Legal Issues Arising out of the Operation and Expansion of ACOs

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Today’s Agenda

1. Governance and Structure
2. Antitrust
3. Fraud and Abuse
4. Tax Issues
5. Liability and State Law Considerations
6. Valuation and Shared Savings Distribution
Part 1

STRUCTURE AND GOVERNANCE
ACOs: Medicare vs. Commercial

- Accountable Care Organizations (ACOs)
- Defined under Medicare Shared Savings Program and Medicare Pioneer ACO Program
- ACOs can also be structured around a commercial population typically involving a specific payor
- While shared savings and quality metrics are common to both the rules governing Medicare ACOs are very different from what parties agree upon for commercial ACOs
Medicare Shared Savings Program Requirements – Legal Structure

- Very Flexible rules on legal structure
  - Entity recognized under state law
  - Must have a TIN
  - Capable of statutory functions of ACO
  - Does not need to be a Medicare provider
Medicare Shared Savings Program Requirements – Governance

1) Need an identifiable governing board, which includes:
   - 75% ACO participants (providers/suppliers) enrolled in Medicare and have a TIN
   - One Medicare beneficiary

2) Leadership and Management, including
   - An executive accountable to the governing board
   - Senior level medical director (board certified)

3) Conflict of interest policy, which includes:
   - Disclosure of relevant financial interests
   - Includes a process to address conflict

4) Compliance functions

5) Processes to promote evidence-based Medicare, report the necessary dates to evidence quality and cost measures, and coordinate
Commercial ACOs – Legal Structure

- Separate legal entity is not necessary
- No TIN requirement
- ACO can be created by series of contracts
- If separate legal entity is created, consider choice of entity issues
  - Business corporation
  - LLC
  - Tax-exempt nonprofit corporation
  - Taxable nonprofit corporation
- Can use commercial joint venture (not permitted for MSSP)
Commercial ACOs – Governance

• Shift in orientation from participants to relative financial contributions
• Tiered management; where are decisions made
  • Owners; participants
  • Role of physicians
  • Committees
Part 2

ANTITRUST
Antitrust Context

- There are longstanding antitrust issues with provider networks that jointly negotiate with payors on price
  - Is there real integration that provides efficiencies – clinical, financial or otherwise?
  - Is joint price setting a necessary element of the network arrangement?
  - Will the venture block competition or cause harms that outweigh benefits (e.g., too much market power, or exclusivity that creates a bottleneck)?
- Medicare ACOs can involve both clinical and financial integration
What are the Antitrust Issues?

• Is the ACO fixing prices?
  • Price fixing is a “per se” offense: agreements among competitors on price are unlawful
  • Even if the competitors have no market power
• Does creation of the ACO increase market power impermissibly?
  • If the ACO is not price fixing there is a second issue: does the ACO have market power its members do not have alone so that it could raise price?
The Rule of Reason

• What’s the issue?
• Section 1 of the Sherman Act
  • Prohibits *agreements* that *reduce competition*
  • Per se rule - No harm to competition need be shown
  • Rule of Reason - Must establish harm to competition
• So: Rule of Reason treatment is important
The Rule of Reason

- Agreements among competing providers
  - Per se treatment for “naked” restraints
  - Rule of Reason treatment if “integrated” and setting price is reasonably necessary to achieve benefits
- Integrated
  - Financially
  - Clinically
The Rule of Reason

• What’s financial integration?
  • E.g. – capitation; fee schedule with a substantial risk withhold

• What’s clinical integration?
  • “the implementation by a network of an active and ongoing program to evaluate and modify practice patterns by the network’s physician participants and the creation of a high degree of interdependence and cooperation among the physicians to control costs and ensure quality”

• Qualifying ACO may jointly negotiate reimbursement terms with commercial payors without price fixing
Part 3

FRAUD AND ABUSE
MSSP ACOs: Fraud & Abuse Waivers

- CMS has established five separate fraud & abuse waivers under the Shared Savings Program.
- In general, these waivers provide considerable flexibility to MSSP participants.
- CAUTION: the waivers have been praised for their breadth but there are limits!
MSSP ACOs: Fraud & Abuse Waivers

- An “ACO pre-participation” waiver that applies to ACO-related start-up arrangements
- An “ACO participation” waiver that applies during the period of when the entity is actively participating in the Shared Savings Program and for a limited time thereafter
- A “patient incentive” waiver for in kind incentives offered by ACOs to beneficiaries to encourage preventive care and compliance with treatment regimens
- A “shared savings distribution” waiver
- A “compliance with Stark Law” waiver
**MSSP ACOs: Fraud & Abuse Waivers**

- The waivers apply only to the Shared Savings Program and participating ACOs
  - The ACA includes separate authority for Secretary to waive fraud and abuse laws for other demonstration projects and pilot programs
- The waivers only apply to Stark, anti-kickback and CMPs and **not** to any other provision of State or Federal law, including the Internal Revenue Code
- The waivers apply uniformly and are self implementing – no need to apply to CMS/OIG
MSSP ACOs: Fraud & Abuse Risks

- Operating in a manner inconsistent with the ACOs organizational documents or representations made to CMS

- Misrepresentations in reports
  - Quality Standards?
  - Other metrics?
Commercial ACOs – Stark Law

• “Financial relationships” under Stark can be created by:
  • Distribution of shared savings, other incentive payments, etc.
  • Ownership distribution if JV model used
  • EHR donation
  • Support services offered by ACO

• Must fit within Stark law exception:
  • Risk sharing exception
  • Employment
  • Personal Services
  • FMV
  • Indirect Financial Relationship
Commercial ACOs – Anti-Kickback

• Payments to physicians intended to induce or reward patient referrals may violate anti-kickback statute
• Shared savings and P4P incentive payments could implicate kickback statute
• Possible safe harbors are:
  • Managed care
  • Employment
  • Personal Services
• If no safe harbor is met, parties should ensure that fair market value payments are made for incentives, and performance metrics are set and measured objectively
Commercial ACOs – CMP Law

• Prohibits a hospital from knowingly making a payment, directly or indirectly, to a physician as an inducement to reduce or limit services provided to Medicare or Medicaid beneficiaries
• When implicated, both the hospital and physician are subject to civil penalties
• Does not apply if payments are made by non-hospital.
• If CMP applies, shared savings/quality incentive metrics should not be tied to cost reduction measures that could be interpreted to encourage reductions in care
• The OIG has published several relevant Advisory Opinions addressing gainsharing and P4P programs
**Fraud and Abuse Strategies**

- Carve-out Medicare and Medicaid patients
  - Possible spill-over problems
- Focus on managed care organization patients
  - Can be difficult to isolate measurement
  - ACO patients may only comprise small percentage of overall business
- Non-hospital entity should pay out savings and incentives
Part 4

TAX ISSUES
Tax Exempt Organizations as ACOs

• Two Questions
  • First: Can an ACO entity obtain recognition as a Section 501(c)(3) tax-exempt organization?
  • Second: Does participation in an ACO arrangement create income subject to unrelated business income tax (UBIT) for an otherwise exempt organization (EO) (usually a hospital) or endanger EO exemption?
Tax Exempt Organizations as ACOs

- Will tax exemption considerations be a major factor?
  - For the first two rounds of ACO selections in 2012, it has been reported that less than half appear to have significant hospital ownership and participation
  - Issued in concert with HHS proposed and final ACO regulations as well as antitrust guidance
Tax Exempt Organizations as ACOs

- Exemption for ACO
  - Whether ACO entity that does not itself provide health services can be exempt from federal income taxes under Section 501(c)(3) has not been tested
  - Possible exempt purposes
    - Promotion of health for benefit of the community
    - Lessening the burdens of government
    - Relief of the poor
Tax Exempt Organizations as ACOs

• In order to lessen the burdens of government, two factors must be present:
  1. The organization must demonstrate that the applicable governmental unit considers the organization’s activities to be its burden, and
  2. The organization’s activities must actually lessen the burden

• Relief of the poor may be available for Medicaid ACOs
• IRS track record on tax exemption for commercial ACOs not promising
  • History with PHOs
  • History with RHIOs
Tax Exempt Organizations as ACOs

- MSSP Participation – Unrelated Business Income Tax and Effect on Exemption per Notice and Fact Sheet
  - Private benefit and inurement
    - Case-by-case analysis, based on all facts and circumstances
    - Deference to CMS regulation and oversight of MSSP
    - IRS “expects” to not find inurement or substantial private benefit if certain factors are present including CMS has accepted ACO into MSSP
Tax Exempt Organizations as ACOs

- Other factors showing no inurement or private benefit
  - EO’s share of economic benefits (including MSSP payments) is proportional to its own benefits/contributions to ACO, taking into account all contributions made by ACO participants, whether in cash, property, or services, and all economic benefits received by participants
  - Note: doesn’t clearly distinguish between allocation of MSSP payments and allocation of ACO profit after payment to providers
  - Any EO ownership interest is proportional/equal in value to capital contributions; all returns of capital, allocations and distributions are proportional to ownership interests
  - EO’s share of losses does not exceed its share of economic benefits
  - Dealings between EO and ACO/participants are at FMV
Tax Exempt Organizations as ACOs

• MSSP Participation – Unrelated Business Income Tax and Effect on Exemption per Notice and Fact Sheet
  • Unrelated business income tax
    • Incentive payments received from ACO not from MSSP (i.e. commercial payors): UBIT? This doesn’t make sense. They are payments for services rendered by the hospital
Part 5

LIABILITY AND STATE LAW CONSIDERATIONS
ACO Liability Issues

- Theories of direct liability can be applied to an ACO
  - (e.g., if an adverse event occurs due to adherence with a clinical protocol)
- Theories of indirect liability can be applied to an ACO
  - (e.g., so-called negligent credentialing of participating providers)
State Law Issues

- Corporate Practice of Medicine
- State Physician Self-Referral Laws
- State Anti-Kickback/Fee-Splitting
- State Antitrust
- State Insurance/Managed-Care Licensing Laws
- State Taxation
Part 6

VALUATION AND SHARED SAVINGS DISTRIBUTION
Valuation of the ACO Business Equity Interest

- Parties to the ACO venture
- ACO capital intensity
  - Nature of working capital contribution
- Need for valuation of equity interests
  - Participant buy/sell transactions
  - ACO roll-ups
  - Division of enterprise equity
  - Return on equity and ROI
- Asset classes contributed to the ACO venture
  - Tangible assets
  - Intangible assets
Business Valuation Methodology Applicable to ACO Business

• Asset-based approach: Adjusted net asset method
  • Identification of asset classes
  • Fair market value inputs for each asset
    • Asset class dictates nature and degree of risk
      • Working capital
      • Tangible assets
      • Intangible assets
    • Valuation methods vary depending on asset class
  • Liabilities and other obligations
Business Valuation Methodology Applicable to ACO Business (cont.)

- Income-based approach: Discounted future cash flow method
  - Projection of ACO cash flows
    - Anticipated shared savings revenues to ACO
    - Other ACO earnings
      - Capitation
      - Fee-based earnings
  - ACO expenses and distributions
    - Administrative overhead
    - Compensation for administrative services
    - Physician compensation
    - Clinical compensation
    - Distributions of shared savings
Business Valuation Methodology Applicable to ACO Business (cont.)

- Income-based approach: Discounted future cash flow method, cont’d
  - Determination and application cost of capital
    - Unsystematic risk
    - ACO-specific unsystematic risk
      - Utilization risk
      - Liquidity risk
      - Participant mix
      - Asset mix
Business Valuation Methodology Applicable to ACO Business (cont.)

- Market-based approach
  - Limited comparable transaction data
  - Limited comparable public company data
- Discounts as applicable for lack of control and marketability
Valuation of Compensation Arrangements

• Administrative services
  • Service arrangements
    • Governance
    • Executive committee
    • Health information management
    • Quality assurance and utilization

• Compensation arrangements, including at-risk element
Valuation of Compensation Arrangements (cont.)

- Clinical services
  - Physician-employees of ACO participants
    - Alignment of incentive compensation with ACO objectives
      - Away from volume-based incentives
      - Toward quality-based incentives
    - Participation in shared savings or losses
  - Securing specialist coverage
    - ACO participant employment of specialists
    - ACO participant contracting for independent specialist availability
Return on Investment

- Nature and degree of risk associated with asset class
- “Waterfall” effects of ordering distributions
- Applied rate of return
Distribution of Shared Savings

• Hierarchy of reinvestment and distribution
  • Reinvestment in the ACO’s infrastructure
    • Technology
    • Facilities
    • Personnel
  • Unbundling among ACO participant and/or ACO provider/supplier classes
    • Hospitals
    • Physicians
    • CAHs, RHCs, and FQHCs
# Shared Savings Distribution Examples

<table>
<thead>
<tr>
<th>Fictitious MSSP</th>
<th>ACO Name</th>
<th>Notes</th>
<th>Infrastructure</th>
<th>Primary Care</th>
<th>Specialists</th>
<th>Hospitals/Inpatient Facilities</th>
<th>Physician Providers</th>
<th>Other</th>
<th>All</th>
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<td>ACO A</td>
<td></td>
<td>15%</td>
<td>30%</td>
<td>25%</td>
<td>25%</td>
<td>30%</td>
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<tr>
<td>ACO B</td>
<td>(1)</td>
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<td>25%</td>
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<td>ACO C</td>
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<td>56%</td>
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<td>ACO D</td>
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<td>36%</td>
<td>16%</td>
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<td>ACO E</td>
<td>(3)</td>
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<td></td>
<td>100%</td>
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<td>ACO F</td>
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<td>ACO G</td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td>100%</td>
</tr>
<tr>
<td>ACO K</td>
<td></td>
<td>30%</td>
<td>49%</td>
<td>21%</td>
<td></td>
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<td>ACO L</td>
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<td>33.33%</td>
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33% Median Infrastructure Allocation
Shared Savings Distribution Examples (cont.)

Notes:

• (1) Expense pool receives 50% until expenses paid; PCPs receive preferential funding at $10K per PCP, then 25% to PCP and 25% to specialists.
• (2) Hospitalists are considered part of specialist percentage.
• (3) Any shared savings will be reinvested in necessary infrastructure; some money will also be used to incentivize physicians to embrace value based care.
• (4) Facility fund surplus is divided 25% to physicians and 75% to hospital; professional fund surplus is 100% physician-allocated.
Shared Savings Distribution Examples (cont.)

• Notes, cont’d:
  • (5) 100% to cover infrastructure; 25% of any available margin after infrastructure ($2M annual cap) will repay initial investment; 75% to participants.
  • (6) 66% PCPs and FQHCs; 17% non-PCP hospitalists; 12% ACO professionals and providers; 5% hospital.
  • (7) Distribution will be modified once shared savings exceed $1 million.
  • (8) Reinvestment in infrastructure, care improvement and redesign activities: 100%.
Distribution Methodology

- Pooling models among ACO participating physicians
  - Group-focused models
  - Individual-focused models
  - Hybrid models
- Scoring participating physician performance
  - Importance of data
  - Objectivity in setting metrics and benchmarks
  - Linking physician performance to ACO objectives
Hypothetical example

Possible drivers for participants and/or providers/suppliers

- Hospitals
  - Top DRG volume
  - Bed-days
  - ER visits

- Physicians
  - PCPs: member-months, scorecard-to-cumulative-score, episodic (encounters, office visits)
  - Specialists: outcomes scorecard-to-cumulative-score, per capita, work RVUs
Distribution Methodology (cont.)

- Hypothetical Example

<table>
<thead>
<tr>
<th>Distribution</th>
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<td>Infrastructure</td>
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<td>Hospital pool</td>
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<td>PCP pool</td>
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<tr>
<td>Specialist pool</td>
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<tr>
<td>Total</td>
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**Distribution Methodology (cont.)**

- Hypothetical example (cont.)

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<td><strong>Total</strong></td>
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<td><strong>Total</strong></td>
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### Distribution Methodology (cont.)

- Hypothetical example (cont.)

<table>
<thead>
<tr>
<th>$1,200,000 Allocable Shared Savings After ROI and Operating Overhead</th>
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<tr>
<td>20 Percent Attributed to Specialist Performance</td>
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<td>Allocation to Specialists:</td>
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<td>AIM: Better Health for Populations (ACO Measures 14–33)</td>
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<td><strong>Total</strong></td>
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Questions?

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