Board oversight and quality-of-care issues: A review of OIG/AHLA's white paper

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The Office of Inspector General (OIG) and the American Health Lawyers Association (AHLA) issued a joint white paper on June 27, 2007 entitled "Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors." According to the OIG/AHLA white paper, a "new era of focus on quality and patient safety [is] rapidly emerging[.]"[1] This white paper is further evidence of the increasing emphasis by the government on the enforcement of quality of care, and is a "must read" for boards of directors, senior management and compliance officers. As a practical matter, given the level of government interest in ensuring quality of care and the significant penalties being imposed on health care entities who fail to meet basic quality standards, boards can no longer take a passive approach to quality issues.

The government's interest in quality-of-care issues has increased exponentially in the recent past. This emphasis on quality and compliance was featured in a *Compliance Today* article published in November 2006, entitled "Government enforcement of quality: Merging quality and compliance." Since then, more government investigations and lawsuits regarding quality-of-care cases have resulted in significant settlements, all of which demonstrate that the government is backing up its rhetoric with enforcement. These investigations and settlements include:

- A settlement of a class action lawsuit for $7.4 million against a Louisiana hospital regarding unnecessary cardiac procedures[2];
- A lawsuit under the False Claims Act, which was dismissed (although the dismissal is being appealed), against a South Carolina hospital alleging, among other things, unnecessary cardiac catheterizations[3];
- The arrests of at least 38 individuals in Florida in connection with a "Medicare Fraud Strike Force" operation in which billing data was used to identify unnecessary services[4]; and
- A $15.4 million settlement against a Florida hospital and its current and former owners regarding allegations that the hospital and its owners paid kickbacks to physicians in return for patient admissions that resulted in medically unnecessary treatments on elderly patients.[5]

The government's focus on quality

So why is the government so focused on quality-of-care issues? The Institute of Medicine (IOM) report "To Err Is Human: Building a Safer Health System,"[6] published in 1999, estimated that up to 98,000 Americans die each year from medical mistakes, making medical mistakes one of the leading causes of death in the country. Alarmed by these statistics, the government is using its enforcement authority to drive quality of care in the name of patient safety. To this end, the OIG/AHLA white paper cites IOM's follow up article, "Crossing the Quality Chasm: A New Health System for the 21st Century,"[7] which recommends that providers can improve quality of care by focusing on six "aims" to be achieved when delivering health care, i.e. health care should be safe, effective, patient-centered, timely, efficient, and equitable.[8] In addition to protecting the public health, the government is promoting quality and safety by changing reimbursement policy to reward providers for quality rather than simply paying for services delivered.

The government has a variety of means with which it identifies quality-of-care problems. As discussed in the OIG/AHLA white paper, many entities are required to undergo state surveys and other state certifications, during which quality issues may be identified. Moreover, quality-of-care issues can be identified through claims analysis and by analyzing quality reporting data, such as adverse event reporting, hospital quality data for annual payment updates, and physician quality reporting data.[9] Finally, quality issues can be brought to the government's attention through whistleblower lawsuits under the False Claims Act. The Deficit Reduction Act of 2005 requires certain health care entities to inform employees about the False Claims Act and its whistleblower protections, which is expected to increase whistleblower lawsuits.

Once quality issues are identified, there are number of theories under which health care entities may be susceptible to civil and criminal liability. The OIG/AHLA white paper identifies the legal theories that may apply to medically unnecessary services and services that are deemed so substandard as to be characterized as "worthless services."[10] In medical necessity cases, the government may allege that services were performed that were not needed, and therefore, should not be reimbursable by Medicare; only services that are medically necessary are reimbursable under federal health care programs. For example, a number of settlements over the past few years involved allegations that providers performed unnecessary cardiac procedures. In worthless services cases, the allegation is not that the services were unnecessary, but rather they are so substandard that no meaningful services were provided at all. The government also may use this latter theory to challenge underlying regulatory violations, such as failure to meet staffing levels.

Providers who are on the losing end of a quality-of-care investigation are typically faced with serious civil penalties and criminal fines. Over the past several years, multi-million dollar civil and criminal settlements have been made against health care providers in connection with allegations of unnecessary or worthless services. In many cases, these government enforcement actions are followed by even costlier class action lawsuits by the affected patients. Also of concern, OIG has the administrative authority to exclude providers from federal health care programs for rendering unnecessary or worthless services.

What the government's interest in quality of care means for boards of directors

In response to these enforcement trends, the OIG/AHLA white paper reminds boards of directors that they must provide an appropriate level of oversight concerning the health care entity's provision of quality health care services in order to satisfy their "duty of care" and, if applicable, the "duty of obedience to corporate purpose and mission."[11] Directors who breach these duties may be exposed to personal liability.[12]

The duty of care owed to the entity by the directors is a legal obligation that the directors exercise appropriate care in their decision making. 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, and
- in a manner that they reasonably believe to be in the best interests of the corporation.[13]

The OIG/AHLA white paper observes that the duty of care has been interpreted as requiring directors to actively inquire into aspects of the entity's operations.[14] Given the recent government interest in quality of care, the OIG/AHLA white paper instructs boards to take a more active role in overseeing quality issues within their organizations in order to satisfy the duty of care.

If the health care entity is a nonprofit organization, the board also is subject to the duty of obedience to corporate purpose and mission.[15] This duty is unique to nonprofit corporations, which are formed to advance a specific purpose (e.g., provide health care for certain types of patients or patients in a specific geographic region). The board is required to ensure that the organization is acting in the furtherance of the defined purpose and mission of the organization, which obligates the board to consider the quality of the services the organization provides.

As the OIG/AHLA white paper indicates, "perfection" is not required in order to discharge the duty of care or duty of obedience to corporate purpose and mission obligations.[16] Instead, it is recommended 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 (including asking the executive staff for periodic education); and
- Requesting periodic updates from the executive staff on organizational quality-of-care initiatives and how the organization intends to address legal issues associated with those initiatives.[17]

If these efforts uncover quality-of-care issues, then additional inquiry may be required in order for boards to satisfy their duties to their organizations.

Practical consequences for boards

As a result of the increased governmental enforcement of quality-of-care issues, boards of directors must take a more active role in evaluating the quality of the care provided by their organizations. In order to fulfill their duties to their organizations, boards should not simply rely on quality departments and medical staffs to police quality issues. Boards must be conversant in quality of care and active in the processes that identify quality-of-care problems and should understand and oversee the integration of quality and compliance. Importantly, directors do not have to address these issues on their own; they should receive periodic reports from management regarding quality of care and may enlist the help of outside lawyers or consultants to help evaluate quality-of-care risk areas within their organizations.

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To assist boards in understanding quality-of-care issues, and to help them satisfy their legal obligations to their organizations, the OIG/AHLA white paper provides a series of questions that board members can use as a starting point for their inquiries into the quality controls existing in the entities they serve. The following questions are very useful, because they encourage a broad-based approach to quality issues.

- What are the goals of the organization'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 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?
- Does the board have a formal orientation and continuing education process that helps members appreciate external 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 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 efforts?
- How are the organization's quality assessment and improvement processes coordinated with its corporate compliance program? How are quality of care and patient safety issues addressed in the organization'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 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 "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?

Although asking the above questions is certainly important to gauging where a health care entity stands with respect to quality-of-care issues, it is not sufficient for the board to just ask the questions. Follow up action is necessary to the extent that quality has not been sufficiently integrated into the compliance functions of the organization. Where shortcomings are identified, the board should take action to allocate resources to address the gaps, and then follow up to make sure the gaps have actually been addressed.

Conclusion

In sum, the OIG/AHLA white paper puts boards of directors on notice that they can no longer sit on the sidelines of the quality enforcement movement. Given the exposure of organizations and individual directors to liability, boards must take action. ■

1 Office of Inspector General/American Health Lawyers Association, "Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors," 1 (June 27, 2007).
2 State Judge OKs $7.4 Million Settlement of Claims of Unnecessary Cardiac Surgery, 11 BNA Health Care Fraud Report 366 (May 23, 2007).
3 Hospital, Whistleblower File Appeals In Fourth Circuit on FCA Qui Tam Decision, 11 BNA Health Care Fraud Report 398 (June 6, 2007).
4 Press Release, U.S. Department of Health and Human Services, Strike Force Formed to Target Fraudulent Billing of Medicare Program by Health Care Companies (May 9, 2007), available at http://www.hhs.gov/news/press/2007pres/05/pr20070509c.html.
5 Florida Hospital, Owners Pay $15 Million to Settle False Claims, Kickback Lawsuit, 10 BNA Health Care Fraud Report 880 (December 6, 2006).
6 Committee on Quality of Health Care in America, Institute of Medicine: To Err is Human: Building a Safer Health System (1999).
7 Committee on Quality of Health Care in America, Institute of Medicine: Crossing the Quality Chasm: A New Health System for the 21st Century (2001).
8 Office of Inspector General/American Health Lawyers Association: "Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors," 9-10 (June 27, 2007).
9 Id. at 16.
10 Id. at 17.
11 Id. at 3.
12 See *In re Caremark International Inc.* Derivative Litigation, 698 A.2d 959, 970 (Del. Ch. 1996), in which the Delaware Chancery Court stated that a director could be held personally liable in some circumstances for losses caused by violations of legal standards resulting from inadequate compliance mechanisms. In re Caremark was affirmed in 2006 by the Delaware Supreme Court in *Stone v. Ritter*, 911 A.2d 362, 369 (Del. 2006).
13 Office of Inspector General/American Health Lawyers Association, "Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors," 4 (June 27, 2007).
14 Id. at 4.
15 Id. at 7.
16 Id. at 4.
17 Id. at 8-9.

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