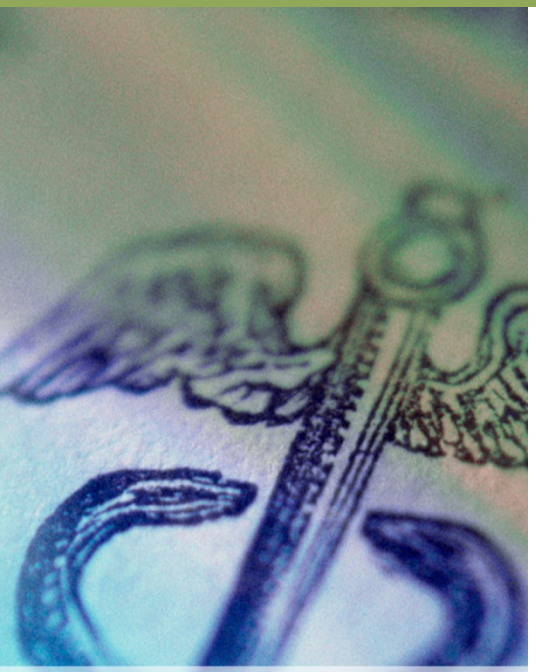

Impact of Health Care Reform on Provider Liability

Coverys Conference

October 21, 2014 – Lansing, Michigan

November 5, 2014 – Boston, Massachusetts

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The Changing Healthcare Landscape

- Market consolidation
  - Hospital/health system mergers
  - Physician practice acquisitions
  - Formation of multi-specialty groups
  - Insurance company joint ventures
- Provider margins are under attack
  - Reductions in Medicare/Medicaid reimbursement with and acquisition of providers
  - Medicare/Medicaid managed care programs
  - Higher costs
  - Private payer reimbursement reductions

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The Changing Healthcare Landscape
(cont'd)

- New models of integrated providers are emerging
  - Co-management arrangements
  - Patient centered medical home
  - ACOs/CINs
  - Coalition of Medicaid managed care providers

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The Changing Healthcare Landscape
(cont'd)

- Shift from "Volume to Value" as a basis of reimbursement
  - Pay for performance
  - ACO/CIN quality metrics
  - Value Based Purchasing metrics
  - Reduced or denied reimbursement for:
    - Hospital acquired conditions
    - Never events – (Billing Medicare for a never event is considered a false claim)
    - Readmissions within 30 days

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The Changing Healthcare Landscape
(cont'd)

- Never Events
  - Surgery on wrong body part
  - Surgery on wrong patient
  - Wrong surgery on a patient
  - Death/disability associated with use of contaminated drugs
  - Patient suicide or attempted suicide resulting in disability
  - Death/disability associated with medication error

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The Changing Healthcare Landscape
(cont'd)

- Hospital Acquired Conditions
  - Foreign object left in patient after surgery
  - Death/disability associated with intravascular air embolism
  - Death/disability associated with incompatible blood
  - Stage 3 or 4 pressure ulcers after admission
- Hospital Quality Standards
  - Specifications Manual for National Hospital Independent Quality Measures (CMS and The Joint Commission)

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The Changing Healthcare Landscape
(cont'd)

- Accountability Measures (heart attack care, heart failure care, pneumonia care, surgical care, children's asthma care, inpatient psychiatric care, venous thromboembolism care, stroke care, perinatal care)

- NCQA's Physician and Quality Certification
- Leapfrog Group
- National Quality Forum
- Agency for Healthcare Research and Quality

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Key Features of an ACO/CIN

- 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.

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Key Features of an ACO/CIN (cont'd)

- Goal of coordinated care:
  - Ensure that patients (especially chronically ill) get the right care at the right time.
  - At the same time, avoid duplication of services and prevent medical errors.
- When an ACO successfully delivers high-quality care and spends more wisely, it will share in the savings it achieves for the Medicare program.

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ACO Standards and Quality Metrics

- 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

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ACO Standards and Quality Metrics (cont'd)

- 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

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ACO Standards and Quality Metrics (cont'd)

- Incorporation of reporting requirements under the Physician Quality Reporting System; and
- Requirements for public reporting by ACOs.

- 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.

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ACO Standards and Quality Metrics (cont'd)

- ACO Quality measures are in four domains:
  - Patient/caregiver experience (7)
  - Care coordination/patient safety (6)
  - Preventive health (8) and,
  - At-risk populations (12): includes 6 measures for diabetes (5 scored as a single composite), 1 for hypertension, 2 for IVD, 1 for heart failure, and 2 for CAD
  - *EHR adoption by PCPs will be included as a quality measure in the Care Coordination/Patient Safety domain and will be given double weight in scoring*
- Changes over time:
  - CMS can specify higher standards and/or new measures to improve quality of care

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Examples of Quality Standards (cont'd)

- Value Based Purchasing Program Measures
  - Starting in October, 2012, will reward hospitals based on the quality of inpatient acute care services provided and not just on the quality delivered.
  - 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.

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Examples of Quality Standards (cont'd)

- 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

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Examples of Quality Standards (cont'd)

- 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
- FY 2014 there will be 13 (1 new) clinical process of care, 8 patient experience and 3 (all new) mortality measures.

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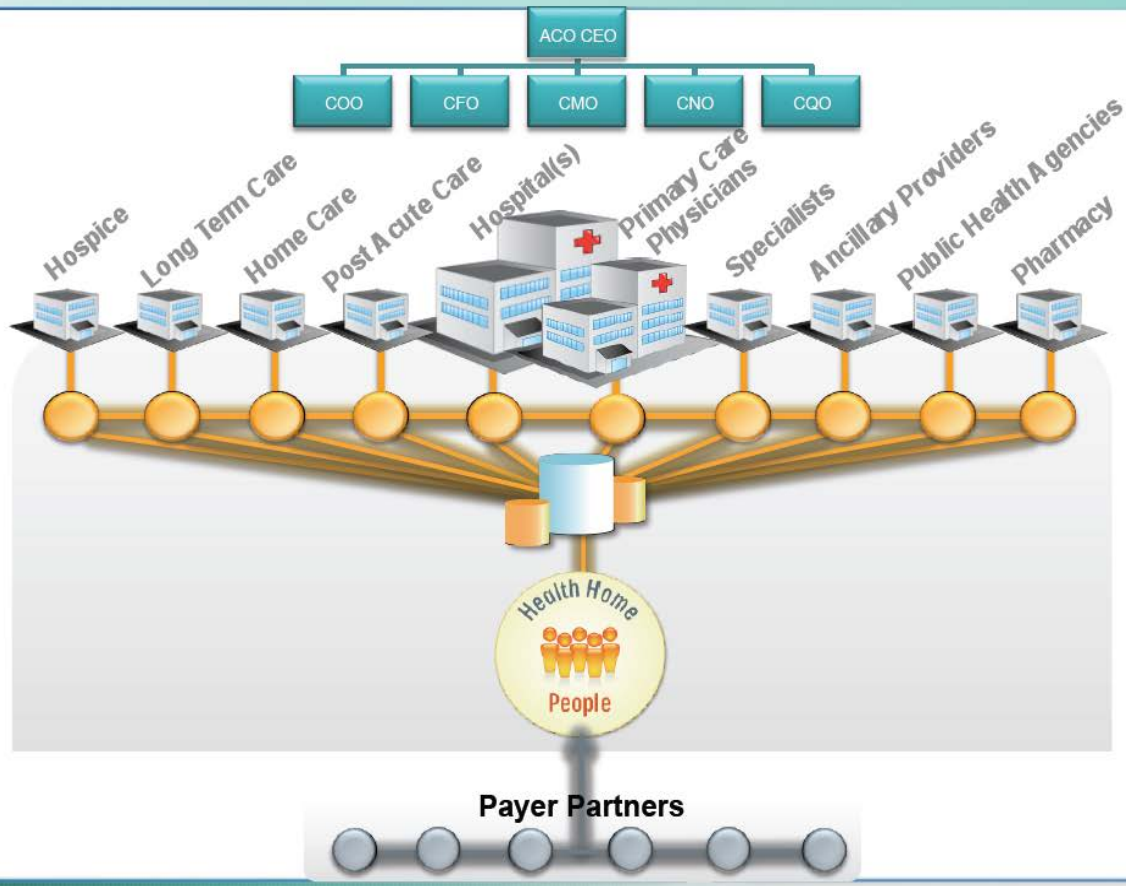
Complete view of an operational ACO



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Impact on Board and Corporate Responsibility

- Traditional corporate duties
  - Duty of care
  - Duty of loyalty
    - Must act in good faith as would an ordinary prudent person and in a manner which they reasonably believe is in the best interests of the corporation
  - Business judgment rule
- Doctrine of Corporate Negligence

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Impact on Board and Corporate Responsibility (cont'd)

- Medicare Conditions of Participation (42 C.F.R. Section 482.12)
- The Joint Commission Hospital Accreditation Standards (See LD.01.03.01)
- "Resources for Health Care Board of Directors on Corporate Responsibility and Health Care Quality (Joint White Paper of OIG/AHLA)

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Corporate Responsibility in Health Care Quality

- The OIG and AHLA collaborated on a publication titled “Resource for Health Care Boards of Directors on Corporate Responsibility and Health Care Quality”
- Was published “for the specific purpose of identifying the role and responsibility of corporate boards and management with respect to its fiduciary obligations to meet its charitable mission and legal responsibilities to provide health care quality services”
- Cites to key questions reflective of standards against which hospital boards will be measured

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Corporate Responsibility in Health Care Quality (cont'd)

- What are the goals of the organization's quality improvement program?
- What metrics and benchmarks are used to measure progress towards each of the performance goals? How is each goal specifically linked to management accountability?
- How does the organization measure and improve the quality of patient/resident care? Who are the key management and clinical leaders responsible for these quality and safety programs?
- How are the organization's quality assessment and improvement processes integrated into overall corporate policies and operations? Are clinical quality standards supported by operational policies? How does management implement and enforce these policies? What internal controls exist to monitor and report on quality metrics?

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Corporate Responsibility in Health Care Quality (cont'd)

- Does the board have a formal orientation and continuing education process that helps members appreciate external quality of patient safety requirements? Does the board include members with expertise in patient safety and quality improvement issues?
- What information is essential to the board's ability to understand and evaluate the organization's quality assessment and performance improvement programs? Once these performance metrics and benchmarks are established, how frequently does the board receive reports about the quality improvement effort?

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Corporate Responsibility in Health Care Quality (cont'd)

- Are human and other resources adequate to support patient safety and clinical quality? How are proposed changes in resource allocation evaluated from the perspective of clinical quality and patient care? Are systems in place to provide adequate resources to account for differences in patient acuity and care needs?
- Do to the organization's competency assessment and training, credentialing and peer review processes adequately recognize the necessary focus on clinical quality and patient safety issues?
- How are these "adverse patient events" and other medical errors identified, analyzed, reported and incorporated into the organization's performance improvement activities? How do management and the board address quality deficiencies without unnecessarily increasing the organization's liability exposure?

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Quality Enforcement Efforts

- **False Claims Act**
  - The OIG has identified that its principal enforcement tools include allegations of violations of the False Claims Act, use of corporate integrity agreements, including the use of external quality of care monitors, as well as civil fines and, in extreme circumstances, exclusion from the Medicare program
  - Actions brought under no care, substandard or worthless services theory
  - The OIG has made the following statement:

    > "To hold responsible individuals accountable and to protect additional beneficiaries from harm, the OIG excludes from participation in federal health care programs individuals and entities whose conduct results in poor care. In enforcement actions against corporate entities, . . . OIG places particular emphasis on high level officials, such as owners and chief executive officers. . . ."

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Quality Enforcement Efforts (cont'd)

- Grand Jury indicted a Michigan hospital based on its failure to properly investigate medically unnecessary pain management procedures performed by a physician on the medical staff.
- A California hospital paid $59.5 million to settle a civil False Claims Act allegation that the hospital inadequately performed credentialing and peer review of cardiologists on its staff who perform medically unnecessary invasive cardiac procedures.

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Quality Enforcement Efforts (cont'd)

- In a settlement with Tenet Health Care Corporation and pursuant to a Corporate Integrity Agreement, a hospital board was required to:
  - Review and oversee the performance of the compliance staff.
  - Annually review the effectiveness of the compliance program.
  - Engage an independent compliance consultant to assist the board and review an oversight of tenant's compliance activities.
  - Submit a resolution summarizing its compliance efforts with the CIA and federal health care program requirements, particularly those relating to delivery of quality care.
- A Pennsylvania hospital recently entered into a $200,000 civil False Claims Act settlement to resolve substandard care allegations related to the improper use of restraints.

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Quality Enforcement Efforts (cont'd)

- **Rogers v. Azmat (2010)**
  - DOJ intervened in a False Claims Act lawsuit alleging that Satilla Regional Medical Center and Dr. Najam Azmat submitted claims for medical substandard and unnecessary services to Medicare and Medicaid . The complaint alleges, among other things, that the defendants submitted claims for medical procedures performed by Dr. Azmat in Satilla's Heart Center that the physician was neither qualified nr properly credentialed to perform. As a result, at least one patient died and others were seriously injured.

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Quality Enforcement Efforts (cont'd)

- The complaint states that Satilla placed Dr. Azmat on staff even after learning that the hospital where he previously worked had restricted his privileges as a result of a high complication rate on his surgical procedures. The complaint also states that after Dr. Azmat joined the Satilla staff, the hospital management allowed him to perform endovascular procedures in the hospital's Heart Center even though he lacked experience in performing such procedures and did not have privileges to perform them.
- The complaint further states that the nurses in Satilla's Heart Center recognized that Dr. Azmat was incompetent to perform endovascular procedures and repeatedly raised concerns with hospital management. Despite the nurse's complaints and Dr. Azmat's high complication rate, Satilla's management continued to allow him to perform endovascular procedures and to bill federal health care programs for these services.
- Settled in 2012 for almost $900,000.00.

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Quality Enforcement Efforts (cont'd)

- Increased enforcement
  - OIG Work Plan
    - Reliability of hospital-reported quality measures data
    - Hospital admissions with conditions coded as "present-on-admission" and accuracy of "present on admissions" indicators
    - Review of Medicaid payments for HACs and never events
    - Acute-care inpatient transfers to inpatient hospice care
    - Safety and quality of surgeries and procedures in surgicenters and hospital outpatient departments

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Quality Enforcement Efforts (cont'd)

- Quality of care and safety of residents and quality of post-acute care for nursing homes
- Hospital reporting of adverse events
- Hospital same-day readmissions
- Hospitalizations and re-hospitalization of nursing home residents
- Review effectiveness of PSO programs

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Quality Enforcement Efforts (cont'd)

- January, 2012 OIG Report: "Hospital Incident Reporting Systems Do Not Capture Most Patient Harm"
  - All hospitals have incident reporting systems to capture events and are heavily relied on to identify problems
  - These systems provide incomplete information about how events occur
  - Of the events experienced by Medicare beneficiaries, hospital incident reporting systems only captured an estimated 14% due to events that staff did not perceive as reportable or were simply not reported
  - Accrediting bodies only review incident reports and outcomes but not the methods used to track errors and adverse events

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Enhanced Exposure to Malpractice, Apparent Agency and Corporate Negligence Liability

- Hospital, along with its medical staff, is required to exercise reasonable care to make sure that physicians applying to the medical staff or seeking reappointment are competent and qualified to exercise the requested clinical privileges. If the hospital knew or should have known that a physician is not qualified and the physician injures a patient through an act of negligence, the hospital can be found separately liable for the negligent credentialing of this physician [Doctrine of Corporate Negligence]
- Doctrine also applies to managed care organizations such as PHOs and IPAs, medical groups and most likely will be extended to ACOs/CINs

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Enhanced Exposure to Malpractice, Apparent Agency and Corporate Negligence Liability (cont'd)

- Emphasis on Pay for Performance ("P4P") and expected or required quality outcomes as determined by public and private payors
- Adverse Events, HACs, ACO metrics, value based purchasing standards can arguably be used as standards of care – all are increasing
- Greater transparency to general public via hospital rankings, published costs and outcomes, accreditation status, state profiling of physicians, etc. – will there be a developing "network" standard of care?
- 30 million new insureds entering the market, many with higher morbidity/mortality
- New sites of care – patient centered medical homes

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Enhanced Exposure to Malpractice, Apparent Agency and Corporate Negligence Liability (cont'd)

- Liability associated with poor transitions of care
- Likely increase in apparent agency claims due to patient perception that continuum of care services are being advertised, marketed and delivered under ACO/CIN branded name
- Credentialing and privileging of all practitioners, i.e., physicians, APNs, PAs, technicians, telemedicine, becoming more complex and difficult to monitor

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Enhanced Exposure to Malpractice, Apparent Agency and Corporate Negligence Liability (cont'd)

- Some questions associated with credentialing and privileging responsibilities:
  - How are core privileges determined?
  - Based on what criteria does hospital grant more specialized privileges?
  - Are ACO/CIN and hospital practices and standards consistent with those of peer networks?
  - Were any exceptions to criteria made and, if so, on what basis?

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Enhanced Exposure to Malpractice, Apparent Agency and Corporate Negligence Liability (cont'd)

- Has each of your department's adopted criteria which they are measuring as part of FPPE or OPPE obligations such as length of stay patterns or morbidity and mortality data?
- Has system incorporated VBP, ACO metrics, P4P, and peer metrics into its credentialing/privileging procedure?
- Is system asking for quality score cards generated by other hospitals, nursing homes, surgicenters, payors?
- Is information being collected, evaluated and reported back to each provider?
- Are meetings set up with providers to review quality score cards and are reasonable remedial measures being taken?
- Are you monitoring and tracking performance throughout the system?

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Enhanced Exposure to Malpractice, Apparent Agency and Corporate Negligence Liability (cont'd)

- Are you enforcing standards?
- With respect to apparent agency arrangements, how are services being marketed and delivered?
- Is system disclosing to patient/insureds the nature of its business, contract, joint venture relationships with independent providers?
- Are clinical, quality improvement, credentialing standards being developed at the corporate parent level?
- What responses to 10 corporate board questions posed in OIG/AHLA white paper?

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