The ACO Legal Environment:
Antitrust, Kickbacks and Other Pitfalls to Avoid

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2011 Health Care Regulatory and Compliance Update

March 1, 2011

ACOs in PPACA

The Basics

- Section 3022 of the Protection and Affordable Care Act (the "PPACA") establishes the Medicare Shared Savings Program.
  - Health care professionals work together to establish Accountable Care Organizations – ACOs
    - Physicians in group practice arrangements, networks of individual physician practices, hospitals, and partnerships or joint ventures between hospitals and physician groups
  - ACOs are held accountable for quality, cost, and overall care of Medicare beneficiaries assigned to them
  - Have the potential to realign provider incentives

ACOs in PPACA

Key Requirements Under PPACA

- A formal legal structure for receiving and distributing shared savings payments
- A leadership and management structure that includes clinical and administrative systems
- Agree to participate in the program for at least three years
- Able to accept assign of at least 5,000 Medicare beneficiaries, and include a sufficient number of primary care physicians for serving those patients
- Have processes relating to quality and coordination of care, such as through the use of telehealth, remote patient monitoring, and other technologies
- Have patient-centered processes that meet criteria specified by the Secretary
- Meet reporting requirements determined by the Secretary
- More to come via regulations expected in February 2011

ACOs in PPACA

Compensation

- **Shared Savings**
  - **ACO is eligible for shared savings payments**
    - If it meets quality and performance standards; and
    - The ACO's estimated Medicare costs are a certain percentage below a benchmark set by the Secretary
  - **Providers are incentivized to improve clinical performance, while at the same time control costs**

- **Partial Capitation** and other payment models
  - Secretary can choose to limit the partial capitation model to ACOs that are highly integrated systems of care and to ACOs capable of bearing risk

Contracts Among Providers

Contracts

- **The legal structure of ACOs will be articulated in contracts between providers and in the organizational documents of any ACO entity**
  - **Network relationships**
    - Ensuring that providers in ACO network are responsible for coordinating all aspects of patient care
  - **Economic relationships**
    - Determining how shared savings will be distributed among physician and other provider members of the ACO
- **Existing managed care contracts may be used as models for ACO relationships**
- **Contracts must be carefully drafted to ensure compliance with the Stark law, the anti-kickback laws, the CMP law and other Federal and State fraud and abuse laws**

Legal Issues

Primary Regulatory Concerns

- Antitrust
- Stark Law
- Anti-kickback Statute
- CMP/Physician Incentive Plan Law
- Tax Issues
- Regulation of Risk Bearing Entities
- Corporate Practice of Medicine

Legal Issues - Antitrust

Key Antitrust Considerations

- Internal structure of provider network within the ACO
    - Federal Trade Commission and U.S. Department of Justice will want to ensure that the ACO does not facilitate unlawful agreements between competitors (i.e., price-fixing or market allocation)
        - ACOs cannot be a means for individual competitors to act as a single entity
        - ACOs cannot use market position to adversely affect competition (i.e., unlawfully exclude competitors through exclusive contracts)

Legal Issues - Antitrust

Key Antitrust Considerations

- The Agencies have found that pro-competitive effects outweigh anticompetitive concerns in the following types of provider networks:
  - Messenger model
  - Substantial financial risk model
  - Clinical integration model
- These models – particularly clinical integration model – indicate that ACOs can be structured in a way that passes muster with the Agencies
  - Barriers posed by antitrust laws are not insurmountable
  - Because this has been done successfully in the past (e.g., Kaiser Permanente, California Public Employees' Retirement System (CalPERS)), ACOs will likely be able to adapt similar integration models

Legal Issues - Antitrust

Key Antitrust Considerations

- ***Financial Integration*** – "share financial risk in such a way that each member has an economic incentive to ensure that the group as a whole produces material efficiencies that will benefit consumers" [1]
  - Agreement by provider network to provide services at a capitated rate
  - Agreement by provider network to provide designated services or classes of services for a predetermined rate
  - Use by a provider network of significant financial incentives for participants, as a group, to achieve specified cost-containment goals

- ***Clinical Integration*** – "comprehensive, coordinated program of care management designed, and likely, to improve quality and cost-effective care"; "use of IT systems, practice guidelines, care protocols, referral policies and quality benchmarks . . . to align efforts to improve [patients'] health and delivery of services"[2]

1. Christine A. Varney, Assistant Attorney General, Antitrust Division, U.S. Dept. of Justice, Remarks as prepared for the ABA/AHLA Antitrust in Healthcare Conference, 5/24/10
2. Id.

Legal Issues - Antitrust

Revelations from the FTC/CMS Workshop – October 5, 2010

Discussed:

- Circumstances under which collaboration among independent providers in an ACO permits ACO providers to engage in joint price negotiations with private payers without running the risk of engaging in illegal price fixing
- Options for dealing with Medicare ACOs that fail to achieve CMS-required quality performance standards
- Ways to encourage formation of multiple ACOs so competition among ACOs will drive improved quality and affordability

Legal Issues - Antitrust

Revelations from the FTC/CMS Workshop – October 5, 2010

FTC concerns:

- Analysis of arrangements where providers are exclusive or non-exclusive to an ACO
- The impact of risk-based contracting on market power assessments
- Ways to assess whether formation of an ACO may allow the ACO to increase price and reduce quality
- The financial, utilization, outcome and patient experience data necessary to monitor and measure the impact of an ACO on prices and quality

Legal Issues – Antitrust/Stark/AKS/CMP

Revelations from the FTC/CMS Workshop – October 5, 2010

- That Dr. Berwick (CMS), Leibowitz (FTC Chair) and Levinson (HHS IG) opened the workshop says it all
- All agencies stated that they would not create barriers to the success of the ACO program
- Re: Fraud and abuse laws, actively considering broad waiver for ACOs
- Re: Antitrust, possible safeharbor, with expedited advisory opinion process

Legal Issues - Stark

Stark Law

- Stark Law prohibits a physician (or immediate family member) with a "financial relationship" with an "entity" from making a "referral" to that entity for "designated health services", for which payment is made by Medicare, absent an applicable exception
  - No intent requirement; strict liability for Stark violations
  - Certain exceptions apply to managed care organizations, and will likely apply to many ACOs:
    - Employment / Personal Services Agreement
    - Fair Market Value
    - Academic Medical Centers
    - Indirect Compensation
    - Prepaid plan enrollee exception
    - Risk-sharing arrangements exception

Legal Issues - Stark

Stark Law

- CMS has proposed a "shared savings" and incentive payment exception to the Stark regulations, but it is not final or effective. 73 Fed. Reg. 38502 (7/7/08)
- Three essential elements of the proposed exception:
  (1) transparency
  (2) quality controls
  (3) safeguards against payments for referrals

  CMS does not intend to promulgate a final "shared savings" and incentive payment exception at this time, suggesting instead that a temporary waiver of Stark requirements by the Secretary may be more appropriate than a permanent exception by CMS

(Remarks of Troy Barsky, Director, Division of Technical Payment Policy, at American Health Lawyers Association Annual Meeting, Seattle, WA 6/29/10)

Legal Issues – Anti-kickback

Anti-kickback Statute

- Prohibits someone from "knowingly and willfully" giving (or offering to give) "remuneration" to another person if such payments is intended to "induce" referrals for the furnishing of health services, or to induce the purchase, order, lease or recommendation of items covered by Medicare
  - Intent requirement; without requisite intent, no violation
- Safe harbors
  - Even without requisite intent, best practice is to structure the arrangement under a safe harbor, if possible (as provided in the law)
  - Existing federal anti-kickback safe harbors:
    - managed care
    - employment
    - personal services

Legal Issues – Anti-kickback

Anti-kickback Statute

- The OIG has not proposed a safe harbor for ACOs or shared savings programs

- Like CMS, the OIG has stated it is not planning to develop a safe harbor for ACOs or shared savings, stating that the Secretary's waiver of kickback prohibitions would be an option for ACO protection

Legal Issues – CMP Law

Physician Incentive Payment Prohibition ("CMP Law")

- Hospital may not knowingly make a payment, directly or indirectly, to a physician as an inducement to reduce or limit services provided with respect to individuals who—
  - are entitled to benefits under Medicare part A or part B or to medical assistance under a State plan, and
  - are under the direct care of the physician
- Applies only in the fee for service context

Legal Issues – ACO Tax Considerations

Tax Status Considerations

- PPACA is silent regarding the tax status of ACOs
- When forming an ACO, organizers will want to strategically consider the tax status of the new entity
  - Tax exempt status may facilitate other funding, contracting, etc.
  - IRS has considered integrated delivery systems (i.e., physician-hospital organizations ("PHO") or preferred provider organizations ("PPO")) which typically do not receive 501(c)(3) status
  - "Promotion of health rationale" could be one basis for exemption (broad)
  - "Lessening burdens of government"
    - IRS has been limiting this basis for exemption in some cases (i.e., Regional Health Information Organizations)

Legal Issues – ACO Tax Considerations

Tax Issues for Tax Exempt Entities Participating in ACOs

- Shared savings or other payments among ACO participants must be consistent with tax-exempt status of the organization
  - IRS analysis of this issue will likely be similar to analysis for gainsharing and pay-for-performance programs
  - Favorable rulings where:
    - Physician groups have provided valuable services needed by the hospital
    - Arrangements resulted in cost savings to the hospital
    - Allocation of awards was capped to reflect fair market value (determined by third party appraiser)
- Potential participants may want to obtain IRS private letter ruling to confirm that participation in ACO will not affect tax status

Legal Issues – ACO Tax Considerations

Tax Issues for Tax Exempt Entities Participating in ACOs

- To what extent will the organization confer a "private benefit" – how much control to be provided to private parties (e.g., physicians) through a tax-exempt financed entity?

- Beware of potential UBIT issues created via a lease of tax-exempt financed space or through a services agreement by a tax-exempt entity

Legal Issues – Risk Bearing Entities

Regulation of Risk Bearing Entities

- Partial Capitation
  - PPACA gives the Secretary the authority to establish payments to providers on a partial capitated basis
  - Partial capitation model would be limited to sophisticated, highly integrated ACOs capable of bearing such risk
- State Insurance Considerations
  - The National Association of Insurance Commissioners ("NAIC") determined that certain risk-bearing arrangements with capitation or other risk-bearing payments arrangements were assuming insurance risk and should therefore be regulated as either insurers, HMOs, or as some hybrid entity
  - ACOs with partial capitation arrangements may be subject to insurance regulations, and should work with counsel to ensure compliance
  - Keep an eye out for DMHC regulations

Legal Issues – Corporate Practice of Medicine

Corporate Practice of Medicine

- **California prohibits the corporate practice of medicine ("CPOM")**
  - CPOM laws prohibit a lay entity to practice medicine or to employ a physician to provide professional medical services
  - Depending on its structure, an ACO must understand the CPOM laws and comply with the CPOM limitations

ACOs – Unknowns

Governance and Structure

- ACOs must determine how governance decisions (i.e., allocation of shared savings) will be made and the type of organization that will best facilitate that governance
- "Best" governance structure will vary from ACO to ACO
  - Size, network, and the needs of the ACO and the individual participants will determine governance
  - Committee structure and design to be created
- ACOs will likely create arrangements among tax exempt and non-tax exempt organizations
- Will the feds require specific structural or operational components?
- Which party will receive the shared savings or partial capitation payment – what are the implications?

ACOs – What Will Be Needed?

ACO Issues List

- Will the ACO be focused on Medicare patients only? Commercial only? Mixed payor? – What is the scope?
- How to populate the ACO board? How much, if any, lay, community, and clinical leadership?
- What functions will be delegated to the ACO Board, and what will be a function of an operating committee(s)?
- How will governance/leadership be structured on the physician side?
- Who will staff and manage the ACO?
- How to pick partners in the ACO?

ACOs – What Will Be Needed?

ACO Issues List

- Financial Model for Clinical Integration?
- Financial Model for Financial Integration?
- Coordinate financial relationships and establish flow of funds among all ACO participants
- Entity organizational documents
- Develop Mechanisms to Track and Report Financial Data
- Develop Mechanisms to Track and Report Clinical Data
- IT Infrastructure
- HIPAA compliance for shared PHI
- Exit strategy or termination events
- More to Come…

ACOs – What Will Be Needed?

What Providers Can Work on Now

The ACO is a new line of business so…

- **Prepare a business plan**
  - What is the opportunity
  - What is the strategy for the ACO to seize the opportunity
  - What physicians – hospitals – others will be "inside" the ACO
  - How will the ACO coordinate care, deliver quality, achieve savings?
  - What staff will be required? IT systems?
  - Project a three year budget
  - Project various revenue models
- **Identify capital needs and sources of funding**
  - Can it work?

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