Accountable Care Organizations
After Healthcare Reform
Structuring ACOs That Avoid Violations of Antitrust, Fraud, Patient Privacy and Stark Laws

A Live 90-Minute Teleconference/Webinar with Interactive Q&A

Today’s panel features:
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Accountable Care Organizations under the PPACA:
Delivery System Reform

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Today’s Agenda

- Health Care Delivery Reform Through Accountable Care Organizations (“ACOs”) under the Patient Protection and Affordable Care Act (“PPACA”)
- ACO Organizational Issues
- ACO Legal Issues

“If you build it, they will come.”
-- Field of Dreams
What is an Accountable Care Organization ("ACO")?

- An ACO is an organization of physicians and other health care providers accountable for the overall care of traditional fee-for-service Medicare beneficiaries who are assigned by CMS to an ACO.
- ACOs are to be financially incentivized by CMS to provide higher quality care and overall cost savings.
- By January 1, 2012, the Secretary of HHS must establish a shared savings program that:
  - promotes accountability for a patient population;
  - coordinates items and services under Medicare parts A and B; and
  - encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery.
What is the Pediatric Accountable Care Organization Demonstration Project?

- Allows qualified pediatric health care providers that agree to be accountable for quality, cost, and overall care of Medicaid and SCHIP beneficiaries to receive payments as ACOs under Medicaid and SCHIP.
- Individual states must submit an application to the Secretary of HHS in order to participate; pediatric ACOs then contract with their approved state.
The new Center for Medicare and Medicaid Innovation ("CMMI") is developing new funding mechanisms to enhance quality and achieve cost savings through ACOs.

CMS stated during its ACO Open Door Forum on June 24, 2010, that it plans to propose ACO regulations in the fall of 2010.

An audio recording and transcript of the CMS Open Door Forum: Medicare Shared Savings Program: Accountable Care Organizations (ACOs) will be posted to the Special Open Door Forum website at, http://www.cms.hhs.gov/OpenDoorForums/05_ODF_SpecialODF.asp and will be accessible for downloading beginning on or around Wednesday, July 7, 2010.
ACOs in a Nutshell

- Groups of providers would work together to manage and coordinate care for Medicare fee-for-service beneficiaries
- Those ACOs that meet quality performance standards will be eligible to receive additional Medicare payments based on risk-adjusted shared savings against historical benchmarks
- Locally focused on quality and cost across the continuum of care
- Inter- and multi-disciplinary care coordination
- Built on collaboration and shared responsibility/accountability
ACOs in a Nutshell (Cont’d)

- Enhanced ability to capture and report data
- Not limited to a single group of providers (e.g., contemplates a full range of providers) or single episode of care (e.g., contemplates bundled case rate payments covering the care of a patient’s entire diagnosis, sometimes called Episode Treatment Groupings or “ETGs”)
- Migration from volume/intensity of care to efficiency and quality
- Financial Model: Shared Savings
Key Elements of an Effective ACO

- ACOs must be aligned with “high value” networks of PCPs, specialists, hospitals, and ancillary providers focused on enhanced outcomes and cost efficiency
- Explicit care integration and coordination mechanisms
- Payment arrangements with governmental and commercial payors that reward cost-effective, high-value (not high-volume) health care and improved outcomes
- Patient-centered “medical homes” that act as a tool to better deliver primary care and coordinate care
- Health information infrastructure to enable community-wide care assessment and coordination, including functional integrated electronic health records (“EHR”)
ACOs – What They Are and What They Are Not

- ACOs are organizational structures to incubate, facilitate, and implement innovative quality care coordination and incentive payment arrangements.

- ACOs are not required to follow a single prescribed organizational form and are not necessarily limited to Medicare.

- “Clinical integration” is at least as important as “Corporate Integration.”

- ACOs require a comprehensive information infrastructure to enable quality care assessment and coordination, including state-of-the-art integrated electronic health records ("EHR").
PHOs vs. ACOs

**PHOs**
- Insurance Risk
- Panel of patients
- Scrum for Share of Revenue
- Charge Based
- Managed Care Leverage
- Pay for quantity (covered lives) and cost savings
- Shared hospital physician governance
- Intervention/episode of care-focused
- Financial and some clinical Integration as necessary to achieve antitrust compliance

**ACOs**
- Performance Risk
- Population of patients
- Rational Allocation of Revenue
- Value Based
- Care Coordination
- Pay for quality and greater cost savings
- Physician leadership – shared governance not required but advised
- Prevention-focused and patient centric care
- Greater clinical and financial integration to achieve efficiencies and quality improvement as well as antitrust compliance
Integration Is More Than Collaboration

- Benchmarking
- Monitoring, Reporting, Counseling
- Performance Improvement Tools
- Technology Infrastructure (e.g. EHR)
- Accountability of Participating Providers and Appropriate Sanctions (Financial and Non-Financial) for substandard performance
- Performance-Based Provider Compensation
  - Productivity
  - Quality
  - Improvement
Requirements for ACOs

- Must have defined processes to promote evidence-based medicine, report on quality and cost measures, and coordinate care

- Must enter at least a 3-year agreement with HHS and have at least 5,000 Medicare beneficiaries, without engaging in risk selection

- Must demonstrate that it meets the defined criteria for “patient-centeredness”
  - Patient and caregiver assessments
  - Use of individualized care plans
Requirements for ACOs (Cont’d)

- Must be accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to ACO; yet apparently no restrictions on beneficiaries receiving non-emergency care from non-ACO providers!

- If the ACO is to be accountable for the overall care of a defined population of Medicare beneficiaries, how can the ACO be successful if its assigned Medicare beneficiaries are not “locked-in” to the ACO providers?
Requirements for ACOs (Cont’d)

- Formal legal structure permitting receipt and distribution of any shared savings and quality bonuses to participating providers
- Sufficient primary care physicians for assigned panel patients (to be determined by CMS)
- As a practical matter, each PCP should have an exclusive contract with only one ACO
- Specialists generally need not be restricted to one ACO (though perhaps exceptions for cardiologists, oncologists, or other “quasi-PCP-gate-keeper” specialists?)
ACOs are about Quality & Cost

- ACOs need to have the ability to capture and report data, at the group and individual provider level, relating to measures necessary to evaluate the quality of care furnished.

- To earn incentive payments, the ACO will be expected to meet Medicare performance standards measuring the quality of care furnished.

- ACOs will be expected to improve the quality and cost of care furnished over time by meeting continually enhancing quality and decreasing costs.
ACOs are about Quality & Cost (Cont’d)

- In determining the quality of care furnished by an ACO, CMS will measure:
  - clinical processes and outcomes
  - patient and caregiver perspectives on care
  - utilization and costs (such as rates of admissions and readmissions) against historical benchmarks [Insert graph?]

- If already cost-effective, will providers be financially penalized by being held to a higher benchmark standard?
ACO Threshold Decisions

- Providers should not wait for new Medicare ACO regulations to become effective
  - Should immediately begin converting existing managed care integrated delivery systems (e.g., PHOs, contractual Hospital/Medical Group/IPA risk-sharing affiliations) into ACOs
  - HMOs and Insurers/PPOs, including Self-funded Employers/Union Trust Funds, will want to contract with ACOs, particularly due to new medical-loss ratio (“MLR”) requirements under the PPACA
Significant Unanswered Questions About ACOs

- What is the minimum organizational effort that is needed to have a successful ACO effort?
- How many PCPs, medical specialists, surgical specialists, hospitals, and other providers need to participate in an ACO to make it effective?
- Will specialists and even PCPs be willing to participate in ACOs given increasingly low levels of Medicare reimbursement and uncertainty of “shared savings” bonuses? How will CMS ensure that ACOs have the ability to provide real-time data related to the ACO program?
- What level of savings below historical Medicare costs will trigger eligibility for bonus payments?
- How will shared savings/compensation be easily and quickly allocated and paid by the ACO to its participating providers?
- How can broad participation in ACOs be achieved in markets where one hospital/system has significantly more market power than other providers? Will weaker providers be left out in the cold?
Significant Unanswered Questions About ACOs (Cont’d)

- Will CMS risk-adjust benchmark reporting to avoid penalizing ACOs that treat very ill patients?
- Can Medicare beneficiaries seek care from providers outside the ACO network?
- Will beneficiaries retain freedom of choice in selecting their individual physicians in an ACO?
- How will beneficiaries be assigned to ACO (e.g., prospective assignment)?
- How will CMS ensure that ACOs have the ability to provide real-time data related to the ACO program?
Possible Comprehensive Health System
ACO Legal Structure

(note that an ACO, in theory, may involve just a single physician group rather than a comprehensive hospital-physician integrated health system legal structure)
Types of ACO Models

- Highly Integrated Models
  - Hospital Employment Model
  - Tax Exempt Affiliated Practice Model
  - Foundation Model

- Partially Integrated Models
  - Joint-Ventured Physician Organization
  - PHO Model

- Contractual Affiliation Models
  - Affiliation Model
  - Management Services Model
  - Service Line Co-Management Model
Highly Integrated Models – Hospital Employment Model

- SYSTEM PARENT
  - HOSPITAL
    - MEDICAL DIVISION (Dept. of hospital)
  - ACO
    - Payors
Highly Integrated Models – Medical Foundation Model

- **SYSTEM PARENT**
  - **HOSPITAL 501(C)(3)**
  - **ACO**
  - **MEDICAL FOUNDATION 501(C)(3)**
  - **GROUP PRACTICE (For Profit)**

- **Payors**
Partially Integrated Models – Joint-Ventured Physician Organization
Partially Integrated Models – PHO Model

SYSTEM PARENT

HOSPITAL 501(c)(3)

ACO CONTRACTING ENTITY (For-Profit)

PAYORS

MEDICAL GROUP (For-Profit)
Contractual Affiliation Models – Affiliation Model

- SYSTEM PARENT
  - ACO
  - HOSPITAL 501(c)(3)
    - ALLIED PROVIDERS
    - IPA
    - MEDICAL GROUP (For-Profit)
Contractual Affiliation Models – Management Services Model

- Provides comprehensive management services to a physician organization in exchange for a fair market value management fee

- The physician practice retains responsibility for and control over practice operations, including financial risk
Contractual Affiliation Models – Service Line Co-Management Contract Model

- **Hospital**
  - Co-Management Fee
- **Newco**
  - Co-Management Co.
  - Specialist
- **Service Line Leadership Council or Operating Committee**
  - Appoint Members
  - Quality Committee
  - Finance Committee
  - Operations Committee
  - Technology & Products
ACO REIMBURSEMENT REFORM AND IMPLICATIONS

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ACOs: Reimbursement Reform

• ACOs to be Effective Will Require Changes in Reimbursement
• ACOs Are Designed to Move From Fee-For-Service Payment of Physicians and Place Risk and Accountability on Providers (Mostly Physicians)
Reimbursement Reform (continued)

• Reimbursement Designed to Reward Efficient Care/Good Outcomes and/or Penalize Failures to Deliver Either

• Reimbursement Will Drive Provider Behavior
Reimbursement Reform (continued)

• Today, Fee-For-Service Payment of Physicians (There is No Real Management of Medicare Physician Services)

• Moving to:
  – Shared Savings Programs (Required By 1/1/12)
  – Bundled Payments/Case Rates
  – Global Payments/Partial Cap
Shared Savings Programs

• Logical First Step Transition: Upside Reward Without Downside Risk

• ACO Assumes Care for a Population With Projections of Expected Cost of Providing Care

• Paid Fee-for-Service With Potential for Additional Payments if (A) Quality Performance Standards Met and/or (B) Costs Redirected Below Benchmark
Shared Savings Programs (continued)

• PPACA Authorizes Secretary to Utilize Specified Payment Models Other Than SSP
  – Partial Capitation Where ACO at Financial Risk for Some, But Not All, of Part A and Part B Services (Such as All Physician Services Provided to a Set Population Over a Set Time)
  – Secretary May Substitute Any Payment Model That the Secretary Determines Will Improve Quality and Efficiency
Shared Savings Programs (continued)

• What Services May ACOs Provide?
• What Services Are Covered and Which Excluded?
• What Are Quality Standards and What Sets Them Apart?
• How Are Cost Benchmarks Set (Adjustments For Age, Sex, Health Conditions, Severity)? Can They Be Measured?
• How Will ACO Contract With Payors?
• What If Out-Of-Network Services Needed?
• How Will ACO Be Paid? How Will ACO Share Payment?
• Do Benchmarks Get Rebased?
• How To Assure No Stinting On Care?
• What Infrastructure Is Needed?
Bundled Payments/Episodes of Care

• One payment for an Episode of Care, Combining Hospital/Physician and Perhaps Other Services in One Payment

• Secretary Required to Establish a Pilot Program for Integrated Care During an Episode of Care Around a Hospitalization
Bundled Payments/Episodes of Care (continued)

• Downside Risk of Services Provided by Different Providers
• In Essence a Budget is Set for An Episode of Care
• Promotes Integrated Care and Efficient Provision of Care by All Involved
• Incentivizes Collaboration
• However, No Incentive to Avoid Episodes of Care in the First Place
In the Bundled Pilot Program

- Secretary Selects Up to 10 Conditions
- Look at Applicable Services to Include:
  - Acute Care Inpatient Services
  - Physician Services In and Out of a Hospital
  - Hospital Outpatient Services
  - Post Acute Services
In the Bundled Pilot Program (continued)

• Episode of Care
  – 3 Days Prior to Hospitalization
  – During Length of Inpatient Stay
  – 30 Days Post Discharge
• Reimbursement For All Services Included in Treating the Condition During the Episode of Care
  – Sole Payment (No Fee-for-Service)
  – Also Patient Assessment and Quality Measures
• No Specification on How Bundled Payment To Be Shared With Those Providing Care
Bundled Payment Issues (continued)

• Key Issues with Bundled Payments:
  – What Services Are Conducive To Being Paid on an Episode of Care/Bundled Payment?
  – What Range of Services Are Included in the Episode of Care?
  – Can ACO Participating Providers Furnish All of the Bundled Services?
  – How Does ACO Ensure Patient Will Follow-Up With ACO Providers and Remain In-Network?
  – What if Patient Experiences Another Medical Condition During the Treatment Period?
  – How is Bundled Rate Set?
Bundled Payment Issues (continued)

– Based on What Data is Bundled Rate Determined?
– What are Quality Standards and How are They Set?
– Do Rates and Quality Standards Adjust Over Time?
– Who Measures Compliance With Quality Standards and How are They Measured?
– How is Cost of Care Benchmark for the Episode Determined?
– What Administrative Infrastructure is Needed to Track and Measure Quality and Cost?
– How to Avoid Stinting?
– How Does ACO Share Bundled Payment Among Participants (and Out-of-Network Providers)?
– Any Limits on Cherry-Picking Patients?
– Who Credentials the Participants in the ACO?
Global Payment/Partial Cap

- Payments to Furnish All or Part of (For Example, Physician Only) Care For a Given Population of Patients Over a Time Period
- Eliminates Volume-Based Payment Incentives
- A Budgeted Cost/Utilization and Associated Payment for ACOs for All or Part of Care for a Population Over a Defined Period
- Often Risk Adjusted Payments (For Such Things as Age, Health Status, etc.) to Help Avoid Providers from Taking "Insurance Risk"
- Still Significant Downside to ACOs and ACO Participants
Global Payment/Partial Cap (continued)

• Key Issues in Global Payments:
  – What Services Are Covered and Which Are Excluded (e.g., Vision, Dental, Mental Health, Neonatology, Pediatric Specialty Surgery, Ambulance)?
  – What is Spectrum of Services Provided by the ACO and What Costs Can it Control?
  – How Will ACO Contract For and Control/Manage Out-Of-Network Services?
  – How to Utilize Outliers?
  – On What Data Are Global Payments Based?
  – Is it Possible that Providers Will Not Assume “Insurance Risk?”
  – What Stop Loss and Risk Corridors Apply; Is Reinsurance Available?
Global Payment/Partial Cap (continued)

- How To Share Payment and Risk Among ACO Participants And At What Levels?
- What Patient Incentives Will Apply (Co-Pays, Deductibles, In-Network Incentives)?
- What Risk Adjusters Apply and How?
- How Will Payments Be Adjusted to Account for Changes In Demographics and Health Conditions?
- Are Payments Adjusted for Eligibility and Fraudulent Identity Risks?
- Who Determines Medical Necessity?
- How To Assure Quality and How Are Quality Standards Set?
- Who Credentials the Participants in the ACO?
- How to Avoid Stinting on Services?
- How to Manage IBNR?
- How to Limit Cherry-Picking of Groups and Avoidance of Sicker Patients/Groups?
Overriding Payment Issues

• If Goal is to Transform How Health Care is Delivered and Given Expense of Providing Accountable Care, it is Critical that Both Private Payors as Well as Government Programs Participate and Utilize ACOs and Similar Payment Arrangements
• Rates Must be Adequate to Fairly Compensate Providers
• What of Unique Attributes of Specified Providers (Children's Hospital, Long Term Acute, Psych Hospital, Sole Community Hospital, CAHs)
• In New Payment Arrangement How Does System Pay For: Capital, Medical Education, Innovation, Geographic Variation - Adequacy of Payment Issue
• Issues of Cost Shift from Below Cost Providers
ACO Legal Issues

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Legal Issues

- Antitrust/Clinical Integration and Market Concentration Issues
- Fraud and Abuse/Stark/CMP
- Tax exemption issues for exempt hospitals
- Representative State Law Issues: HMO/Insurance, Corporate Practice of Medicine, Peer Review
Antitrust & Clinical Integration

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Can ACO participants jointly contract with payors?
- Single Entity
- Financial Integration
- Clinical Integration
- Market Power
Tests for Determining Unreasonable Restraint of Trade

- **Per se**: so obvious that the challenged activity is anti-competitive that there is no need to review facts: Conclusive Presumption of Illegality

- **Rule of Reason**: defendants can prove that pro-competitive benefits outweigh anti-competitive effects

- Prohibits agreements between two or more non-integrated entities that unreasonably restrains trade
If providers in an ACO are considered a single entity, they are incapable of violating Section 1.

If providers in an ACO are not considered a single entity, then they must demonstrate sufficient financial and/or clinical integration through which they can operate as a single entity for antitrust purposes.
ACOs & Antitrust (Cont’d)

- **Financial Integration**
  - Capitation
  - Percentage of premium
  - Withholds
  - Bundled payments

- **Clinical Integration**
  - Four advisory opinions; three favorable
  - Match PPACA clinical integration requirements
### ACOs & Antitrust (Cont’d)

The FTC has considered other factors, as well, in its evaluation of clinical integration programs to achieve procompetitive efficiencies that will benefit patients/consumers.

<table>
<thead>
<tr>
<th>ACO Requirements</th>
<th>MedSouth</th>
<th>GRIPA</th>
<th>Tri-State</th>
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<tbody>
<tr>
<td>Accountable for quality, cost and overall care of patients</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Formal legal structure that allows organization to receive and distribute payments</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Includes sufficient number of primary care physicians for number of patients</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Leadership and management structure that includes clinical and administrative systems</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Reports on quality, utilization and clinical processes and outcomes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Defines processes to promote evidence-based medicine, reports on quality and cost measures, and coordinates care, such as through use of telehealth, remote patient monitoring, and other technologies</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Meets patient-centeredness criteria specified by HHS</td>
<td>TBD</td>
<td>TBD</td>
<td>TBD</td>
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The FTC has reviewed and approved the following provider networks whose clinical integration programs have been reviewed and approved in advisory opinions:

- Tri-State
- MedSouth
- GRIPA
## ADDITIONAL FACTORS RELEVANT TO FTC ANALYSIS OF CLINICAL INTEGRATION PROGRAMS

<table>
<thead>
<tr>
<th>FACTOR</th>
<th>MedSouth</th>
<th>GRIPA</th>
<th>Tri-Health</th>
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<tbody>
<tr>
<td>Use of health information technology</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Physician investment of capital</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Non-exclusive contracting by physician members</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Joint contracting ancillary to expected procompetitive efficiencies</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Enforcement mechanisms to ensure member compliance</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Policy statements by federal officials recognize that clinical integration can achieve pro-competitive benefits

- Efficiencies → cost savings passed to consumers
- Improvements in **quality**
- Expanding services beyond current offerings
ACOs & Antitrust (Cont’d)

- Market Power
  - Overinclusive
  - Forecloses competition
  - Safety Zones
    - Exclusive vs. non-exclusive physician networks
Antikickback/Stark/CMP Law

• Today Three Principal Laws Designed To Regulate Fraud and Abuse in Fee-For-Service Health Care Financial Relationships
  – Antikickback Statute (AKS) (42 U.S.C. 1320a-7b(b))
  – Stark Law (Stark) (42 U.S.C. § 1395nn)
  – Civil Monetary Penalty Law -- Limiting Hospital Payments to Reduce or Limit Provision of Medical Care (CMP Law) (42 U.S.C. § 1320a-7a(b)(1))
Current Laws Principally Address

• Potential for Overutilization in Our Fee-For-Service Payment System
• Removal of Financial Considerations from Medical Decision-Making
• No Payments for Referrals
• Unfair Competition
• In Hospital PPS System: Avoid Stinting on Care (Underutilization of Necessary Care)
With ACOs

• Change in Our Payment System
  – Moving Toward
    – Payment for Better Outcomes (Meeting Quality Targets)
    – Provision of More Efficient Care, Avoiding Unnecessary Care (Lowering Costs) While Not Stinting on Medically Necessary Care
    – More Risk on Providers to Make Them Accountable
Nature of Financial Relationships

• ACO Receipt of Payment From Payors
• Payments by ACO (or Payors) to Provider Participants
• Distributions by ACO to Any Equity Owners
• Do ACO Owners and Participants Have Other Relationships Outside of ACO Structure? Does any Fee-For-Service Business Remain?
Effect of ACO Legal Structure on Legal Analysis

- Integrated Delivery Systems with Participants All in a Single Entity or Fully Controlled Entities and With Employed Physicians
- Academic Medical Center
- Partially Integrated with Some Independents
- Independent Providers Linked by Contract
- ACO with Equity Owners (Including Physicians) vs. Non-Stock Tax-Exempt Entity
- Is ACO a Provider on its Own?
• How Will AKS, Stark and CMP Law Apply to
  – Shared Savings Programs
  – Bundled Payments
  – Capitation Programs
Share Savings/Gainsharing Programs

- Have Been Analyzed
- Still Fee-For-Service Arrangements
- OIG Special Advisory Bulletin in 1999
- Gainsharing Advisory Opinions Under AKS and CMP Laws
- Stark Law Proposed Exception July 7, 2008
- Employment Exceptions Under AKS and Stark (But Not the CMP Law)
- Academic Medical Center
Share Savings/Gainsharing Programs

Advisory Opinions and Proposed Stark Exception

- Narrow Pathway with Many Safeguards
- Do They Provide Sufficient Flexibility for ACOs to Work?
- Safeguards Include:
  - Evidentiary Support for Quality/Performance Targets
  - What Targets are Inappropriate?
  - Objective Historical and Clinical Measures to Set Targets
  - Written Disclosures to Patient of Participants and Their Participation
  - No Disproportionate Focus on Federal Health Care Program Patients
  - Independent Monitoring To Ensure Quality of Care Delivered
  - Per Capita Distributions to Physicians
  - Reasonable Time Limitation of One to Three Years
  - Amount of Incentive Limited in Amount
  - Restricted Participation to Existing Physicians on Staff: So as Not Used to Pick Up New Referrals
BUNDLED PAYMENTS AND GLOBAL OR PARTIAL CAPITATION

• Focus on Sharing of Payments by ACO
• Stark Law: What Exceptions Are Available?
  – Employment
  – Academic Medical Center
  – Risk Sharing
  – Personal Services/Fair Market Value/Indirect Compensation
BUNDLED PAYMENT/CAPITATION Stark Law (continued)

• Personal Services, Fair Market Value, and Indirect Compensation
  – Volume or Value of Referrals or Other Business Generated
  – Fair Market Value Compensation
  – Compensation Set in Advance (Not in Indirect Compensation Exception)
  – Commercially Reasonable (Not in Personal Services Exception)
  – No Activity that Violates Promotion of Federal Law

• In this Context:
  – What is FMV?
  – Can Compensation Be "Set in Advance?"
  – Is Compensation Commercially Reasonable?
  – Does it Violate Other Laws? (CMP Law?)
BUNDLED PAYMENT/CAPITATION
Anti-Kickback Statute

• Focus on Payments from ACO to Participants
  – Employment
  – Risk Sharing
  – Personal Service and Management Contract Safe Harbor
    • Set In Advance
    • Fair Market Values
    • Volume or Value of Referrals or Other Business
    • No Promotion of Businesses Violating Other Law

• But Are Payments Intended to Induce Referrals?
BUNDLED PAYMENTS/CAPITATION

CMP Law

• No Employment Exception
• Is Hospital Payment Involved?
• In Managed Care Area:
  – Different Standard
  – Medicare HMO and Competitive Medical Plans
  – Medicare Advantage
  – Medicaid Risk
• Need More Flexibility
OTHER RISKS TO BE REGULATED IN ACOs

- Setting Targets
- Reports on Meeting Targets
- Stinting without Better Outcomes
- Cherry-Picking Patients/Avoidance of Sicker Patients
Tax Exemption

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Overview of Key concepts for Tax Exemption under IRC §501(c)(3):

- Must organize and operate exclusively for charitable purposes [as defined by 501(c)(3)]
  - With no Private Benefit (a de minimus amount of profits or earnings may be distributed to individuals or non-exempt entities, provided none is an “insider”)
  - And no Private Inurement (per se violation of tax laws; no de minimus exception)
Can a nonprovider ACO contracting entity be tax-exempt?

- PHO analysis: More than incidental private benefit
- Community benefit analysis:
  - Does not have to provide health care services
  - Community Board
  - Activities further charitable purposes
  - Reduces health care costs
  - Reduces medical errors
Will participation in a taxable ACO jeopardize exempt status?

- Primary purposes test
  - Corporation vs. LLC
- Inurement
- Private Benefit
Can an ACO Help Physicians Acquire EHR?

- The potential incentives available to hospitals for the “meaningful use” of EHR are of particular significance to ACOs, since EHR will constitute an essential part of their requisite clinical integration.

- Physicians and other eligible professionals who provide substantially all of their professional services in facilities that are hospital-based outpatient department locations are eligible to receive Medicare and Medicaid EHR incentives.
Can ACO Providers Share Patient Data? Yes, pursuant to HIPAA and HITECH

- **Affiliated Covered Entity** – ACO with 2 or more legally separate covered entities under common ownership – permitted to act as a single covered entity for HIPAA compliance

- **Organized Health Care Arrangement** – ACOs that are separately owned covered entities may share protected PHI for the benefit and management of any joint health care operations

- **ACO/MSO Integration Models** – ACOs must enter into a Business Associate Agreement with the MSO
Accountable Care Organizations: Representative State Law Issues

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Representative State Law Issues

- Corporate Practice of Medicine
- HMO/Insurance/Managed Care Contracting Laws
- Peer Review Laws
Most states have laws that prohibit, to varying degrees, the “corporate practice of medicine” (“CPOM”).

CPOM laws generally prevent unlicensed lay entities from employing physicians or otherwise contracting with physicians to furnish medical care.

CPOM laws may limit the flexibility of physicians and non-physicians to structure ownership and employment arrangements of an ACO.

Some states with strong CPOM laws (e.g., California and Texas) have laws providing for non-profit-owned "medical foundations" to permit non-profit hospitals to engage physicians indirectly to provide medical care.

“Friendly Physician” or “Management” models in CPOM states will require careful regulatory analysis to minimize regulatory risk.
Representative State Law Issues:
HMO/Insurance/Managed Care Contracting Laws

- Capitated Payments?
  - In a number of states (e.g., California, Colorado, Illinois, Florida, New York, and Pennsylvania) an ACO contracting entity that is not a licensed provider or a medical foundation would be prohibited from assuming capitated or other substantial financial risk unless such entity is licensed by the state to assume such financial risk.
  - In some states, such as California, even providers that lack a state health plan license may not capitate or assume substantial financial risk other than under contract with a licensed HMO.
  - In those states, an ACO may engage in fee-for-service contracting as permitted by CPOM (including case rates and other bundled pricing) but are restricted from capitating or otherwise assuming substantial financial risk unless they have the required state HMO, PPO or insurance license.
Examples of State Managed Care Laws that May Apply to ACOs include:

- California’s Knox-Keene Act
- Illinois’ PPO Regulations under the Health Care Reimbursement Reform Act of 1985
- Pennsylvania’s Department of Insurance Regulations
- Colorado’s Division of Insurance Regulations
- Florida’s Definition of Fiscal Intermediary Service Organization

ACO may be required to obtain a State third party administrator (“TPA”) license
ACOs will need to credential, discipline, and terminate physicians who do not meet quality and cost-effective care coordination standards.

How will the ACO peer review interact with the affiliated hospital’s medical staff peer review?

Federal Immunity for Peer Review Participants: Health Care Quality Improvement Act (“HCQIA”)

Purpose of HCQIA is to improve quality of medical care nationally.

Intended to strengthen the professional peer review process by providing immunity from civil liability to physicians in exchange for their honest assessment of their peers.

State law may provide hearing rights (e.g., California Business and Professional Code §§ 809 et seq; Potvin).
Representative State Law Issues: Peer Review (Cont’d)

- HCQIA establishes minimum procedures
- Protects only decisions based on quality concerns
- Provides immunity from damages actions (except civil rights claims) to hospitals and participating physicians complying with HCQIA requirements
- Note that only hospitals are mandated to query and report to the NPDB under the HCQIA
In order to invoke HCQIA’s provisions for qualified or conditional immunity, the professional review action must have been undertaken:

- In the **reasonable belief** that the action was in furtherance of the **quality** of health care; and
- After a **reasonable effort** to obtain the facts of the matter has been made; and
- After adequate notice and hearing procedures are afforded to the practitioner involved or after such other procedures as are fair to the practitioner under the circumstances; and
- In the **reasonable belief** that the facts warranted an adverse determination regarding the physician’s application, privileges and/or membership.
Representative State Law Issues: Peer Review (Cont’d)

- State “Any Willing Provider” and due process requirements may limit ability of ACOs to terminate providers from their networks or to deny providers access to their networks without permitting some form of appeal.

  - removal of a preferred provider by an insurer must be both substantively rational and procedurally fair; terminated physician has a right to a hearing if the contract is a substantial portion of the physicians income.
  - other states have not followed the *Potvin* holding thus far, but may have other statutory regulations or common law restrictions on provider termination: As ACOs become more important, their legal fair hearing requirements may expand to mimic medical staff fair hearing requirements.

- Also, state laws may exist that prohibit taking a physician off of a preferred provider list for reporting quality concerns or advocating on behalf of patients or disclosing financial incentives provided by HMOs.
Will ACO quality standards create opportunities for plaintiffs’ medical malpractice attorneys to hold ACO participating physicians and other providers to higher than otherwise applicable community standards of care?

Nothing in the PPACA prohibits that result, though Congressman Henry Waxman made a public statement on the floor of the House of Representatives that this result is not intended by the PPACA.