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Avoiding Regulatory Land Mines in Commercial ACOs

Robert Belfort, Partner Healthcare Industry
Martin Thompson, Partner Healthcare Industry
Manatt, Phelps & Phillips, LLP

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Agenda

Antitrust

Fraud and Abuse

Tax Exemption

State Insurance Regulation

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Traditional Joint Venture Analysis Is Applicable to Commercial ACOs

- Market Structure
- Collateral Restraints
- Spillover Collusion

MSSP and Other Agency Guidance

MSSP ACO Policy Statement Can Also Provide Useful Insights into Agency View of Commercial ACOs

MSSP ACO Policy Statement Recognizes Traditional Joint Venture Issues with Special Rules for Market Share Analysis

Other Agency Publications Also Provide Guidance and Safety Zones

Agency Guidance and Safety Zones Relevant to ACOs

1996 Healthcare Enforcement Statements:

- Financial integration sufficient to justify joint sales
- Market share safety zone for physician networks
  - 20% for exclusive networks
  - 30% for non-exclusive
- No safety zone for multi-provider networks
- “Market” Loosely Defined

Agency Guidance and Safety Zones Relevant to ACOs (cont'd.)

2000 Antirust Guidelines for Collaborations Among Competitors [Joint Ventures]:

- Collaboration and participants not more than 20% of each market in which competition may be affected
- "Market" Loosely Defined

2011 ACO Policy Statement [MSSP]:

- Not more than 30% of each common service
- "Market and "Service" defined specifically , but not necessarily as defined by law
- Facilities must be non-exclusive
- Physicians may be exclusive unless have more than 50% market share

Critical Antitrust Concepts – Procompetitive/Anticompetitive Ancillary Restraints

Joint Sales:

- Integration – [More to Come]

Definition: Why Does it Matter?

- Guidelines
  - Financial
  - Clinical – Outside Safety Zone

Collateral Restraint:

- Anti-steering; MFN; anti-tiering, etc.
- Tying
- Exclusivity
- Information restrictions

Spillover Effects: Facilitating Collusion

- Information Exchanges
- Joint Management

Integration

Maricopa – 1982

Joint Pricing Not Ancillary

- But: Financial Integration Distinguished
- Capitation – Maricopa
- Withhold/Case Rates/Other financial Incentives (FTC/DOJ)
- 1996: Clinical Integration Acknowledged
  - 1996 Enforcement Statements: Program to evaluate and modify practice patterns and create interdependence and cooperation

Integration (cont'd.)

Favorable FTC Advisory Opinions

- 2002: MedSouth [also 2007]
- 2007: GRIPA
- 2009: TriState
- 2013: Norman PHO

Failed Efforts

- 2006: Suburban Health Organization
- 2008: FTC v North Texas Specialty Physicians (5th Circuit)

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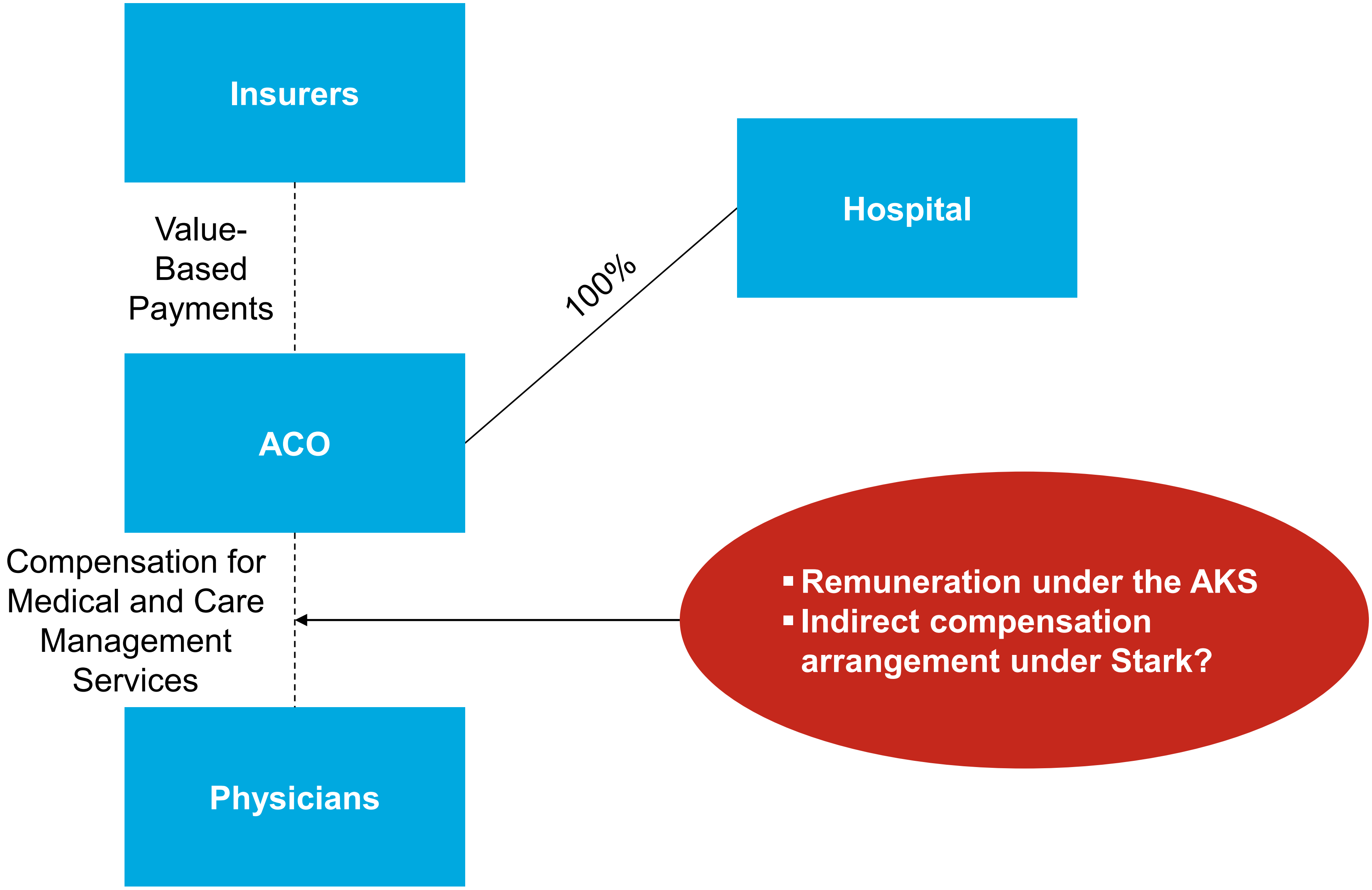
Business Dynamics Drive ACO Fraud and Abuse Concerns

	Assets	Limitations
Hospitals	▪ Capital for infrastructure development ▪ IT and compliance capacity	▪ Do not make most health care decisions ▪ Not always well positioned to engage patients
Physicians	▪ Best positioned to control costs ▪ Best positioned to engage patients ▪ Control most referrals	▪ Limited access to capital ▪ Limited IT and compliance capacity

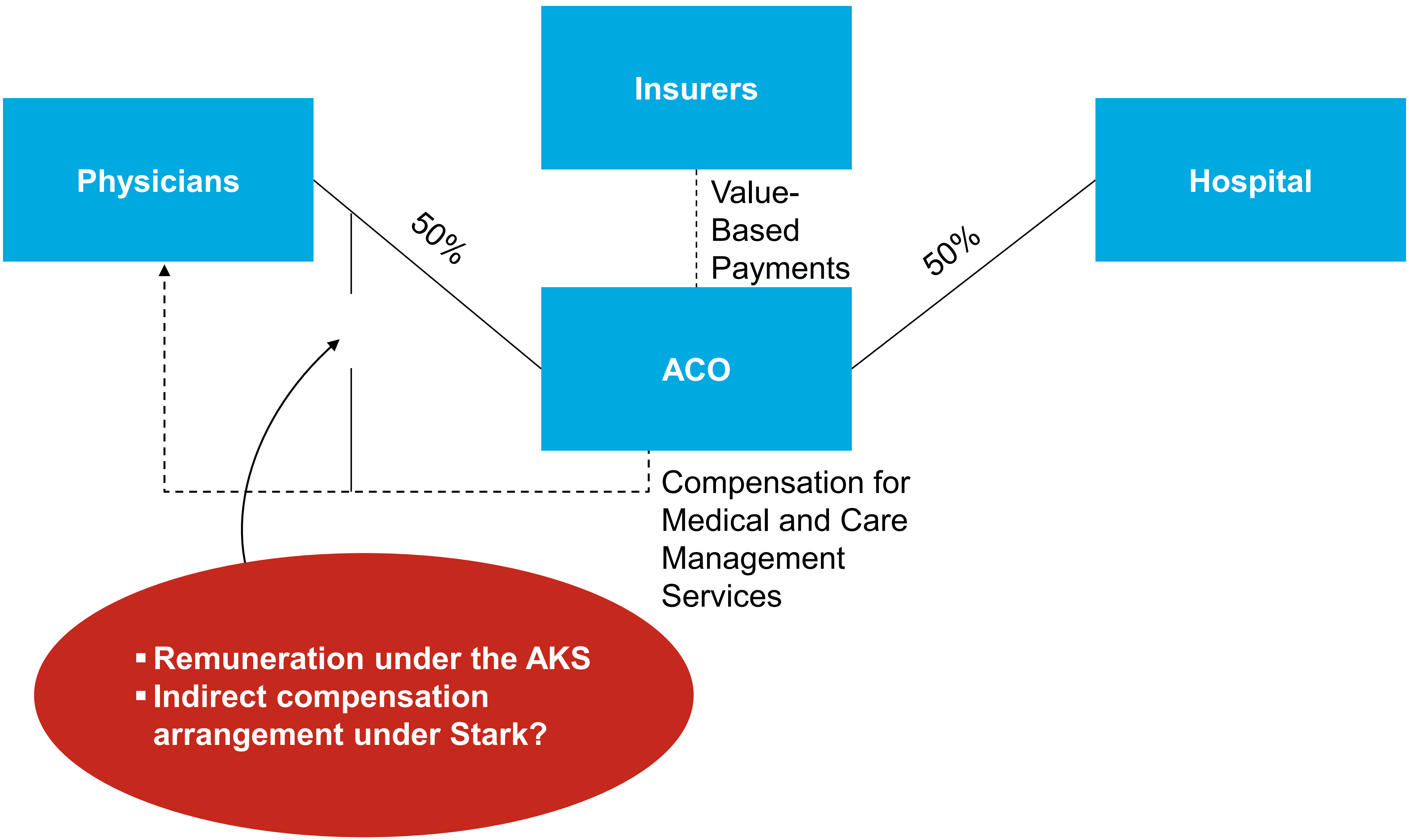
Fraud and Abuse Framework: Stark vs. the Anti-Kickback Statute

Stark	Anti-Kickback Statute
Prohibits physicians from referring patients for DHS covered by Medicare (and Medicaid?) to entities with which they have a financial relationship unless exception applies	Prohibits any person from knowingly exchanging remuneration for referrals for items or services covered by a federal health care program
Must satisfy exception; improper intent not necessary for violation	Safe harbors are not mandatory; law is intent based
Indirect financial relationships not created if physician's direct, aggregate compensation is not tied to referrals	Direct and indirect financial relationships basically treated in the same manner
Civil penalties only	Civil and criminal penalties

Fraud and Abuse Issues in Hospital Subsidiary ACO Model



Fraud and Abuse Issues in Hospital-Physician Joint Venture ACO Model



Stark Risk Sharing Exception and Anti-Kickback Safe Harbors

Stark Risk Sharing Exception	AKS Managed Care Safe Harbor	AKS Health Plan Discount Safe Harbor
Covers any "risk-sharing arrangement" between an MCO or IPA and a physician (either directly or indirectly through a subcontractor) for services provided to enrollees of a health plan.	Covers payments made by Medicare Advantage or Medicaid managed care plan to provider for health care items and services.	Covers discounts on fees offered by providers to health plans.
Should protect shared savings or similar risk-sharing payments from commercial ACOs to physicians.	Does not protect commercial health plan payments.	Protects only discounts from providers, not shared savings or similar risk-sharing payments.
Does not protect ACO investment relationships.	Does not protect ACO investment relationships.	Does not protect ACO investment relationships.

Medicare Shared Savings Program Fraud and Abuse Waivers

Waiver	Key Terms
Pre-participation Waiver	1. Covers “start up arrangements” pre-dating MSSP participation agreement 2. Good faith intent to participate in MSSP 3. Diligent steps to develop ACO in target year 4. Bona fide determination by ACO governing body that arrangement “reasonably related to purposes of MSSP” 5. Documentation 6. Public disclosure
Participation Waiver	1. ACO participates in MSSP 2. ACO satisfies MSSP governance and management rules 3. Same as items 4-6 in pre-participation waiver
Shared Savings Waiver	Covers distribution of shared savings by Medicare ACO to its participants

When Can MSSP Waivers Apply to Commercial ACO Arrangements?

"Although we are not providing a specific waiver for private payer arrangements at this time, we believe avenues exist to protect flexibility for ACOs participating in commercial plans. First, nothing precludes arrangements 'downstream' of commercial plans (for example, arrangements between hospitals and physician groups) from qualifying for the participation waiver ... The participation waiver does not turn on the source of the funds for the arrangement."

"Arrangements with similar purposes but that are unrelated to the Shared Savings Program are not covered by the term 'purposes of the Shared Savings Program.' Arrangements that involve care for non-Medicare patients as well as Medicare beneficiaries are eligible for the waiver."

Preamble from CMS on MSSP Waivers, 76 Fed. Reg. 67992 (11/2/2011)

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Can ACOs Be Tax Exempt?

- IRS recognizes that Medicare ACOs are entitled to an exemption because they “lessen the burdens of government”
- Greater uncertainty about whether:
  - Commercial ACO can be exempt
  - Commercial ACO LLC profit distributions to hospital are exempt from taxation

How Must ACO Relationships Be Structured to Avoid Private Benefit/Inurement?

- Exempt organization's share of economic benefits derived from ACO is proportional to the exempt organization's contributions
- Must exempt organization's ownership interest in ACO be proportional to its capital contributions? Not necessarily, says IRS. Must look at "totality of circumstances" to determine if benefits are proportional to contributions.

IRS Notice 2011-20

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Existing Risk-Sharing Regulatory Scheme

- Intermediaries between HMOs and providers must be certified as IPAs. No comparable certificate for parties downstream from insurers.
- Prepaid capitation regulated by DFS. Other HMO risk sharing arrangements regulated by DOH
- Requirements depend on nature of risk – security deposit, adequate balance sheet or guarantees may be required
- Assuming "insurance risk" from self-insured employers prohibited

Proposed ACO Regulations

- Voluntary certification option if contracting with state-licensed HMOs or insurers.
- ACOs may decide to voluntarily seek certification to get benefit of waivers of state antitrust, fraud and abuse, and antitrust laws.
- Certification required if ACO wants to assume insurance risk from self-insured employers

For More Information…

Robert Belfort
Partner, Healthcare Industry
Manatt, Phelps & Phillips, LLP
rbelfort@manatt.com
212-830-7270

Marty Thompson
Partner, Healthcare Industry
Manatt, Phelps & Phillips, LLP
mthompson@manatt.com
714-371-2530