


# Effective ACO Compliance

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## Objectives

- Understand Accountable Care Organizations (ACOs), including Medicare Shared Savings Programs (MSSPs), within the framework of the “Triple Aim”; costs, quality (individuals and populations), and patient experience
- Learn the quality and compliance obligations of ACOs
- Discuss practical solutions to implementing and maintaining an effective ACO compliance program

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## THE HEALTH CARE DILEMMA: ARE ACOS THE ANSWER?



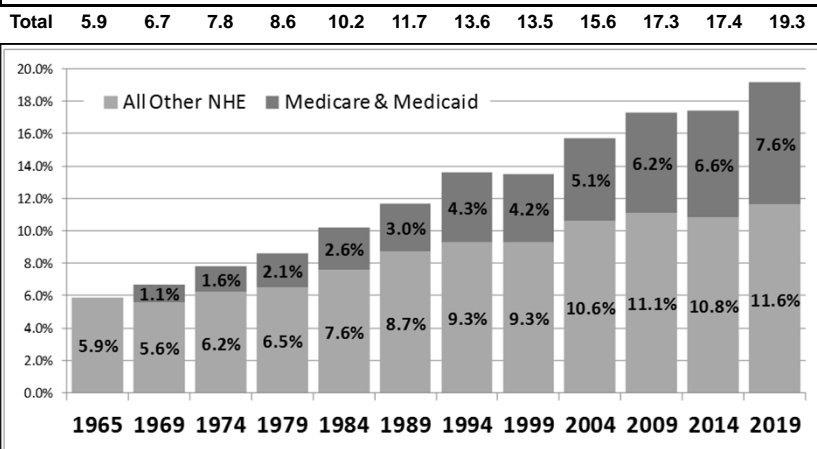
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### What is contributing to what is occurring in our industry?

- Cost, cost and more cost, year after year
- The recession - health care cost does not flex down
- Health care became political because the budget is political
- ...and because we didn't fix our own problems as an industry

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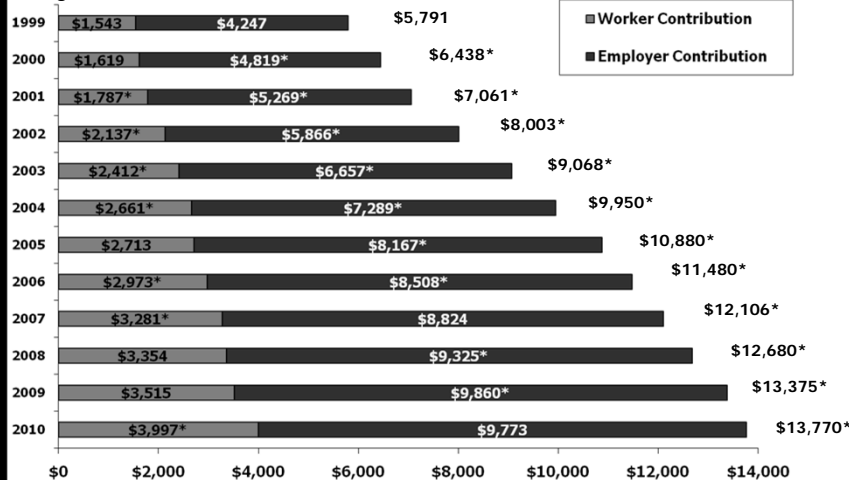
# The Value Equation in Healthcare



Source: Centers for Medicare & Medicaid Services (CMS)

# The Value Equation in Healthcare

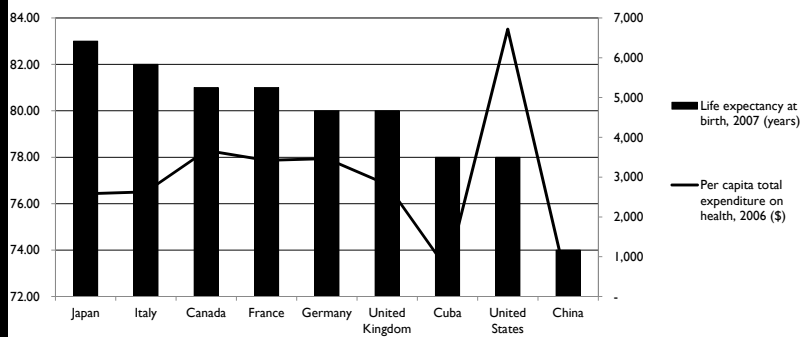
## Average Premiums



\* Estimate is statistically different from estimate for the previous year shown (p<.05).  
Source: Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 1999-2010.

## Average Annual Cost Compared to Life Expectancy

### The Cost of a Longer Life

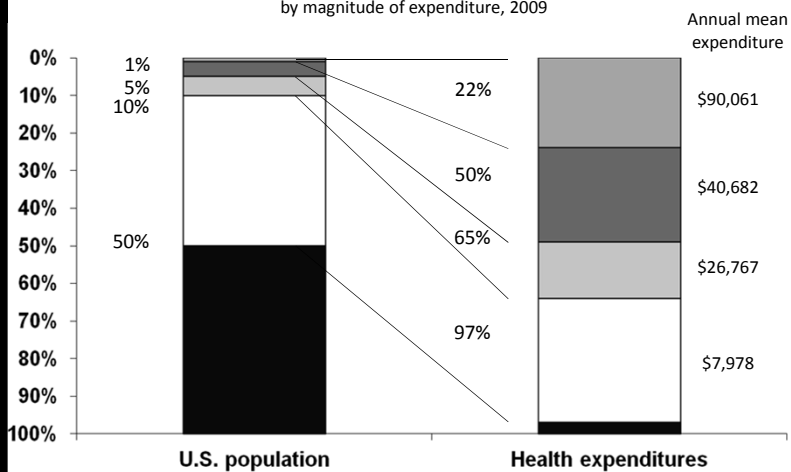


Source: Adapted from data provided by the WHO

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## Where are the costs concentrated?

Distribution of health expenditures for the U.S. population, by magnitude of expenditure, 2009



Source: Agency for Healthcare Research and Quality analysis of 2009 Medical Expenditure Panel Survey.

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## A Framework that Works

*Irrespective of the payment and system, what have we learned about value?*

Incentives must be aligned to promote behavior

Clinical integration and care coordination drive quality

Quality promotes health and is a means to efficiency

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## Stages of Accountability

Episodic Cost
Total Cost

Rewards  
Patient  
Volume

Fee-for-Service

Pay-for-Performance

Episodic Bundling

Global Payment

Full Risk / % of Premium

Rewards  
Patient  
Health

→  
 Provider Accountability

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Patient Centered Medical Home

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Accountable Care Organization

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## Accountable Care Organizations

- **Definition:**
  - ACOs are groups of doctors, hospitals, and other health care providers, who come together voluntarily to give coordinated high quality care to the patients they serve. Coordinated care helps ensure that patients, especially the chronically ill, get the right care at the right time, with the goal of avoiding unnecessary duplication of services and preventing medical errors.
- **What are the Benefits?**
  - Shared savings
  - Patients likely to have a better overall health care experience in a coordinated system
  - Quality is likely to be enhanced because of coordination and aligned incentives
- **Who's ready?**
  - Many providers are already in networks – ACOs likely will serve to increase collaboration – IDS's, hospitals that employ physicians
  - Existing risk bearing organizations will increase "membership" and already have infrastructure and experience in managing risk
  - FFS multi-specialty medical groups and clinic organizations likely have a lot of the infrastructure and have an opportunity to try risk on for size

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## CMS ACO Programs

- **Medicare Shared Savings Program (MSSP)**
  - January 2013: 250 ACOs were serving >4 million people
- **Advance Payment Model (introduced by CMMI)**
  - Thirty five participating ACO's
  - Assist with start-up resources to safety-net providers (critical access, rural, and physician-owned) to foster participation
- **Pioneer ACO Model (introduced by CMMI)**
  - 32 new ACOs launched in January 2012
- **Physician Group Practice Transition Demonstration**
  - After five-year pay-for-performance demo, six large physician groups launched as new ACOs in January 2011 to participate in a shared savings agreement

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## Commercial ACOs

- Even before the passage of ACA, organizations were exploring shared risk and integrated care delivery
- Initiated by physician-lead health systems, integrated delivery systems, commercial payers and other types of organizations.
- Distinct from Medicare ACOs in that a commercial payer, rather than Medicare, is the entity providing the financial incentives for quality and cost performance to the provider organizations
- Gaining momentum
- Waivers, discussed later, do not apply to commercial ACOs

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## ACO Challenges

- Resource and capital investment
  - Management
  - Health information technology
  - Development of care management processes
  - Implementation of compliance programs
  - Restructuring of internal operations
- Navigating through the legal and contractual arrangements
  - Patient attribution methods
  - Data-sharing agreements
- Potential downside risk if there are financial losses

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## ACO Critical Success Factors

- Breadth of network (specialties, settings) and avoid leakage
- Identify opportunities to reduce unnecessary services and costs for given population
- Collaboration (trust and shared vision) with strong physician engagement to lead cost reduction and meet quality measures
- IT integration
- Quality and performance improvement
- Plus for those experienced in managing risk through capitation

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## MEDICARE SHARED SAVINGS PROGRAM BASICS



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## Legal Framework

- ACA Section 3022
  - Added new section 1899 to the Social Security Act
  - Established a Shared Savings Program
- 42 CFR Part 425
  - CMS regulations implementing ACO statute
- Other Laws
  - Anti-Kickback Statute
  - Stark Law
  - Gain Sharing CMP
  - Patient Inducement CMP
  - False Claims Act

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## Eligibility Requirements

- Professionals in group practice arrangements
- Networks of individual practices
- Joint venture arrangements between hospitals and professionals
- Hospitals employing professionals
- Subset of critical access hospitals, rural health clinics, and federally qualified health clinics

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## Legal Entity

- Required to be a legal entity capable of:
  - Receiving and distributing shared savings
  - Repaying shared losses
  - Establishing, reporting, and ensuring all its participating providers comply with program requirements, including quality performance
  - Performing all other requirements of the ACO
- Existing organizations that meet the legal requirements can participate
- If ACO is formed by two or more otherwise independent participants (i.e. hospital and physician group) must form a new legal entity
- ACO must have a tax identification number (TIN) but not required to be a certified Medicare provider

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## Governance

- ACO must establish and maintain a governing body
- ACO participants (providers) must have at least 75% control of the ACO's governing body (or must describe why it cannot meet those requirements and how the ACO will engage participants in governance)
- Does not require "proportionate control" by each ACO participant
- Must include a Medicare beneficiary on the board

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## Leadership and Management

- Operations must be managed by an executive
  - Must certify that ACO participants are willing to be accountable and report on quality, cost, and care
  - Appointment and removal of the executive must be under the control of the governing body
  - Executive leadership team must have demonstrated the ability to effectively direct clinical practice to improve efficiency and outcomes
- Clinical management and oversight must be managed by a senior-level medical director
- Providers must make a meaningful commitment (financial/human) investment in clinical integration
- ACO must describe how it will establish and maintain an ongoing quality assurance and process improvement program

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## Clinical Processes and Patient Centeredness

- ACO must provide documentation that describes how it will:
  - Promote evidence-based medicine
  - Promote beneficiary engagement
  - Report internally on quality and cost
  - Coordinate Care
- ACOs can choose the tools for meeting these requirements
- CMS will monitor to make sure the ACO does not impede the ability of beneficiaries to seek care from providers outside the ACO network

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## Patient Centeredness

- Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey
- Beneficiary involvement in ACO governance
- Process for evaluating the health needs of the ACO's assigned population
- System for identifying high-risk individuals
- Development of individualized care plans for targeted populations, including integration of community resources
- Resources (technology or labor) for care coordination
- Process for communicating clinical knowledge and evidence-based medicine to beneficiaries in an understandable way
- Written standards for beneficiary communication
- Beneficiary access to their medical record
- Infrastructure for measuring clinical and service performance by physicians

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## Number of Primary Care Providers

- ACOs are required to have at least 5,000 Medicare beneficiaries assigned each performance year
- ACOs must include sufficient primary care professionals for the number of beneficiaries assigned
- CMS is not prescriptive as to the specific number, type, or location of providers

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## Program Integrity Requirements

- Lead compliance official who reports to the governing body
- Mechanism for identifying compliance problems
- Method for ACO employees/contractors to report suspected problems
- Compliance training
- Requirement to report suspected violations to the appropriate law enforcement agency
- Conflict of Interest policy
- CMS will screen ACOs and ACO participants for history of program integrity issues

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## ACO Marketing

- Intended to ensure that ACOs don't prevent assigned beneficiaries from taking advantage of all their benefits
- Limit the potential for ACOs to market themselves as "endorsed" by Medicare
- Requires CMS approval of ACO marketing materials
- ACO required to certify that any marketing materials used will comply with the marketing requirements
- Required to use template language supplied by CMS when available
- Failure to comply may render the ACO not in compliance with patient-centeredness requirement

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## Three-Year Participation Agreement

- For ACOs approved to participate in 2012, the first participation year is their start date (4/1/12 or 7/1/12) through 12/31/13 – the following two performance periods are calendar-year
- ACOs subject to all regulation changes (except eligibility, calculation of sharing rate, and beneficiary assignment)
  - ACOs would be required to comply with changes related to quality and performance standards
  - Require submission of a supplement to the original application
  - May have the option of voluntarily terminating agreement without penalty
  - ACO changes require CMS notification and could result in termination

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## Data Sharing

- ACOs required to submit TINs and NPIs for each participating provider
- CMS will provide aggregated data reports on the ACO populations at the beginning of the first performance period and quarterly thereafter
- CMS will provide limited beneficiary identifiable data
- ACOs will receive claims data monthly for assigned beneficiaries (Parts A, B, and D)
- ACO required to explain how data will be used to evaluate performance and improve quality

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## Beneficiary Assignment

- Beneficiaries will be assigned to ACOs based on where they receive primary care services for the most recent 12 months
- Assigned to ACOs that serve the plurality of beneficiaries' primary care services
- Two-step process
- Providers used for assignment must be exclusive to the ACO


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## Models

- Shared-savings-only payment model (one-sided model)
  - Up to 50% share in achieved savings
- Savings and Loss payment model
  - Up to 60% share in achieved savings (two-sided risk model)
- Depends on how well the ACO exceeds minimum quality performance standards


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## Quality Measures

- ACOs are required to report on 33 measures (discussed in more detail later)
  - Patient/caregiver experience
  - Care coordination/patient safety
  - Preventative health
  - At-risk populations
- Sources
  - Survey
  - Claims
  - EHR incentive program
  - Physician Quality Reporting System
- Scoring
  - Year 1 – Pay for reporting
  - Year 2 – Pay for performance – 25 of 33 measures
  - Year 3 – Pay for performance – 32 of 33 measures

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## Monitoring ACO Performance

- CMS methods for monitoring
  - Patient complaints
  - Analysis of data
  - Site visits
  - Audits
- ACOs (including all providers, suppliers, and contracted entities) required to give the government the right to inspect all books, contracts, records, and documents
- Noncompliance
  - Warning
  - Corrective action plan
  - Special monitoring plan
  - Termination

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## Fraud and Abuse Waivers

- Pre-participation
- Participation
- Shared-savings distribution
- Compliance with Stark
- Patient incentive

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## Pre-Participation Waiver

- Covers “start-up arrangements” between providers
- Good faith intent to participate in MSSP
- Diligent steps to develop ACO in target year
- “Reasonably related to purposes of MSSP”
- Documented
- Public disclosure

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## Participation Waiver

- ACO participates in MSSP
- Includes six-month period after expiration or termination
- ACO satisfies MSSP governance and management rules
- “Reasonably related to purpose of MSSP”
- Documented
- Public disclosure

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## Shared Savings Distribution

- Covers distribution of shared savings by ACO to participants, providers and suppliers
- Does not cover distribution of shared savings or incentives paid by commercial insurers
- Commercial insurer payments may be protected under ACO participation waiver or existing Stark and anti-kickback exceptions

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## Compliance with Stark Law

- Provides protection from anti-kickback statute enforcement for any arrangement that satisfies a Stark exception
- Do not need to analyze to determine if arrangement complies with anti-kickback safe harbor
- Limited value

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## Patient Incentive Waiver

- Covers free or below FMV items or services (not cash)
- ACO participates in MSSP
- Reasonable connection between items or services and beneficiary's medical care
- Items or services are
  - For preventive care
  - To advance adherence to treatment, drug regime, care plan, or chronic disease management

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## QUALITY PERFORMANCE STANDARDS



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## Domains

- Patient/caregiver experience – 7 measures
- Care coordination/patient safety – 6 measures
- Preventive health – 8 measures
- At-risk population
  - Diabetes – One measure which is a composite of five measures
  - Hypertension – One measure
  - Ischemic Vascular Disease – Two measures
  - Heart failure – One measure
  - Coronary artery disease – One measure which is a composite of two measures

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## Quality Performance Scoring

- Year 1 – Complete and accurate reporting for all quality measures
- Year 2 – Performance against 25 measures, reporting for remaining 8 measures
- Year 3 – Performance for 32 measures, reporting for measure of functional status
- CMS intends to establish national benchmarks for ACO quality measures before start of pay-for-performance year
- Minimum attainment level set at a national 30% or 30<sup>th</sup> percentile of performance benchmark
- Sliding scale based on level of performance
- At 90% or the 90<sup>th</sup> percentile maximum points earned
- Diabetes and CAD scored “all-or-nothing”
- EHR adoption is double-weighted

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## Quality Performance Scoring

- CMS will add the points earned for individual measures within each domain and divide by total points for the domain to get the four domain scores
- Domains weighted equally
- Domain scores are averaged to determine the overall quality performance score
- Minimum attainment level on at least 70 percent of the measures in each domain required to avoid corrective action plan

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## Patient/Caregiver Experience

- Clinician and Group Consumer Assessment of Health Care Providers and Systems (CG CAHPS)
- Measures:
  - ACO 1 – Getting timely care, appointments, and information
  - ACO 2 – How well your providers communicate
  - ACO 3 – Patient rating of provider
  - ACO 4 – Access to specialist
  - ACO 5 – Health promotion and education
  - ACO 6 – Shared decision making
  - ACO 7 – Health status/functional status
- 1- 6 are pay-for-reporting in year one and pay-for-performance in years 2 and 3.
- ACO 7 is pay-for-reporting in all three years

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## Care Coordination/Patient Safety

- ACO 8 – Risk standardized all condition readmission
  - Source – Claims
  - Pay-for-reporting years 1 and 2, pay-for-performance year 3
- ACO 9 – Ambulatory sensitive conditions admissions: Chronic Obstructive Pulmonary Disease (COPD) or Asthma in older adults
  - Source – Claims
  - Pay-for-reporting year 1, pay-for-performance years 2 and 3
- ACO 10 – Ambulatory sensitive conditions admissions: heart failure (HF)
  - Source – Claims
  - Pay-for-reporting year 1, pay-for-performance years 2 and 3

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## Care Coordination/Patient Safety


- ACO 11 – Percent of primary care physicians who successfully qualify for an EHR program incentive payment
  - Source – EHR incentive program reporting
  - Pay-for-reporting year 1, pay-for-performance years 2 and 3
- ACO 12 – Medication Reconciliation
  - Source – GPRO Web interface
  - Pay-for-reporting year 1, pay-for-performance years 2 and 3
- ACO 13 – Falls: Screening for future fall risk
  - Source – GPRO Web interface
  - Pay-for-reporting year 1, pay-for-performance years 2 and 3

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## Preventive Health

- ACO 14 – Influenza immunization
  - Source – GPRO Web Interface
  - Pay-for-reporting year 1, pay-for-performance years 2 and 3
- ACO 15 – Pneumococcal vaccination for patients 65 years and older
  - Source – GPRO Web interface
  - Pay-for-reporting year 1, pay-for-performance years 2 and 3
- ACO 16 – Body mass index (BMI) screening and follow-up
  - Source – GPRO Web interface
  - Pay-for-reporting year 1, pay-for-performance years 2 and 3


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## Preventive Health

- ACO 17 – Tobacco Use: Screening and cessation intervention
  - Source – GPRO Web Interface
  - Pay-for-reporting year 1, pay-for-performance years 2 and 3
- ACO 18 – Screening for clinical depression and follow-up plan
  - Source – GPRO Web interface
  - Pay-for-reporting year 1, pay-for-performance years 2 and 3
- ACO 19 – Colorectal cancer screening
  - Source – GPRO Web interface
  - Pay-for-reporting years 1 and 2, pay-for-performance year 3

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## Preventive Health

- ACO 20 – Breast cancer screening
  - Source – GPRO Web Interface
  - Pay-for-reporting years 1 and 2, pay-for-performance year 3
- ACO 21 – Screening for high blood pressure and follow-up documented
  - Source – GPRO Web interface
  - Pay-for-reporting years 1 and 2, pay-for-performance year 3

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## At Risk Population - Diabetes

- ACO 22 – Diabetes composite (all or nothing scoring):  
Diabetes Mellitus: Hemoglobin A1c Control (<8%)
  - Source – GPRO Web Interface
  - Pay-for-reporting year 1, pay-for-performance years 2 and 3
- ACO 23 – Diabetes composite (all or nothing scoring):  
Diabetes Mellitus: Low density lipoprotein control
  - Source – GPRO Web interface
  - Pay-for-reporting year 1, pay-for-performance years 2 and 3
- ACO 24 – Diabetes composite (all or nothing scoring):  
Diabetes Mellitus: High blood pressure control
  - Source – GPRO Web interface
  - Pay-for-reporting year 1, pay-for-performance years 2 and 3

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## At Risk Population - Diabetes

- ACO 25 – Diabetes composite (all or nothing scoring):  
Diabetes Mellitus: Tobacco non-use
  - Source – GPRO Web Interface
  - Pay-for-reporting year 1, pay-for-performance years 2 and 3
- ACO 26 – Diabetes composite (all or nothing scoring):  
Diabetes Mellitus: Daily aspirin or antiplatelet medication  
use for patients with diabetes and ischemic vascular  
disease
  - Source – GPRO Web interface
  - Pay-for-reporting year 1, pay-for-performance years 2 and 3
- ACO 27 – Diabetes composite (all or nothing scoring):  
Diabetes Mellitus: Hemoglobin A1c poor control
  - Source – GPRO Web interface
  - Pay-for-reporting year 1, pay-for-performance years 2 and 3

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## At Risk Population – Hypertension and Ischemic Vascular Disease

- ACO 28 – Hypertension (HTN): Controlling high blood pressure
  - Source – GPRO Web Interface
  - Pay-for-reporting year 1, pay-for-performance years 2 and 3
- ACO 29 – Ischemic Vascular Disease (IVD): Complete lipid panel and LDL control (<100 mg/dL)
  - Source – GPRO Web interface
  - Pay-for-reporting year 1, pay-for-performance years 2 and 3
- ACO 30 – Ischemic Vascular Disease (IVD): Use of aspirin or another antithrombotic
  - Source – GPRO Web interface
  - Pay-for-reporting year 1, pay-for-performance years 2 and 3

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## At Risk Population – Heart Failure and Coronary Artery Disease

- ACO 31 – Heart Failure: Beta-blocker therapy for left ventricular systolic dysfunction (LVSD)
  - Source – GPRO Web Interface
  - Pay-for-reporting years 1 and 2, pay-for-performance year 3
- ACO 32 – Coronary Artery Disease (CAD) Composite (all or nothing scoring): Lipid Control
  - Source – GPRO Web interface
  - Pay-for-reporting years 1 and 2, pay-for-performance year 3
- ACO 33 – Coronary Artery Disease (CAD) Composite (all or nothing scoring): Angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) therapy – diabetes or left ventricular systolic dysfunction (LVEF < 40%)
  - Source – GPRO Web interface
  - Pay-for-reporting years 1 and 2, pay-for-performance year 3

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## DEVELOPING AN EFFECTIVE COMPLIANCE PROGRAM



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## ACO Compliance Obligations

- “The ACO must agree, and must require its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to the ACOs activities to agree, or to comply with all applicable laws including, but not limited to the following:
  - Federal criminal law
  - The False Claims Act
  - The anti-kickback statute
  - The civil monetary penalties law
  - The physician self-referral law”

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## ACO Responsibility for Participants and Providers/Supplies

“Notwithstanding any arrangements between or among an ACO, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities, the ACO must have ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its agreement with CMS...”

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## Mandatory ACO Compliance Plan Elements

- Designated compliance official who is not legal counsel to the ACO and reports directly to the ACOs governing body
- Mechanisms for identifying and addressing compliance problems
- Method for employees and contractors of the ACO, as well as its participants, providers/suppliers and other vendors, to anonymously report suspected compliance problems
- Compliance training for ACO as well as its participation and providers/suppliers
- Mechanism for ACO to report probable violations of law to an appropriate law enforcement agency

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## Building from Existing Program

- If ACO is same entity as existing provider
  - Can use same compliance officer and program structure
  - Supplement existing policies, training and auditing to target unique ACO risk areas
- If ACO is new legal entity developed for MSSP
  - Can leverage compliance program of one or more ACO participants
  - “Lease” hotline, auditing staff and trainers
  - Copy/adapt policies, training materials, etc.

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## Conflicts of Interest

- MSSP regulations require 75% of the ACO board consist of representatives of ACO participants
- Participants will all have business relationships with ACO
- Conflict of Interest policy must:
  - Provide for disclosure of financial interests
  - Create procedure for identifying and addressing conflicts
  - Establish remedies for violation of the policy

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## Where to Start?

- Compliance readiness assessment
- Compliance Plan
- Application
- Monitoring

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## Compliance Readiness Assessment

- Alignment
  - Current level of alignment between physicians, hospital, and other providers
  - Matching values, culture, objectives
  - Ability to work as a team
- Technology
  - Development of EHR
  - Participation in HIE's
  - Availability for sharing data and coordinating care
- Data Requirements
  - Market assessment
  - Population assessment
  - Quality metrics
  - Actual cost at the DRG and CPT level
- Ability to leverage current compliance program

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## Gap Assessment

- Are the following in place or do they need to be implemented?
  - Legal entity with independent governance structure
  - Job descriptions for committees
  - Deemed clinically and financially integrated by the FTC
  - Medical Director for clinical oversight
  - Compliance officer working under defined policies
  - Experience distributing shared savings
  - Distribution plan to align incentives with ACO initiatives
  - Network Participation Agreement for all participating physicians agreeing to comply with ACO requirements

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## Gap Assessment, continued

- Are the following in place or do they need to be implemented?
  - Quality Assurance mechanism
  - Physician engagement
  - Required use of evidence-based medicine
  - Required use of care registries
  - Required reporting of PQRS metrics
  - Collect CAHPS
  - Collect remaining ACO metrics
  - Beneficiary representation in governance
  - Beneficiary access to medical records
  - Care coordination strategy

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## Application (2013)

- Section 1 – Contact information
- Section 2 – General Information
- Section 3 – ACO meets antitrust definition of “newly formed”
- Section 4 – ACOs legal entity
- Section 5 – Governing body
- Section 6 – ACO leadership and management
- Section 7 – Participation in other Medicare initiatives involving shared savings
- Section 8 – Management of shared savings
- Section 9 – ACO participants
- Section 10 – Data Sharing
- Section 11 – Clinical processes and patient centeredness
- Section 12 - Certification

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## Application Checklist

- Supporting narratives/documentation included in submission
  - 4.2 History, mission and organization
  - 4.8 Organizational chart showing the flow of responsibility
  - 5.14 Governing body template
  - 8.20 Shared savings narrative
  - 8.21 Electronic funds transfer authorization agreement
  - 9.22 Provider participant TIN list
  - 9.26 Sample participation agreement
  - 9.26 ACO participation template
  - 9.28 Executed ACO participation agreements
  - 10.32 Data sharing narrative

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## Application Checklist, continued

- **Quality Narratives, included in submission**
  - 11.34 Quality assurance and process improvement
  - 11.35 Promoting evidence based medicine
  - 11.36 Promoting beneficiary engagement
  - 11.37 Internal reporting on quality and cost metrics
  - 11.38 Promoting coordination of care
- **Supporting Documents, not included in submission**
  - 4.7 Articles of incorporation
  - 5.13 Conflict of interest
  - 6.17 Compliance plan

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## Monitoring Requirements

- **Application commitments**
- **Public reporting requirements**
- **Data certification**
  - False Claims Act violation for providing information known to be false
- **Quality performance**
  - Source documentation review
- **Avoidance of at-risk beneficiaries**
- **Referrals and cost shifting**

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## Other ACO Compliance Issues

- Developing accurate marketing materials
- Avoiding cherry picking
- Complying with patient notification requirements
- Ensuring patient freedom of choice (limits on mandatory referrals within ACO)
- Ensuring patient access to all covered services (no under-utilization)
- Record retention
- Protecting privacy of patient data

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## Top Ten ACO Compliance Tips

10. Culture is key
9. Messaging is crucial
8. Governance integrity is essential
7. Get it right up front – focus on underlying conditions
6. Build a certification trail
5. Coordinate among participants
4. Leverage existing efforts
3. Integrate quality and compliance
2. Don't forget about privacy and security
1. Proactively audit new and existing issues and address identified problems

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## QUESTIONS AND DISCUSSION

