



Legal Issues for Accountable Care Organizations

Health Care Reform Strategies

Navigating America's New Health Care System

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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



PPACA's Key Requirements

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; and
- ❖ Meet reporting requirements determined by the Secretary.
- ❖ More to come via regulations expected in the Fall 2010.

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.
 - ❖ 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 members of the ACOs
- ❖ Contract models may be found in Managed Care Contracts
- ❖ Contracts must be carefully drafted to ensure compliance with the Stark Law, the Anti-kickback Laws and other Federal and State fraud and abuse laws



Contracts with Third Parties

Third Party Contracts

❖ ACOs will likely need to engage third parties to perform many of the functions that will be required of them. Contracts will be essential with these entities. Examples include:

- ❖ Third party administrators
- ❖ Information technology vendors
- ❖ Billing and claims management firms
- ❖ Care coordination
- ❖ Staffing companies



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.
 - ❖ Non-profit 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)



Tax Considerations

Tax Issues for ACOs Within Non-Profit Entities

- ❖ Shared savings or other payments among ACO participants must be consistent with tax-exempt status of the organization
 - ❖ IRS analysis of this issues 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



Governance and Structure

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
- ❖ ACOs will likely join exempt and non-exempt organizations
 - ❖ Forming a new corporation
 - ❖ 501(c)(3) considerations
 - ❖ Must determine whether NewCo will be tax exempt, whether status of other participants will be affected
 - ❖ Forming an LLC
 - ❖ Create an informal organization that exists solely because of contracts between ACO providers



Capital Development Issues

Capital Development

- ❖ Many ACO will require initial capital funding for staffing, systems, rents, etc. How those funds are raised will implicate various legal issues.
- ❖ Must assure compliance with applicable investment laws re disclosures, etc.
- ❖ Self-funded
 - ❖ Larger, more sophisticated organizations likely to be self-funded
 - ❖ Potential liability for members providing funding
 - ❖ Must comply with Federal and State fraud and abuse laws
- ❖ Investor-funded
 - ❖ If members of the ACO are also investors, must ensure that there is no liability under Federal and State fraud and abuse laws
- ❖ Considerations when providing returns to investors
 - ❖ Compliance with laws
 - ❖ Maintaining PPACA's purposes: coordination of care, efficiency vs. investor profit



Fraud & Abuse: Stark Law

Stark Law

- ❖ Stark Law prohibits a physician (or family member) with a “financial relationship” with an “entity” from making a “referral” to that entity for “furnishing” “designated health services”, for which payment is made by Medicare, absent an applicable exception.
 - ❖ No intent requirement; strict liability for Stark violations, absent an exception
 - ❖ Certain exceptions apply to managed care organizations, and will likely apply to many ACOs:
 - ❖ Prepaid plan enrollee exception
 - ❖ Risk-sharing arrangements exception
 - ❖ Proposed exception for shared savings plans - directly applicable to ACOs
 - ❖ Not a guarantee
- ❖ General consideration
 - ❖ If a hospital participating in an ACO provides remuneration, this will likely create a “compensation relationship”
 - ❖ Ensuring that hospitals do not provide remuneration will help eliminate a major source of Stark liability



Fraud & Abuse: Anti-Kickback Law

Anti-Kickback Law

- ❖ 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.
 - ❖ If payments are not intended to induce referrals, ACO arrangements will likely not implicate the Anti-Kickback Law
 - ❖ Intent requirement; without requisite intent, no violation
- ❖ Safe harbor
 - ❖ Even without requisite intent, best practices are to safe harbor the arrangement (as provided in the law) if it involves remuneration
- ❖ Given the complexity of Fraud & Abuse laws and the consequences for violations, engaging sophisticated legal counsel is advisable when establishing an ACO.



Anti-Trust Issues

❖ 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)



Anti-Trust Issues

❖ 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 (i.e., Kaiser Permanente, California Public Employees' Retirement System (CalPERS)), ACOs will likely be able to adapt similar integration models



Regulation of 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



Corporate Practice of Medicine

Corporate Practice of Medicine

- ❖ Many states prohibit the corporate practice of medicine (“COPM”)
 - ❖ COPM laws prohibit a business corporation to practice medicine or to employ a physician to provide professional medical services
 - ❖ COPM regulations often include exceptions:
 - ❖ i.e., hospitals may employ physicians because hospitals are formed for the specific purpose of treating patients, and are themselves licensed entities
 - ❖ i.e., physicians can provide medical services through a professional or service corporation so long as each shareholder of the corporation is a licensed physician
- ❖ Depending on their structure, ACOs must understand the COPM laws in their state and comply with COPM regulations



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