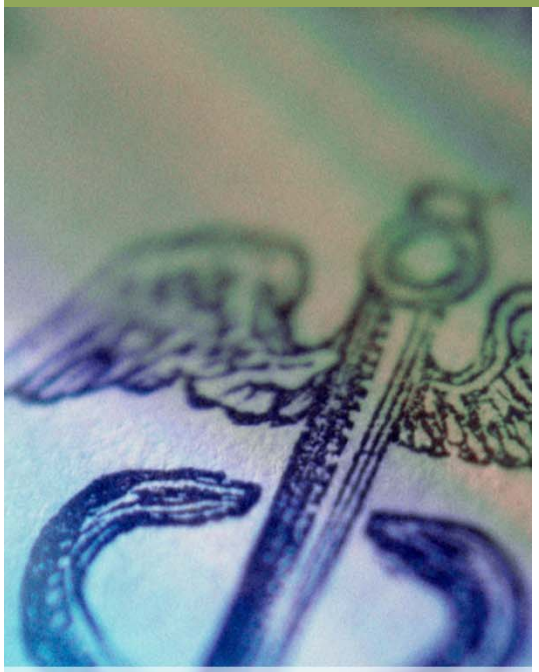

Impact of Health Care Reform on Provider Liability

November 20, 2013

Michael R. Callahan
Katten Muchin Rosenman LLP
Chicago, Illinois
+1.312.902.5634
michael.callahan@kattenlaw.com
(bio/events/publications) www.kattenlaw.com/callahan

Katten
Katten Muchin Rosenman LLP

100099580

Michael R. Callahan

Katten Muchin Rosenman LLP
Chicago, Illinois
+1.312.902.5634
michael.callahan@kattenlaw.com
www.kattenlaw.com/callahan (bio/events/publications)

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

- Medicare offers several ACO programs:
  - Medicare Shared Savings Program: Provides an option for Medicare providers to become an ACO which bases reimbursement and the possibility of receiving an additional portion of Medicare revenue tied to satisfying required quality outcome measures.
  - Advance Payment Program: Supplementary incentive program for selected participants in the Shared Savings Program.
  - Pioneer ACO Mode: Designed for early adopters of coordinated care.

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ACOs Currently Participating in Shared Savings Initiatives

- As of July 1, there are over 250 Accountable Care Organizations (ACOs) in 40 States and Washington, D.C.
  - This total includes:
    - 32 ACOs participating in the testing of the Pioneer ACO Model by the Center for Medicare and Medicaid Innovation (Innovation Center) announced last December, and
    - 6 Physician Group Practice Transition Demonstration organizations that started in January 2011.
- Providers participating in Medicare shared savings initiatives care for more than 4.4 million beneficiaries.

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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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ACO Standards and Quality Metrics (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
- 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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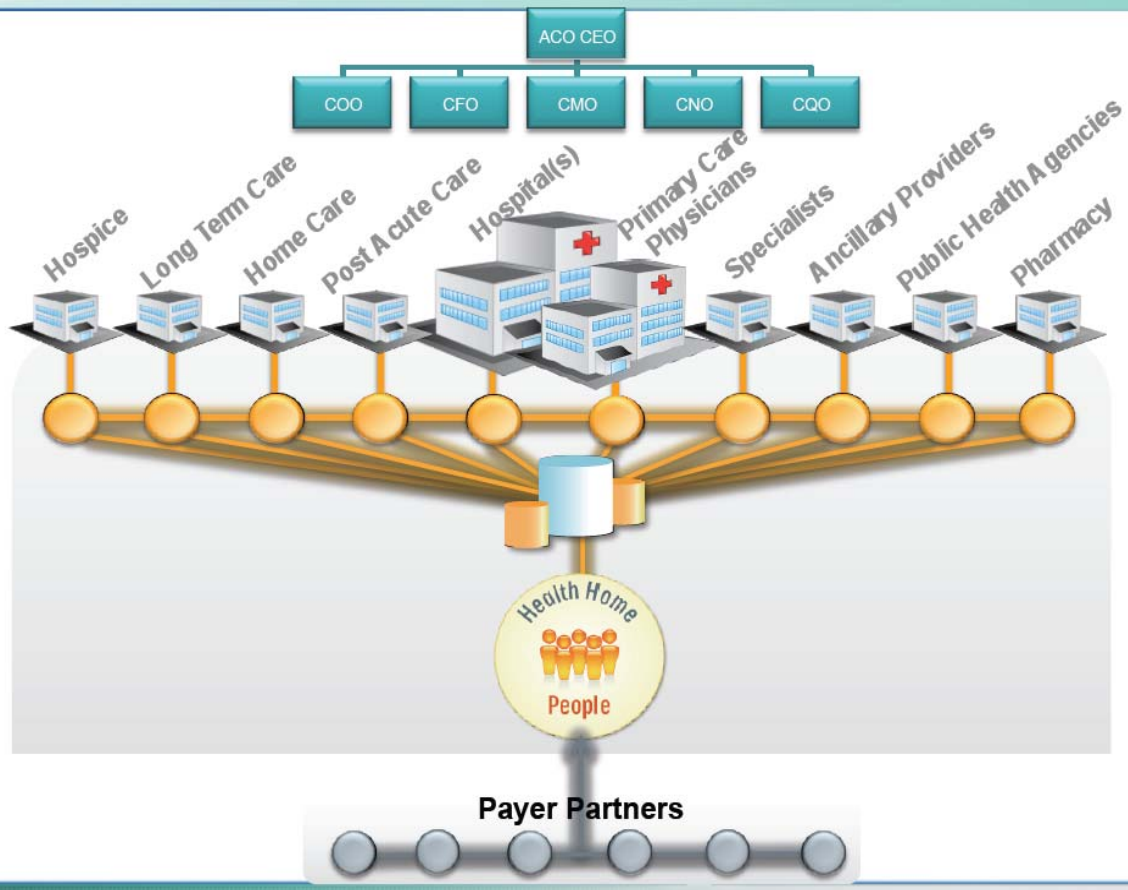
Complete view of an operational ACO



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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
  - 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 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.

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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.

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Quality Enforcement Efforts (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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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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Challenges to Decision to Exclude/ Terminate Based on Poor Performance

- Because the failure of a provider to meet a quality metrics standard now has a direct adverse impact on a hospital's or system's reimbursement, provider's failure to adjust and improve performance requires imposition of remedial measures which can include termination from managed care plans, participation in one or more delivery sites, the medical staff or the ACO/CIN
- Physician performance and impact on cost containment also must come under closer scrutiny and may result in similar disciplinary action even if quality is acceptable
- "Economic credentialing" is now more of a reality then ever before

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Challenges to Decision to Exclude/ Terminate Based on Poor Performance (cont'd)

- The legal challenges to adverse membership decisions include:
  - Antitrust
    - Exclusive contracts for hospital based and non-hospital based services
      - Challenges are not likely to succeed but what impact on current providers?
      - Should base on strong quality/economic grounds on which to support Board decision

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Challenges to Decision to Exclude/ Terminate Based on Poor Performance (cont'd)

- Adoption of conflict of interest or similar policy that bars new applicants or terminates existing providers from membership if they have a financial, economic or employment relationship with a competing entity
- Easier to implement, enforce and defend for initial applicants if supported by objective facts
- Application to existing "medical staff" versus "ACO staff" members is much more difficult. At a minimum a hearing needs to be provided (See Murphy vs. Baptist Hospital)

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Challenges to Decision to Exclude/ Terminate Based on Poor Performance (cont'd)

- **Recommendations**
  - All exclusive/recruitment/development plans should be Board driven albeit with physician involvement
  - Any physician participation should be in the form of a "recommendation" – should not be allowed to veto or make final decision
  - Decisions should be based on objective and quantifiable information fully reviewed and vetted
  - Decisions and standards should be implemented, where possible, through medical staff bylaws, rules, regs, or policies or board policies
  - Any adopted policy must evaluate impact on prospective and current members on medical, allied and ACO/CIN staffs
  - Need to incorporate standards into employment/independent contractor agreements

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Challenges to Decision to Exclude/ Terminate Based on Poor Performance (cont'd)

- **Title VII Claims**
  - Title VII makes it "an unlawful employment practice for an employer . . . To discriminate against any individual with respect to his compensation, terms, conditions, or privileges of employment because of such individual's race, color, religion, sex or national origin." (42 U.S.C. § 2000e – 2(a)(1))
  - This provision applies to acts of discrimination, such as termination, and acts that create a hostile work environment
  - As a general rule, independent members of the medical staff, even practice groups with an exclusive contract with the hospital, are not deemed to be "employees" under Title VII

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Challenges to Decision to Exclude/ Terminate Based on Poor Performance (cont'd)

- However, in Solomon v. Our Lady of Victory Hospital (Western District, N.Y., No. 1:99-cv-48 (4/3/12) a federal district court, on remand from the Second Circuit, held that although Dr. Solomon was an independent member of the medical staff, the fact that she was subject to a supervision under hospital's quality assurance program and required to undergo a three month re-education program and mentoring program presented a genuine issue of material fact as to whether she should be treated as an employee under the thirteen factor test enunciated by the U.S. Supreme Court in Community for Creative Non-Violence v. Reid (490 U.S. 730 (1989))

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Challenges to Decision to Exclude/ Terminate Based on Poor Performance (cont'd)

- Second Circuit had held that while hospital policies that merely reflected professional and governmental standards that when imposed, establish an employer/employee relationship under Title VII, these standards as applied to Dr. Solomon may have been driven by maximizing revenue and/or in retaliation for her complaints of harassment
- Although the hospital argued that its policies and review of plaintiff's cases were driven, if not required by, state and federal law, because the plaintiff argued that her cases were subjected to greater scrutiny due to her complaints about sexual harassment, there was a genuine issue of material fact as to whether the extent of the hospital's control of her performance as to allow the Title VII claim to go forward

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Challenges to Decision to Exclude/ Terminate Based on Poor Performance (cont'd)

- **Recommendations**
  - Systems need to incorporate quality utilization metrics into bylaws, rules, regs, policies and contracts and continuously update
  - Standards need to be uniformly applied to independents and employees
  - Need to address whether termination of employed provider does or does not trigger a hearing under the bylaws – HCQIA immunity issue

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Challenges to Decision to Exclude/ Terminate Based on Poor Performance (cont'd)

- Joint Commission takes the position that termination of the medical staff membership and clinical privileges of an employed physician requires that they be entitled to hearing rights if based on quality of care issues
- No Data Bank report required for an employed practitioner but remember HCQIA does not apply to discrimination claims

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Additional Recommendations

- 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
- A failure to incorporate and 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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Additional Recommendations (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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Additional Recommendations (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
- 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).
- Patient Safety Organization Overview – a Legal Perspective, October 3, 2013 http://www.kattenlaw.com/36376
- Patient Safety Organizations
  To Participate or Not: That is the question, April 30, 2010
  http://kattenlaw.com/files/21297_Callahan_CHRMS_4-30-10.pdf

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Additional Recommendations (cont'd)

- 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
  - Corporate Compliance Plan
    - Stark, Anti-Kickback, CMP
      - Government Investigations, November 11, 2013 http://www.kattenlaw.com/36616
  - HIPAA Compliance Plan
    - Practical Guidance and Proposed Solutions in Response to HIPAA Omnibus Final Rule, February 21, 2013 http://www.kattenlaw.com/Practical-Guidance-and-Proposed-Solutions-in-Response-to-HIPAA-Omnibus-Final-Rule-02-21-2013
  - Credentialing/Confidentiality Compliance Plan

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Some Remaining Questions (cont'd)

1. Is or can an ACO be a health care entity for HCQIA query, reporting and immunity purposes?
2. Under what circumstances can an ACO be considered a "provider" under the Patient Safety Act for purposes of participating in a patient safety organization ("PSO")?
3. Is an ACO eligible for or what criteria must be met in order to qualify for state confidentiality/immunity protections?
4. What risks, if any, are there if different credentialing/privileging/peer review standards are developed for ACOs versus hospitals?

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Some Remaining Questions (cont'd)

5. Can an ACO be held liable under negligent credentialing/corporate negligence/apparent agency or related liability principles?
6. How does an ACO best incorporate/implement ACO quality metrics, value based purchasing and similar quality standards as part of its credentialing/privileging/ peer review procedures?
7. Does the sharing of peer review, credentialing or otherwise protected information by and between a hospital/ACO and other providers in the ACO adversely affect confidentiality protections? What are ways to structure information sharing arrangements in order to maximize confidentiality protections?

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Some Remaining Questions (cont'd)

8. How will an ACO balance the requirement to provide quality and utilization data to payers against the need or preference to keep certain information confidential?

9. Should hearing procedures be the same for ACOs and hospitals or should and can they be more streamlined? Can they be modified and still maintain HCQIA and other immunity protections?

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Some Remaining Questions (cont'd)

10. Will or should the standards for remedial/corrective action be different, i.e., should overutilization or failure to satisfy quality metric standards, which is turn can reduce shared savings or other forms of reimbursement, serve as a basis for action, including termination?
11. What should be the inter-relationship between ACO and medical staff/AHP membership and ACO membership? Should removal from one result in removal from the other?

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