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# Doing What Really Matters: The Compliance Connection to Health Care Quality

## Several Suggestions for How to Effectively Integrate Quality-Oriented Issues into Workflow

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The role of the compliance officer is now well established in many health care organizations, yet many compliance activities have been restricted to liabilities associated with false claims, upcoding, and other billing transgressions. Further, many compliance officers and their staff operate in some ways parallel to but apart from the fundamental activities of the health care enterprises they serve. Because of concerns about the independence of the compliance function, compliance can find itself isolated from the strategic and operational center of the organization.

No matter the internal view of where the center lies, every sector of the health care industry — whether hospital, physician practice, medical device manufacturer, billing company, imaging center, or nursing home — has as its ultimate obligation and purpose to contribute to clinical processes of care for patients; whether to cure them, heal them, or palliate them. Today, the strategic mission of any health care enterprise is to provide optimal quality of care to patients, the ultimate beneficiaries of their *raison d'etre.*

Parallel with the maturation of the compliance industry, demands to demonstrate that health care enterprises are providing optimal quality of care can be seen in the multiplying statutory, contractual, regulatory, and market-based programs mandating transparency, pay-for-performance, reported sentinel events, and more. Few people, however, are aware that every single model compliance guidance from the Office of Inspector General (OIG) also makes reference to quality. In addition, beginning in 2002, every one of the OIG's work plans has included a reference to quality.

From the perspective of the Department of Justice, the new quality era began with the Tucker House case[1] in

which the facility paid $535,000 and agreed to apply clinical practice guidelines for the treatment of bedsores when the government charged the facility with false claims for every day of care it had been paid for patients who had developed aggravated decubiti. The theory of the case turned on the fact that one of the contributing factors in bad bed sores is malnutrition; therefore, each claim by the facility for a day of payment was false since the facility implicitly did not feed the patients effectively. The theory was further applied throughout the country in more than 40 additional settlements, often instigated by whistleblowers.

In 2003, a hospital in Michigan pled guilty to criminal charges and paid a $1.05 million fine when a prolific anesthesiologist on staff performed unnecessary pain management procedures for which the hospital was paid the associated facility fees. Patients suffered significant complications from the unnecessary surgeries around which false claims arguments were fashioned. Similarly, the unnecessary surgery at the Tenet Hospital in Redding, California, led to the sale of the hospital in response to prosecutorial initiatives.

Against this flourishing background, it is noteworthy that James G. Sheehan, associate attorney in the U.S. Attorney's Office in Philadelphia, has now targeted quality in even more innovative ways. With the advent of pay-for-performance programs in Medicare, both for hospitals and physicians, Sheehan has made it abundantly clear that his offices will be interested in "the quality we are paying for."[2] He has stated that he is interested in seeing the reduction of medical errors and adverse events; improvement in actual clinical outcomes; compliance with clinical practice guidelines or other clinical requirements; and reduction in cost of care for the same outcomes.

The core question around which fraud enforcement will focus in the quality arena is conduct by an institution which perpetuates care of less than optimal quality. Sheehan's attention is directed to gross and systemic leadership failures where there has been notice, warning, and failure to act; intentional acts by individuals; false reporting or failure to report quality-relevant failures; "appalling outcomes;" and more.

Although these new prosecutorial initiatives may be startling, readers should note that there are longstanding bases for exclusion from Medicare based on quality failures. When an entity provides items or services to patients (whether or not eligible for benefits under Medicare or Medicaid) that are substantially in excess of the patient's needs or of a quality that fails to meet professionally recognized standards of care,[3] there is no need for a criminal prosecution nor recovery of enormous false claims dollars to bar the provider from Medicare.

On the other hand, there are also significant civil money penalties to be imposed for quality failures. Examples include claims for a pattern of medical items or services that a person knows or should know are not medically necessary;[4] provision of false or misleading information that could be expected to lead to a premature discharge;[5] and hospital payments to physicians to reduce services[6] — the provision which inhibits gain sharing except in very narrow circumstances.

All tolled, it is hard to imagine how compliance officers can claim to be doing their job if they are not fully integrated in the quality improvement activities of their organizations — and particularly in hospitals and physician enterprises. In terms of where clinical standards of behavior are emerging, the activities of the Institute for Healthcare Improvement (IHI) are expanding and defining a new world. Beginning with "The 100,000 Lives Campaign" through which more than 3,000 hospitals holding 80 percent of the beds in the United States pledged to deliver six specific combinations of services to reduce needless deaths, the clinical standard of care was changed overnight.[7]

Now, as of December 2006, IHI has launched the "5 Million Lives Campaign" to

prevent needless harm. Among the tenets of the latter campaign is "Getting Boards On Board," which focuses expressly on the obligation of the directors of health care institutions to take direct responsibility for the quality of care rendered by their organizations. It is no longer enough for health care organizations to mouth the truism that "quality is job one." The measures of demonstrated performance are real; they are clear; and they have teeth.

What is a compliance officer to do? In the spirit of independent compliance reporting, raising the consciousness of the board and administration of a health care entity to these quality mandates is now a critical task, at least as compelling as improving their technical billing compliance sensitivity. The liability of boards on these issues is far greater than even five years ago.[8]

Helping them understand that there are many significant opportunities within the boundaries of the Stark and anti-kickback statutes for hospitals and physicians to work together in common cause for quality in ways that benefit the physicians financially will advance the hospital's cause.[9] There are many quality-focused strategic initiatives with compliance implications. For all health care industry sectors concerned about compliance, compliance officers should review the OIG's last four years' work plans to understand the quality-relevant initiatives currently underway.

How can a compliance officer effectively integrate quality-oriented issues into workflow? Develop a strategy to work with the risk management and quality improvement departments to determine where compliance ought to be involved. Think about how standardization of care in accordance with good clinical practice guidelines can bolster and support the likelihood of meeting the new standards.[10] Participate in efforts to monitor such concordance.

Quality *data* ought to be a critical focus of attention. Become familiar with the quality metrics, report card, and transparency initiatives applicable to your enterprise. Find out who is reporting what and to whom. Develop effective techniques to monitor these reports over time for accuracy, completeness, and as bellwethers for other problems in the organization. Quality data liabilities are the big iceberg here; not only are they now the bases for compliance liabilities on their own, but identified quality failures often point to other process problems.

In the last analysis, the new world order in health care is patient centric and quality driven. Compliance is no longer just about money. Its inescapable connection to quality is vital to the essential purpose of the health care enterprise — whatever type of business that might entail.



**Endnotes:**

1. *U.S. v. GMS Mgmt. — Tucker Inc.*, No. 96-1271 (E.D. Pa. 1996).
2. www.gosfield.com/LatestIssues.
3. 42 U.S.C. §1320 a-7(b)(6)(B).
4. 42 U.S.C. §1320 a-7a(a1) (1)(E).
5. 42 U.S.C. §1320 a-7a(a)(3).
6. 42 U.S.C. §1320 a-7-a(b).
7. Alice G. Gosfield, J.D. & James L. Reinertsen, M.D., *The 100,000 Lives Campaign: Crystallizing Standards of Care for Hospitals*, HEALTH AFFAIRS, Nov./Dec. 2005, at 1560-1570.
8. Michael W. Peregrine & James R. Schwartz, *Key Nonprofit Corporate Law Developments in 2006*, 16 BNA HEALTH L. REP. 55-62 (Jan. 11, 2007).
9. Alice G. Gosfield, J.D., *In Common Cause for Quality*, *in* HEALTH LAW HANDBOOK 177-222 (WestGroup 2006), *available at* www.gosfield.com/PDF/commoncausequalityCh5.pdf.
10. *See* Alice G. Gosfield, J.D. & James L. Reinertsen, *Doing Well by Doing Good: Improving The Business Case For Quality*, June 2003, www.uft-a.com; Alice G. Gosfield, J.D., *The Doctor-Patient Relationship As The Business Case For Quality*, 37 J. Health L. 197-223 (Spring 2004).

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