Quality of care and compliance: Existing challenges and first steps for hospitals

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Compliance officers, in-house counsel, and other health care professionals should by now be aware that the government has made quality of care a top priority. The government's three-prong approach seeks to:

- incentivize quality of care through payment reform,
- drive quality of care transparency through public reporting, and
- enforce quality of care through the False Claims Act and other federal and state mechanisms.

Many of these professionals understand that quality of care poses significant compliance risks to hospitals, including potential individual liability for the high-ranking executives, board members, physicians, and owners. Despite their awareness, these same professionals are struggling to figure out how to address quality of care and minimize its attendant compliance risks.

Foley & Lardner LLP is providing *Compliance Today* with an ongoing series of articles designed to address these questions. This article, the first in the series, highlights the challenges hospitals face when managing quality-of-care compliance. It also discusses the first steps a hospital should take to address the compliance implications of quality-of-care failures, including education and a quality of care/legal risks audit. Several topics are broadly discussed, including Recovery Audit Contractor (RAC) audits, all of which will be addressed in greater depth as this series of articles unfolds. Forthcoming articles will include: (1) tools and mechanics of a quality of care/legal risks audit; (2) quality of care enforcement; (3) quality-based payments and reimbursement; (4) quality of care compliance and the medical staff; (5) public reporting and quality of care; and (6) quality of care, data mining, and RAC audits.

Awareness and education challenges

Before a hospital can address the compliance implications of quality of care, its leadership must understand the connections between quality and compliance. Executives, board members, key leadership, and physicians need, at a minimum, a general understanding of the government's quality-of-care efforts regarding payments, public reporting, and enforcement. Educating these key leaders on quality- of-care compliance is an essential first step in the process.

The lack of board education and oversight on quality issues is troubling. A Joint Commission research effort conducted interviews with CEOs and Board Chairs at 30 hospitals in 14 states, and revealed that "the level of knowledge of landmark Institute of Medicine (IOM) quality reports among CEOs and board chairs was remarkably low" and that there were significant differences between the CEOs' perception of the knowledge of board chairs and the board chairs' self-perception.[1] This disconnect has not been lost on the Office of Inspector General (OIG), that is beginning to look to boards to ensure fiscal integrity and oversight.[2]

One approach to education would divide key personnel into categories (e.g., executives, board members, physicians, and care staff) and provide tailored education to each group. Certain quality-of-care issues are more appropriate for the board, whereas other issues would resonate better with physicians. Use education modules (again tailored to each group) for the training. This approach can help standardize the education process, collect feedback from the trainees, and create a documented record of the hospital's quality-of-care education efforts.

The order in which personnel are trained is also an important aspect to consider. Certain key executive positions (e.g., CEO, general counsel, director of quality) will be the champions for a compliance officer who is seeking resources for quality of care efforts, and therefore, it is important for those individuals

to hear the message first. Educating the board is the next step and there is already an excellent resource available for board education: *Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors*.[3] This resource, issued jointly by the OIG and the American Health Lawyers Association (AHLA), 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."[4]

Boards must provide an appropriate level of oversight of health care services to satisfy their core fiduciary duties to the hospital. Board members who breach these duties may be exposed to personal liability. Board members owe a duty of care, 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 that an ordinarily prudent person would exercise in similar circumstances, and in a manner they reasonably believe to be in the best interests of the hospital.

Because the duty of care has been interpreted to require that directors actively inquire into the hospital's operations, educational materials should be designed to help board members ask knowledgeable and appropriate questions related to quality and quality reporting requirements, as well as the metrics employed. Education and active involvement will help board members establish, and affirmatively demonstrate, that they have followed a reasonable process for quality oversight.

Boards need not approach these issues alone. Once the board is "on board" with the compliance officer's quality-of-care efforts, the board should seek periodic updates from executive staff on hospital quality-of-care initiatives and how the hospital intends to address legal issues associated with those initiatives. When quality shortcomings are identified, the board should allocate appropriate resources to address the gaps including, for example, enlisting the help of outside attorneys and consultants to evaluate quality risk areas within the hospital.

Organizational challenges

Hospitals are large, complex organizations created (like many other large businesses) in a bureaucratic structure with specialized departments and groups, each focusing on a different aspect of the hospital. This structure is useful for efficiency and specialization, but has limited capabilities to readily share information across and between departments. This problem is known as "siloing." Lewis Morris, Chief Counsel to the Department of Health and Human Services (HHS) OIG, recognized the issue when he said,

> "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."[5]

Compliance, Quality, and Peer Review departments each deal, to a certain degree, with quality-of-care issues, and there is an overlap of subject matter. Yet, a hospital's compliance program traditionally is separate and distinct from its quality assurance and peer review programs. That type of structure does not permit the information exchange necessary to recognize and address the compliance risks that can arise from poor quality of care. Hospitals need to develop structures that can transcend the department silos and exchange quality-of-care information, at least among the three departments for which this exchange has become critical.

Challenges in the peer review process

Critics of the medical staff peer-review process claim it has proven itself an ineffective tool to resolve quality and safety issues, both from the physician and the hospital perspective. They contend that the current peer review process is subject to bias and political motive and cannot adequately help a hospital meet government-imposed mandates on quality of care. Of course, the peer review process offers certain benefits. It enables physicians to speak frankly, at a peer-to-peer level, on quality issues and care processes. They are sometimes more persuasive and receptive when dealing with each other and often show greater respect to the clinical judgment of trained, experienced peers.

The most significant limitation in the traditional peer review process, and the one which poses the greatest compliance risk, is that the process is largely retrospective and based on isolated, past incidents. Constantly looking backward, rather than identifying patterns of care failures, the process is always reactive, not proactive. The hearings are often lengthy and can suffer significant delay caused by the subject physician or simply the unavailability of the hearing panel. These delays can permit a pattern of poor quality or unnecessary care to persist before the peer review process is able to react.

Hospitals must consider new approaches to integrate into the peer review process. Consider real-time chart audits based on daily monitoring of key quality indicators. If a

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pattern emerges, the hospital can take action. Also consider a greater emphasis on patterns (and projected patterns) of care. Physicians should be permitted a degree of freedom in their treatment style, but certain care approaches pose a higher risk than others. Treatments and medications constantly evolve, and the hospital should identify and address physicians who use outdated, high-risk processes before bad outcomes are manifested. Because nearly half of physicians do not report medical incompetence by their peers, the hospital cannot rely on physicians to police themselves.[6]

Challenges in the traditional medical staff structure

As physician roles continue to change, the traditional medical staff structure finds itself ill-equipped to adapt to emerging compliance and quality-of-care challenges. There are an increasing number of hospital-based physicians, including hospitalists, intensivists, obstetrical hospitalists, and pediatric hospitalists. Specialty lines have begun to blur with cross-credentialed physicians playing multiple roles on the care team (e.g., interventional radiology/cardiology/neurology). The growing number of outpatient-based physicians has complicated the credentialing process and led to reduced collegiality with the specialists and hospital-based physicians.

As hospitals adapt to these physician-driven changes, regulators mandate further change, such as competency-based credentialing, standardization of care processes, and increased medical staff oversight of quality.

Another key change is the increased public reporting of quality data, both on the hospital level and the individual physician level. Hospitals must crunch their own data and understand it, not wait for the government to do so first. Additional transparency by the medical staff, who share quality data, is essential and can be achieved with a better medical staff infrastructure, improved design, and aligned incentives to address national patient safety and quality mandates.

Need for effective incentive strategies

Many would argue that a lack of effective hospital-physician collaboration strategies exist to provide incentives based on quality of care. In this respect, hospitals and physicians are co-dependent and should collaborate on new structures. Hospitals must enlist physician support to meet quality targets and earn pay-for-performance incentives. Similarly, physicians must enlist hospitals to offer systems that drive quality across the continuum of care.

Current, traditional equity joint-ventures often fail to align physician and hospital interests in improving quality of care. Consumer-driven health care and increased access to quality data will eventually lead to greater patient choice and create consumers who are better informed and more discerning about the hospital and physician they choose. Hospitals need to develop viable, compliant incentive structures to connect physicians and reward desirable behavior patterns and quality-of-care efforts. New structures need to focus on quality, reducing waste, and promoting transparency to assist the hospital's own data mining efforts. These new joint ventures should also account for coordinating the care delivered by providers outside the venture.

Quality of care/legal risks audit

Many hospitals are hampered in providing consistent quality of care and are simply unaware of their compliance vulnerabilities, because they have not subjected their quality-of-care "processes" to the level of scrutiny they devote to other compliance concerns, such as billing and claims submission or physician financial relationships. This requires a broad-based, coordinated approach among the administration, the medical staff, physicians, nursing staff, risk managers, utilization review, Quality department, Compliance department and legal counsel.

A quality-of-care/legal risks audit is an important step in addressing quality of care and compliance. Such an audit identifies areas of potential quality breakdowns and helps establish internal quality controls, two key areas a hospital should immediately address to reduce the risk of an adverse government-enforcement action. A quality-of-care/legal risks audit, ideally performed by objective outside health care counsel under the attorney-client privilege, can reveal the true operational landscape of a hospital. Because of siloing and the various structural and operational challenges discussed above, it is difficult to imagine a hospital adequately addressing its quality-of-care compliance risks without this broad-based approach.

Patient care is the heart of a hospital's enterprise, and some key personnel may hesitate to scrutinize their hospital's quality of care. They might fear an audit will reveal a slew of previously unknown problems, which the hospital would then need to remedy. They might also believe (with regard to liability) that ignorance is bliss, and would rather not know of existing problems. Such attitudes are understandable but misguided.

In light of the OIG/AHLA guidance, board members have an affirmative duty to understand their hospital's quality-of-care risks. Affirmatively choosing not to conduct a quality-of-care compliance audit, simply because the hospital fears the results, could constitute willful ignorance or reckless disregard of the failures, if the problems later become known in a government investigation

or whistleblower lawsuit. Moreover, the underlying quality-of-care failures will continue to exist and can pose an ever-increasing compliance risk (false claims, malpractice, or otherwise), whether or not the hospital knows about the failures.

A responsible, less-invasive alternative to the audit process would be to perform a risk assessment based on key quality-of care-and compliance factors. The underlying concepts would be the same as those in the quality-of-care/legal risks audit, but the investigation would not run as deep as an audit. This process would give the compliance officer a general understanding of the hospital's risks. The results would highlight and prioritize key risk areas, which the compliance officer can then report to the board. A quality-of-care/legal risks audit could then be performed on selected, priority risk areas.

Quality of care and RAC audits

As the RAC programs start again, hospitals should be particularly concerned about quality-of-care compliance risks. In the time since the RAC audits were temporarily suspended, the government has announced a significant number of quality-of-care initiatives regarding reimbursement methodology. Commencing October 1, 2008, Medicare will no longer reimburse for certain hospital-acquired conditions unless the condition was present on admission.[7] Where previously, hospitals were required to report only certain quality indicators, Medicare's impending Value-Based Purchasing plan will deny payment altogether.[8] State Medicaid programs, including Massachusetts, Minnesota, and New York, have announced plans to deny payment for medical errors and/or certain hospital-acquired conditions. These are just a few of the quality-of-care payment changes, to say nothing of the growing enforcement focus on quality-of-care failures.

RAC auditors are aware that hospitals have invested significant resources to address and reduce traditional billing errors. They are also aware that many of these same hospitals have not invested the resources to address and reduce quality-of-care errors. It should be no surprise when RAC auditors focus their data mining efforts on quality-of-care issues. The RAC audits might reveal patterns of substandard care or medically unnecessary surgeries, all submitted for reimbursement. Hospitals must ready themselves to address and defend against quality-of-care issues brought by RAC auditors.

Conclusion

Quality of care, with its attendant impact on payments, public reporting, and enforcement, should be a major concern for hospitals. Traditional structures and business models are not designed to best respond to the government's mandates on quality of care and compliance. Hospitals will need to work with the compliance officer, the Quality department, and legal counsel, who are experienced in these quality of care issues, to implement new models and incentives to promote quality of care.

The first step in the process is to educate key personnel and board members. After enlisting their support, the hospital should consider undergoing a quality-of-care/legal risks audit or, at least, a risk assessment based on those same factors.

Addressing quality of care proactively, and integrating it with compliance, will give a hospital a financial and operational advantage. Those same investments in quality-of-care compliance can provide additional returns by minimizing litigation exposure and enforcement actions based on poor quality. Hospitals that refuse to recognize and address quality-of-care risks and failures should not be surprised to find themselves subjected to whistleblower suits, RAC audits on quality of care, or (worse yet) excluded from federal programs. ■

1 "Getting the Board on Board: Engaging Patient Boards in Quality and Patient Safety," 32 Joint Commission Journal on Quality and Patient Safety 179-187 (April 2006)
2 "Driving for Quality in Long-Term Care: A Board of Directors Dashboard," HHS and HCCA joint report (January 2008)
3 Arianne N. Callender, et al., The Office of the Inspector General of the U.S. Department of Health and Human Services and The American Health Lawyers Association, Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors (2007)
4 See footnote No. 3
5 Lewis Morris, Chief Counsel to the Office of United States Inspector General of Health and Human Services, on September 25, 2007
6 According to Institute of Medicine as a Profession, "Survey on Medical Professionalism," Annals of Internal Medicine (December 4, 2007)
7 Medicare Program: Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rules, 72 Fed. Reg. 47130, 47200 (Aug. 22, 2007)
8 The Deficit Reduction Act of 2005 authorized CMS to develop for Medicare a hospital pay for performance model (known as Value-Based Purchasing). Pub. L. 107-191

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