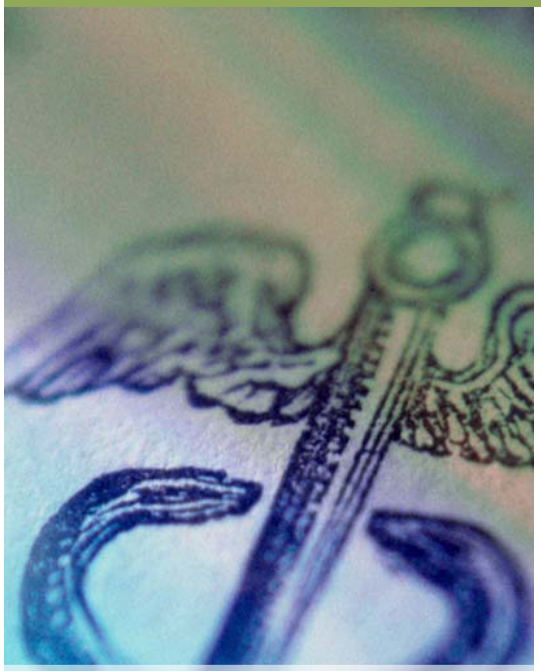

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Impact of Health Care Reform on Provider Liability:

Issues and Proposed Solutions

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The Changing Healthcare Landscape

- Consolidation of market
  - Hospital mergers
  - Practice acquisitions
- Provider margins are under attack
  - Reductions in Medicare/Medicaid reimbursement
  - Higher costs
  - Private payer reductions
- New models of provider integration are emerging
  - Co-management arrangements
  - Patient centered medical home
  - ACOs

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The Changing Healthcare Landscape
(cont'd)

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

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The Changing Healthcare Landscape
(cont'd)

- Increased enforcement
  - 2012 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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The Changing Healthcare Landscape
(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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The Changing Healthcare Landscape
(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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Examples of Quality Standards

- 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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Examples of Quality Standards (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

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Examples of Quality Standards (cont'd)

- ACO Standards and Quality Metrics
  - Have a management structure that includes clinical and administrative systems
  - Have defined processes to:
    - 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

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Examples of Quality Standards (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

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Examples of Quality Standards (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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Examples of Quality Standards (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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Examples of Quality Standards (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)

- Patient experience survey:
  - CMS will pay to administer patient experience surveys (CAHPS) in 2012 and 2013
  - Beginning in 2014, ACOs must select an approved survey vendor to administer the survey and report results to CMS
- Alignment with PQRS reporting
  - Use of GPRO tool to report ACO measures qualifies you for the physician quality reporting bonus payments – good example of alignment and reinforcing incentive for ACO

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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

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Examples of Quality Standards (cont'd)

- Other Criteria for FY 2014
  - Eight Hospital Acquired Condition Measures
    - Foreign object retained after surgery
  - AHRQ Patient Safety Indicators (PSIs), Inpatient Quality Indicators (IQIs), and Composite Measures
  - Mortality measures

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Corporate Responsibility in Health Care Quality

- In 2007 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 ten 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 goals 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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Corporate Responsibility in Health Care Quality (cont'd)

- How are the organization's quality assessment and improvement processes coordinated with its corporate compliance program? How are quality of care and patient safety issues addressed in the organization's risk management and corrective action plans?
- What processes are in place to promote the reporting of quality concerns and medical errors and to protect those who ask questions and report programs? What guidelines exist for reporting quality and patient safety concerns to the board?

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Examples of Quality Enforcement Efforts

- 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
- The OIG has made the following statements:
  - "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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Examples of 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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Examples of 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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Examples of Quality Enforcement Efforts (cont'd)

- Rogers v. Azmat (2010)
  - DOJ interviewed 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.

Examples of 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.

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Examples of Quality Enforcement Efforts (cont'd)

- 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.

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So Now What?

- Compliance plans need to be updated or prepared which reflect the provider's commitment to improving quality as per the areas identified by the OIG
- Even if not seeking ACO certification at this time, hospital should review the ACO final rules as a future standard on which private and public reimbursement and standards of care will be based

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So Now What? (cont'd)

- A failure to comply with ACO, VBP and other developing standards, including a pattern of HACs and Never Events, may also have a direct or indirect impact on provider responsibilities:
  - 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)

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So Now What? (cont'd)

- Providers therefore need to incorporate these quality metrics and standards into their policies and procedures
- Standards need to be developed that track performance 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

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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
- 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

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So Now What? (cont'd)

- It is important that provider 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).

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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?

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So Now What? (cont'd)

- Will new bylaws, rules, regulations and policies be required given the fact that the ACO must be al 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?

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