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OIG Report on Board Oversight and Quality of Care: What It Means for Health Care Boards of Directors

Action: On September 13, 2007, the Department of Health and Human Services' Office of Inspector General (OIG) and the American Health Lawyers Association (AHLA) issued a joint report, *Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors* (Report).

Impact: The Report recognizes that enforcement of quality of care has reached new levels of activity and urges boards of directors (Boards) to make immediate and serious efforts to understand their hospitals' ability to monitor and provide quality care. Individual False Claims Act (FCA) liability is now a very real risk for high-ranking officers, board members, and legal counsel for health care organizations. Boards, along with their legal counsel, must ensure that proper oversight occurs.

Effective Date: Immediately.

> "When looking at some of these very large [health care] corporations, there is a siloing of responsibility, which has the effect of inadequate cross[ing] 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."
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> — Lewis Morris, Chief Counsel to the Office of United States Inspector General of Health and Human Services, on September 25, 2007.

Introduction

The Report reflects the increasing emphasis on quality of care, and should be required reading for Boards, senior management, and compliance officers. According to the Report, a "new era of focus on quality and patient safety [is] rapidly emerging, and oversight of quality also is becoming more clearly recognized as a core fiduciary responsibility of health care organization directors." Given the level of government interest in enforcing quality of care, and the significant penalties imposed on health care providers who have failed to meet quality standards, Boards cannot take a passive approach to quality issues.

The government's interest in quality of care continues to increase, and its investigations regarding quality of care have resulted in significant settlements and convictions, all of which

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demonstrate that the government is enforcing its rhetoric, as the following indicates:

- On July 27, 2007, California regulators imposed a $3 million fine on a California hospital system for failure to provide adequate oversight of quality assurance programs, including peer review and patient complaint management. The problems were discovered by analyzing randomly selected charts following patient complaints.
- A rural hospital in Northern California was accused of permitting physicians to perform unnecessary cardiac catheterizations, angioplasty, and open-heart surgeries. As a result, and to avoid the hospital's exclusion from federal health care programs, the hospital's parent organization entered into a $54 million settlement with the United States Department of Justice and agreed to divest the hospital by selling it to an unrelated third party.
- An FCA action against a Baton Rouge, Louisiana hospital for medically unnecessary surgeries resulted in a $3.8 million settlement.
- 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.
- A hospital in Tampa, Florida paid over $900,000 to settle charges that it permitted a neurosurgeon to perform unnecessary spinal operations in violation of the FCA.
- The chief executive officer 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 an anesthesiologist was convicted of mail fraud and sentenced to three years in prison, the hospital and other physician defendants pleaded guilty, and served over 1,000 hours community service and paid more than $1 million in fines.
- A Louisiana cardiologist was indicted on multiple counts of health care fraud and one count of criminal forfeiture for performing unnecessary angiograms and angioplasties.
- A Florida hospital and its current and former owners paid $15.4 million to settle an 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.

Focus on Quality of Care

Why is the government focused on quality of care issues? In the late 1990s, the increased attention on quality and safety of patient care gave rise to numerous studies identifying quality breakdowns and safety risks in the American health care system. The 1999 Institute of Medicine (IOM) report, *To Err is Human,* identified medical mistakes as one of the leading causes of death in the country, and estimated that nearly 98,000 Americans die each year from substandard health care. *To Err is Human* immediately caught the attention of both the government and the health care community. Tales of egregious substandard medical care raised further awareness of health care safety risks. In turn, these studies and stories gave birth to new initiatives to improve the safety, efficacy, and transparency of health care and fueled the current trend of quality of care enforcement.

IOM's 2001 follow-up article, *Crossing the Quality Chasm: A New Health System* for the 21st Century, recommends that hospitals improve quality of care by focusing on the six aims of health care, namely that health care should be: (1) safe, (2) effective, (3) patient-centered, (4) timely, (5) efficient, and (6) equitable. In addition to enforcement activities, the government is promoting quality and safety by changing reimbursement policy to reward hospitals for quality care, rather than simply paying for services delivered; and by promoting transparency through public reporting.

What Quality of Care Means for Boards

In response to these enforcement actions, the Report reminds Boards that they must provide an appropriate level of oversight of health care services in order to satisfy their core fiduciary duties to the hospitals. Board members who breach these duties may be exposed to personal liability.

The duty of care owed to the hospital by Board members is a legal obligation requiring them to exercise appropriate care in their decision-making process. Generally, the duty of care is satisfied when directors act:

- In good faith
- With the care an ordinarily prudent person would exercise in like circumstances

- In a manner that they reasonably believe to be in the best interests of the hospital

The duty of care has been interpreted to require that directors actively inquire into the hospital's operations. The Report is therefore designed to help Boards ask knowledgeable and appropriate questions related to quality and quality reporting requirements as well as the metrics employed. The questions raised in the Report are not intended to set forth any specific standard of care, nor to foreclose arguments for a change in judicial interpretation of the law, or resolution of any conflicts in interpretation among various courts. Rather, the Report will help Boards establish, and affirmatively demonstrate, that they have followed a reasonable process for quality oversight.

Perfection is not required to discharge the duty of care or obedience to corporate purpose and mission. Instead, the Report recommends that Boards exercise general oversight of patient safety and quality of care issues by:

- Understanding the emergence of quality of care issues, challenges, and opportunities
- Overseeing the development of specific quality of care measurement and reporting requirements
- Requesting periodic updates from executive staff on hospital quality of care initiatives and how the hospital intends to address legal issues associated with those initiatives

Practical Approaches Boards Should Consider

As a result of the increased enforcement of quality, Boards should take a more active oversight role in the quality of the care provided at their hospitals. Boards should not rely solely on medical and non-medical staff to police quality issues; they should instead become conversant with quality of care and active in the processes that identify quality of care problems. Boards also should understand and oversee the integration of quality and compliance. But Boards need not approach these issues alone, and are advised to seek periodic quality of care reports from management and enlist the help of attorneys and consultants to evaluate quality risk areas within their hospitals.

To assist in understanding quality of care issues, the Report provides a series of questions Boards may use as a starting point for their inquiries into quality of care issues.

- What are the goals of the hospital's quality improvement program?
  - What metrics and benchmarks are used to measure progress towards each of these performance goals?
  - How is each goal specifically linked to management's accountability?
- How does the hospital measure and improve the quality of patient care?
  - Who are the key management and clinical leaders responsible for these quality and safety programs?
- How are the hospital's quality assessment and improvement processes integrated into other 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?
- Does the Board have a formal orientation and continuing education process for quality and 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 hospital's quality assessment and performance enhancement programs?
  - Once these performance metrics and benchmarks are established, how frequently does the Board receive reports about the quality improvement efforts?
- How are the hospital's quality assessment and improvement processes coordinated with its corporate compliance program?
  - How are quality of care and patient safety issues addressed in the hospital's risk assessment and corrective action plans?
- What processes are in place to promote the reporting of quality concerns and medical errors, and to protect those who ask questions and report problems?
  - What guidelines exist for reporting quality and patient safety concerns to the Board?
- 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 the hospital's competency assessment and training, credentialing, and peer review processes adequately recognize the necessary focus on clinical quality and patient safety issues?
- How are "adverse patient events" and other medical errors identified, analyzed, reported, and incorporated into the hospital's performance improvement activities?

- How do management and the Board address quality deficiencies without unnecessarily increasing the hospital's liability exposure?

Answers to these questions can help gauge where a hospital is positioned with respect to quality of care issues. Shortcomings should be identified and the Board should allocate appropriate resources to address the gaps.

Conclusion

The Report places Boards on notice that they can no longer be on the sidelines of the quality enforcement movement. Given the liability exposure, Boards should take action to integrate quality into the hospital's compliance program to ensure that compliance risks associated with quality of care failures are identified and dealt with immediately and proactively.

The Report is available online:
http://oig.hhs.gov/fraud/docs/complianceguidance/CorporateResponsibilityFinal%209-4-07.pdf

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