# Legal & Policy Issues Related to ACO Formation by Independent Physician Groups

Troy Barsky
Arthur Lerner
Crowell & Moring LLP
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# Background

- Government Programs
  - ACOs
    - Medicare Shared Savings Program
    - Pioneer ACO Model
  - Bundled Payment for Care Improvement
  - Comprehensive ESRD Care Initiative
  - Medicaid and Dual Eligible Initiatives
- Commercial Payer Initiatives
  - ACOs
  - Capitated / Risk Based Arrangements

# Group Practices & ACOs

- Integration:  Necessary to survive?
- Medicare ACOs
  - Beneficiary requirements
  - Most groups will need to integrate in order to participate
- Commercial ACOs
  - New generation of collaborations focused on outcomes, quality, clinical care criteria, data sharing, and cost
- Options for Integration
  - Employment
  - Joint venture
  - Loose affiliation or network
- Integration  ~ independence conundrum

# ACO challenges for “independent” physician groups

- Can physician-centric ACOs meet expertise, capital investment, and budget requirements for successful ACO operation in Medicare or commercial setting

- Can medical groups team with hospitals or others in ACOs and stay independent?
  - What does “independent” mean?
    - Separate Tax ID?
    - Self-employed?
    - Make own entrepreneurial decisions within scope of “partner” relationship?
    - Keeping all options open vs. making hard choices?

# Rock and a hard place?

- Waivers and other exceptions may provide flexibility that allows hospitals to bear brunt of cost and physicians to still quality for significant benefits
  - Will this cost physicians their independence even if they are not “acquired” and do not become employees?
  - Can medical groups take advantage of waivers’ existence without letting hospital “deep pocket” translate into effective loss of independence?

# Others in the sandbox

- Is there potential for partnering with others?
  - Managed care/health insurers – fewer fraud and abuse issues
  - Vendors of informatics
  - Ancillary health providers

# Legal compliance issues

- What are key legal concerns?
  - Overutilization
    - Stark Law / Anti-Kickback Statute
    - Medically Unnecessary Services
  - Stinting on Medically Necessary Care
    - Civil Monetary Penalties
  - Transactions by charitable organizations that involve “private inurement” or “private benefit”
  - Antitrust

# Anti-kickback law

- Knowing receipt or offer of remuneration to induce or in exchange for referring patients or ordering or recommending the purchase of services or services covered in whole or in part by Medicare, Medicaid or other federally funded health programs.

# Stark law

- Referrals by physicians to a provider of "designated health services" if the physician has a non-excepted financial relationship with the provider

# Payments to induce reduction or limitation of services

- Federal statute prohibits hospitals from making payment, directly or indirectly, to induce a physician to reduce or limit services to Medicare or Medicaid beneficiaries under the physician's direct care.

# Antitrust

- Bona fide ACO ventures face antitrust difficulties principally if they obstruct or blockade competition
- Extensive guidance available

# Fraud & Abuse waivers for Medicare ACOs

- Medicare Shared Savings Program Waivers
  - Congress authorized the Secretary to waive laws as necessary to carry out the Medicare Shared Savings Program
- Waivers issued by CMS were quite broad, but not without limitation
  - Waiver applies if terms of the waiver are met, no separate application
  - Public disclosure requirements
  - Applies to the Stark law, Anti-Kickback Statute and Civil Monetary Penalty Law.
  - Does not pre-empt state law or other federal laws such as anti-trust or tax law.

# Content of Fraud & Abuse waivers

- Pre-Participation: Covers such expenses as start-up costs
- Participation: Covers transactions during the participation period and for a reasonable time thereafter
- Shared Savings: Covers distribution of shared savings payment
- Stark Law-Compliant: If transaction is compliant with the Stark law it will be deemed to be compliant with the Anti-Kickback Statute
- Waiver for Patient Incentives: Covers in kind benefits from ACOs to beneficiaries to encourage preventative care and adherence to medical treatments

# Ongoing waiver considerations

- Broad waivers now, but will it last?
- HHS Waiver: “We plan to narrow the waivers . . . unless information gathered through monitoring or other means suggests that the waivers . . . are adequately protecting the Medicare program and beneficiaries from the types of harms associated with referral payments or payments to reduce or limit services.”
- Future Deadlines
  - Shared Savings waiver must be finalized by Nov. 2014
  - Comprehensive ESRD Care Initiative
- How many participants are taking advantage of waivers?

# IRS stance

- Private inurement or private benefit concerns addressed if
  - Arm's length written agreement governs terms for Medicare ACO
  - Exempt hospital's share of benefits/risks proportional to investment and contribution
  - Contracts and transactions entered into by the tax-exempt organization with the ACO and the ACO's participants, and by the ACO with the ACO's participants and any other parties, are at fair market value
- Distribution of shared savings should not be unrelated business income to exempt organization

# Legal & policy issues

- Contracting Issues
  - State law Requirements
    - Will they conflict with Medicare regulatory requirements?
  - Incentive payment distribution methodology
    - Transparency: Ensuring all participants agree and understand requirements.
    - Who will be responsible for coverage of shared risk?

# Legal & policy issues

- Corporate governance
  - Medicare Shared Savings Program is quite prescriptive in board structure and responsibilities
  - Most ACOs will require new corporate entity
  - Seventy-five percent of board must be comprised of representatives of participants, but that does not apply to ownership shares
  - Increased focus on board duties
  - Conflicting fiduciary duty

# Beyond Medicare – Commercial ACOs

- More flexibility in corporate structure & governance
- No new waiver protection from fraud & abuse laws so existing fraud and abuse laws apply
- Potential risk if arrangement might be viewed as kickback for referral of government business or if financial arrangement triggers Stark law exposure
- But a variety of arrangements are allowable, as providers have worked in a variety of provider network settings for many years
  - For some safe harbors, payments need to be made at fair-market value and not based on the volume or value of referrals
  - More latitude under safe harbors for physician incentive plans and under various existing risk sharing arrangement or managed care safe harbors
  - Managed Care Stark Exceptions

# Where are we now

- Current Status of Medicare ACOs
  - Approximately 250 ACOs in the program with enrollment increasing
  - Around 220 Shared Savings Program ACOs
  - 32 Pioneer ACOs
  - Collectively serving approximately 4 million beneficiaries
  - Approximately half are physician-led organizations that serve less than 10,000 Medicare beneficiaries
  - Another model is joint venturing with a managed care company – Universal American affiliates have teamed with physician groups to form a large number of Medicare ACOs
  - ACOs geographically distributed across the country, with higher concentration in metropolitan areas.

# Where is it going

- Exercise of government waiver authority?
  - Will the government extend waivers, and if so, will they be more narrow in the future?
- Other government guidance?
  - Advisory Opinions regarding specific factual scenarios
  - Fraud Alerts and Increased Monitoring by CMS or other oversight agencies
- Increased focus on board responsibility
  - Will CMS relax or modify requirements in the future to allow both commercial and Medicare ACOs to align business models?

# More crystal ball gazing

- Center for Medicare & Medicaid Innovation
  - Will CMS continue to focus on ACO model or turn to other models such as bundled payment?
  - What types of waivers will be issued for these programs?
- Will Fraud & Abuse laws change?
  - Will the government issue new regulations to allow for more innovative programs beyond demonstrations and the Medicare Shared Savings program?
  - Stark: No risk of program or patient abuse standard for new regulations
  - Legislative Change: "Improved Healthcare at Lower Cost Act of 2013."

# Back to the question

- Integration AND independence?
  - Can medical groups retain independence in ways that matter to them?
  - Numerous options available
  - Legal pathways created
  - Commitment level?
  - Partners?

# Contact Information

**Troy Barsky**

**Arthur Lerner**

**Crowell & Moring LLP**

1001 Pennsylvania Ave, NW

Washington, D.C. 20004

Phone: (202) 624-2500

tbarsky@crowell.com

alerner@crowell.com