Accountable Care Organizations – The Future Integrated Health Care Delivery Model?

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Discussion Items

• ACOs and Their Role in Health Reform
• Many Unanswered Questions – The Inter-Agency Meetings in DC
• Possible ACO Structural Models for Health System
• Antitrust and Clinical Integration Issues
• Fraud and Abuse, Stark and CMP Considerations
• State Law Issues
Accountable Care Organizations (ACOs)-
The Future of Health Care Delivery?

Is this the only real reform of the health care delivery system in the Patient Protection and Affordable Care Act (PPACA)?
What The PPACA Does

• Insures 35 million uninsured Americans by adding 20 million to Medicaid and creating the state health benefit exchanges to expand the market for individuals and small business.

• Adds extensive new federal regulation of private health insurance plans.

• Expands quality, innovation and efficiency efforts through new demonstration projects and pilot programs.
What The PPACA Does Not Do

• **Does not** insure every person in the country.
  – 23 million will remain uninsured

• **Does not** create a new payment system.
  – Medicaid, Medicare, employer-provided, medigap, and state exchange-based insurance will coexist; fee-for-service payment will still be the standard.

• **Does not** restructure the delivery of health care, but sets in motion a potentially significant change—the ACO.
What is an ACO?

- Sections 3022 and 10307 of the PPACA (PL 1110-148) set out the framework for Medicare ACOs to be implemented by January 1, 2010. However, CMS still has to issue rules before stakeholders can decide to participate. A proposed rule is to be issued by the end of 2010.

- The basic premise for ACOs is that they can facilitate medical care coordination among providers to improve the quality of care for Medicare beneficiaries and reduce unnecessary spending. Private health plans could also find ways to work with Medicare qualified ACOs.

- The ACO provisions are part of the law’s Medicare “Shared Savings” programs, sending the clear signal that ACOs will be expected to reduce Medicare spending.
Administration Sees the ACO as a Key Element in Health Reform

• White House has hosted meetings on ACOs.

• White House is pushing regulators (CMS, OIG, FTC and others) to find ways to make ACOs work.

• White House is pushing CMS to have listening sessions with stakeholders before writing the draft rules and has set an aggressive rulemaking schedule.
Here Is What the PPACA Says About ACOs

• An Accountable Care Organization is defined as an organization of health care providers that agrees to be accountable for the quality, cost, and overall care of Medicare beneficiaries enrolled in the traditional fee-for-service program who are assigned to it.

• For ACO purposes, “assigned” means those beneficiaries for who the professionals in the ACO provide the bulk of primary care services. Assignment will be invisible to the beneficiary, and will not affect their guaranteed benefits or choice of doctor.
Here Is what the PPACA Says About ACOs (continued)

• A beneficiary may continue to seek services from the physicians and other providers of their choice, whether or not the physician or provider is a part of an ACO.

• Organizations that may become a Medicare recognized ACO include:
  – 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; and
  – Other forms that HHS may determine to be appropriate.
More PPACA Requirements

- Requirements an organization will have to meet to be a Medicare ACO
  - Have a formal legal structure to receive and distribute shared savings;
  - Have a sufficient number of primary care professionals for the number of assigned beneficiaries, which will be 5,000 at a minimum;
  - Agree to participate in the program for at least a 3-year period;
  - Have sufficient information regarding participating ACO health care professionals as the Secretary determines necessary to support beneficiary assignment and for the determination of payments for shared savings;
  - Have a leadership and management structure that includes clinical and administrative systems;
  - Have defined processes to (a) promote evidenced-based medicine, (b) report the necessary data to evaluate quality and cost measures (this could incorporate requirements of other programs, such as the Physician Quality Reporting Initiative (PQRI), Electronic Prescribing (eRx), and Electronic Health Records (EHR)), and (c) coordinate care; and,
  - Demonstrate it meets patient-centeredness criteria, as determined by the Secretary, such as the use of individualized care plans.
More PPACA Requirements (continued)

• Qualifying for Shared Savings
  
  – CMS will set annual Medicare savings benchmarks for ACOs based on previous per-beneficiary expenditures for Parts A and B services. The benchmark for each ACO will be adjusted for beneficiary characteristics and other factors determined appropriate by the Secretary, and updated by the projected absolute amount of growth in national per capita expenditures for Part A and B.

  – ACOs that meet the specified quality performance standards will be eligible to receive a share of any savings if the actual per capita expenditures of their assigned Medicare beneficiaries are a sufficient percentage below their specified benchmark amount. There are no penalties for ACOs that do not meet the savings targets.
Potential Legal Conflicts

• ACOs could run afoul of several federal laws
  – Stark
  – Anti-kickback
  – Civil money penalties
  – Antitrust
  – Federal Trade Commission
Will the Legal Conflicts Be Resolved?

• The Secretary of HHS has authority to waive many Medicare requirements that might impede the development of ACOs but must seek cooperation of other agencies to waive other laws.

• FTC, OIG and CMS held a public meeting to discuss these problems and hear from stakeholders.

• Requires complex, nearly simultaneous rulemaking to avoid conflicts and encourage participation.
Other Issues to be Resolved

- The lack of specificity in the statute and the limited real world experience with ACOs means that there are many important questions that will need to be addressed by federal regulators and potential participants.
  - Will the shared savings justify the costs of becoming an ACO?
  - Can ACOs control costs and maintain quality if they don’t control all of the patient’s medical services?
  - What mechanism will CMS use to assign beneficiaries to ACOs?
  - What criteria will CMS use to determine who qualifies to be an ACO?
  - How is CMS going to assess quality across diverse organizations with different patient populations?
  - On what basis will CMS attribute savings?
  - How will specialists participate in ACOs?
  - Are there state and federal tax implications if for-profit medical practices and not-for-profit hospitals and other institutions try to form joint venture ACOs?
  - Keep an eye on MedPac and the Physician Group Participation (PGP) Demonstration Project
ACOs: Legally Flexible Concept

- Example of existing entities that can qualify:
  - An IDS with hospitals, physicians and other providers under common control
  - Affiliated Provider Network (clinically and/or financially integrated)
  - An MSO Integration Model (EMR deployment) with Affiliated IPA
  - Multispecialty Group Practice
  - PHO (clinically and/or financially integrated)
  - A joint venture of two or more of the aforementioned
Affiliated Physician Organization ACO Model

Health System Parent

Hospital

ACO

Affiliated Group Practice

Payors
Physician-Hospital Organization (PHO)-ACO Model

- Health System
- Hospital
- Physician Organization
- ACO
- Payors

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MSO Integration ACO Model

System Parent

Payor

MSO/ACO

Hospital

IPA

MD

MD

MD

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Hospital Physician Employment ACO Model

Health System

Hospital

ACO

Payors

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Comprehensive Health System ACO Model

Health System

- Affiliated Medical Group
- Hospital
- Home Health
- Clinics
- SNF

IPA

ACO

Community Physicians

Payors

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ACO Challenges: Financial & Governance

• Multiple Payors providing inconsistent incentives
• Cost of Infrastructure/EMR
• Decisions on Dollar Allocations
• Composition of ACO Governing Board (Physician Leadership)
• Decision Making Committees (Compensation, Finance, Quality, Technology)
• Moving from Shared Savings model (Level I ACO) to Bundled (hospital-physician) and Capitation (Level III ACO) Payments
Legal Challenges and Considerations

• Antitrust Issues
• Clinical Integration-what is it?
• Anti-kickback/Stark/CMP Laws
• Tax Exemption
• Patient Privacy and Sharing Data
• Florida State Law Issues
Antitrust Issues:

• Can ACO participants jointly contract with Payors?

• Agreements between two or more “non-integrated” entities that unreasonably restrains trade prohibited [Sherman Act Sec 1]

• If providers in an ACO are considered a single entity – they are incapable of violating Section 1

• If not considered a single entity, do the ACO providers demonstrate sufficient financial and/or clinical integration?
Antitrust – (cont.)

• 1996 FTC DOJ Health Care Statements of Antitrust Enforcement Guidance are Outdated

• New “Safety Zones” for ACOs that achieve health reform goals (improved care at lower costs) are needed

• Financial Integration (Capitation, Bundled Payments)

• Clinical Integration - The New Normal
Clinical Integration—What Is It and Why Is It Important?

• Factors relevant to FTC analyses of clinical integration programs, Instructive Favorable Advisory Opinions
  – Participants accountable for care outcomes
  – Evidence based clinical protocols and processes outcomes
  – Use of health information technology
  – Non-exclusive contracting by physicians
  – Joint contracting is ancillary to expected procompetitive (expanding service, cost savings, measured quality improvement)
Antitrust Market Power Must be Considered

• Market Power
  – Overinclusive
  – Foreclosures on competition
  – Safety zones?
Anti-kickback/Stark/CMP Laws

• Current legal framework focuses on abuses of FFS Payment System (over-utilization, payment for referrals, underutilization of needed hospital care)

• Health Reform – will change the existing Payment System

• New Financial Relationships emerge from ACO Models that do not fit the existing legal paradigm
New ACO Financial Relationships:
New ACO Financial Relationships:

- ACOs receipt of payment from Payor
- ACOs payments to the providers
- Distributions to the ACO owners
- Other potential relationships between/among the providers outside the ACO structure
- Is the ACO a provider on its own?
- How are specific payment models addressed (Shared Savings Program, Bundled and Capitation Models)
New ACO Shared Savings/Gainsharing Arrangements

• These arrangements have been analyzed (but not in context of ACOs)
• OIG Gainsharing Opinions (AKS/CMP)
• Stark Proposed Exception (July 2008)
• Employment exceptions (under AKS and Stark)
• Are these sufficient to work in ACO context using Shared Savings Model (in 2012)
• Advisory Opinions and Proposed Stark Exception are narrow and have numerous Safeguards
Shared Savings/Gainsharing: Safeguards

- Evidentiary support for quality/performance targets
- Certain Targets may be inappropriate (which ones?)
- Need historical and clinical measures to set the targets
- Written disclosure to Patients
- No disproportionate focus on Medicare/Medicaid
- Per capita distributions to physicians
- Reasonable time limit (1-3 years)
- Amount of incentive limited
- Participation restricted to existing physicians on medial staff (no new referrals)
Bundled Hospital-Physician Payments: Stark

• What Stark exceptions are available for these payments from ACO to participants?

- Employment?
- Risk Sharing?
- Personal Services/FMV/Indirect Compensation?
Bundled Hospital-Physician Payments: AKS

• What Safe Harbors are available for ACO payments to providers?

- Employment?
- Risk Sharing?
- Personal Services/Management Contract Safe Harbor (set in Advance, FMV, not based on V/V of referrals or other business)?
Bundled Hospital-Physician Payments: CMP

- Is Hospital payment involved?

- Physician Incentive Payment Rules (PIP)?
- Need additional flexibility for new ACO Models
ACO-Tax Exemption?

• Key 501(c)(3) Consideration:

ACO must organize and operate exclusively (primarily) for charitable purposes and

– No private benefit (de minimus amount of earnings/profits may be distributed to nonexempt entities or individuals, non-insiders)

– No Private Inurement (physicians are insiders; per se violation, no de minimus exception)
ACO-Tax Exemption (cont’d)

Key Questions:

• Can Nonprovider ACO contracting entity be tax-exempt?
  – IRS Rulings on PHOs and MSOs are instructive
  – Community benefit analysis (reducing health care costs and medical
    errors furthers charitable purpose – provision of health care services not
    necessary; Community Board emphasis)

• Will participation in a taxable ACO jeopardize 501(c)(3) health
  system status?
Sharing Patient Data in ACOs

HIPAA Analysis: Can ACO Providers share PHI?

• **Affiliated Covered Entities** – ACO with two or more covered entities under common control – acts as a single CE for HIPAA Compliance

• **Organized Health Care Arrangement (OHCA)** – ACOs separately owned covered entities may share PHI to manage any “joint health care operations”

• **ACO/MSO Integration Model** – ACO Participants have a Business Associate Agreement with the MSO
ACO Affiliated Covered Entities: HIPAA

Health System Parent

ACO

Hospital

Affiliated Physician Group

Nursing Home

ACO Participants
ACO – OHCA Sharing: HIPAA

ACO

Payor

Hospital

Cardiology Group

Co-Management of Cardiovascular Service Line Program

Contractual JV Hospital/Physician Committee

(Separately Owned Covered Entities)

PHI

PHI

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ACO/MSO Integration Model: HIPAA
Florida State Law Issues for ACOs

- Health Care Clinic Act
- Patient Brokering Act/Fee-Splitting Prohibition
- State Patient Privacy Laws
- Fiscal Intermediary Service Organization ("FISO")
- Third Party Administrator ("TPA") license
Florida State Law Issues (cont’d)

Health Care Clinic Act

• Is the ACO entity a “CLINIC” – does ACO provide health care services and tender charges for reimbursement of services

• Non Provider ACOs should not be subject to 400.990 Licensure

• Provider ACOs may be exempt from 400.990 (e.g. ACOs owned by hospitals)
Florida State Law Issues (cont’d)

**Patient Brokering Act**  [817.505 F.S.]

- Criminal Statute prohibiting of any commission, rebate, bonus, kickback, or engaging in split fee arrangements in return for referring patients/patronage to a health care provider

- New financial arrangements among ACO participants and new payment models raise issues

- If AKS Safe Harbor Met – home free
Florida State Law Issues (cont’d)

Patient Privacy Laws

• Florida stricter than HIPAA

• Notice of Privacy Practice – Inclusion of ACO uses of medical information

• Patient Consent authorizing disclosure to ACO and purpose of disclosures/uses/healthcare operations

• Treatment of Sensitive Information (HIV, substance abuse, mental health)
Florida State Law Issues (cont’d)

- **Fiscal Intermediary Services Organization Registration** [641.316]
- Does ACO perform “fiscal intermediary services” requiring registration?
- Passed in 1997 to deal with companies that arranged and administered “provider networks for HMOs
- FISO services include: receiving reimbursements on behalf of providers, performing accounting, financial reporting, compensation and other fiduciary services for providers pursuant to their contracts with HMOs
- Exempted entities: FISO owned by hospitals, insurers, TPAs, physician group practices
- Non Provider ACOs contracting with HMOs may be subject to registration (Fidelity bond requirements)
Florida States Law Issues (cont’d)

**Third Party Administrator** [626.88 F.S.]

- Is ACO an “administrator”? Does it adjust or settle claims for ERISA plans, health insurers, under health care risk contracts with an insurer/HMO, or perform billing and collection services on behalf of health care providers?

- Possible Exemption: ACOs for hospitals providing billing claims and collection services solely for hospital and its physicians’ behalf for services under the scope of Chapter 395
Next Steps:

• Assess the Systems “Accountable Care Capabilities”
• What Scope of Services will be offered through the ACO?
• Which Providers and Care Settings should be involved?
• What is the status of Clinical Integration (processes and technology – EMR/EH strategies)?
• What is the geographic market (any Market Power concerns)?
• Consider participating in ACO Rule Making Process
• Begin exploring possible ACO Models
• Assess commercial payor interest to test innovate payment projects through the ACO
• Assess system’s ability to assume risk through an ACO model
• Consider participation in Demonstration/Pilot programs (“First-Mover Advantages”)
Questions and Discussion