The Board’s Role in Compliance: Quality, Community Benefit, Patient Safety and Other Emerging Trends

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Role of the Board in Health Care

Is There a Crisis of Public Trust?
Role of the Board in Health Care

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

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
Health Care Environment

- Health care is one of the most highly regulated industries in the country
- As health care costs rise, government scrutiny of the health care industry increases
- In response to increased government regulation, many health care organizations voluntarily developed and implemented compliance programs to identify and resolve compliance problems

Health Care Environment

- High profile Wall Street accounting cases – Enron and Worldcom (2001)
- Regulatory scrutiny – Whistleblower lawsuits
- Sarbanes-Oxley – Best practice or threshold expectations (2002)
- Charity care and collection suits (2004)
- IRS audits (2005)
- OIG, IRS, Joint Commission issuance on board governance (2007)
Health Care Environment

- For every $1 million invested in government enforcement efforts, the government recovers nearly $10 million in overpayments, damages, fines and settlements
- Notably, the government does not limit its enforcement efforts to only those who *deliberately* engage in activities to defraud the government

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

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
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.

- Fiduciary duties (cont’d):
  
  - Duty of Loyalty – place interest of corporation above own and act in what reasonably believe is the best interest of the organization.
  
  - 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

Non Profit vs. For Profit

- Duties are equivalent but the constituencies to whom directors are accountable are not

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
- Exercise reasonable oversight with respect to the program's implementation and effectiveness
- Increased focus on quality and patient safety
  - Emerging as enforcement priority for regulators
  - Increases expectation regarding oversight of corporate affairs
Scope of Board Understanding and Oversight

- Employee responsibility and accountability
- Policy development
- Code of conduct
- Education, training and communication
- Reporting
- Integrity line
- Monitoring
- Auditing
- Ongoing evaluation and reporting

Board Role in Identifying and Mitigating Risks

- 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:
  - Higher regulatory scrutiny
  - Increased level of involvement of board in compliance
  - SOX – For profit and non-profit
  - Increased role in mission and values, particularly in non-profit environment

- Additional Trends:
  - Community Benefit
  - Health Care Quality
  - Patient Safety

Ensuring an Effective Compliance Program

- First Stage: Getting the rules right, hotlines, etc.
- Second Stage: Ownership by business managers, executive leadership and board
- Third Stage: Mission and values, compliance as critical to overall organizational culture
- Fourth Stage? Compliance and performance – the bottom line
Compliance and Performance: The Next Phase

Aren't issues of community benefit, quality, and patient safety direct indicators of organizational performance? What is the role of compliance in these issues?

Community Benefit and Compliance

A Broad View

Non-profits health care organizations are committed to building communities where the needs of people are primary to the business objectives of individual institutions.

A non-profit’s performance should be assessed by looking at several factors:

1. Whether the organization’s strategic and opening plans are based on valid data and community-based input regarding access to care, health, and functional status of the community and population served;
A non-profit’s performance should be assessed by looking at several factors (continued):

2. Whether its strategies for health improvement are based on a broad range of issues that affect health status, function, and quality of life;

3. Is there community representation on the organization’s governing body, and designed to reach out to the community or population served to assure that its concerns and needs are addressed;

4. The extent to which the organization collaborates with others and builds effective relationships to ensure that community interests comes before self-interest; and to create a more equitable, rational, and effective system of care;

5. The organization’s history of continuing to provide services or products in geographic location, community, or population segment to meet a need where others have exited; and

6. The non-profit’s role in providing leadership and other resources to support public advocacy to improve care and funding for the vulnerable and underserved.
Congressional Hearings

- Senator Grassley, Chair (R-IA) considering legislation to extend federal oversight over governance/operation of non-profits

“Some tax-exempt health care providers do not differ markedly from for-profit providers in their operations, attention to the benefit of the community or their levels of charity care”

- Mark Everson-
  Commissioner IRS


- Senator Grassley’s “Staff discussion draft” issued July, 20, 2007
  - Followed on heels of IRS Interim Report (same date)
  - Value of exemption to non-profit hospitals at least $12.6 billion annually
  - Non-profits provide “only slightly more” uncompensated care than for-profits (CBO, Dec. 06)
  - “In brief, some non-profit hospitals are helping pull the wagon when it comes to charity care but far too many non-profit hospitals are sitting in the wagon – receiving significant tax breaks but providing little or nothing in the way of charity care for those in need in our society.”
Report Recommendations

- Adopt and widely post written charity care policy
- Provide rolling average charity care of at least 5% patient operating expense or revenues over 3 years
- Special rules for hospital joint ventures with for-profits:
  - Charity care policy for JV
  - Hospital has reserved rights to implement, oversee charity care policy
  - JV’s charity care credited towards hospital’s numbers
- Community needs assessment (‘‘in consultation with local advocates… and local Department of Health officials’’)

Report Recommendations

- Cap charges to uninsured/under-insured at lower of (i) Medicare/Medicaid, or (ii) actual cost
- Board requirements:
  - Represent broad interests of public, ‘‘especially advocates or representatives of those benefiting from charity care’’
  - <25% comprised of hospital employees
  - <25% physicians and management
  - Direct responsibility for charity care, discount, eligibility policies; 990 review; community needs benefit
Report Recommendations

- Proposed Sanctions

- If fail to meet quantitative charity care requirements:
  - Excise tax equal to 2x shortfall
  - Revocation of exempt status for repeated failures
  - Exclusion from Medicare

- If violate JV requirements:
  - Excise tax on individual managers equal to 25% of excess benefit
  - Impose penalties not only for excess benefit, but also where “the exempt hospital receives a disproportionate financial detriment.”

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On the Brink of Tax Reform?

- Senate Report is not legislation, but may influence IRS policy and be springboard for significant hospital tax legislation
- Watch for IRS’ final report on community benefit compliance in September 2008
**IRS Good Governance Guidelines**

- In February 2007, the IRS released “suggested” governance guidelines for exempt organizations, focusing on 9 areas:
  - Mission
  - Board size, use of executive committee
  - Policies regarding:
    - Code of ethics, whistleblowers
    - Financial transparency, accessibility
    - Audit independence
    - Compensation of officers, insiders
    - Document retention
- Not legally binding, but will be incorporated into IRS’ audit activity

**IRS 990 Reforms**

- Issued June 14, 2007; comment period closed September 14
- Proposed changes include:
  - New summary page (“Part I”) providing snapshot of key governance, financial information
  - New section (“Part II”) regarding governance and transparency, for example:
    - Composition of board, degree of “independence”
    - Policies regarding conflicts, whistleblowers, document retention
    - Audit committee
    - Board review of IRS 990
IRS 990 Reforms

- New “Schedule H – Hospitals”
  - Financial reporting of community benefit
  - Annual community benefit report
  - Description of charity care, policies

- Overall themes
  - Transparency
  - Accountability
  - Good governance

- Implementation
  - 2008 tax year

Community Benefit and Compliance Summary

Summary

- Expanding standard for non-profits in health care
- Charity care requirements
- IRS good governance standards
- IRS 990 reforms: Community Benefit Report
- Attorney General oversight
- Compliance and non-profit status will remain hot issue
### 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.

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#### Quality and Compliance

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

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

- The U.S. scored 15th out of 19 countries in mortality 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.”


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**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 administrative decisions that preclude provision of good quality care?*
Quality and Compliance

AHLA/OIG White Paper

- Summary of connection between quality and health regulation/compliance
- Suggestions to Boards on Right Questions to Ask

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?
Quality and Compliance

AHLA/OIG White Paper: Key Questions

- 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?

Quality and Compliance

AHLA/OIG White Paper - Conclusion

“Health care boards of directors will need to exercise their oversight responsibilities in this area diligently and assure that their organizations are pursuing these opportunities in compliance with evolving legal requirements.”
### Patient Safety and Compliance

**The Patient Safety Act of 2005**

- Authorizes the creation of patient safety organizations (PSOs) to be certified by the Secretary of Health and Human Services.
- Authorizes creation of a national patient safety database network to provide a resource for health care organizations.
- Defines data parameters and requires standardized data sets be developed for health care organizations’ voluntary reporting to PSOs.

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### Patient Safety and Compliance

**The Patient Safety Act of 2005 (continued)**

- Acknowledges that a voluntary data-gathering system is more supportive than a mandated system when the goal is to encourage learning and not to dispense punishment.
- Establishes “patient safety work product” as privileged and confidential, not subject to subpoena, Freedom of Information Act (FOIA) request or disciplinary proceeding use.
- Protects reporters from retaliatory adverse employment actions.
Patient Safety and Compliance

The Patient Safety Act of 2005 (continued)

- Establishes redacted reporting standards that do not identify patient or provider
- Sets a timeline (18 months after implementation) for the first report from the patient safety database

Patient Safety and Compliance

HHS Proposed Regulation – February 2008

- How PSO’s can be formed
- How will work confidential reporting by clinicians
- How data will be shared
- How clinicians can receive feedback
- How penalties will be imposed for breach of confidentiality
Patient Safety and Compliance

HHS Agency for Health Care Research and Quality (AHRQ)

- Will administer rules
- Responsible for enforcement of confidentiality
- To issue guidance on how entitles to be listed as PSO’s, even before publication of final rule

Comments on proposed regulation due April 14
# The Board Role in Compliance

## Summary

- “Good Governance” is being defined in greater detail
- Increased tie between organizational performance and compliance
- Boards more engaged in “future” compliance matters and organizational risks
- Quality, Community Benefit, Patient Safety are now on the list

## QUESTIONS