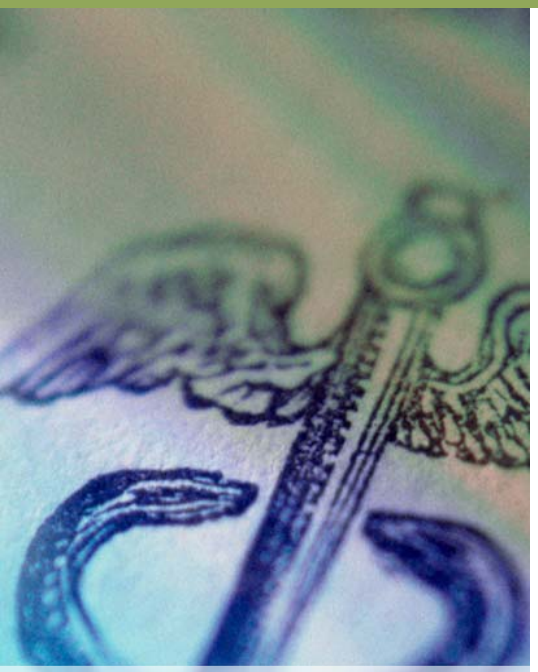

American Health Lawyers Association
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Systems-Based Approach to Quality: Critical Liability and Accreditation Challenges and Exposures

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Topics to be Covered

- Origins and overview of systems-based approach to quality
- Fiduciary duty, corporate negligence and FCA liability drivers and challenges
- Malpractice and corporate negligence exposures from increased transparency
- Antitrust liability exposure to hospitals from non-employed practitioners
- Title VII liability exposure to hospitals from non-employed practitioners and the loss of HCQIA immunity
- Operationally practical tools to overcome the challenges and avoid the exposures

Systems-Based Approach to Quality

- A management structure that includes clinical and administrative systems and processes that can operate multiple businesses under a single entity
- The processes must:
  - Promote evidenced-based medicine
  - Report to all stakeholders the necessary data to evaluate quality and cost as compared to required measures as applied throughout the system
  - Care of the patients must be coordinated across all sites and disciplines to ensure efficiencies, improve quality and to reduce unnecessary costs
- All participants must be individually and collectively responsible and all must be held accountable

Health Care Reform

- P4P standards
- Never events
- Hospital acquired conditions
- Movement from “volume to value” as a basis for reimbursement
- Patient Protection and Affordable Care Act
  - Accountable Care Organizations
  - Defined quality metrics
  - Emphasis on clinical integration
- Value based purchasing standards
- Accreditation tied to quality performance
- NCQA accreditation standards
- Bundled Payments

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

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 (2007))

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 to key questions reflective of standards against which hospital boards will be measured

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?

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?

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?

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. . . ."

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.

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.

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.

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.

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

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

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

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

- 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

Enhanced Exposure to Malpractice and Corporate Negligence Liability

- 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.

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

- Some questions associated with this duty:
  - How are core privileges determined?
  - Based on what criteria does hospital grant more specialized privileges?
  - Are hospital practices and standards consistent with those of peer hospitals?
  - Were any exceptions to criteria made and, if so, on what basis?

Enhanced Exposure to Malpractice 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 incorporate VBP, ACO metrics, P4P, and peer metrics into its credentialing/privileging procedure?
- Is system asking for quality score cards generated by other providers?
- 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 tracking performance throughout the system?

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 or from the medical staff
- Physician performance and impact on cost containment also must come under closer scrutiny and will result in similar remedial action even if quality is acceptable

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

- The legal challenges to adverse membership decision include:
  - Antitrust
    - Exclusive contracts for hospital based services – system prevails
    - Exclusive contracts for non-hospital based services
    - Challenges are not likely to succeed by what impact on current providers?
    - Must have strong quality/economic grounds on which to support Board decision

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

- Exclusive contract through employment – same as above
- Exclusive contract for ED coverage – coverage is a duty and therefore challenge is not likely to be successful
- 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)
- Challenges to credentialing/privilege decisions

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

- **Recommendation**
  - All exclusive/recruitment/development plans should be Board driven and Board decision albeit with physician involvement
  - Any physician participation should be in the form of a "recommendation" and not a veto or 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 and allied staffs
  - Need to incorporate standards into employment/independent contractor agreements

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

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))

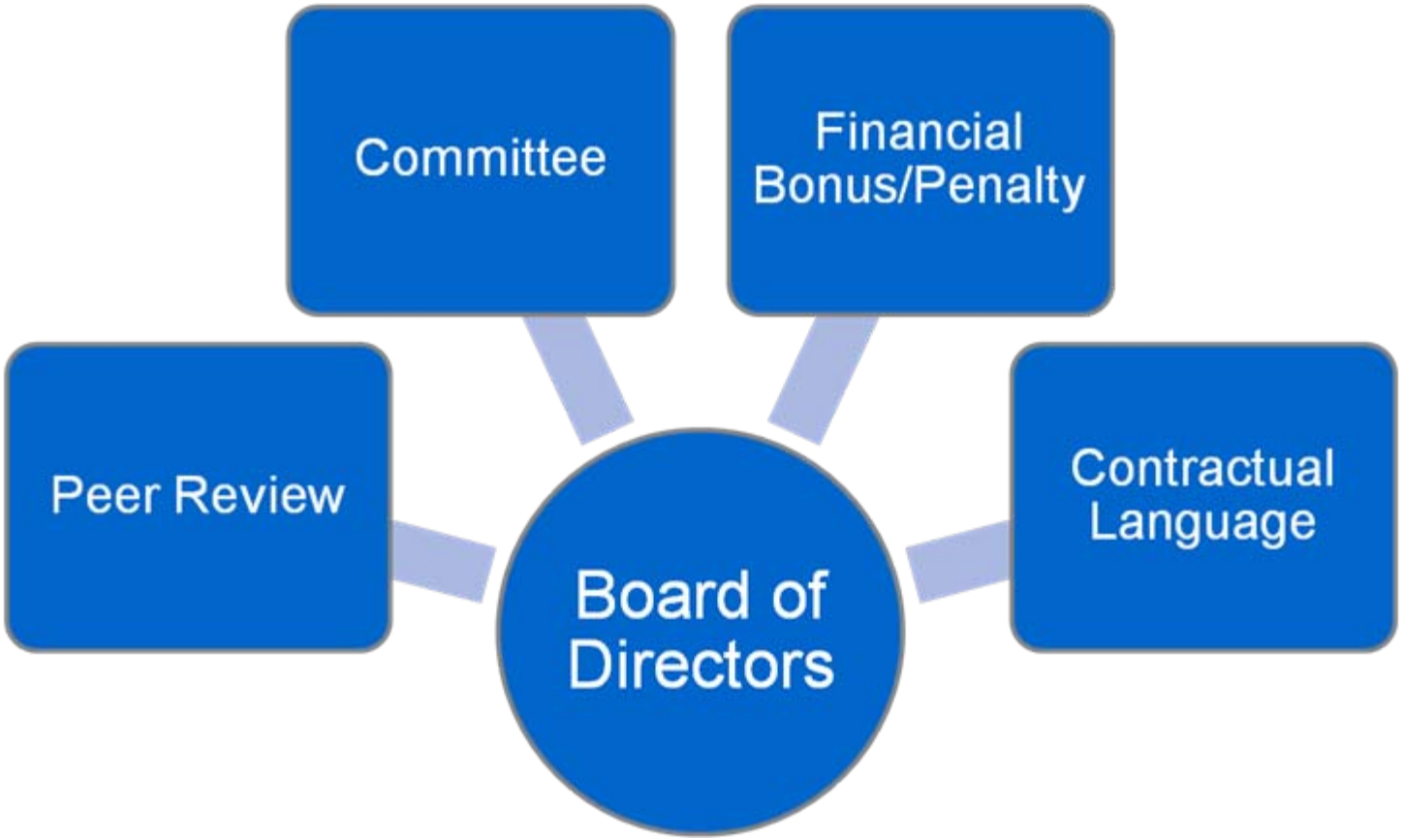
Challenges to Decision to Exclude/ Terminate Based on Poor Performance (cont'd)

- 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

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
    - 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 a Data Bank reportable event

Transition of Credentialing Providers in New Initiatves



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Board / Medical Staff Actions Around Quality Metrics

- Historically, the Board of Directors of the Hospital delegated credentialing/privileging decisions to the Medical Staff to govern inpatient/outpatient privileges based on a threshold level of competency
- The Medical Staff policed its members through creating disciplinary process to investigate and act upon complaint filed against its members. However, the Medical Staff did not create specific quality benchmarks to evaluate its Physicians performance

Evolution of Health Care and Impact on Credentialing

- New entities seek to assess initial and ongoing qualifications of providers
- Organization must define new levels of baseline competency and crate infrastructure to measure quality of care delivered
- Challenges include creating the IT infrastructure necessary to mine the data to properly evaluate quality of care
- Need to Develop effective means for reporting and addressing quality concerns and protecting the privacy of the data
- Create mechanism to track and report individual performances against defined benchmarks

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ACOs

- **Accountable Care Organizations**
  - Delivery Network or Physician Panel typically created through invitation process to like-minded Physicians
- **Clinical Value or Other Committee delegated by ACO Board authority to define and address performance around quality standards**
- **CMS MSSP Performance Metrics (33 metrics)**
  - 1st Year: Report Only
  - 2nd, 3rd Year: Report and Perform
- **CMS program requires ACOs to institute a Corrective Action/Performance Improvement Plan**
  - Remedial Process to ensure that Physicians meet the performance criteria necessary for (i) Shared Savings Distribution, or (ii) continued participation in the ACO

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Employed Physicians

- **In contrast to due process rights of Medical Staff members, Employed Physicians have contractually designated process to address lack of performance which typically includes (i) mentoring, (ii) notice and right to cure, or (iii) termination with or without cause**
- **To ensure Group performance, mechanisms include:**
  - Front-End Due Diligence
  - Physician Advisory Council (e.g. Mentoring, Proctoring)
  - Compensation Committee/Comp Model create financial incentive to perform against benchmarks
  - Sharing Information with Medical Staff