NAVIGATING THE LEGAL ISSUES OF A COMMERCIAL ACO

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COMMERCIAL ACO

What is it?

It’s likely to be:

- Stand alone arrangement negotiated with a payor
- A CMS approved entity authorized under Health Care Reform

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What is it?

- No other widely recognized structure or specific definition\(^2\)

- Common themes of reduction of cost increases; financial incentives to improve quality and patient experience for defined group

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Basic Structure

- The ACO may be expected to:
  - Provide an administrative structure and a network of providers, both integrated (employed by ACO organization) and independent providers
  - Have written agreements with network providers in place
    - Amendment needed for ACO requirements or compliance?
  - Obtain patient/member authorizations or consents, if necessary, for participation in ACO
  - Assume provide greater responsibilities
    - Cost and quality reporting
    - Clinical care standards and coordination of reporting
    - Administrative responsibilities for ACO administration
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Basic Structure

- Limited Liability Company structures/capital
  - ACO ability to repay losses; financial security/guarantee

- There may be an “attribution of patients” methodology for tracking of patients and financial calculations

- Additional MSSP ACO requirements include: legal status; shared governance; leadership and management; size of network; evidence-based medicine; beneficiary engagement; internal reporting on quality and cost; care coordination; patient-centeredness criteria; and compliance

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Contract Provisions

- Parties: ACO as a separate legal entity.\(^3\)

- Claims data
  - Who owns it, has access to it, and what audit rights exist? What can it be used for?

- Communications with members/patients and process for review and approval of those communications.\(^4\)

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\(^3\) See, supra, n.1, and 42 C.F.R. §425.104(a) requiring MSSP ACO to be a “legal entity” that is formed or recognized or authorized under applicable state, federal or tribal law and is authorized to conduct business in each state in which it operates.

\(^4\) See, 42 C.F.R. 425.310 for MSSP ACO marketing communications restrictions and 425.312 concerning notification to beneficiaries.
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Contract Provisions

- Information technology
  - ACO products and software; payor interface and system requirements
  - Provider system requirements and associated costs
  - ACO and/or provider network eligibility to access and use payor or ACO IT applications
    - Provider use for non-ACO patients

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5 See, 42 C.F.R. 411.357(u) and (v) for Physician Self-Referral (“Stark”) Law exceptions for community-wide health information systems and electronic prescribing items and services.

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Contract Provisions

- Competition
  - The commercial payor may request protections against the provider network or ACO competing against the payor. The scope of the competition restriction is important for ACO or providers to consider in relation to other commercial or governmental payor or ACO applications.
  - The ACO may seek protection against the payor competing with the ACO or excluding the ACO provider network from other products.
  - Potential for illegal restraints of trade, tying arrangements, group boycotts, and market divisions exists.

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6 See generally, 42 U.S.C. 18042(c)(3)(B) concerning ACA Section 1322 Consumer Operated and Oriented Plans (“CO-OPs”) and the governance requirements in relation to “insurance industry involvement and interference.”
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Contract Provisions

- HIPAA privacy and security standards/confidentiality
  - Reasonable efforts to limit the requested information to the minimum necessary to accomplish the purpose of the intended use, disclosure or request
  - Tracing the PHI, analyzing its uses and assuring appropriate for treatment, payment or health care operations
  - State law provisions more restrictive in mental health, genetic testing and HIV/AIDS information; see also federal substance abuse treatment program requirements, 42 C.F.R. Part 2.

MSSP “look-alike” provisions: MSSP compliance; number of members; quality assurance and improvement; promote evidence-based medicine; patient engagement; member access to information; coordination of care; member choice; cost shifting; required referrals; compliance plan.

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7 See, 42 C.F.R. 425.100 et seq. for MSSP ACO requirements.
8 See, 42 C.F.R. 425.304 for MSSP ACO prohibitions on illegal inducements, certain required referrals and cost-shifting prohibitions.
9 See, 42 C.F.R. 425.300.
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Contract Provisions

- Independent medical judgment vs. care coordination and practice standards

- Cooperation with payor audits and evaluations
- Rights to data and intellectual property
- How to resolve questions that arise during the term of the agreement\(^\text{10}\)
- Changes in law provisions\(^\text{11}\)

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\(^{10}\) See, 42 C.F.R. 425.214 applicable to MSSP ACOs.

\(^{11}\) See, 42 C.F.R. 425.212 applicable to MSSP ACOs.
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Contract Provisions

- Termination provisions
  - Basic negotiated terms including breach of the ACO agreement
  - MSSP “look-alike” terms for too few attributed members; no “shared savings” revenue; no longer CMS approved ACO;\(^\text{12}\) or breach of competition terms

- Record Retention
  - Ten years for MSSP ACO arrangements\(^\text{13}\)
  - How long do records of commercial ACO waiver-type “arrangements” need to be retained?

\(^\text{12}\) See, 42 C.F.R. 425.216-220 applicable to MSSP ACOs.

\(^\text{13}\) See, 42 C.F.R. 425.314(b)(2).

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Understanding The Payment Mechanism

- Better able to identify issues, negotiate and understand agreement
- Measurement, performance and changes during the term of the agreement

- Lawyer’s understanding is critical:
  - Contracting
  - Antitrust/healthcare regulatory analysis
  - State insurance/regulation considerations
State insurance regulation

- CMS may require ACOs to provide a statement of compliance from the state insurance regulator

*We would emphasize that under the Shared Savings Program, the Medicare program retains the insurance risk and responsibility for paying claims for the services furnished to Medicare beneficiaries, and that the agreement to share potential losses against the benchmark would be solely between the Medicare program and the ACO.*


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The Pioneer ACO Model Innovation Agreement, section J, requires:

*The Pioneer ACO must comply with state laws applicable to risk bearing entities, or provide a written attestation to CMS that it is exempt from such licensure or other related licensure requirements based on discussion with appropriate state agency.*

- Is commercial ACO appropriately licensed as “risk-bearing entity” under Iowa law, is it exempt or is it an organized delivery system?  

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14 See, 641 Iowa Admin. Code Ch. 201, concerning organized delivery systems.
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Payment Structure Can Affect More Than Finance

- The payment mechanism can determine how the commercial ACO contracts on behalf of the ACO network of providers
- Is an MSSP ACO involved?
- Is there a sharing of substantial economic risk?

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Single Signature Authority

- In order for a commercial ACO to be able to jointly negotiate payor arrangements on behalf of a network of providers that includes independent providers who are also competitors:
  - The ACO must be an MSSP ACO;
  - The ACO network must share substantial economic risk; or
  - The ACO network providers must be sufficiently clinically integrated

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15 Other ACO initiatives sponsored by the Center for Medicare & Medicaid Innovation are given the same treatment so long as those ACOs are substantially clinically or financially integrated. See infra n.28.
17 See, FTC cites relating to Clinical Integration, infra at pp. 32-33.
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Payment Structure Can Affect More Than Finance

Reimbursement Methods

- Fee for Service “plus”
- Quality incentive payments
- Bundling
- Partial capitation
- Capitation

Form of Agreements/Antitrust Analysis

- Messenger model; independence in pricing & markets
- Single signature, sharing of substantial economic risk

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Clinical Integration Can Affect More Than Care Delivery and Patient Experience

Degree of Clinical Integration

- Independent Providers
- FTC Advisory Opinions
- MSSP ACO

- The degree of clinical integration in a commercial ACO provider panel can determine if the ACO can contract on behalf of all members of the provider panel.

- This “single signature authority” can exist when independent providers are sufficiently clinically integrated; when they share substantial economic risk; or when the ACO is a CMS approved ACO (that is substantially clinically or financially integrated contracts on behalf of the providers).
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Regulatory Analysis

- Clinical and financial relationships may implicate
  - Physician Self-Referral Law\textsuperscript{18}
  - Anti-Kickback Statute\textsuperscript{19}
  - Gainsharing Civil Monetary Penalties Law\textsuperscript{20}
  - Beneficiary Inducements Civil Monetary Penalties\textsuperscript{21}
  - Antitrust Laws\textsuperscript{22}
  - Federal and/or state income or real estate tax exemption provisions
  - Any state self-referral or anti-kickback laws

\textsuperscript{18} 42 U.S.C. 1395nn
\textsuperscript{19} 42 U.S.C. 1320-7b(b)
\textsuperscript{20} 42 U.S.C. 1320a-7a(b)(1) and (2)
\textsuperscript{21} 42 U.S.C. 1320a-7a(a)(5)

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Regulatory Analysis

- If the commercial ACO is a CMS approved MSSP ACO, the availability of applicable waivers\textsuperscript{23} needs to be reviewed for possible application to the commercial ACO arrangement. If there is not a CMS approved ACO, then the regulatory analysis of the commercial ACO may be different. Contract provisions addressing the parties’ intent in this regard could be considered. (Fair market value; no benefit for referral of patients, etc.)

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Regulatory Analysis If MSSP ACO Is Involved

- Consider MSSP Waiver availability – no clear or express application to commercial ACOs stated in the MSSP regs\textsuperscript{24} or the OIG Waivers.\textsuperscript{25}

\textsuperscript{24} Supra, n.1.
\textsuperscript{25} Supra, n.23.

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Regulatory Analysis If MSSP ACO Is Involved

- Antitrust Statement\textsuperscript{26} contains express application to commercial ACOs:

  \textit{The Policy Statement is intended to ensure that health care providers have the antitrust clarity and guidance needed to form procompetitive ACOs that participate in both the Medicare and commercial markets.}\textsuperscript{27}

  ...  

  The analytical principles underlying the Policy Statement also would apply to various ACO initiatives undertaken by the Innovation Center within CMS as long as those ACOs are substantially clinically or financially integrated.\textsuperscript{28}

- First step only; market power analysis necessary.\textsuperscript{29}

\textsuperscript{27} \textit{Id.} (emphasis added).  
\textsuperscript{28} \textit{Id.}, n.19.  
\textsuperscript{29} See, FTC/DOJ Statement safety zone and conduct to avoid discussion. \textit{Id.}, n.26.
ACO governance and membership needs to be reviewed if payor relationships change.
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Regulatory Analysis – Additional Antitrust Consideration

- ACO governance and membership needs to be reviewed if payor relationships change.

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Regulatory Analysis – If No MSSP ACO Is Involved

- Antitrust –
  - Understanding payment mechanism (fee for service vs. capitation)
  - If the network of providers is integrated into a single economic entity under Copperweld, single signature authority applies.
  - If the network of providers has independent providers, the following methods of operation should be considered:
    - Messenger model if fee for service and inadequate clinical integration
    - Sharing of substantial economic risk could permit single signature authority
    - Clinically integrated network could permit single signature authority
    - FTC/DOJ Statement applicability

31 4 Trade Reg. Rep. (CCH) ¶13,153 at 20,831.
32 Supra, n.17.
33 4 Trade Reg. Rep. (CCH) ¶13,153 at 20,817.
34 Supra, n.26.
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Regulatory Analysis – If No MSSP ACO Is Involved

- Physician Self-Referral (Stark) Law compliance considerations –
  - Is a provider involved who bills for “designated health services” that are paid under a government health care program (Medicare or Medicaid)?
  - Will arrangement meet the risk sharing exception?\(^\text{35}\)
  - Is arrangement consistent with Affordable Care Act triple aim?
  - Might the Waivers apply?

\(^{35}\) See, 42 C.F.R. 411.357(n).

- Anti-Kickback Statute –
  - No remuneration or benefit to (1) induce referral or furnishing of item or service paid for by federal health care program; or (2) the purchase, lease or order of any good, facility, service or item paid under a federal health care program.
  - Managed care exception applicable?\(^{36}\)

\(^{36}\) See, 42 C.F.R. 1001.952(o).
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Regulatory Analysis:

- Scope of providers to whom shared savings can be distributed
  - MSSP rules may restrict to only those ACO participants or providers/suppliers with whom ACO has a written agreement
  - Relevant to scope of “waiver” protection
  - Shared Savings Distribution Waiver language: “or (b) used for activities that are reasonably related to the purposes of the Shared Savings Program.” (76 Fed. Reg. 68,001 (Nov. 2, 2011).

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Regulatory Analysis:

- Documentation of “reasonably related” purposes
  - What are the “reasonably related” to the purposes of the ACO “look-alikes” for commercial ACOs? How do you document consistencies with the ACA triple-aim (better care for individuals; better health for populations; lower growth of health care expenditures)?
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Regulatory Analysis: Tax Exemption Issues


- IRS Fact Sheet 2011-11 (October 20, 2011) – IRS released additional guidance on tax exempt organization involvement with ACOs
  - Reflects more flexible approach to commercial ACOs
  - Non-MSSP activities not inconsistent with tax exempt status
  - Non-MSSP ACO possible qualification for exemption not ruled out

Clinical Integration Authorities


Clinical Integration Authorities


- In re Alta Bates Medical Group, Inc. FTC, No. 051 0260, settlement announced June 4, 2009