

Basic Legal Issues in Implementing Healthcare Payment Incentives

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What is Value-Based Purchasing?

- VBP holds physicians and hospitals accountable for following clinical guidelines and achieving successful outcomes.
- VBP converts the way physicians manage patients into a metric.
- VBP metrics will determine a portion of the physician's and hospital's reimbursement.

What is Value-Based Purchasing?

- VBP stresses a process to improve the quality of healthcare delivery by promoting efficiency and effectiveness.
- VBP implements a vehicle to incentivize delivery of care consistent with evidence-based medicine.
- Evidence-based medicine replaces intuition-based decision making.

Elements of Quality

- Quality is made up of interdependent elements:
 - Physical Outcomes – Did the patient's condition improve?
 - Service Outcomes – What was the patient's perception of the care?
 - Cost Outcome – Were the medical resources appropriately consumed?

Business Case for Quality Care

- Better medical protocols and processes (*e.g.*, quality indicators) lead to better physical outcomes.
- Better physical outcomes reduce complication rates and reduce costs associated with the care.
- Better physical outcomes and less costly care result in higher patient satisfaction.

Unintended Consequences

- Improved quality of care should result in reduced patient complications.
- Reduced complications, though, may shrink profit margins.
- Why? Because complications may result in higher DRG payments for care to Medicare patients that may produce higher margins.
- Perverse reimbursement incentives that are tied to improved quality may arise.









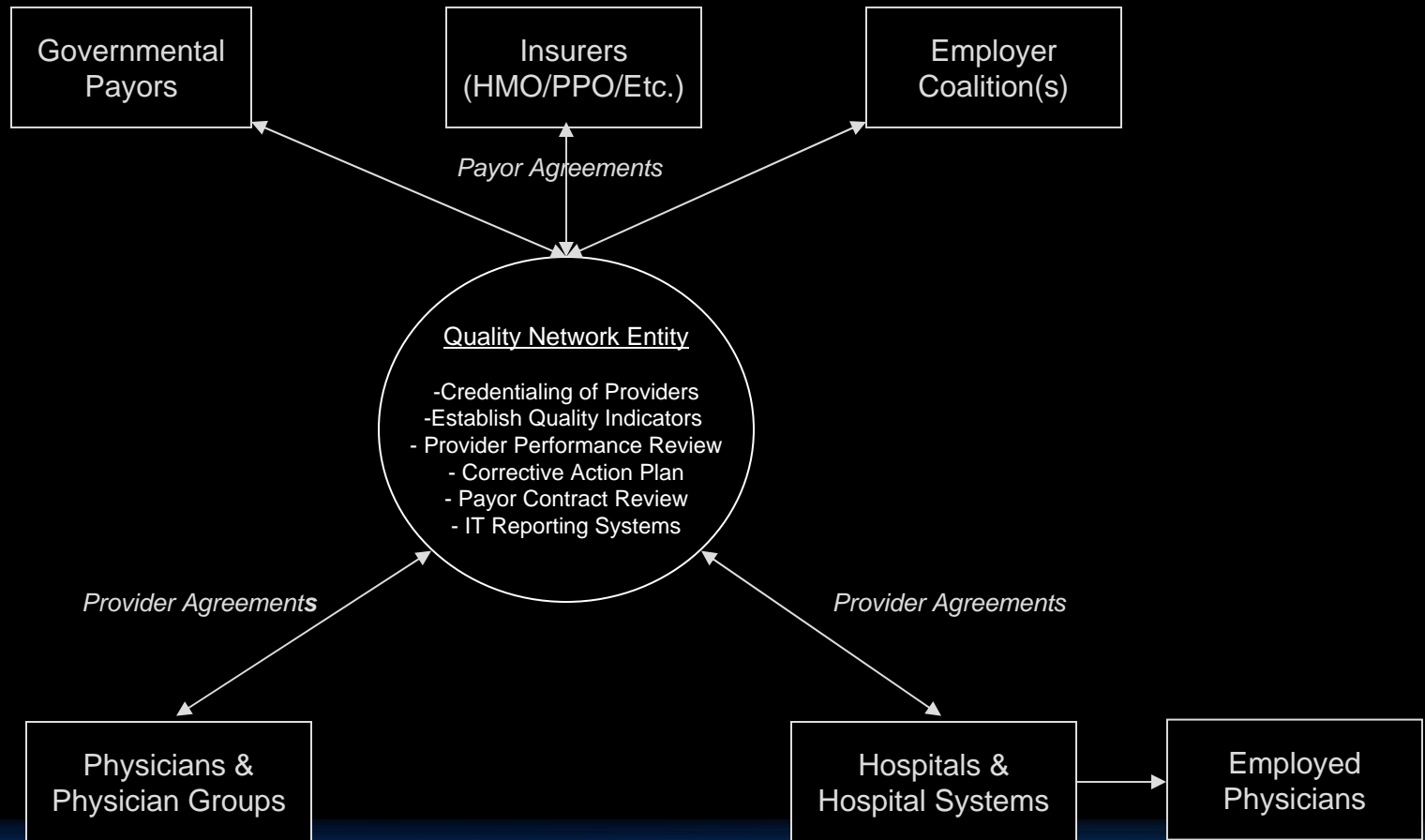




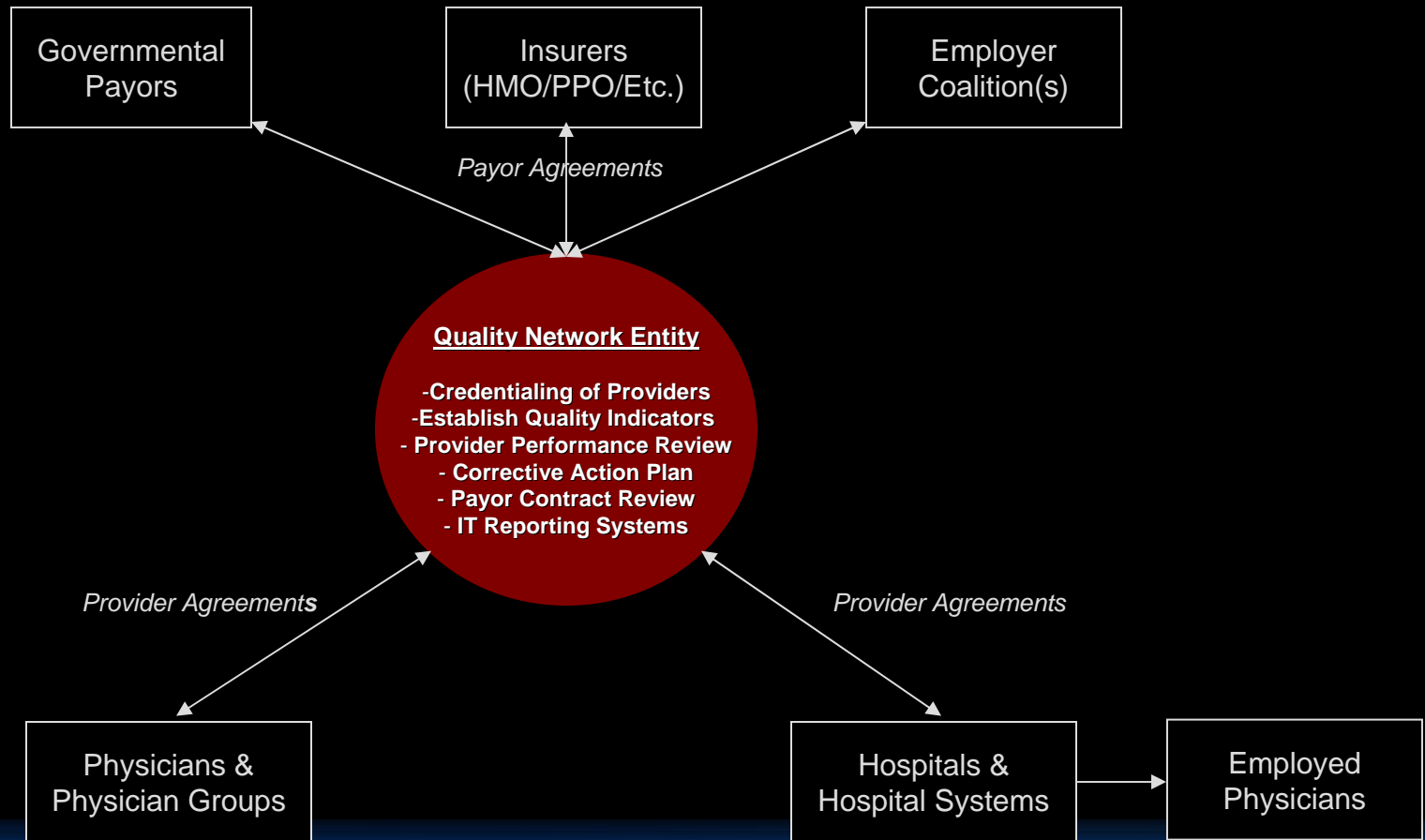




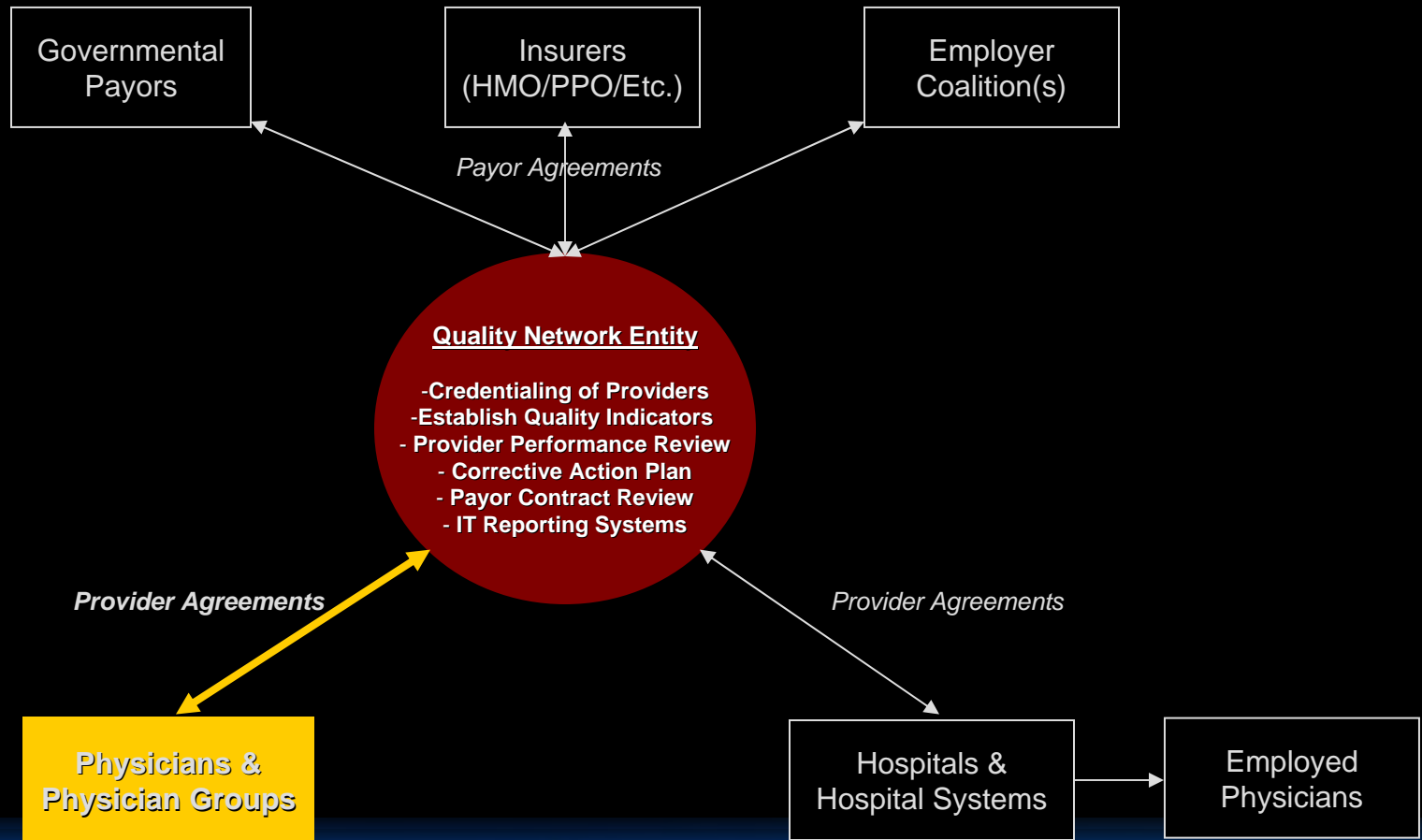
Physician/Hospital Quality Network



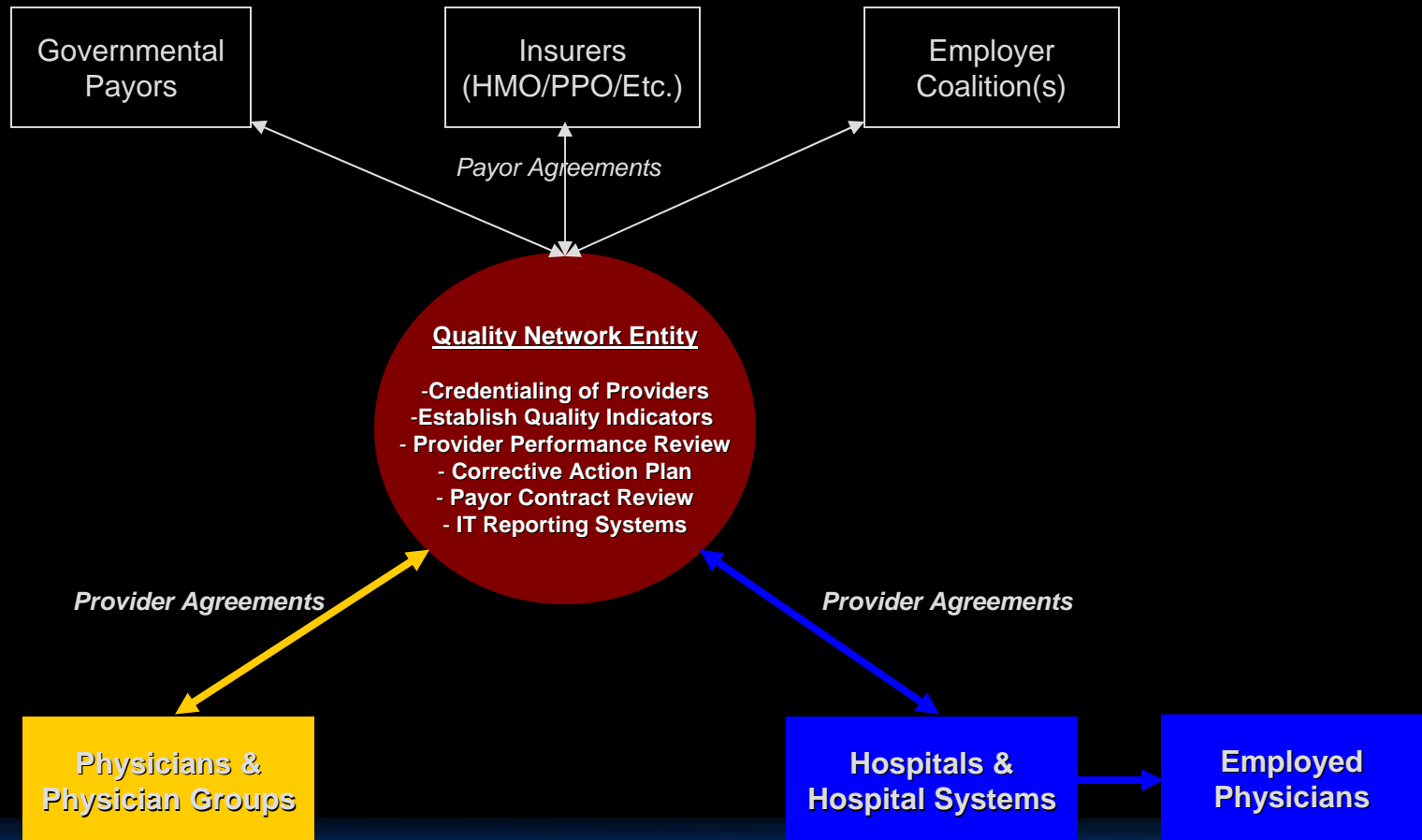
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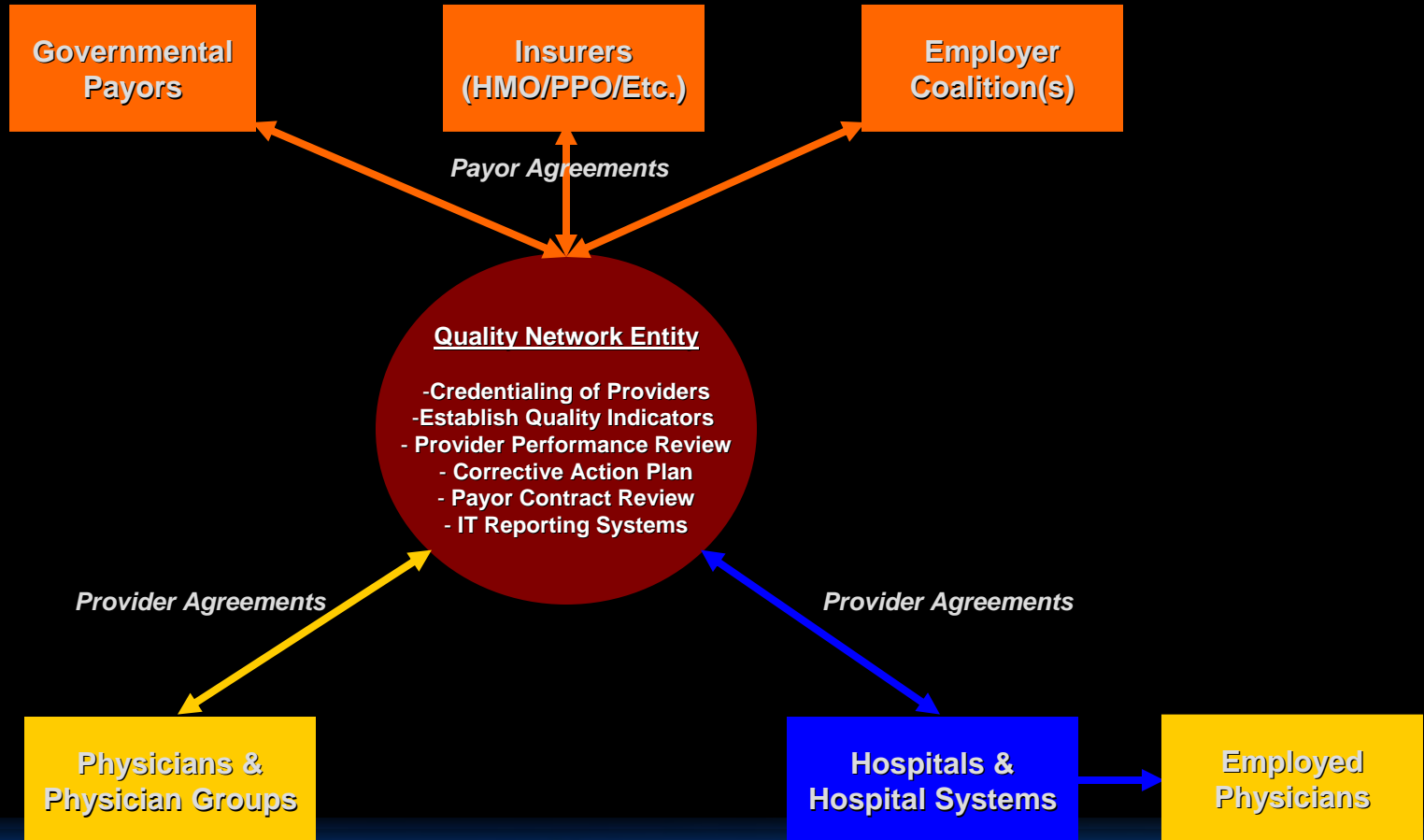
Physician/Hospital Quality Network



Physician/Hospital Quality Network



Physician/Hospital Quality Network



VBP Contracting Considerations

- *Attribution*—How is attribution of responsibility for meeting quality indicators measured?
- *Quality Indicators*—Who controls selection of the quality indicators?
- *Data Collection*—Who is responsible for data collection and dissemination?

VBP Contracting Considerations

- *Remedies*—What remedies do participating providers have for use of incorrect data or information?
- *Rewards*—Does the payment methodology reward only the top performers, or does it recognize improvement in performance?
- *Credentialing*—Does the network control the make up of the physician panel?

VBP Contracting Considerations

- *Timing & Corrective Action*—What options are provided to participating providers for corrective actions?
- *Score Cards & Transparency*—What do the provider network or payor do with collected data regarding participating providers?

Legal & Regulatory Issues

- Physician Self-Referral Laws
- Federal and State Anti-Kickback Statutes
- Civil Monetary Penalties Act
- Antitrust
- Network Exclusion
- Defamation (Slander/Libel)
- Malpractice
- Privacy
- ERISA
- Tax

Physician Self-Referrals

- Stark Law prohibits a physician from referring Medicare and Medicaid patients for designated health services to entities with which the physician (or an immediate family member) has a financial relationship.
- Inpatient and outpatient hospital services qualify as designated health services.

Physician Self-Referrals

- If a Hospital contributes funds as part of a VBP or gainsharing program, a financial relationship with the participating physicians may be created.
- If so, the financial relationship must satisfy each and every element of a Stark exception.
- Possible Stark exceptions for a VBP arrangement:
 - Personal Services Exception
 - Fair Market Value Compensation Exception
 - Electronic Items and Services Exception
- State law Stark-type statutes

Health-e Information Technology Act of 2008

- Introduced 9/15/2008; pending in committee (HR 6898)
- Physicians who install and utilize an approved system will be eligible for incentive payments totaling about \$40,000 over five years.
- Hospitals that install and utilize an approved system will be eligible for payments of up to several million dollars.

Health-e Information Technology Act of 2008

- Incentive payments are available only to those
 - who use a system that meets standards for **interoperability, security, and clinical utility** and
 - who can demonstrate that they are using the system in a clinically meaningful way.
- Eventually, Medicare payments will be reduced for those who do not use a qualified system.

Federal Anti-Kickback

- Prohibits the solicitation of, offering of, or payment of any type of remuneration (directly or indirectly, in cash or in kind) in exchange for referrals or the arranging for the furnishing of health care service opportunities.
- Federal anti-kickback statute applies to federal health care programs such as Medicare, Medicaid, and Tricare.
- State law equivalents – Governmental Programs, All Payors, etc.
- Possible anti-kickback safe harbors for a VBP arrangement:
 - Investment Interest Safe Harbor
 - Personal Services and Management Contracts Safe Harbor
 - Electronic Items and Services Safe Harbor

Civil Monetary Penalties

- Prohibits a hospital or critical access hospital from knowingly making a payment directly or indirectly to a physician as an inducement to reduce or limit services to Medicare or Medicaid beneficiaries under the physician's care.
- Incentives from a hospital to a physician designed to increase quality related to a VBP program must be examined in light of CMP.

Gainsharing

- OIG Advisory Opinion No. 08-09.
- Medical center has agreed to share with groups of orthopedic surgeons and a group of neurosurgeons a percentage of the medical center's cost savings.
- For the surgeons' implementation of a number of cost reduction measures in certain surgical procedures.
- The cost savings are measured based on the surgeons' reduction of waste and use of specific medical devices and supplies during designated spine fusion surgery procedures.

Antitrust

- Price Fixing
 - **Financial integration**
 - Capitation
 - Risk withholds
 - **Clinical integration**
 - In re MedSouth
 - North Texas Specialty Physicians
 - Suburban Health Organizations
 - Brown & Toland
 - Advocate Health Partners

Antitrust

- Joint negotiation by competitors must be ancillary to clinical integration and not vice versa.
- Joint negotiations by competitors must occur after a network is clinically integrated.
- Successful clinical integration programs require substantial work by physicians.
- Messenger model used in non integrated models will become unworkable in a VBP world.

Network Exclusion

- Provider exclusions from groups and networks.
- Physician groups may use scorecard to determine whether to hire a new physicians or terminate a member of the group.
- *See Poliner v. Texas Health Systems, 3/27/2006:* Jury verdict in federal court awarding a physician \$366 million in damages for improper suspension of privileges.

Network Exclusion

- Fifth Circuit reversed and held:
 - Dr. Poliner failed to rebut the presumption that the peer review action complied with HCQIA, and
 - The evidence “independently established” the actions complied with the statute.
- Note, however, this decision was decided under the HCQIA protections.

HCQIA

- HCQIA provides privilege to certain peer review records and decisions of a “health care entity.”
 - A licensed **hospital**
 - An entity that provides health care services (*i.e.*, **HMO or physician group practice**) and that follows a formal peer review for the purpose of furthering quality care
 - A **professional society** of health care providers that follows a formal peer review process for the purpose of furthering quality care
- Is your VBP network a “health care entity”?

Defamation

- Do peer review privileges protect a physician report card that questions the quality of a physician's skills?
- Are credentialing and termination decisions of a network protected from discovery?
- Can patient surveys that contain negative information about a physician be discovered in a lawsuit?
- *Washington State Medical Association v. Regence BlueShield (Wa. Sup. Ct.-King Co.; 9/20/2006).*

Fair Procedure Doctrine

- California Supreme Court Decision applied the common law “fair procedure doctrine” to exclude a medical group from a provider panel by insurer.
- California state law decision
 - May have limited application outside of California
 - May be used in other states as precedent to create an “any willing provider” cause of action

Fair Procedure Doctrine

- Elements of the Fair Procedure Doctrine:
 - An organization possesses substantial power over a market.
 - Such power need not be monopolistic control over the ability of the physician to practice.
 - Failure to admit an ordinary competent medical provider to a panel will significantly impair the provider's ability to practice in the market.
 - Organization does not have a fair procedure for rejecting application.

Fair Procedure Doctrine

- State statutes may require a process for consideration of physician applications for membership in provider panels.
- California amended its workers' compensation laws after the Palm Medical Group case was filed.
- The amended law required the development of written criteria by an organization for provider application review process.

Fair Procedure Doctrine

- Problem for quality networks
 - How do you judge applicants if you do not have data?
 - How do you obtain quality data?
 - How do you differentiate between applicants?
 - How do you remove providers who have been admitted and do not follow quality guidelines?

Malpractice

- Do quality indicators increase exposure to malpractice claims?
- Are the determinations of quality rankings admissible in a malpractice lawsuit?
- What types of lawsuit discovery will be allowed to obtain the data of a VBP network, payors or analysis of a physician group of its physicians?

Privacy

- Sharing of patient information under VBP will impact privacy laws.
- Applicable laws:
 - HIPAA
 - Other federal privacy requirements, as applicable (generally governing drug and alcohol abuse records and mental health records)
 - State privacy requirements

ERISA

- Do undisclosed financial incentives paid by an HMO to physicians to contain medical costs amount to fraud and violate ERISA?
- Is an HMO a fiduciary for beneficiaries of an ERISA plan when it makes mixed eligibility and treatment decisions when acting through its contracted physicians?
- In Pegram V. Hedrich, the U.S. Supreme Court found that Congress did not intend to treat an HMO as a fiduciary in mixed eligibility and treatment decisions.

Tax-Exempt Entities

- Creation of a VBP Network by tax-exempt hospitals may impair the exempt status of the entity.
- Tax Code prohibits
 - Private inurement
 - Private Benefit
- VBP Governance
 - Financial issues
 - Clinical issues

Lessons to be Learned

- Federal and state regulatory environment is still focused on existing payment methodologies and may impede value based purchasing.
- Care must be taken to consider these regulatory restriction in VBP developments.
- There are clear indications that Congress supports VBP in some form.
- Congress should modify existing statutory law to give clear guidance to VBP networks to facilitate development of VBP.

Lessons to be Learned

- Federal and State laws must be modified to recognize the change in payment incentives.
- Until that happens, the regulatory impediments to VBP development cannot be ignored.

Q & A



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