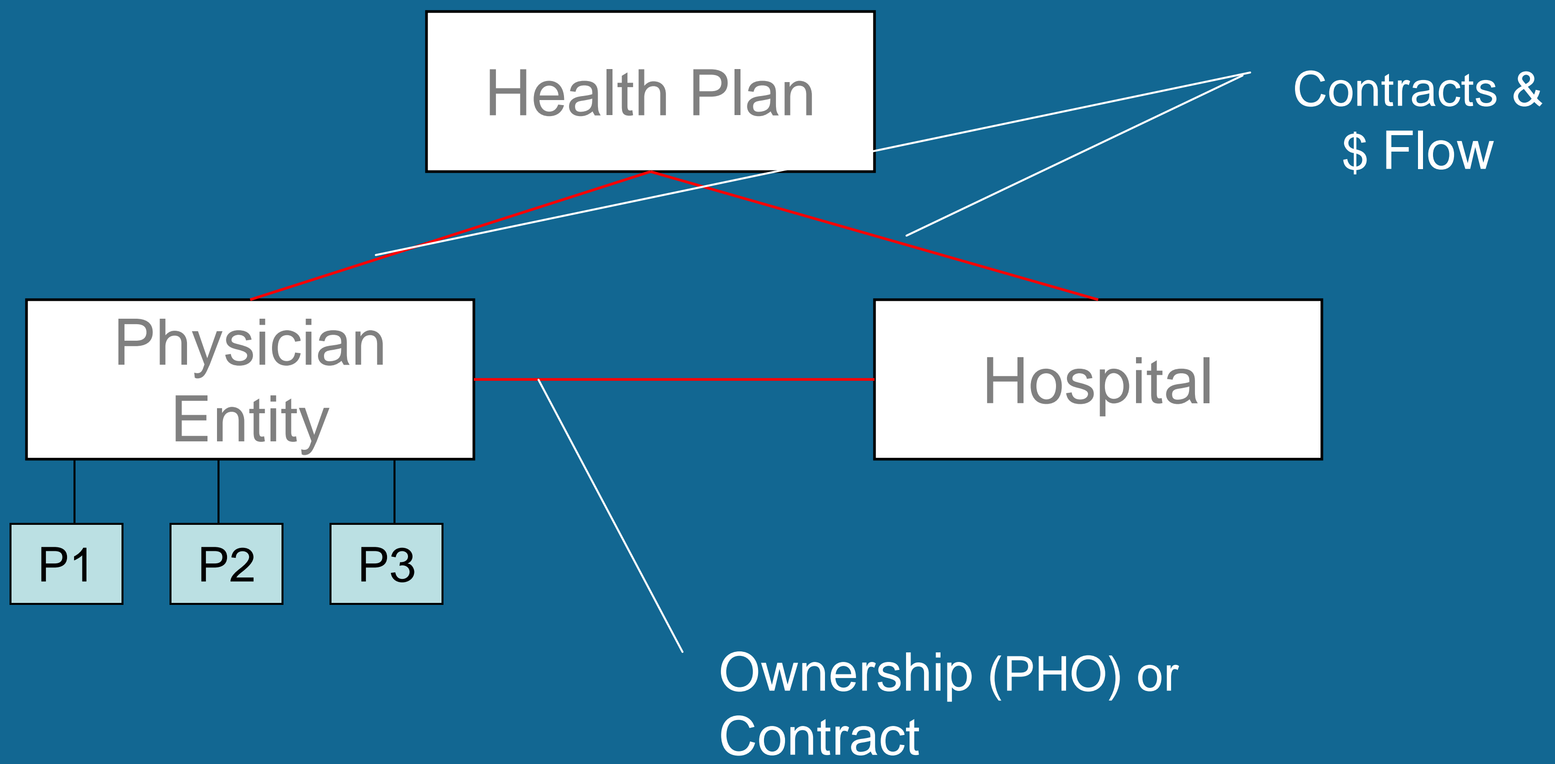
Hybrid Program



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Hybrid Program (alternative)

Health Plan

Contracts &
$ Flow

Independent Administrator

Physicians

Hospital

Ownership (PHO) or
Contract

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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
- Address perception that other cost and quality control approaches are not adequate to address perceived issues and problems

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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

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The Dark Side

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

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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.

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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

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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 – Basics *(cont'd).*

Financial Relationship = an ownership or compensation arrangement

Compensation Arrangement = any arrangement involving any remuneration between a physician (or an immediate family member of such physician) and an entity other than as permitted under an exception

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Stark Law – Possible Exceptions

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

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Regulatory Review

- Gainsharing was initially reviewed by the IRS with regard to permissibility for non-profit tax exempt hospital. It was approved from the tax perspective.

- July 1999 DHHS-OIG Special Advisory Bulletin, Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries; 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."

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History of Regulatory Review *(cont'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

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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

Key Elements of §411.357(x)

- Performance measures must use verifiable “objective methodology” supported by “credible medical evidence” that are “individually tracked”
- Quality measures used must be listed in CMS Specification Manual for National Hospital Quality Measures
- Include baselines, targets and thresholds for determining payments to physicians
- Minimum 5-member physician “pools” for each performance measure
- 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

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

- 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, with participating physicians or physician organizations, or other entity participating at time of review in an incentive or shared savings program at the hospital
- Maintain physician access to items, services, and supplies previously available and assure decision-making autonomy on patient care decisions
- Physicians cannot have financial interest in use of an item, supply, or device that is linked to a hospital payment
- Hospital may not limit availability of otherwise appropriate new technology
- 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.)*

- Written detailed contract executed by parties listing each performance measure and payments linked to it
- Term of between 1 and 3 years
- Baselines – assure that no payments made for improvements in quality or cost savings realized in prior period
- Limit amount and duration of payments and clearly define baseline costs for shared savings programs
- 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
- Distributed to physician organizations or "pools" for distribution on *per capita* basis
- Paid directly to physicians or physician organizations

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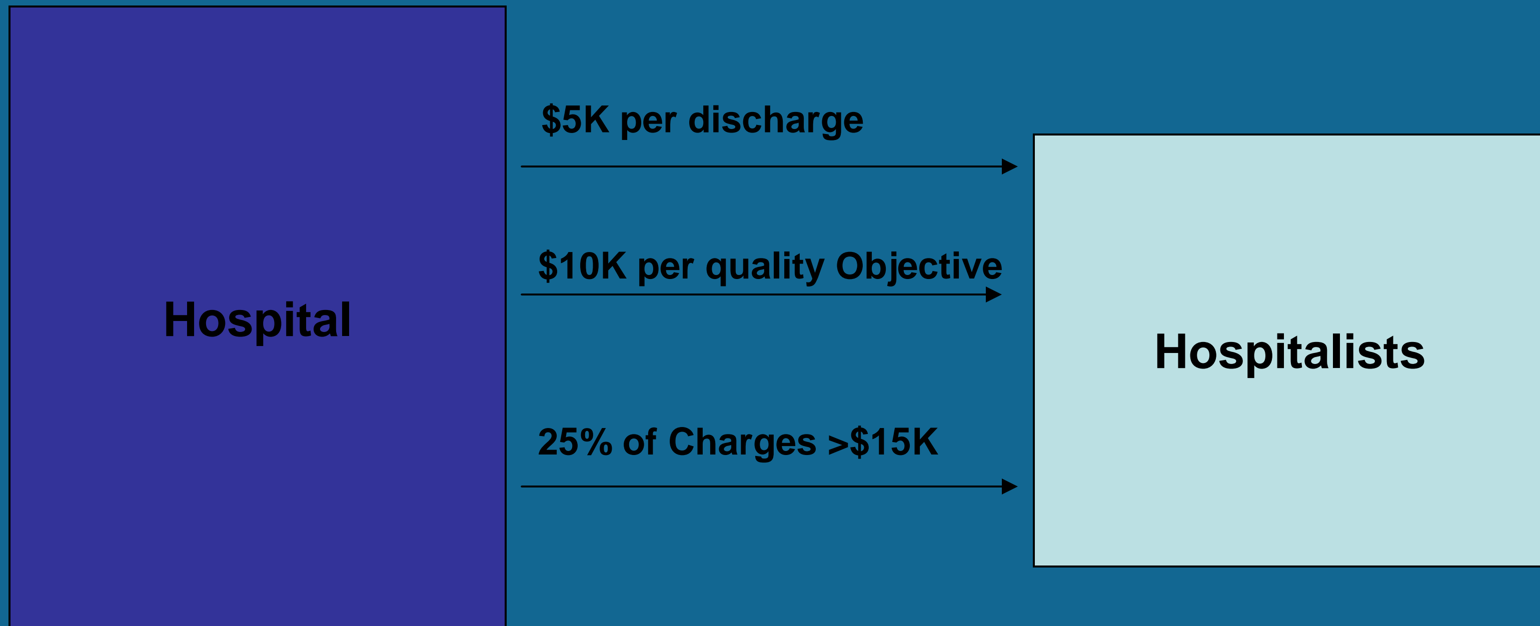
Key Elements of §411.357(x) *(cont'd.)*

- Payments may not take into account any increase in volume of Federal health care patient procedures or services above baseline for prior period
- 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.
  - Rebasing of performance measures.
  - Form of written notification provided to patients.

Example: Services Agreement - (provider-sponsored P4P)



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Example: Services Agreement - (provider-sponsored P4P)

- Payment per discharge
  - Per patient fee– based on volume/value?
- Quality Objective payments
  - 10% Decrease in pressure ulcers
  - 95% patients checked for Pneumonia w/i 24hrs
  - 100% Pneumonia patients given Clearfill
  - 20% Decrease in readmission rate
- Bonus payment
  - Outlier payment
  - 25% of charges– is this the right metric?

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Example: Risk Pool Arrangement - (hybrid P4P)

- Identify set of DRGs targeted for program growth and performance improvement
- Hospital and physicians agree to establish performance incentive pool
  - Notify providers based upon DRG schedule and discharge status
  - 15% of remittance transferred to single account for pool distribution, monitored by estimated A/R payment
- Oversight provided by governing board
  - Establish LLC/PHO
  - Establish governance committee, no corporation

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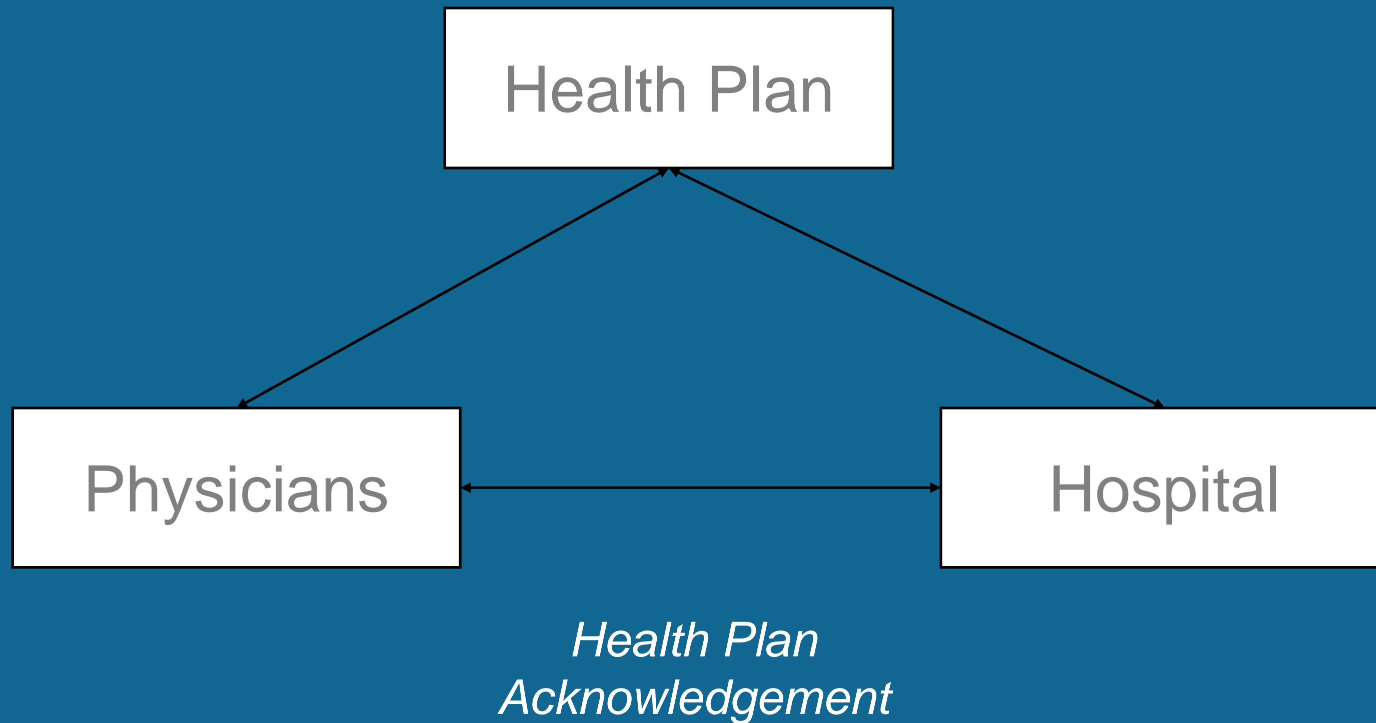
Example: Risk Pool Arrangement - (hybrid P4P)

CONTRACTS



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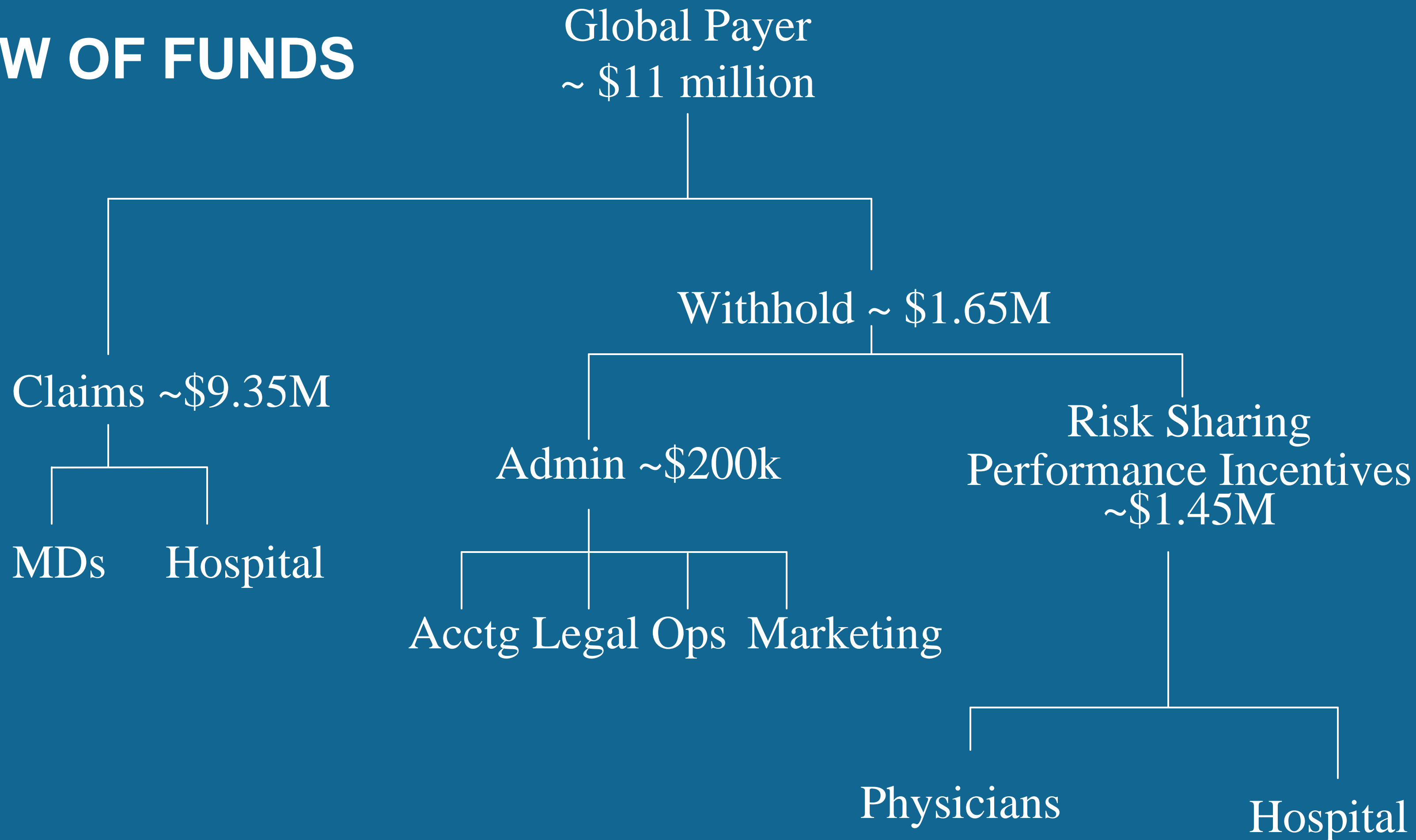
Example: Risk Pool Arrangement -(hybrid P4P)



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Example: Risk Pool Arrangement - (hybrid P4P)

Performance System Allocation Percentages

	% of Pool	Type
▪ Cost	*30*	Individual
▪ Quality	*30*	Network
▪ Satisfaction	*20*	Network
▪ Participation	*20*	Individual

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Example: Risk Pool Arrangement - (hybrid P4P)

Network Performance Incentives Measures

Financial:	Individual Case Mix Adjusted Cost per Case
Clinical:	Mortality, Morbidity, Clinical Process Measures
Satisfaction:	Patient Satisfaction, Member Satisfaction
Participation:	Clinical Education Forums, Performance Improvement Committees, Educational Presentations, Charity Care Cases

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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?

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