

**Delaware State Bar Association  
HEALTH LAW SECTION  
February 8, 2013  
Meeting held at Law Office of Balick & Balick**

**PRESENT: Bryan Keenan; Diane Andrews; Nicholas Heesters; Angela Priest; Tiphannie Miller; Joanne Ceballos; Nate Trexler; Teresa Cheek.**

**BY TELEPHONE: Ben Schwartz.**

**PRESENTER: Matthew Jones, Esquire of Duane Morris.**

Minutes:

- Meeting called to order by Joanne at 1215.
- Discussion: Matt Jones, Esq. from Duane Morris, provided presentation entitled: "ACOs, Mergers and Clinical Integration: Legal Considerations." Questions entertained by Matt at conclusion of presentation.  
(See Attached handout which summarizes presentation).
- Minutes approved from meeting held on December 11, 2012.
- Discussion held regarding the formation of a CLE committee; Chancery Court section and Elder Law section of DSBA expressed interest in holding a joint CLE/CME course. Nate Trexler volunteered to chair this effort on behalf of Health Law section with Ben Schwartz, Diane Andrews and Teresa Cheek agreeing to serve on the committee for this project.
- Joanne circulated the "Bio" form for those members of the Health Law section who are interested in posting their respective biographical information on the DSBA Health Law Section website.
- Next meeting scheduled to be held at Timothy's on the Riverfront in Wilmington on April 19, 2013; business will be conducted, including election of officers for next year, with a happy hour to follow from 4-6 pm; dues will be utilized to fund this event.
- Motion to adjourn.

*Respectfully submitted by: Diane M. Andrews, R.N., Esquire*



# ACOs, Mergers and Clinical Integration: Legal Considerations

February 8, 2013

Matthew C. Jones, Esq.

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## Accountable Care Organizations (ACOs) (Medicare Shared Savings Program)

- What is an ACO?
  - A group of providers of services and suppliers working together to manage and coordinate care for Medicare fee-for-service beneficiaries
  - Term is commonly used to refer to ACOs that participate in both the Medicare Shared Savings Program and other commercial risk contracts
- Providers of services and suppliers that are part of an ACO can continue to receive traditional Medicare fee-for-service payments, and are eligible for additional payments based on meeting specified quality and savings requirements
- ACOs have a “three-part aim”:
  - Better care for individuals
  - Better health for populations
  - Lower growth in expenditures

*IMPACT on Health Care Consumers?*

## ACOs (cont.)

- Key elements of ACO model involve:
  - A team of hospitals, physicians and other professionals
  - A designated Medicare fee-for-service population that accepts the ACO as its caregiver
  - Patients are assigned to an ACO based on their primary care physician *→ MUST have PCP?*
  - A primary care physician may only participate in a single ACO; specialists may participate in multiple ACOs
  - A set of performance and quality benchmarks against which the ACO's financial performance is measured
  - A formula for sharing savings among the professionals when the ACO performs better than the agreed-upon performance and quality benchmarks
- Participation in an ACO is completely voluntary *- for who? if consumer doesn't participate - what can happen?*  
*1. what*

## ACOs (cont.)

- Entities that are eligible to form an ACO include:
  - Professionals in group practice arrangements (i.e., physicians, nurse practitioners, physician assistants and other healthcare practitioners)
  - Networks of individual practices or independent practice associations (IPAs)
  - Partnerships or joint ventures between hospitals and physicians and other professionals
  - Hospitals employing physicians and other professionals
  - Critical Access Hospitals (CAHs)
  - Rural Health Clinics (RHCs)
  - Federally Qualified Health Centers (FQHCs)
  - Any other groups that the Secretary of HHS deems appropriate

## ACOs (cont.)

- ACOs must:
  - Enter into a 3-year agreement with the Secretary of HHS
  - Create a structure that is legally authorized to receive and distribute payments for shared savings to professionals, hospitals and other service providers
  - Have the necessary leadership and management structure that includes clinical and administrative systems
  - Define processes that promote evidence-based medicine and patient engagement
  - Collect data on cost and quality
  - Coordinate the delivery of patient care using telehealth, remote patient monitoring and other types of distance medicine
  - Perform patient and caregiver assessments to demonstrate to the Secretary of HHS that the ACO is patient-centered
  - Collect data and report on utilization and costs, clinical processes, clinical outcomes and patient and caregiver care experience

## ACOs (cont.)

- Two different “tracks” for ACOs:
  - “One-sided risk model”:
    - Providers and government share savings only, with no sharing of losses, for the first 3 years
    - Sharing of savings and losses in 4th year and thereafter (if agreement extends beyond 3 years)
  - “Two-sided risk model”: Providers and government share in savings and losses for all 3 years (but shared savings payments to ACO are greater than in one-sided model)
  - ACO may choose either model, but may not switch between models
- After initial 3-year period, all ACOs will be under “two-sided model”

## Legal Considerations for ACOs

- Major areas of concern:
  - Antitrust
  - Stark Law
  - Anti-kickback Statute
  - Exempt Organization/Section 501(c)(3) Law & Regulations

## Antitrust Basics

- In a merger, parties' entire businesses and operations are combined
  - Formation of merged entity must be analyzed pursuant to antitrust principles, but not ongoing post-merger operations
- In a joint venture, must consider competitive issues in:
  - Formation of integrated entity; and
  - Post-formation conduct
- ACOs are typically structured as joint ventures, in which the participants do not combine their entire businesses and operations into the ACO

★  
most  
ACO  
set up

## Antitrust Basics - Joint Ventures

- Avoid *per se* illegal conduct
  - Agreements not to compete among competitors, without integration, are *per se* illegal (no “carving up the market”)
  - Look for financial risk sharing/financial integration (will always avoid antitrust violation) and/or clinical integration (may avoid antitrust violation)
- Try to fit within a “safety zone”
  - “Safety zones” describe conduct that FTC/DOJ will not challenge under antitrust laws, absent extraordinary circumstances
  - If conduct falls within an FTC/DOJ “safety zone,” just focus on avoiding collusion outside the scope of the JV
- If the “rule of reason” applies (i.e., not *per se* illegal, but no “safety zone”):
  - Rules considers whether relationship in question is likely to have anti-competitive effects (e.g., higher prices, less consumer choice)
  - If so, rule evaluates whether potential pro-competitive effects (e.g., enhancing efficiency) are likely to outweigh anti-competitive effects
  - Consider relevant market(s), competitive effects and efficiencies, and limit restraints on competition to those *reasonably necessary to achieve efficiencies*

## Antitrust Basics (cont.)

- Financial integration vs. Clinical Integration
  - Simple example:
    - If a JV provides care at capitated rate for all patients in a plan, there is financial risk sharing and *financial integration* between/among the JV members (and, therefore, no *per se* illegal conduct)
    - Even without sharing of financial risk, where providers implement common clinical protocols and an active and ongoing program to evaluate and modify practice patterns and create a high degree of interdependence and cooperation to control costs and ensure quality, there is *clinical integration* (and, therefore, no *per se* illegal conduct)

## ACOs & Antitrust

- FTC/DOJ ACO Policy Statement (2011):
  - ACOs fall in safety zone if they meet CMS eligibility criteria for and participate in CMS Shared Savings Program (satisfies requirement of financial or clinical integration, so no *per se* illegal conduct)
  - Participating independent providers performing common services must have a combined market share of 30% or less in each participant's primary service area
  - Physician practices with higher market shares may still fall within safety zone, if located in rural areas
  - Hospitals and ambulatory surgery centers in an ACO must be non-exclusive to the ACO in order for the ACO to fall within the safety zone
  - Must apply rule of reason analysis to ACOs that do not participate in CMS Shared Savings Program (i.e., commercial ACOs)

## ACOs & Antitrust (cont.)

- Conduct to Avoid (from FTC/DOJ ACO Policy Statement):
  - Protect against improper sharing of competitively sensitive information that could lead to collusion in sale of services outside the scope of the ACO
  - Competitive concerns for ACO with high market share (i.e., 50% or more) may be mitigated by avoiding the following:
    - Preventing private payors from directing their beneficiaries to certain providers, even if they are outside the ACO
    - Tying sales of the ACO's services to a private payor's purchase of other services outside of the ACO (such as affiliates of a hospital)
    - Contracting on an exclusive basis with physicians, hospitals, ambulatory surgery centers or other providers
    - Restricting health plans' ability to provide enrollee access to cost, quality, efficiency and performance information

## Stark Law

- Prohibits a physician from making a referral to an entity with which the physician (or a family member) has a financial relationship, for the furnishing of “designated health services” (DHS) for which payment otherwise may be made by Medicare
- Financial Relationship:
  - A direct or indirect *ownership or investment interest* in any entity that furnishes DHS; or
  - A direct or indirect *compensation arrangement* with an entity that furnishes DHS
- Strict liability civil statute - no “unintentional” or “inadvertent” violations allowed
- Stark Law has *exceptions* that offer complete protection, if all elements are met
  - Getting “close” to an exception is of no value, because intent is not an element of the Stark Law

## Stark Law (cont.)

- Designated Health Services:
  - Clinical laboratory
  - Physical therapy, occupational therapy, and speech-language pathology
  - Radiology and certain other imaging
  - Radiation therapy
  - Durable medical equipment
  - Parenteral and enteral nutrients
  - Prosthetics and orthotics
  - Home health
  - Outpatient prescription drugs
  - Inpatient and outpatient hospital services

## Stark Law & ACOs

- In October 2011, CMS & OIG published 5 “ACO waivers” (which are not codified in the C.F.R.):
  - ACO pre-participation waiver
    - Allows an ACO participant or ACO provider/supplier (e.g., hospital) to furnish or fund ACO development services for economic benefit of all of the ACO’s participants, including referring physicians
  - ACO participation waiver
    - Allows an ACO participant or ACO provider/supplier to fund or otherwise support an ACO’s operations during the term of the ACO’s participation agreement, including arrangements benefiting other ACO participants or ACO providers/suppliers
  - Shared savings distributions waiver
    - Protects distributions to ACO participants and ACO providers/suppliers, and to outside parties if paid as compensation for activities reasonably related to the purposes of the Shared Savings Program

## Stark Law & ACOs (cont.)

- More ACO “waivers”:
  - Compliance with Stark Law waiver
    - Protects arrangements that implicate the Stark Law, and that qualify for one of the Stark Law exceptions, from liability under the Anti-kickback Statute and the Gainsharing Civil Monetary Penalties Law (no separate analysis under those statutes is required)
  - Patient incentive waiver
    - Allows ACOs to offer Medicare beneficiaries preventative care items or services, or other in-kind services or items, designed to advance certain clinical goals
- Waivers only apply to accountable care organizations with bona fide intent to participate in, or that actually participate in, the CMS Shared Savings Program (i.e., not commercial ACOs)
- Waivers are in addition to, and not in replacement of, other Stark Law exceptions

## Anti-kickback Statute

- *Criminal* offense to knowingly and willfully offer to pay, solicit or receive any remuneration to induce referrals of items or services that are reimbursable by any federal health care program
- Similar to, but broader than Stark Law
  - If even “one purpose” of the remuneration is to induce referrals, a violation may have occurred
- Intent-based statute
  - Prosecutor must prove that the defendant engaged in alleged conduct “knowingly and willfully”

## Anti-kickback Statute (cont.)

- Has “Safe Harbors,” which are similar to exceptions under Stark Law
  - Specific conditions under which various types of business arrangements are immune from prosecution
- Common themes:
  - Fair market value
  - Written agreement of at least 1 year duration
  - Commercially reasonable business purpose
- Examples:
  - Personal services & management contracts
  - Sale of practice
  - Bona fide employees
  - Group purchasing organizations

## Anti-kickback Statute & ACOs

- The 5 ACO waivers described above also apply to Anti-Kickback Statute
- Thus, payments described in the waivers will not violate the AKS prohibition on payments made with the intent to induce referrals for services that are reimbursable under Medicare or Medicaid

## Exempt Organization/Section 501(c)(3) Law & Regulations

- Exempt organization (EO) participants in a JV must ensure that their JV activities further and are consistent with their charitable missions
- EOs must ensure compliance with IRS prohibition on “private inurement”:
  - No part of the net earnings of an EO may “inure to the benefit of any private shareholder or individual” (commonly referred to as an “insider,” i.e., person having a personal and private interest in activities of the organization and (usually) in a position to exercise influence over its business or affairs)
  - Occurs only if a non-arm’s-length transaction or event involving an organization benefits an insider
- EOs may also incur “unrelated business income tax” (UBIT) at normal corporate rates, on their activities that are deemed not to be “substantially related” to the exercise or performance of their exempt function activities

## Exempt Organization/Section 501(c)(3) & ACOs

- IRS guidance released in March 2011 provides that an EO's participation in a Medicare ACO will generally be substantially related to its charitable purposes (by lessening the burdens of government), and will thus not generate UBIT
- IRS also reiterated some existing EO principles, such as:
  - Transactions among ACO participants must be fair market value
  - EO's share of economic benefits from ACO must be proportionate to its contributions to the ACO
- Unclear whether an ACO's non-Medicare activities (i.e., contracting with commercial payors) will also be considered substantially related to the charitable purposes of its EO participants

## Traditional Merger/Integration

- Comparison to ACO model:
  - Antitrust:
    - Virtually no issues with ongoing operations, at least “internally” within the merged organization, because both financial and clinical integration are achieved
    - Similar analysis with respect to formation of organization
  - Stark Law:
    - No ACO “waivers” apply, so each financial relationship between a DHS entity and a referring physician must meet one of the other Stark Law exceptions (employment, equipment & space rental, personal services, etc.)
  - Anti-kickback Statute:
    - No ACO “waivers” apply, so all remuneration between components of the organization must be analyzed to ensure that it is not made to induce referrals of items or services that are reimbursable by any federal health care program (or fits within a “safe harbor”)
  - Exempt Organization/Section 501(c)(3) Issues:
    - Very little difference between ACO and “merger”
    - IRS ACO guidance does not really provide any “extra” protection

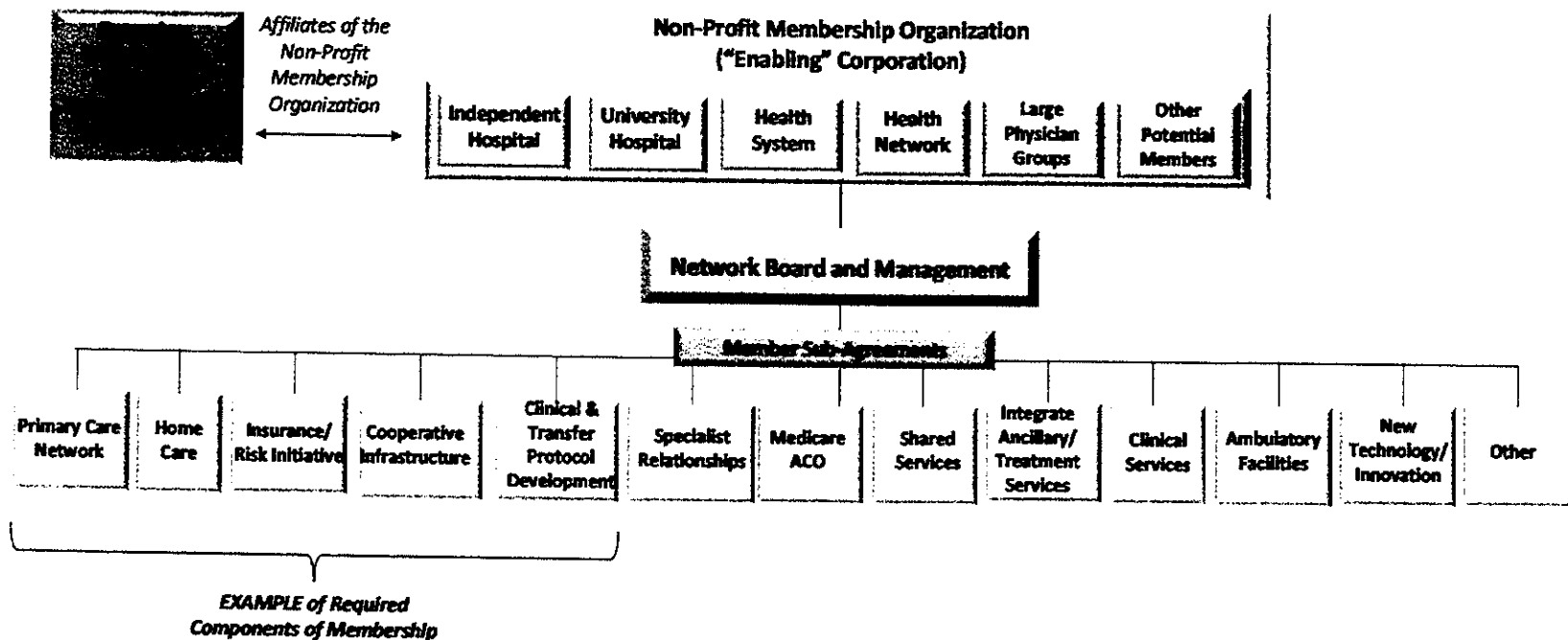
## Traditional Merger/Integration (cont.)

- Other benefits of traditional merger/integration, in relation to ACOs:
  - Centralized control over entire enterprise
  - Possibility for more economies of scale/efficiencies within organization (less duplication of support services)
  - Enhanced ability to obtain financing
  - Fewer issues with conflicting “outside” relationships and restrictions (Ethical & Religious Directives, relationships with other organizations, etc.)

## Integration Without Merger (“IWM”)

- Alternative to traditional clinical integration/merger transaction (“Merger Lite”)
- In merger, parties’ entire businesses and operations are combined
- Integration Without Merger involves two or more provider organizations collaborating on a selective basis for substantial, mutual benefits
- Usually they are brought together through creation of a non-profit membership organization, which enables them to work together in areas of mutual choosing
- Participating members can be situated within a contiguous geography or collaborate from a distance on certain initiatives (e.g., back office functions)
- Resulting relationships range in intensity, purpose and scope depending on circumstances of the participants
- Can provide “best of both worlds” since participating organizations preserve their independence while achieving many benefits similar to merger
- With IWM, both overall relationship and *each individual collaborative project/JV* must be analyzed separately under applicable legal principles

# Possible IWM Structure<sup>1</sup>



<sup>1</sup>Diagram © TRG Healthcare, LLC

Questions?