

Large Urology Group Practice Association

Accountable Care Organizations

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Basic Premise for ACOs

- Facilitate medical care coordination among providers
- Improve quality of care
- Reduce unnecessary spending

Dr. Berwick – CMS Administrator

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

ACO Vision

- A care delivery organization (not a financing mechanism)
- Patient at center of activity
- Memory about patients
- Attends to hand off of patients from one part of health delivery system to another
- Waste and inefficiency reduced
- Investments where they count
- Prevention and proactive
- Reduce dependence on hospitals
- Data-rich
 - Track outcomes over time
 - Transparency on costs
- Better care at lower costs
- From fragmented to integrated care

Medicare Shared Savings Program and Medicare Accountable Care Organizations: Section 3022 of Affordable Care Act

- Definition of “Accountable Care Organization”:

An organization of healthcare providers that agrees to be accountable for the quality, cost, and overall care of Medicare beneficiaries, enrolled in the fee-for-service program and who are assigned to it.

Organizations that may Become Medicare ACOs

- Physicians and other professionals in group practices
- Physicians and other professionals in networks of practices
- Partnerships or joint venture arrangements between hospitals and physicians/professionals
- Hospitals employing physicians/professionals
- Other forms as determined by HHS Secretary

CMS Regulations

- Better define eligibility
- Clarify permissible levels of integration

Basic Statutory 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

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 must be sufficient percentage below specified benchmark
- Benchmark
 - Based on most recent three years of per beneficiary expenditures for Part A and B services for Medicare fee-for-service beneficiaries assigned to ACO
- No penalty if fail to reach savings target

Assignment of Medicare Beneficiaries to ACO

- Assigned beneficiaries: Those beneficiaries for whom ACO providers provide bulk of primary care services
- Assigned beneficiaries not limited to ACO and its providers – Can seek services from other providers of choice
- CMS process for assignment of beneficiaries?

ACO Legal Issues

- Federal fraud and abuse and physician self-referral laws
- Antitrust laws
- State fraud and abuse and self-referral laws
- State corporate practice of medicine laws
- State HMO/insurance/managed care contracting laws
- Federal income tax exemption issues for tax-exempt hospitals

Civil Monetary Penalty Law (“CMPL”)

- Prohibits a hospital from knowingly making payments to 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

ACO Problem Under CMPL, AKS and Stark

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

Existing Regulatory Guidance

- OIG Advisory Opinions on gainsharing
- Proposed Stark exception for incentive payment and shared savings program

Favorable Factors Common to OIG Advisory Opinions and Proposed Stark Exception

- 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

CMS October 5 Workshop on Accountable Care Organizations

- Federal Trade Commission (“FTC”)
 - Antitrust
- HHS Office of Inspector General (“OIG”)
 - Civil Monetary Penalty Law and Anti-Kickback Statute
- Centers for Medicare and Medicaid Services (“CMS”)
 - Physician Self-Referral Law/Stark

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

OIG/CMS Overview

- Section 3022 Waiver Authority
- How Secretary should exercise waiver authority
- Safeguards needed under waiver
- Future: Beyond waiver authority, other exceptions/safe harbors

OIG/CMS Questions to Panel

- Waiver v. exception
- Broad waiver v. case-by-case waiver
- Types of monitoring: self v. government
- Role of IT/EHR
- Legal structure/governance

Antitrust

- Price fixing
- Division of markets (geographic and product)
- Mergers which lessen competition
- Monopolization and attempted monopolization
- Illegal group boycotts

Price Fixing

- Sherman Act Section 1 prohibits contracts, combinations and conspiracies that unreasonably restrain trade
 - Applies to:
 - Independent, competing providers
 - Does not apply to:
 - Physicians within the same group practice
 - A hospital and its full-time, employed physicians
 - A hospital and its controlled affiliates

Price Fixing

- *Per se* illegality vs. rule of reason
- Rule of reason
 - Anti-competitive effects v. pro-competitive efficiencies

Pro-Competitive Efficiencies

- Improve quality
- Reduce costs

Pro-Competitive Efficiencies cont'd

- Financial integration
 - Capital investment in necessary infrastructure
 - Financial risk
- Clinical integration
 - Clinical protocols addressing utilization and quality
 - Program to evaluate and modify practice patterns
 - Interdependence and cooperation among physicians to control costs and achieve quality

Price Fixing

- Independent competitors in arrangements with private payors
 - Is ACO and its providers at “financial risk”?
 - Has ACO achieved sufficient clinical integration?
 - Will a CMS-approved Medicare ACO be entitled to antitrust protection?

Mergers

- Will development of ACOs trigger more consolidation of providers?
- Is ACO dominant in its market?
- Is ACO exclusive? (Providers negotiate with payors only through ACO and may not join other ACOs)

Group Boycotts

- Excluding access to ACO
- Refusals to deal with payors

FTC Panel

- 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

Proposed Safe Harbor Under Consideration

- Newly formed joint venture must comply with all statutory and regulatory requirements under Section 3022 of the Affordable Care Act
- Must participate in Medicare-shared savings program
- Procedures and policies must be same for Medicare patients and private pay patients
- Rule of reason analysis

ACO Scale

- How large must ACO be for effectiveness?
- Importance of scale
 - To measure performance and achieve program objectives
 - To spread costs of infrastructure, staff and other resources
 - To spread risk effectively
- Scale v. Market Power

ACO Exclusivity

- Can non-exclusive ACO be effective?
- Can non-exclusive ACO achieve clinical integration?

FTC Questions to Panel

- 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 (FTC/Justice Department 1996 Statements of Antitrust Enforcement Policy in Health Care), should there be a separate safe harbor specific to ACOs?
- How large must an ACO be in order to deliver care effectively?

FTC Questions to Panel cont'd

- Has there been much consolidation or announced consolidation since passage of Affordable 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?

How Will Specialists Participate in ACOs?

- Hospital Driven Models
 - Covenant Health Partners
Lubbock, Texas
 - Tucson Medical Center
Tucson, Arizona
 - Advocate Physician Partners and Advocate Healthcare
Oak Brook, Illinois
- Physician Group Driven Model
 - Patients First Health Care
Washington, Missouri

Open Questions

- Will financial rewards be enough to justify the costs of becoming a certified ACO?
- How can ACOs control costs and maintain quality outcomes if they do not manage 100% of the patient's medical services? (Freedom of assigned Medicare beneficiaries to go outside their assigned ACO)
- What mechanism will CMS develop to assign beneficiaries to ACOs?
- What are the criteria CMS will use to determine which groups qualify to be ACOs?

Open Questions cont'd

- How is CMS going to assess quality across different organizations with different patient populations?
- How will CMS attribute savings (against ACOs own prior performance or against similar ACOs)?
- Participation of medical and surgical specialists in ACOs?