Governance, Leadership, and Quality: Moving the Whole Organization Forward

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Governance in Health Care

The Role of the Board in Exercising Reasonable Oversight
Role of the Board

- Responsible for conduct and management of a company and its affairs
  - Act in best interests of company and in good faith at all times
  - Disclose conflicts of interest
  - Be engaged and aware

*Expectation is that boards are exercising oversight to assure their organizations are in compliance with evolving legal requirements.*

Role of the Board

- Fiduciary duties of corporate directors require that they keep themselves adequately informed concerning the operations of the company:
  - Duty of Care – take adequate steps to inform themselves in making decisions and act as an ordinary prudent person would act in the same or similar circumstances
  - Duty of Loyalty – place interest of corporation above own and act in what reasonably believe is the best interest of the organization
Role of the Board

- Fiduciary duties (cont’d):
  - Duty of Obedience – obey and be faithful to the organization’s mission
  - A compliance program designed to assure compliance with applicable legal requirements helps meet these duties

Role of the Board in Health Care

- Today’s Environment
  - Scrutiny from national, state and local regulators
  - Increased competition and larger organizations
  - Questions from patients/consumers, media and others on motives and behaviors
    - Conflicts on Interest, Compensation, Patient Safety
    - Fraud, Charity Care, Joint Ventures, Non-Profit Status
Role of the Board

• Non-Profit vs. For-Profit
  – Duties are equivalent but the constituencies to whom directors are accountable are not

Role of the Board

• For-Profit Constituencies
  – Fiduciary duty is owed to corporate shareholders and they are accountable to shareholders

• Non-Profit Constituencies
  – May be held accountable by a number of groups
    • Primary source – State Attorney General if organization exists for the stated purpose of providing for the public good
    • IRS – insofar as it seeks to enforce qualifications of being a 501(c)(3)
    • Creditors - growing body of law establishing the persons to whom directors owe duty expands to creditors
Role of the Board

• SOX and the Non-Profit
  – Voluntary but raises the bar as states adopt some provisions in nonprofit legislation
  – Adopted as “best practices” by larger nonprofits
  – Audit Committees
    • Independent Directors
    • Financial Expert
  – Auditor Independence
    • Demonstrate independence of firms
  – Controls and Procedures
    • Ensure meeting reporting obligations

The Board and Compliance

• Understand the content and operation of the compliance and ethics program

• Be flexible and prepared for ever expanding scope of compliance and ethics issues
  – Increased focus on quality and patient safety
    • Emerging as enforcement priority for regulators
    • Increases expectation regarding oversight of corporate affairs

• Exercise reasonable oversight with respect to the program’s implementation and effectiveness
Scope of Board Understanding and Oversight

- Meeting the Elements of an Effective Compliance Program:
  - Employee responsibility and accountability
  - Policy development
  - Code of conduct
  - Education, training and communication
  - Reporting
  - Integrity line
  - Monitoring
  - Auditing
  - Ongoing evaluation and reporting

- Ensure that the organization’s governing authority is knowledgeable about the content and operation of the ethics and compliance program

  AND

- Exercise reasonable oversight with respect to the program’s effectiveness

Question: What is an “effective program” in today’s environment?
Board Role in Identifying and Mitigating Risks

• Recap of Trends:
  – Compliance and Ethics – Increased role in mission and values, particularly in non-profit environment
  – SOX – For profit and non-profit
  – Community Benefit
  – Tax
  – Health Care Quality and Patient Safety

Higher regulatory scrutiny = Increased level of board awareness/involvement

Compliance and Performance: Connecting the Dots with Quality

Aren't issues of regulatory compliance and outcomes in quality and patient safety direct indicators of organizational performance?
Ensuring an Effective Compliance Program

- First Stage: The foundation … getting the structure in place.
- Second Stage: Integrating quality indicators into operations … ownership by front-line managers, executive leadership and board members
- Third Stage: Mission and values, compliance as critical to overall organizational culture … take them off the wall and bring them alive (e.g. providing exceptional care to patients and family members)
- Fourth Stage: Compliance and performance – the bottom line

Compliance and Quality:
Connecting the Dots

Aren't issues of regulatory compliance and outcomes in quality and patient safety direct indicators of organizational performance?

What is the role of compliance in these issues?
Role of the Board in Health Care Quality

Defining Quality of Care and the Critical Need to Implement Quality Initiatives

“The American health care delivery system is in need of fundamental change. Many patients, doctors, nurses and health care leaders are concerned that the care delivered is not, essentially, the care we should received… Quality problems are everywhere affecting many patients. Between the healthcare we have and care we could have lies not just a gap, but a chasm.” Crossing the Quality Chasm, Institute of Medicine, 2001, p.1

Quality and Compliance

• Connection between Compliance and Quality Management
  – Compliance & Regulatory Affairs is working to link quality and compliance processes in an effort to better prepare for business trends such as Pay for Performance
  – The enforcement trend includes a push by the OIG to link prosecution under the False Claims Act and reimbursement to quality of care measures
A scorecard on the U.S. health care system developed by the Commonwealth Fund in 2006 showed the following results, among others:

- For 37 key indicators for five health care system dimensions (quality, access, equity, outcomes and efficiencies), the overall U.S. score was 66 out of a possible 100.
- Efficiency was the single worst score among the five dimensions. For example, in 2000/2001, the U.S. ranked 16th out of 20 countries in use of electronic health records.
- The U.S. is the worldwide leader in costs.

Quality and Compliance (continued)

- The U.S. scored 15th out of 19 countries in morality attributable to health care services.
- Basic tools (i.e., Health IT) are missing to track patients through their lives.
- We do poorly at transition stages – hospital readmission rates from nursing homes are high; our reimbursement system encourages “churning”.
- Improving performance in key areas would save 100,000 to 150,000 lives and $50 billion to $100 billion annually.
Quality and Compliance

A scorecard on the U.S. health care system…
(continued)

The U.S. should expand health insurance coverage; implement major quality and safety improvements; work toward a more organized delivery system that emphasizes primary and preventative care that is patient-centered; increase transparency and reporting on quality and costs; reward performance for quality and efficiency; expand the use of interoperable information technology; and encourage collaboration among stakeholders.

As Don Berwick, a recognized national quality expert, stated in *Health Affairs* in 2005. “Right from the start it has been one of the great illusions in the reign of quality that quality and cost go in opposite directions. There remains very little evidence of that.” Robert Galvin, “A Deficiency of Will and Ambition: A Conversation with Donald Berwick,” *Health Affairs* Web Exclusive, January 12, 2005.
Quality and Compliance

Theories of Liability under False Claims Act

• Medically Unnecessary Services
• Provision of Substandard Care (or no care at all)

What amounts to substandard care or administration decisions that preclude occurrence of good quality care?

Quality and Compliance

AHLA/OIG White Paper:

• Connection between quality and health regulation/compliance
• Recommendation to Boards on:
  — Duty of Board on Health Care Quality Issues
  — Education and Training on Quality Issues
  — Questions Board Members Should Ask
  — Appropriate Oversight and Structure
Quality and Compliance

AHLA/OIG White Paper: Key Questions

• What are the benchmarks/metrics of our QI program?
• How are our managers accountable to these goals?
• Who are the key managers/leaders responsible for QI?
• How is our QI and QA integrated in with our other compliance policies?
• What are our reporting processes? How can we ensure that reports are accurate?
• Does our credentialing process focus on quality and safety?
• How is the board involved in assessing quality deficiencies?

Top Take-Aways

Summary

• “Good Governance” is being defined by regulatory agencies in greater deal
• Greater tie between organizational performance and compliance
• Boards more engaged in “future” compliance matters and organizational risks
• Quality is now high on the list with Tax, Community Benefit and others closing in behind.
GOVERNANCE & QUALITY

• How does leadership help?
  – Culture
  – Resources
  – Incentives
  – Attention
    • Dashboards
    • Focus activities on success

• Who are leaders
  – CEO
  – CMO/Medical Director
  – CNO
  – Head Pharmacist
  – Etc.
GOVERNANCE & QUALITY

- What is the evidence

Breadth of involvement in quality measures

FIGURE 9. Quality index relative to monthly review frequency.
Board focus on quality

Leadership influence

FIGURE 8. Quality level by most influential position (cross-tabulation of position against high- versus low-quality level).
CMO—CEO who’s in charge

![Diagram](image)

**FIGURE 9.** Relationship between Quality Index score and most influential position.

GOVERNANCE & QUALITY

- University Health Consortium Study
  - How are the top-performing hospitals different?
  - Roadmap for leadership
GOVERNANCE & QUALITY

• Shared sense of purpose
  – Hospital leaders articulate that patient care comes first
  – Leaders are dissatisfied with the current state of quality and safety
  – Service excellence is added to the focus on quality and safety
  – Service, quality, and safety are seen as a source of competitive advantage

GOVERNANCE & QUALITY

• Leadership Style
  – The CEO is passionate about service, quality, and safety, and has an authentic, hands-on style
  – Everyday events are connected to the larger purpose through stories and rituals
  – Governance structures and practices minimize conflict between missions
  – The institution is led as an alliance between the executive leadership team and the clinical department chairs
GOVERNANCE & QUALITY

• Accountability system for service, quality, and safety
  – Prioritizing, developing measures, and setting goals are centralized, and the tactics to improve are decentralized
  – The chairs accept responsibility for quality and safety within their departments
  – There is accountability, innovation, and redundancy at the unit level

GOVERNANCE & QUALITY

• A focus on results
  – There is a relentless effort to improve, employing performance against external standards as a measure of success
  – Results outweigh the approach to performance improvement
  – There is a focus on human behavior and work redesign as the keys to improvement
  – Technology is employed as an accelerator and not as a substitute for work redesign
GOVERNANCE & QUALITY

- Collaboration
  - Collaboration characterizes the relationships between administration, physicians, nurses, and other staff
  - Recognition of employee contributions at every level is frequent
  - Employees value each other’s critical knowledge when problem solving
Overview

I. The Quality Revolution
II. Three-Prong Approach to Quality of Care
   ▪ Payment Reform
   ▪ Public Reporting
   ▪ Government Enforcement
III. Problems Under Current Structures
IV. Recommended Solutions

The Quality Revolution

• Since the 1999 IOM report, *To Err is Human*, there has been an increased national focus on quality.
• The Institute for Health Care Improvement, Leapfrog, Joint Commission, and CMS have established national quality initiatives.
• Quality is the top priority for physicians and hospitals in 2008.
The Quality Revolution

CMS’ 9th Statement of Work for Medicare QIOs
- Covers August 2008 – July 2011
- Highlights the need for providers to be proactive in assessing and addressing quality of care issues.
- QIOs will be responsible for meeting performance targets as well as partnering with Medicare and related Medicare organizations.

The Quality Revolution

Four Main Themes in CMS 9th Statement of Work (SOW)
- Beneficiary Protection
- Patient Pathways
- Prevention
- Patient Safety
The Quality Revolution

Other Quality Initiatives
• Institute for Healthcare Improvement
  – Launched “100,000 Lives” campaign in 2004.
  – Declared success and launched “5 Million Injuries” campaign in December, 2006 (goal of December, 2008).
  – Recommends interventions for patient safety (such as, medication safety or falls prevention); critical care (ventilator bundle, central line bundle, rapid response teams, etc.); reducing mortality, etc.
  – www.ihi.org

Other Quality Initiatives (cont’d)
• LeapFrog
  – Organization of health care purchasers with a mission to trigger “giant leaps” forward in safety, quality and affordability of health care by:
    (1) informed decision-making
    (2) providing incentives and rewards to promote quality
  – 4 Main “Leaps”
    • CPOE
    • ICU staffing
    • High risk treatments (evidence based referrals)
    • Safe practices (27 procedures to reduce error)
      – www.leapfroggroup.org
The Government’s Three-Prong Approach To Quality of Care

• Incentivizing Quality Care Through Payment Reform
• Driving Quality of Care Through Public Reporting
• Enforcing Quality of Care Through the False Claims Act
Prong 1: Incentivizing Quality of Care Through Payment Reform

- The new paradigm for reimbursement.
- CMS is transforming payment policy from passive payer of services to active purchaser of high value health care.
- Private payors also are changing payment policies to pay for quality.

Incentivizing Quality of Care Through Payment Reform

- “I strongly support linking provider payment to quality care as a way to make Medicare a better purchaser of health care services. Today, Medicare rewards poor quality care. That is just plain wrong and we need to address this problem.”
  
  Sen. Chuck Grassley,
  Budget Hearing with Michael Leavitt
  February 7, 2007
Incentivizing Quality of Care Through Payment Reform

Pay for Performance

- Financial incentives for:
  - Adhering to recommended tasks or processes.
  - Adopting desired tools or infrastructure.
  - Meeting or improving measured outcomes.
- Sometimes includes cost savings or efficiency targets (aka “gainsharing”).

Prong 3: Enforcing Quality of Care Through the False Claims Act

- The FCA is emerging as the government’s most powerful tool to enforce quality of care.
- Physicians, executives, and board members face real risks for poor quality of care.
Enforcing Quality of Care Through the False Claims Act

- "You will see more and more physicians going to jail."
  - Kirk Ogrosky, Deputy Chief for Health Care Fraud, Department of Justice, Criminal Division (Dec. 4, 2007)

- "We're holding those individuals accountable."  "You may not go to jail ... but we will take your money."

Six themes present in cases:
- Unnecessary treatment/procedures
- Kickbacks
- Big admitters receiving special treatment
- Fraudulent documentation
- Poorly structured, or failure to follow, internal process
- Underlying regulatory violations
Enforcing Quality of Care Through the False Claims Act

*Elements of a False Claim*

- Submit or cause to be submitted, a claim for payment;
- Claim is false or fraudulent (false statement); and
- Scienter: “Knew or should have known” or “reckless disregard” for the truth or falsity of the claim.
  - *No specific intent needed*

- The government uses a variety of legal theories under the FCA to attack quality failures, but all follow the same principle: *the government will not pay for medically unnecessary or substandard care.*
Enforcing Quality of Care Through the False Claims Act

Traditional Theories
- Claims for services not rendered
- Unbundling
- Claims for services not covered (e.g., wound care kits, urinary incontinence devices)
- Duplicate payments

Quality of Care Theories
- Express False Certification
- Implied False Certification
- Worthless Services
- Criminal Statutes

Express False Certification
- Based on a provider’s false certification that the care provided met the legal requirements for payment.
- Fraudulent claims arise when a provider falsely certifies compliance with statutes or regulations that are a precondition of government payment.
Enforcing Quality of Care Through the False Claims Act

- **Express False Certification**
  - Not all courts have adopted this theory.
  - Not all false certifications of compliance are sufficient to render a claim fraudulent.
    - Generally, the certification must have affected or coaxed the government’s decision to pay.
    - Many courts hold a certification on a claim for payment includes an allegation of compliance with the Anti-Kickback or Stark self-referral laws and is, therefore, a precondition for government payment.

- **Implied False Certification**
  - Alleged fraud is not based on a false statement contained in the claim itself, but rather on an *implied representation* that the underlying care provided to the patient complied with the regulations and statutes that define the conditions required to bill for the service.
  - Some courts limit it to cases where the provider knowingly submits a claim that violates a statute or regulation which “expressly condition[s] payment on compliance with its terms.”
  - Other courts allow more broad applicability.
Enforcing Quality of Care Through the False Claims Act

• *U.S. ex rel Landers v. Baptist Memorial Health Care Corp.*, W.D. Tenn., (12/17/07)
  – Distinguished between Conditions of Participation and Conditions of Payment. Violation of Conditions of Participation insufficient to trigger FCA liability.
  – The Court found that conditions of participation are not the equivalent of conditions of payment, but are quality of care standards directed towards an entity’s continued ability to participate in the Medicare program rather than a prerequisite to a particular payment.
  – Rejected both express and implied theories.

• “Although [Baptist’s] alleged non-compliance with Conditions of Participation may lead to prospective corrective action or even termination, [Landers] has not presented any evidence the [hospital] would have been ineligible to receive payment of its Medicare claims during a potential period of noncompliance.”
• “In contrast, [Baptist has] presented ample evidence that even assuming they failed to comply with Conditions of Participation and/or applicable standards of care, the Government would nevertheless have continued to reimburse their claims at least for a period of time.”
Enforcing Quality of Care Through the False Claims Act

• **Exercise caution!**
  • In FCA context, the distinction between conditions of payment and conditions of participation has been deemed “a distinction without a difference” by Ninth Circuit. *U.S. ex rel. Hendow v. Univ. of Phoenix* (9/5/06).
  • The court’s approach in *Landers* directly contradicts the government’s movement regarding quality of care enforcement.

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Enforcing Quality of Care Through the False Claims Act

• **Worthless Services**
  – Focuses squarely on the quality of care provided, rather than on express or implied certifications of compliance with laws or regulations.
  – High standard. As one court described it, “the performance of the service [must be] so deficient that for all practical purposes it is the equivalent of no performance at all.”
  – The scienter element must be satisfied; *(i.e., the defendant must know or act in reckless disregard or deliberate ignorance of the fact the service being billed to the government was worthless)*
Enforcing Quality of Care Through the False Claims Act

**Criminal Enforcement**
- In particularly egregious cases, the government can, and has, criminally prosecuted individuals associated with quality of care violations.
- The criminal charges at the government’s disposal include laws prohibiting health care fraud, mail and wire fraud, false statements, and kickbacks.
- The significant criminal penalties for hospitals, high-ranking individuals, doctors reflect the seriousness of the government’s approach to quality of care violations.

“[F]raudulent furnishing of medically unnecessary invasive procedures not only causes financial harm but puts patients at significant risk. The Office of Inspector General will vigorously investigate such cases and require appropriate corrective action to safeguard future patient care.”

Daniel Levinson, Inspector General
U.S. Department of Health and Human Services
August 17, 2006
Enforcing Quality of Care Through the False Claims Act

- In 2006, a FCA action against a Baton Rouge, Louisiana hospital for medically unnecessary surgeries resulted in a $3.8 million settlement.

- In 2003, a medical center in Chicago, Illinois was found to have paid physician kickbacks that resulted in medically unnecessary care. The hospital administrator and several physicians received prison sentences and were required to make restitution payments totaling over $26 million.

- In 2006, a Louisiana cardiologist was indicted on multiple counts of healthcare fraud and one count of criminal forfeiture for performing unnecessary angiograms and angioplasties.

- In 2002, the CEO and members of the Medical Executive Committee at a Michigan hospital were indicted on charges of criminal conspiracy, mail fraud and wire fraud by billing for medically unnecessary pain procedures.

  The government’s case centered on the hospital’s allegedly deficient peer review procedures, which failed to curtail the unnecessary pain procedures.

  After the anesthesiologist who performed the procedures was convicted of mail fraud and sentenced to three years in prison, the hospital and other individual physician defendants pleaded guilty, serving over 1,000 hours community service and paying over $1,000,000 in fines.

- In 2007, a Florida hospital and its current and former owners paid $15.4 million to settle a FCA lawsuit involving allegations that the hospital paid kickbacks to physicians in return for patient admissions that resulted in medically unnecessary treatments on elderly patients.
Enforcing Quality of Care Through the False Claims Act

  - Distinguished between Conditions of Participation and Conditions of Payment. Violation of Conditions of Participation insufficient to trigger FCA liability.
  - The Court found that conditions of participation are not the equivalent of conditions of payment, but are quality of care standards directed towards an entity’s continued ability to participate in the Medicare program rather than a prerequisite to a particular payment.
- *Exercise caution!*

Enforcing Quality of Care Through the False Claims Act

- New legal/compliance risks to consider:
  - Knowledge arising from data reporting.
  - Work force encouragement to “whistleblow.”
  - Processes and structures are not effective in identifying quality failures.
- May lead to:
  - False Claims Act liability
  - Corporate liability
  - Liability of board members, owners and high-ranking officers
### Problems for Physicians and Hospitals Under Current Structures

- Hospital Peer Review and Quality Management.
- Traditional Medical Staff Structure.
- Other Structural Problems (Siloing).
- Board Education and Oversight.
- Physician and Hospital Collaboration.

### Problems Under Current Structures

**Number 1 Problem:** Hospital Peer Review and Quality Management are Not Structured to Proactively Drive Quality of Care
- Historical process is retrospective and based on incidents.
- Processes may be lengthy, biased (friends or competitors), and ineffective.
- Delays can lead to evidence of a pattern of poor quality or unnecessary care.
- Is evidence based medicine now the standard of care?
- According to “Survey on Medical Professionalism” by the Institute of Medicine as a Profession, *Annals of Internal Medicine* (December 4, 2007, nearly half of physicians do not report medical incompetence by peers.)
Problems Under Current Structures

Number 2 Problem: Traditional Medical Staff Structure is Not Designed For New Paradigm
- Blurring of specialty lines (ex. Interventional radiology / cardiology / neurology).
- Increasing number of hospital based physicians (ex. Hospitalists intensivists, OB hospitalists, Peds hospitalists).
- Growing number of outpatient based physicians, reducing collegiality with specialists and hospital-based physicians and impacting credentialing.
- Regulators mandating change (i.e. competency based credentialing, standardization of care processes, and increased medical staff oversight of quality).

Number 3 Problem: A Siloing of Responsibility

- “When looking at some of these very large [health care] corporations, there is a siloing of responsibility, which has the effect of inadequate cross of information between the peer review/quality people and the compliance people. The different components of a health care organization need to communicate and exchange information with each other and boards of directors can encourage this process.”

Lewis Morris,
Chief Counsel to the Office of Inspector General,
U.S. Department of Health and Human Services
September 25, 2007
Number 4 Problem: Lack of Board Education and Oversight

- Interviews conducted with CEOs and board chairs at 30 hospitals in 14 states.
- “The level of knowledge of landmark IOM quality reports among CEOs and board chairs was remarkably low…”
- There were significant differences between the CEOs’ perception of the knowledge of board chairs and the board chairs’ self-perception.
- “We are beginning to look to boards to ensure fiscal integrity and CIA oversight.” Lewis Morris, September 25, 2007.
- “Driving for Quality in Long-Term Care: A Board of Directors Dashboard,” HHS and HCCA joint report (January 2008).
Problems Under Current Structures

Number 4 Problem: Lack of Board Education and Oversight

- “Driving for Quality in Long-Term Care: A Board of Directors Dashboard,” HHS and HCCA joint report (January 2008).
- Government-industry roundtable addressed practical ways for boards to monitor the quality of care issues in long-term care facilities.
- The Report addresses four distinct areas:
  - Demonstrating and improving a commitment to quality
  - Key structural processes
  - Key outcome categories
  - Challenges and opportunities for Boards

Number 5 Problem: Lack of Effective Physician-Hospital Collaboration Strategies

- Hospitals need to enlist physician support to meet quality targets and earn the pay for performance incentive payments.
  - It is often difficult to enlist physician support by simply coaxing, cajoling, scolding, etc.
  - Particularly true if you do not (or cannot) employ physicians.
- Physicians need to enlist hospitals to help with systems to drive quality across the continuum of care.
Recommended Solutions

What is needed for the future
• Five solutions to consider:
  – Audit quality controls/legal risks
  – Integrate quality and compliance
  – Improve board education and oversight
  – Redesign medical staff structure
  – New strategies for hospital/physician collaboration

QUESTIONS
Graphs were from:

**Engagement of Leadership in Quality Improvement Initiatives: Executive Quality Improvement Survey Results** Thomas Vaughn, PhD, MHSA, Mark Koepke, JD, MHA, Eugene Kroch, PhD, William Lehrman, PhD, Sunil Sinha, MD, MBA, and Samuel Levey, PhD. *J Patient Saf & Volume 2, Number 1, March 2006*

Description of UHC study results was from:

**Organizational Factors Associated with High Performance in Quality and Safety in Academic Medical Centers** Mark A. Keroack, MD, MPH, Barbara J. Youngberg, JD, MSW, Julie L. Cerese, MSN, Cathleen Krsek, MSN, MBA, Leslie W. Prellwitz, MBA, and Eoin W. Trevelyan, DBA. *Academic Medicine, Vol. 82, No. 12 / December 2007*