Accountable Care Organizations

Implications Under Physician Self-Referral, Anti-Kickback, Civil Monetary Penalty and Antitrust Laws

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Medicare Accountable Care Organizations: Section 3022 of Affordable Care Act Basic Requirements for ACO Participation

- Formal legal structure to receive and distribute shared savings
- Minimum of 5,000 assigned beneficiaries
- Sufficient number of primary care professionals and sufficient information on professionals for beneficiary assignment and payments
- Participation in program for at least three years
- Leadership and management structure (including clinical and administrative systems)
- Processes to promote evidence-based medicine

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Qualification for Shared Savings

- Participating ACO must meet specified quality performance standards for each 12-month period
- Eligibility to receive share of any savings
  - Actual per capita expenditures of assigned Medicare beneficiaries must be sufficient percentage below specified benchmark
- Benchmark
  - Based on most recent three years of per-beneficiary expenditures for Part A and B service for Medicare fee-for-service beneficiaries assigned to ACO

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What ACO Legal Issues Covered Today: Issues Within Jurisdiction of Federal Trade Commission (FTC), Centers for Medicare & Medicaid Services (CMS) and Health and Human Services (HHS) Office of Inspector General (OIG)

- What ACO legal issues not covered today
  - Federal income tax exemption issues for tax-exempt hospitals
  - State law issues
  - Contract law/Contract enforceability issues

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Civil Monetary Penalty Law (CMPL)

- Prohibits a hospital from knowingly making payments to a physician to induce reduction or limitation of services to Medicare or Medicaid Beneficiaries

Anti-Kickback Statute (AKS)

- Prohibits payment, or offer of payment, to induce referral of items/services covered by Medicare/Medicaid

Physician Self-Referral Law/Stark

- Physician prohibited from referral of Medicare/Medicaid patients for designated health services to an entity with which physician has a financial relationship unless the relationship falls within an exception

ACOs Implicate CMPL, AKS and Stark

- Physicians in ACO paid share of any cost savings and based on quality performance standards

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ACO Problem With CMPL, AKS and Stark

- No statutory or regulatory safe harbor or exception specific to ACOs
- Existing safe harbors/exceptions
  - Limited usefulness

CMPL/AKS

- OIG advisory opinions on gainsharing
- OIG will not impose sanctions if sufficient safeguards to ensure quality of care

Favorable Features of Advisory Opinions

- Current members of hospital's medical staff
- Participation by a group of at least five physicians
- Payment by hospital to group of physicians on an aggregate basis
- Payment by physician group to each physician on *per capita* basis
- Objective measurements for changes in quality
- Annual resetting of cost savings baselines
- Independent reviewer/auditor to review program prior to commencement and annually
- Cost sharing capped at 50% of cost savings
- Duration of program
  - No more than three years
- Written notice to patient prior to procedure

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2008 Proposed Stark Exception for Incentive Payment and Shared Savings Programs

- Transparency
- Quality controls
- Safeguards against payment for patient referrals

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Quality or Cost Savings Measures

- Objective methodology
- Verifiable
- Supported by credible medical evidence

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Independent Medical Review

- Prior to implementation and annually

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Physician Participation and Payment

- Only physicians currently on medical staff
- Pools of at least five physicians
- Payment to each physician on *per capita* basis
- Cap at 50% of cost savings
- Duration of 1-3 years

Cost Savings

- Savings measured from baseline standards
- Annual rebasing of quality standards

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Quality of Care

- Must show actual improvement from baseline standard
- No payment if quality of care diminished

Documentation

- All documents available to Secretary upon request
- Notice/Disclosure to patients

Other Requirements

- In writing
- Compensation formula set in advance
- Not based on volume/value of referrals
- Minimum term of one year

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Panelists for CMP/AKS/Stark

- Jeffrey Micklos, Esq. – Federation of American Hospitals
- Jonathan Diesenhaus, Esq. – American Hospital Association
- Tom Wilder, Esq. – Association of Health Insurance Plans
- Marcie Zakheim, Esq. – National Association of Community Health Centers
- Robert Saner, Esq. – Medical Group Management Association
- Ivy Baer, Esq. –Association of American Medical Colleges
- Chester Speed, Esq. – American Medical Group Association
- Jan Towers, Ph.D., CRNP, American Academy of Nurse Practitioners
- Nora Super - AARP

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OIG/CMS Overview

- How Secretary should exercise waiver authority
- Safeguards needed under waiver
- Future: Beyond waiver authority, other exceptions/safe harbors

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Dr. Berwick's Triple A Objectives

- Better care for patients
- Better health for public generally
- Lower cost per capita

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Will waiver positively affect ACOs and, if so, how?

If decide to exercise waiver authority, what needs to be included in waiver?

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Assuming waiver authority is exercised, what else should HHS consider?

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What types of providers and business arrangements should waiver cover?

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What safeguards should be part of waiver?

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Types of monitoring

Self monitoring

Government monitoring

What is the role of IT/EHR?

Legal Structure / Governance

- Should HHS dictate specifics regarding legal structure and governance?

Future: Beyond Waiver Authority

- What is working under current fraud and abuse laws and what can be used to build on?

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Antitrust

- Prohibited Activities
  - Pricing fixing among competing providers
  - Division of geographic markets
  - Division of product markets
  - Mergers which may substantially lessen competition
  - Monopolization and attempted monopolization

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Antitrust (cont'd)

- Illegal Group boycotts through wrongful or exclusionary means
- Sharing of confidential fee and other competitive information

Antitrust (cont'd)

- Statutes
  - Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1,2
  - Sections 7 of the Clayton Act, 15 U.S.C. § 18
  - Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45
  - State Antitrust Laws

Antitrust (cont'd)

- Guidance/Enforcement Policies
  - Statements of Antitrust Enforcement Policy in Health Care ("Statements")
  - Horizontal Merger Guidelines

Antitrust (cont'd)

- Enforcement Agencies
  - Department of Justice
  - Federal Trade Commission
  - State Attorneys General

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Antitrust (cont'd)

- ACOs
  - Most ACOs will involve multiple independent providers
    - Hospitals
    - Physicians
    - AHPs
    - Medical Home
    - Surgicenters
    - Nursing Homes

Antitrust (cont'd)

- Under different arrangements
  - Employment
  - Independent Contracts
  - Multispecialty physician groups
  - Joint ventures
  - Co-management arrangements

Antitrust (cont'd)

- ACO Antitrust Issues
  - Price fixing among independent competitors in non-risk arrangements with private payors

    Note:

    - In Medicare/Medicaid arrangements where government unilaterally sets the price, there are no antitrust issues
    - How are contracts being negotiated?
    - Is ACO and its provider members at "financial risk" – capitation, bundled fees, global fees?

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Antitrust (cont'd)

  - Has ACO achieved sufficient "clinical integration" to allow contract negotiations on behalf of all ACO members?
  - Will CMS/FTC/OIG view a certified ACO as a clinically integrated arrangement for antitrust purposes or "presumptively integrated"?
- Division of geographic and/or product markets
  - This conduct reduces competitors and consumer options and is likely to lessen competition and decrease quality

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Antitrust (cont'd)

- Mergers, affiliations, acquisitions which may substantially lessen competition
  - The development of ACOs will likely trigger more consolidation activity among providers
  - Existing standards under Merger Guidelines and case law will clearly monitor resulting combinations within each strata of providers i.e., hospitals, physicians by specialty
  - FTC/DOJ will examine either before or after the fact if the ACO is exclusive and posseses market share beyond safety zone safe harbors (20% exclusive and 30% non-exclusive)

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Antitrust (cont'd)

- Will CMS also be evaluating an ACO's market power with FTC before certification is given?
- If smaller states are urging larger systems and groups to participate in ACOs, will this preempt federal intervention under state action doctrine if actively monitored by the state?

- Illegal group boycotts
  - Excluding access to ACO
  - Refusals to deal with payors

FTC Comments, Questions and Panel Responses

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FTC Panelists

- Gloria Austin, Brown & Toland
- Terry Carroll, Fairview Health Services
- Dr. Lawrence Casalino, Weill Cornell Medical College
- Mary Jo Condon, St. Louis Area Business Health Coalition
- John Friend, Esq., TMC HealthCare
- Dr. Robert Galvin, Equity Healthcare
- Elizabeth Gilbertson, HEREIU Welfare Fund
- Douglas Hastings, Esq., Epstein, Becker Green
- Harold Miller, Center for Health Care Quality and Payment Reform
- Dr. Lee Sacks, Advocate Physician partners & Advocate Health Care
- Dr. Dana Safran, BC/BS Massachusetts
- Trudi Trysla, Fairview Health Services
- Joseph Turgeon, CIGNA
- Dr. Cecil B. Wilson, American Medical Association
- Dr. William C. Williams, Covenant Health Partners/Covenant Health Care
- Dr. Janet S. Wright, American College of Cardiology

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Proposed Safe Harbor Under Consideration

- Newly formed joint venture or legal entity must comply with all statutory and regulatory requirements under Section 3022 of the Affordable Care Act
- Must participate in the Medicare shared savings program

Proposed Safe Harbor Under Consideration (cont'd)

- The operational processes, procedures, policies, etc., for Medicare patients and private pay patients must be the same
  - FTC to apply a rule of reason analysis
  - Proposed safe harbor to be unveiled during the Fall
  - FTC considering whether CMS certification of ACO, which requires adoption of clinical and administrative systems, evidence-based medicine, etc., will be treated as sufficiently clinically integrated for purpose of negotiating price on behalf of all ACO providers with private payors

Other Clinical Integration Factors

- Mechanisms to provide cost effective quality care
- Standards and protocols to govern treatment and utilization of services
- Information systems to measure and monitor individual physician and aggregate network performance

Other Clinical Integration Factors (cont'd)

- Procedures to modify physician behavior and assure adherence to network standards and protocols
- Web-based health information technology system that will help identify high-risk and high-cost patients and will facilitate the exchange of patients' treatment and medical management information in order to more aggressively manage patients care than could achieve working independently

Other Clinical Integration Factors (cont'd)

- Develop clinical practice guidelines and monitor physicians adherence to them
- Develop software to review episodes of care, i.e., all of the medical care and services a patient receives from the onset of an illness or disease through final treatment to determine where performance improvement will have the greatest financial and quality benefits

Other Clinical Integration Factors (cont'd)

- Information used to review and, as appropriate, modify specific clinical guidelines or care protocols
- Identify instances of both overutilization and underutilization of services with physicians to address these issues

FTC Questions

- How many years of performance outcomes and metrics should FTC review in determining whether quality of care is improving?
- What, if anything, should FTC do if prices are increasing during this interim period?
- Given the existing safe harbors in the Statements related to market share, should there be a separate safe harbor specific to ACOs?
- How large must an ACO be in order to deliver care effectively?

FTC Questions (cont'd)

- Has there been much consolidation or announced consolidation since passage of the Accountable Care Act?
- Should any proposed safe harbor consider the geographic area in which providers compete differently than currently assessed?
- To what extent can exclusivity increase an ACO's market power? Is exclusivity necessary in order to be successful?

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