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Building a Foundation for Accountability and Affordability…Healthcare Reform in 2011 and Beyond

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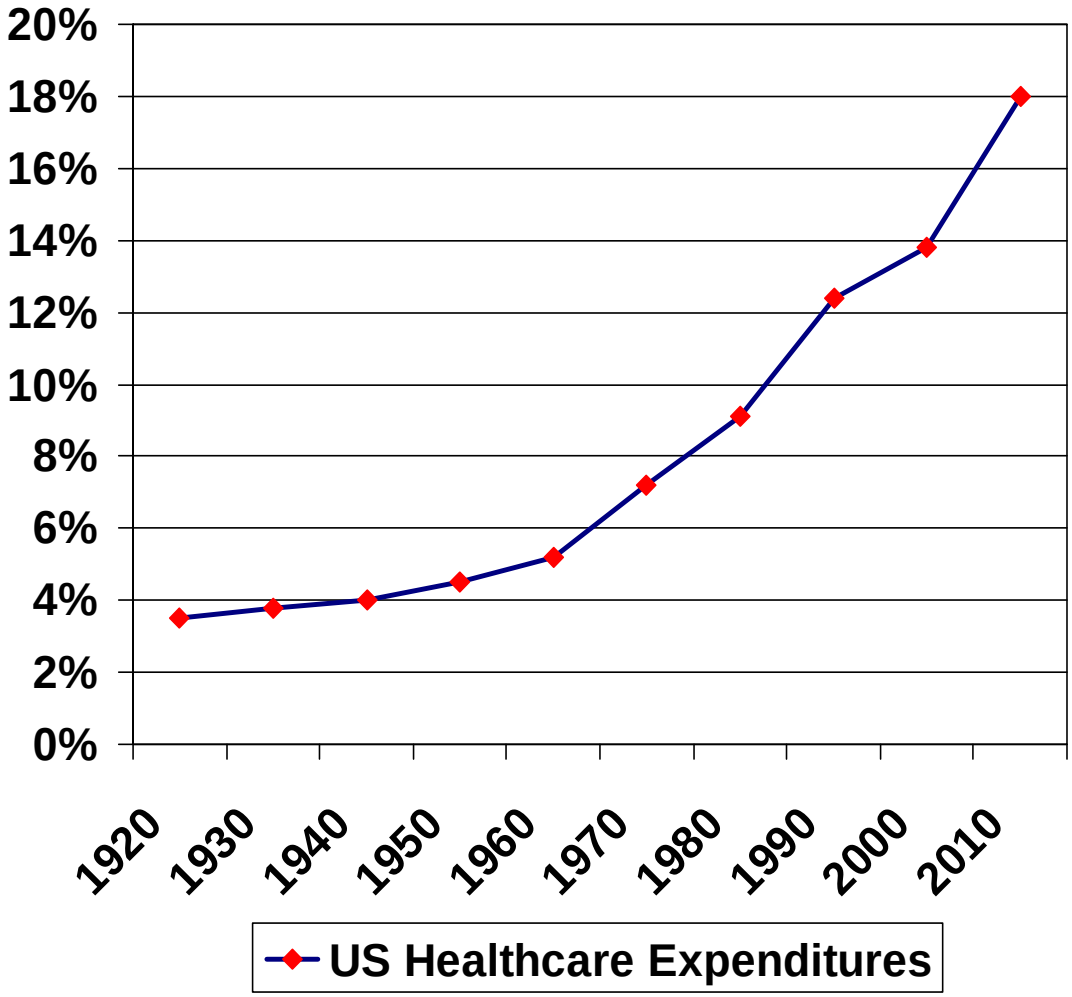
U.S. Healthcare Expenditures % of GDP



What is an ACO?

- An organization of healthcare providers that agrees to be accountable for the quality, cost, and overall care of Medicare beneficiaries who are enrolled in the traditional fee-for-service program who are assigned to it.
- For ACO purposes, "assigned" means those beneficiaries for whom 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. 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.

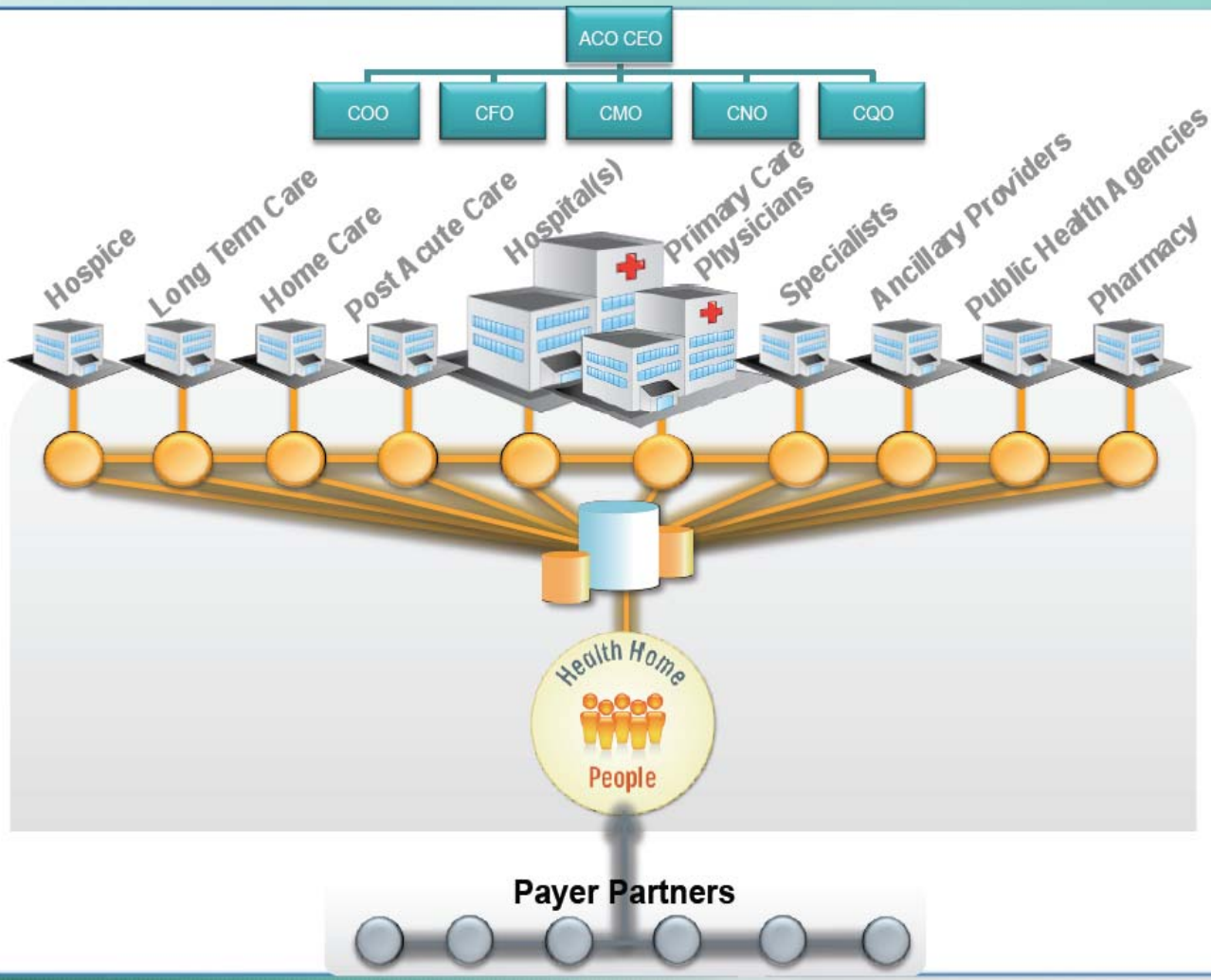
What forms of organizations may become an ACO?

- Physicians and other ACO professionals in group practices
- Physicians and other ACO professionals in networks of practices
- Partnerships or joint venture arrangements between hospitals and ACO professionals
- Hospitals employing physicians/professionals
- Other forms that the Secretary of Health and Human Services may determine appropriate

ACO requirements

- Have a formal legal and governance structure to receive and distribute shared savings that is recognized under state law
- Have a sufficient number of primary care professionals for the number of assigned beneficiaries (to be 5,000 at a minimum)
- Agree to participate in the program for not less than a 3-year period
- Have sufficient information regarding participating ACO healthcare professionals as the Secretary determines necessary to support beneficiary assignment and for the determination of payments for shared savings

Complete view of an operational ACO



ACO requirements

- Have a management structure that includes clinical and administrative systems
- Have defined processes to:
  - Promote evidenced-based medicine
  - 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)
  - Coordinate care

ACO requirements (cont'd.)

- Demonstrate it meets patient-centeredness criteria, as determined by the Secretary
- Quality assurance program must establish internal performance standards for quality, costs and outcomes improvements and hold ACO providers accountable, including termination

How will ACOs qualify for shared savings?

- Consistent with the overall purpose of the Affordable Care Act, the intent of the Shared Savings Program is to achieve high-quality health care for patients in a cost-effective manner. As part of CMS's goal to provide better care for individuals, defined as "safe, effective, patient-centered, timely, efficient, and equitable," the regulations propose:
  - Measures to assess the quality of care furnished by an ACO;
  - Requirements for data submission by ACOs;
  - Quality performance standards
  - Incorporation of reporting requirements under the Physician Quality Reporting System; and
  - Requirements for public reporting by ACOs.

How will ACOs qualify for shared savings? (cont'd.)

- ACOs that do not meet quality performance thresholds for all measures would not be eligible for shared savings, regardless of how much per capita costs were reduced.

Proposed Quality Measures for ACO Quality Performance Standard

- The Proposed Rule proposes 65 quality measures that must be reported to CMS based on data submitted by ACOs, which must meet applicable performance criteria for all three years. (See pp. 19571–19591 of the April 7, 2011, Federal Register.)
- In year one, an ACO must provide full and accurate measures reporting with respect to all 65 measures.
- In years two and three and thereafter, the quality performance standard will be based on a measures scale with a minimum attainment level described in the Proposed Rule.

Proposed Quality Measures for ACO Quality Performance Standard (cont'd.)

- Measures are divided into five domains:
  - Patient/caregiver experience (7 measures)
  - Care coordination (16 measures)
  - Patient safety (2 measures)
  - Preventative health (9 measures)
  - At-risk population/frail elderly health (31 measures relating to diabetes, heart failure, coronary artery disease, hypertension, chronic obstructive pulmonary disorder and frail elderly)

Impact of Failure to Comply

- Where an ACO fails to meet the minimum attainment level for one or more domains, the ACO would receive a warning and a requirement to reevaluate the following year. If the ACO continues to underperform on the quality performance standard in the following year, the ACO agreement will be terminated.
- If an ACO fails to report one or more measures, a written request would be sent to the ACO requiring the submission of the required data and a reasonable explanation for the delay in reporting. If the ACO continues to fail to report without a reasonable explanation, the ACO agreement will be immediately terminated.

Impact of Failure to Comply (cont'd.)

- ACOs that exhibit a pattern of inaccurate or incomplete recording or failure to make timely corrections following a notice to resubmit may be terminated from the Shared Savings Program and would be disqualified from sharing in savings in each year in which they underperform.
- Measures are expected to evolve over time to include other highly prevalent patient conditions as well as additional measures for hospital-based care and quality measures for care furnished in other settings such as home health services and nursing homes.

Requirements for Quality Measures Data Submission by ACOs

- CMS proposes to make available a CMS-specified data collection tool and a survey tool for the 65 identified measures, although some are already being reported through methods such as the Physician Quality Reporting System, eRx, HITECH program data and Hospital Compare.
- The expectation is that the random sample for measures reported must consist of at least 411 assigned beneficiaries per measures set for each domain.

Requirements for Quality Measures Data Submission by ACOs (cont'd.)

- The government retains the right to validate data entered into the system and to audit for compliance. Failure to report quality measure data accurately, completely and timely or to timely track such data may subject an ACO to termination or other sanctions.
- Assuming compliance with all other requirements, an ACO that obtains the total potential points for all five domains within the quality performance standard will share in 60% of the savings generated under the two-sided model, versus 50% under the one-sided model.

Requirements for Quality Measures Data Submission by ACOs (cont'd.)

- The first year only requires complete and accurate reporting of all quality measures. Thereafter, savings will vary based on an ACO's actual performance on measures as compared with identified benchmarks.

Value Based Purchasing Program Measures

- For the FY 2013 Hospital VBP Program, CMS adopted final rules on April 30th, effective July 1st, on the use of clinical process-of-care measures as well as measures from the Hospital Consumer Assessment of Healthcare Providers and Systems, (HCAHPS) survey that document patients' experience of care.

Value-Based Purchasing Program

- Under the VBP Program, CMS will pay acute care inpatient prospective payment system (IPPS) hospitals value-based incentive payments for meeting minimum performance standards for certain quality measures with respect to a performance period designated for each fiscal year.

Clinical Process of Care Measures

- Acute myocardial infarction
  - Primary PCI received within 90 minutes of hospital arrival
- Heart Failure
  - Discharge Instructions
- Pneumonia
  - Blood cultures performed in ED prior to initial antibiotic received in hospital

Clinical Process of Care Measures (cont'd)

- Healthcare-associated infections
  - Prophylactic antibiotic received within one hour prior to surgical invasion
- Surgeries

Survey Measures

- Communication with Nurses
- Communication with Doctors
- Responsiveness of Hospital Staff
- Pain Management
- Communication About Medicines
- Cleanliness and Quietness of Hospital Environment
- Discharge Information
- Overall Rating of Hospital

Other Criteria for FY 2014

- Eight Hospital Acquired Condition Measures
  - Foreign object returned after surgery
- AHRQ Patient Safety Indicators (PSIs), Inpatient Quality Indicators (IQIs), and Composite Measures
- Mortality measures

So, Now What?

- Compliance with ACO quality performance standards will be mandated in order to remain eligible for the Shared Savings Program and will affect the percentage of savings that can be shared among ACO participants.
- Physicians will likely be required to produce their own quality/utilization report card at time of appointment/reappointment
- Physicians/AHPs likely will be denied membership if not performing up to standards

So, Now What?

- Compliance with VBP standards will affect whether or not hospital receives incentive based payments.
- Compliance may also have a direct or indirect impact on provider responsibilities:
  - under accreditation standards
  - doctrine of corporate negligence and related civil liability theories
  - DOJ/OIG expectations on board responsibility for delivering quality health care services which could trigger False Claims Act exposure. (Azmat case)

So, Now What? (Cont'd)

- ACOs and participating providers therefore need to incorporate these quality metrics and standards—minimally at the ACO entity level, but probably at the local provider level as well (e.g., participating hospitals, physician groups, ASCs).
- Standards need to be developed that track the 65 ACO measures and the VBP measures, and ensure that they are communicated to providers and then monitored for compliance.
- Providers need to receive periodic reports regarding their individual and comparative performances.

So, Now What? (Cont'd)

- Remedial action plans need to be developed that are designed to assist providers in meeting standards but can include the ability to suspend or terminate participation, at least at the ACO entity level, and possibly at the local provider level.
- Performance results should be taken into consideration at the time of appointment, reappointment and contract renewal, and some internal administrative process/fair hearing for participants who are excluded should be provided.

So, Now What? (Cont'd)

- It is important that an ACO evaluate its processes and procedures, reports, analyses, etc., so as to maximize available confidentiality and immunity protections under state and federal law (e.g., participation in a Patient Safety Organization under Patient Safety and Quality Improvement Act of 2005).
- Is an ACO a "provider" under the Patient Safety and Quality Improvement Act of 2005 a Patient Safety Organization purposes?

So, Now What? (Cont'd)

- Is an ACO a "health care entity" under the Health Care Quality Improvement Act for purposes of:
  - Data Bank query and reporting obligations
  - Immunity protections
- Can an ACO be sued under the Doctrine of Corporate Negligence?
- Should there be an ACO medical/provider staff in lieu of a hospital medical staff?

So, Now What? (Cont'd)

- Will new bylaws, rules, regulations and policies be required given the fact that the ACO must be a legal entity?
- Should the standard hearing procedures remain the same or be modified?
  - Is non-compliance with utilization standards reportable if terminated or if membership denied?
  - Is non-compliance with quality metrics standards reportable if terminated or if membership denied?
  - Should termination from ACO result in termination from a hospital/provider staff and visa versa?

So, Now What? (Cont'd)

- Is economic credentialing the new reality?
- How will existing antitrust standards apply to exclusionary membership decisions?

ACO Membership: First Step

- Determine which providers can achieve the “Triple Aim?”
  - Provide Better Coordinated Care
  - Practice according to Evidenced Based Guidelines
  - Deliver Cost Efficient Care
- Delivery Network Committee comprised of System administrators and Physicians determines Members:
  - All on Hospital’s Medical Staff or Subset of Providers
  - Assess physicians that can achieve High Quality/Low Cost Care
- If not, then could face:
  - Political Issues from Excluding Certain Physicians

Oversight of Provider Behavior

- To whom is a Provider “Accountable”?
- Who will monitor Provider Performance?
  - Full Time Chief Medical Officer-Section 425.5 (“clinical management and oversight must be managed by Full-Time Senior-Level Medical Director who is physically present on a regular basis, who is a Board-Certified Physician and licensed in State where ACO operates”)
  - Board of Directors
  - Quality or Peer Review Committee
  - Service Line Heads, Chairs, Partners in Group
- Need to have ability to exclude Physicians who do not meet Quality and Cost Targets, or ACO will not achieve Shared Savings Payment and Can Face Downside Risk

ACO Membership & Antitrust Issues

- Antitrust Challenges for Exclusion from ACO
  - Market Power Challenge if include too many Providers
  - Proposed Antitrust Guidance
    - Over 50% Mandatory Review
    - 30% to 50% gray zone
    - Under 30%
  - Restraint of Trade
  - Achieve Clinical Integration among Providers without creating unnecessary leverage against Health Plans to raise prices

Economic Credentialing

- AMA defines Economic Credentialing as “use of economic criteria unrelated to quality of care or professional competence in determining a physician’s qualifications for initial or continuing hospital medical staff membership or privileges”
- “Loyalty Credentialing”—based on Physician ownership of a competing facility or ACO
- In the ACO world of Economic or Loyalty Credentialing, Physicians will take action for their colleagues owning competing entities

Delegated Credentialing

- Delegated Credentialing: Could be provided by variety of Entities:
  - Hospital Medical Staff
  - ACO Medical Staff
  - Provider Health Plan
  - Other Payers
- Cross-Termination among different Credentialing bodies
- Liability of the Different Entities taking on Credentialing for the ACO

Credentialing Guidelines

- ACO Credentialing should review following guidelines as part of Credentialing Process:
  - CMS Requirements (2004): Hospital must ensure that all practitioners who provide clinical care are individually evaluated by a Medical Staff and that those practitioners posses current qualifications and demonstrated competencies for the privileges granted
  - Joint Commission Ongoing Professional Practice Evaluation ("OPPE" 2008): Require hospitals to review physicians based on criteria that can be viewed as having quality elements and financial elements
  - MS.06.01.05: The decision to grant or deny privileges is an objective, evidenced based process

Other Vehicles for Peer Review

- Summa uses System Quality Committee to act as Peer Review Committee to review Incident Reports including those involving sentinel events, and monitor all safety events, patient complaints, claims and lawsuits
- Can ACO attempt to qualify as Patient Safety Organization ("PSO")?

ACO Quality Committee

- Sample of Clinical Value Measurement and Resource Management Committee Core Functions:
  - Development and monitoring of routine ad hoc reports of clinical resource/utilization and quality reporting for care
  - Preparation of summary reports with recommendations for strategic direction relative to quality and utilization of clinical resources
  - Oversight of Peer Review, credentialing and re-credentialing of Physicians (either directly or via delegation agreement)
  - Oversight of utilization and care management activities (either directly or via delegation agreements)

System Quality Committee

- Sample of System Quality Committee Charter:
  - To act as a Peer Review Committee in receipt and review of incident reports (and/or unusual reports) including those involving sentinel events and near-misses
  - To oversee and facilitate the implementation of an accountable care delivery system within the Accountable Care Organization
  - Review Peer Review and Quality Assurance information in accordance with Ohio law, including ORC 2305.24 et. seq.

Lessons Learned

- What Entity or which Providers Determines eligibility criteria for ACO?
  - Hospital's Medical Staff/System Leaders/Subset of Physicians
- Expect Challenges to Data Upon Which Decisions are Made—Establish strong infrastructure and IT for Hospitals and Physicians to:
  - Gather, analyze, report and provide alerts based on clinical data and financial information in real time
  - IT Systems need to support caregivers change by facilitating immediate high quality care, enabling follow-up and feedback