

HEALTH INDUSTRY ALERT

NEWEST OIG/AHLA CORPORATE RESPONSIBILITY RESOURCE PLACES ONUS ON BOARDS TO OVERSEE QUALITY OF CARE

The Office of Inspector General (OIG) and the American Health Lawyers Association (AHLA) have just issued guidance entitled “Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors” (the Resource), which is the third in a series of co-sponsored educational documents for boards of directors of health care entities. This Alert highlights the aspects of the Resource that significantly affect how health care organizations address health care quality as a potential enforcement and compliance issue and offers practical tips regarding these issues.

As the Resource’s title indicates, this latest installment of board-oriented guidance is focused on the oversight responsibility that boards have regarding health care quality within their organizations. The Resource includes a lengthy discussion of the fiduciary duty obligations of health care boards in the quality of care context, including the duty of care and the duty of obedience to corporate purpose and mission. It also provides a detailed discussion of the larger health care quality trends and initiatives that are currently at the center of the changing environment within the U.S. health care system – i.e., the growing “quality movement.” The Resource also emphasizes the increasing role of government in enforcing health care quality, and, finally, it provides a series of suggested questions for boards to consider in developing an understanding of “the scope and operation of the organization’s quality and safety initiatives.” Although presented as an educational resource, like the prior board-oriented guidance documents, the Resource will more likely than not operate as a de facto standard for the extent to, and manner in, which health care boards are involved in overseeing quality of care.

First, according to the Resource, health care quality oversight is “becoming more clearly recognized as a core fiduciary responsibility of health care organization directors.” This is so “because promoting quality and preserving patient safety are core to the health care industry and the reputation of each health care organization;” “health care quality measurement and reporting obligations are receiving heightened attention;” and “quality is also emerging as an enforcement priority for health care regulators.” Thus, health care boards are urged to exercise the same level of fiduciary responsibility for quality and safety issues that are employed for financial and regulatory compliance issues. This fiduciary responsibility is primarily exercised through the “duty of care” that entails reasonable inquiry. This generally means that health care boards need to exercise appropriate oversight of their organization’s quality efforts by keeping informed on

quality developments, asking questions of management about specific quality initiatives within the organization and probing further if red flags are raised.

Practical Tip: Health care organization management officials should ensure that their boards are apprised of this Resource at an upcoming scheduled board meeting and be prepared to discuss the organizations' current approaches to ensuring health care quality and planned initiatives for improving health care quality.

Second, the Resource declares that the "duty of care with respect to quality of care also is implicated by the related duty to oversee the compliance program." According to the Resource, this means that boards must be cognizant of the "emerging legal and compliance issues associated with quality of care initiatives, and direct executive leadership to address those issues." As set forth in detail in section IV of the Resource, over the past several years, the federal government has ramped up its enforcement efforts against alleged quality of care failures, particularly through the controversial method of bringing such cases as violations of the civil False Claims Act (FCA). The OIG has also been more aggressive in the use of its own administrative authorities to exclude individuals and entities who allegedly provide substandard care or impose burdensome corporate integrity agreements that include extensive outside monitoring provisions. Although quality of care FCA cases have historically been brought against nursing homes, the government has been signaling for the past couple of years that it is prepared to bring such cases against other industry participants, including acute care hospitals. Indeed, the OIG included quality of care as a major risk area discussion in its 2005 Supplemental Compliance Program Guidance for Hospitals. The OIG's guidance on risks often reflects current enforcement priorities or activities.

Notwithstanding the fact that the Resource is intended to be an educational document, its publication is yet another strong signal that the federal government is fully intending to expand its quality of care enforcement initiatives into the hospital and other health entity contexts. Of course, as the Resource notes, enforcement actions based on medically unnecessary care (with an implicit patient safety dimension) have already been brought against hospitals. There would not appear to be any publicized evidence, however, that the government has brought actions against hospitals alleging "failure of care" or "worthless service" issues, which have been common in the nursing home industry (but it may be currently investigating such cases). In any event, boards will be expected to ensure that organizational management is effectively integrating its corporate compliance program functions with its traditional quality oversight systems. This integration process presents a host of challenges as in many organizations' corporate compliance functions, and quality systems have traditionally operated substantially independent of each other.

Practical Tip: Senior management, medical leadership, senior officials with responsibility for quality systems and corporate compliance officers should confer regarding the extent to which the quality system and compliance function can be integrated effectively, with particular attention paid to the interrelationship between the two areas with respect to risk assessments, corrective action plans and internal reporting.

Third, in its discussion of the current "quality movement," the Resource asserts that the six-part definition of health care quality set forth in the Institute of Medicine's (IOM's) seminal publication *Crossing the Quality Chasm* (safe, effective, patient-centered, timely, efficient and equitable) has become the recognized industry standard. Significantly, it urges health care organizations and their boards to be "mindful of its implications." Therefore, even though the Resource posits that it is not intended to establish any specific standard of care, like most OIG guidance documents, when various standards are mentioned, discussed or highlighted, they invariably become established as de facto standards.

Practical Tip: Organizations should conduct risk assessments that measure their clinical quality against the IOM standards and use the results to inform future quality improvement initiatives.

Fourth, the Resource focuses heavily on the myriad ways in which health care purchasers, payors and regulators are promoting various collaborative arrangements in order to better align overall quality and cost efficiency within the health care system. According to the Resource, “innovative hospital-physician financial relationships” are key to achieving the IOM quality definition. These include “pay-for-performance demonstrations, gainsharing initiatives, electronic health record implementation efforts, outpatient care centers, service line joint ventures, and management and leasing arrangements.” However, such new arrangements may implicate various health care fraud and abuse laws. As a consequence, providers will need to ensure that they implement new quality systems in a “legally compliant manner.”

Practical Tip: Organizations should ensure that any new quality-related initiatives are analyzed internally by compliance and/or legal counsel as well as outside counsel, as appropriate.

In summary, the Resource makes it abundantly clear that health care boards will be expected to assume a leadership role in the current health care “quality movement.” For many boards this is already the case. Government regulators, including the OIG, however, may now begin holding boards and organizations as a whole accountable in ways that will substantially affect their finances and reputations.

CONTACT INFORMATION

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