



Combining Disciplines: Making the Connection Between Compliance, Risk and Quality Management

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Conventional Wisdom: Divide Quality, Compliance, and Risk

Health care organizations tend to segregate operations, and related risks, into management 'silos'. The conventional wisdom is that segregation of risk allows large or complex organizations to address issues and tasks by breaking them down into manageable components. The division of tasks into segregated units of work is also a characteristic of large organizations with complex structures and strong departmental management.¹

As the prevailing regulatory and liability operating environment becomes increasingly complex in health care, the division and segregation of risk becomes in itself a risk exposure. Many health care organizations have not yet fully embraced the concept of developing connections between the disciplines of quality management, corporate compliance, and risk management. Likewise, organizations that provide malpractice and general liability insurance are well behind the curve when it comes to connecting the importance of risk management, regulatory compliance, and quality management as loss prevention tools.

Traditional segregated structures for these related functions are no longer the best protection for a health care organization in the current regulatory, medical liability, and enforcement climate. Complex changing risk environments will force evolution of the jobs traditionally performed by the compliance officer, risk manager, and quality manager. Organizations that recognize the importance of combining efforts will be much better prepared to deal with issues such as pay for performance, quality and compliance investigations, and increased associated medical liability risk.

The Quality Avalanche

For years, the compliance profession has heard a quality of care message from Office of Inspector General (OIG), Centers for Medicare Services (CMS), and Department of Justice (DOJ) leaders. Notable among these message bearers are the Lewis Morris, who was instrumental in the development of the OIG Long Term Care Compliance Guidance. Kimberly Brandt was co-developer of the OIG Compliance Guidance for Physician Practices. Tim Meehan and Jim Sheehan are US Attorneys recognized as leading prosecutors of quality and compliance issues. Even as compliance began to function as a

¹ Ching, Ward R.H., *Enterprise Risk Management: Laying a Broader Framework for Health care Risk Management*, ASHRM Risk Management Handbook, 4th Edition, 2004, p. 3. Jossey-Bass Inc. / AMA Press

profession in health care, regulators and prosecutors addressed the need for quality improvement in the delivery of health services.²

In recent years these message have become even more urgent, as studies from organizations such as the National Institute of Health (NIH), the National Institute of Medicine (IOM) and others addressed the injuries and deaths associated with medical errors and inadequate quality of care.

In 2005, an article in the Journal of the American Medical Association (JAMA) cited studies in two states which illustrated that hospital progress toward developing patient-centered safety programs is proceeding at a slow pace. The journal noted:

“Data are consistent with reports that patient safety system progress is slow and is cause for great concern...”³

The latest public advertising and education campaign of the NIH notes that according to the National Institute of Medicine (IOM), 120 patient deaths per day occur in US hospitals due to medical errors, more than are due to motor vehicle accidents, breast cancer, or AIDS.⁴

A widespread perception of inadequate quality in health care services has been driven by these widely promoted studies, highly publicized legal and regulatory actions, and an aggressive plaintiff’s bar that effectively and widely uses mass media.

In addition to increased demands for measurable quality improvements, most health care systems are struggling with staffing shortages and the sheer volume of patients that must be seen in order to meet demand or maintain economic viability. Patient volume increases are driven by an older population with more co-morbidities and diagnostic needs; population growth surges in suburban areas; and the need to process larger numbers of patients more quickly in many medical services due to limited reimbursement. Staffing concerns that lead to quality concerns are evident in current nursing staff shortages and a projected pending shortage of physicians. Current forecasts project physician shortfalls of 85,000 to 200,000 doctors by the year 2020, and project that patient demand for care at current rates will far outstrip the number of physicians who will be available in the United States by that time.⁵

Combined regulatory compliance and quality enforcement has already affected some areas of the health care industry, such as long term care. A number of landmark cases,

² US Department of Health and Human Services (HHS), Office of Inspector General (OIG), *Final Compliance Guidance for Nursing Facilities*, 65FR14289, 3/16/2000, and *Final Compliance Guidance for Individual and Small Group Physician Practices*, 65FR59434, 10/5/2000

³ Longo, D., et al, *The Long Road To Patient Safety: A Status Report on Patient Health Systems*, Journal of the American Medical Association , 294 JAMA No. 22, 12/14/2005

⁴ US National Institute of Health (NIH) , US National Library of Medicine, *Medical Errors Focus of New Campaign*, Preidt, R., *HealthDay*, 3/13/2007, ScoutNews, LLC.

⁵ American Medical Association (AMA), *Physician Shortage? Push is on for more Medical Students*, Croasdale, M., amednews.com, 3/14/2005

such as USA vs. Borne and Dynastar (Eastern District, LA, 2003-2005), include findings that the facility and management systemically failed to provide adequate care for residents. The case included prosecution under 18 USC 1347, as a criminal scheme to defraud health care programs.

Hospital and physician cases prosecuted by the Department of Justice under failures to provide appropriate quality of care include the 2003 United Memorial Hospital case, which resulted in a deferred prosecution agreement for inadequate quality related to anesthesia and pain management services. Concerns included the volume of patients treated, a lack of sterile technique, a lack of improvement among patients, and patient complaints.

The Redding Hospital investigation in 2005 involved allegations of lack of medical necessary involving cardiac surgeries. Prosecutors noted thirteen medical malpractice lawsuits were filed against involved physicians between 1988 and 2002. This Tenet Healthcare Corporation case was triggered by a quality of care whistleblower.

Many compliance officers and quality of care advocates clearly see a new regulatory approach toward including quality of care as a component of regulatory compliance programs. This is evident in many developing initiatives, such as private and public sector Pay for Performance (P4P) programs, Reporting Hospital Quality Data for Annual Payment Updates (RHQDAPU) under the Medicare Modernization Act of 2003, and hospital mandatory reporting requirements for serious events and incidents in 24 States.

Healthcare is experiencing a quiet avalanche of quality oriented regulation that will directly affect the way care is delivered in every venue. A key indicator of this avalanche of quality measures is the profound emphasis on quality of care and compliance seen clearly in the latest Corporate Integrity Agreement (CIA) issued for Tenet Healthcare Corporation.

Tenet's new CIA: Why its' different

On September 27, 2006, Tenet Healthcare Corporation signed an annual update of its' ongoing Corporate Integrity Agreement (CIA) with the OIG. The new agreement has much similarity to other similar documents. It is also profoundly different.

For the first time, the OIG has inserted in this landmark CIA very specific language directed at quality of care measures and improvement. Language in the document and appendices specifically addresses quality improvement, quality indicators and measures, and Physician led quality monitoring. Twenty three of the documents' sixty three pages address or name quality issues to some degree.

The impact of the new Tenet CIA is subtle and powerful. For the first time, specific groups of quality monitors and indicators are required by the OIG for a large, national organization of approximately 70 hospitals. In order to avoid further prosecution under the Civil False Claims Act (FCA), Tenet has agreed to implement these measures as part of the CIA and their internal Corporate Compliance Program.

The Tenet CIA includes requirements for measures such as:⁶

- A clinical quality department, including a Chief Medical Officer, senior officers and clinical quality staff
- Clinical Audits
- Physician Credentialing
- Physician Privileging
- Physician Peer Review
- Evidence Based Medicine Programs
- Standards of Clinical Excellence
- Utilization Management and Review
- Quality Metrics
- Other quality improvement measures

Health care organizations may argue that many of these processes currently exist in their facilities. The urgency of the Tenet CIA is that these functions must demonstrate their effectiveness and performance, not just their existence.

Compliance Officers, Quality Managers, and Risk Managers would be well served by a study of this landmark CIA. It is available at www.tenethealth.com, or can be seen in the OIG Fraud Prevention and Detection page at www.oig-hhs.gov.

Quality as a Component of Compliance

When we consider hospital management of regulatory compliance, quality of care, and other risks, it is easy to perceive that most of these large, multi-layered organizations tend to put various types of risk into ‘silos’ or compartments. Hospitals are by nature diverse and highly structured operating environments. They include financial, operations, support, and clinical services. The professionals associated with these various disciplines tend to structure tasks along the lines of their expertise. A strong physician element tends to add a further layer of structure over all things that may be deemed clinical.

The challenge personified by the Tenet CIA is to coordinate and integrate regulatory compliance and quality of care.

If spread among other health care organizations, such an effort has the potential to revolutionize how we look at compliance, quality, and risk and their impact on a health care organization.

The means to mandate quality performance in health care already exists. Medicare Conditions of Participation (CoP) have been found to extend beyond payment requirements to include quality concerns. A fraudulent representation or failed promise to comply with CoP could make subsequent claims false. CoP requirements include

⁶ Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Tenet Healthcare Corporation, 9/27/2006.

Patient Rights (64 FR 36069, 1999); Quality Assessment and Performance Improvement (68 FR 3435, 2003); Authentication of Verbal Orders (42 CFR 482.24(c)(1) and other pertinent issues. Additional regulatory enforcement authority is found in 18 U.S.C. §1035, False Statements Concerning Health Care. And of course, new P4P programs are expected to carry larger and larger payment incentives and penalties for hospital and physician tracking and failure to track key indicators of quality.

Healthcare employers are also prohibited against taking action against quality whistleblowers. The Patient Safety and Quality Improvement Act of 2005 (42 U.S.C. 299c-21) states, in part:

“A provider may not take adverse employment action....against an individual...Based on good faith reported information...To the provider...Or to a Patient Safety Organization....”

Experience has proven over time that when government enforcement agencies identify a measurable unmet public need, such as quality improvement in healthcare, and develop over time the means to address the need, enforcement actions predictably follow.

The inescapable conclusion is that compliance has moved from the arena of reimbursement regulation to a new venue that encompasses regulation, quality, and risk as critical components of a combined process.

Studying the Root of the Problem

Separated by organizational silos, many quality managers, compliance officers and risk managers may not realize they are tackling similar root problems. Similar compliance, risk, and quality concerns can be commonly identified through compliance audits, root cause analysis, or malpractice claims studies.

Several areas of exposure are, not surprisingly, common to each discipline. These include:

- Inadequate medical record documentation
- Poorly executed patient Informed Consent
- Inadequate patient education
- Poor Physician-Patient communications
- Lack of Medical Necessity for performed medical services
- Improper Performance of medical services

In 2006, medical liability insurer American Health care Providers Insurance Services (AHPIS, Philadelphia, PA) commissioned a study of medical malpractice claims data collected by the Physician Insurer’s Association of America (PIAA).

PIAA is an association of 57 malpractice insurers across the United States, which collectively provides insurance to 60% of U.S. Physicians. PIAA has compiled and studied claims data submitted annually by insurers since the mid 1980s.

One goal of the study was to identify if common risk exposures face medical liability, compliance, and quality disciplines. Study findings were analyzed by senior staff including a board certified corporate compliance officer and licensed health care risk manager with hospital, long term care, and medical practice operations experience, underwriters, and claims managers. The fully developed study data was refined into specialty-specific presentations accredited with the American College of Continuing Medical Education (ACCME) for use as a risk reduction tool for AHPIS insured physicians.

The PIAA study examined the following data:

- Leading allegations listed in medical malpractice claims
- Frequency (number of claims filed) and severity (indemnity cost)
- Average indemnity payments made for each type of allegation
- Severity of claims filed in 2005 compared to the average of previous years
- Patient conditions and specific procedures or medical events identified in claims

Some of the data collected over a ten year period, 1985-2005, for all medical specialties, indicate:

- Failures to monitor or supervise medical cases resulted in 16,430 cases with a total indemnity payout value of \$1.2 billion dollars
- Medication errors resulted in 9,326 cases with a total indemnity payout value of \$369 million dollars
- Procedures performed when not indicated or necessary resulted in 6,702 cases with a total indemnity payout value of \$382 million dollars
- Failure to communicate or instruct patients resulted in 4,771 cases with a total indemnity payout value of \$118 million dollars⁷

A study of claims by associated medical or legal issues revealed the following:

- Problems with Medical Records accounted for 5,051 claims with a total indemnity payout value of \$603 million dollars
- Premature Discharge accounted for 2,625 claims with a total indemnity payout value of \$242 million dollars
- Lack of Adequate Facilities or Equipment accounted for 1,985 claims with a total indemnity payout value of \$217 million dollars
- Improper Conduct by Physicians accounted for 1,943 claims with a total indemnity payout value of \$70 million dollars
- Unnecessary Treatment accounted for 1,693 claims with a total indemnity payout value of \$118 million dollars

⁷ Physician Insurers' Association of America (PIAA), Risk Management Review, As of Close Year 2005, *Cumulative Analysis: January 1, 1985-December 31, 2005*, 5/8/2006

- Breach of Confidentiality accounted for 918 claims with a total indemnity payout value of \$8 million dollars
- Failure to Conform with Regulations / Statutes accounted for 902 claims with a total indemnity payout value of \$68 million dollars
- Pharmacy Error accounted for 355 claims with a total indemnity payout value of \$18 million dollars
- Managed Care Referral Problems accounted for 276 claims with a total indemnity payout value of \$15 million dollars⁸

The phrase “total indemnity payout value” refers only to the amounts paid to (by jury award or settlement) claimants. This does not include any associated costs, such as legal defense or lost time.

Studies conducted internally by AHPIS indicate 112 physician man-hours are needed to participate in defense against one case. This does not include lost productive time associated with re-scheduling cases or patient appointments previously scheduled during that 112 hour period. Those familiar with medical malpractice defense note that notice of depositions or court dates are not usually received with great advance warning. Usually, it is necessary for affected physicians to cancel and re-schedule appointments and procedures at the last minute, resulting in greater associated costs for both the medical practice and any affected hospitals. The associated productivity and quality impact of lawsuit defense is significant.

Most risk management issues are directly related to regulatory compliance and quality of care concerns. The issues revealed by many compliance audits are surprisingly similar to those found by quality audits and malpractice risk studies.

The Hammer

More than a decade ago, health care organizations slowly began to realize that they must have a corporate compliance program, management of the program by a compliance officer, and essential elements of compliance as outlined in various program guidance documents issued by the OIG. Many compliance officers will remember that a significant educational effort was required to obtain buy-in to these efforts at the administrative, board, and physician level. The importance of instituting compliance programs became clearer when the Federal False Claims Act (FCA) was implicated in non-compliance. As compliance officers know, penalties that can be implicated under the FCA are serious. Most savvy organizations moved more nimbly to institute compliance programs under the threat imposed by the compliance ‘hammer’ of the FCA. The effect on health care billing and reimbursement systems has been revolutionary. But even with the impact of corporate compliance programs, the OIG still can still claim FY2006 savings or recoveries of \$38.2B, including \$35.8 B in implemented actions, \$789.4M in audit receivables, and \$1.6B in investigative receivables.⁹

⁸ Physician Insurer’s Association of America (PIAA), *Claims by Associated Medical and Legal Issues, Cumulative Analysis, January 1, 1985- December 31, 2005*, As of Close Year 2005, 5/8/2006

⁹ Department of Health and Human Services (HHS), Office of Inspector General (OIG), *Semiannual Report to Congress*, April 1, 2006-September 30, 2006

Clearly, regulatory compliance investigation exposure is a major source of medical-legal and financial risk for health care organizations. Administration knows the exposures involved in an implication of the FCA must be carefully avoided, and as with any business, resources are dedicated to addressing these high severity risk issues. Many organizations have over time dedicated resource dollars and manpower to initiatives designed to solely serve quality initiatives, but these programs have been frequently geared toward events such as accreditation surveys or addressing immediate problems. Some academic centers and large organizations demonstrate they understand the connection between quality and value by dedicating significant resources to quality. But for the most part, quality has been commonly relegated to Medical Staff and Nursing Quality Assurance or Quality Improvement activities, with too few resources allocated to these efforts.

Under the Tenet CIA, Administration should be on notice that quality is a primary and major concern, equal to, and soon to be considered part of, the regulatory compliance program that has in the past protected against allegations of billing and reimbursement fraud and abuse.

An analysis of the medical liability climate clearly illustrates that case frequency (number of cases) and severity (cost of cases) is increasing. Even with a ‘soft’ medical malpractice insurance climate, the average indemnity payment for each type of case allegation has increased in virtually every medical specialty.

For the first time, quality improvement and management is under the same economic ‘hammer’ that regulatory compliance initiatives have been since the passage of the Health Insurance Portability and Accountability Act (HIPAA) in 1996. Another economic hammer that must be recognized is the costs of medical malpractice insurance, representation and defense.

The New Direction

Compliance is now moving in a new, fundamental, and powerful direction. We can reasonably expect that the OIG perceives an opportunity to improve quality of care by implicating the FCA in situations where quality does not meet standards (such as are outlined or implicated in documents like the Medicare CoP or accepted by usage in the prevailing community Standard of Care). Using the FCA as an enforcement tool, the OIG is now requiring one large health care organization to demonstrate quality monitoring and improvement. Many experts believe we will soon see similar elements in Corporate Integrity Agreements for all affected organizations. The extent of OIG expectations will not be limited to those organizations with a CIA, but will eventually extend to all health care organizations. Even today, forward thinking compliance officers see the tacit connection between compliance and quality enforcement.

Compliance and Quality Management must also include and address medical liability risk and Risk Management. In an increasingly litigious environment, imagine the potential malpractice exposures faced by a health care provider or organization identified as being

under a quality of care compliance audit or prosecution. An even more chilling scenario would involve specific types of medical treatments named in quality investigations. There is a significant potential for individual and class action suits, and it is unlikely the well-informed national plaintiff's bar will fail to see this connection.

The cost of malpractice insurance is growing daily, as is the cost of average indemnity payments for settled or paid claims. This cost directly affects the bottom line of all health care providers and creates additional problems for health care organizations, including availability of physicians, ability to provide services, and physicians and hospitals being simultaneously named in suits.

The New Conventional Wisdom: Combine Compliance, Quality, and Risk Management

Compliance professionals must realize a serious movement has occurred in the industry. We're moving away from the 'old' compliance paradigm of managing billing, documentation, and reimbursement systems. The "new" reality is that health care providers are suspected not only of incorrectly billing but of providing quality of care that is below acceptable standards. Compliance as a profession must move toward enforcing quality delivery of medical services that are also correctly accounted for, documented, and billed.

Compliance officers typically are highly accountable individuals. This reflects the training and the standards of the profession. The new compliance and quality paradigm will demand that they become accountable for a new arena previously reserved for clinical Peer Review, Quality Assurance, or Quality Improvement programs. Inserting the compliance program in these areas will require reeducation for management, nursing, and physicians. It will also require compliance-type accountability systems. Auditing and monitoring systems in traditional hospital QA, QI, and Peer Review have been subject to limited funding and staffing. As they directly affect clinical practice, they have been managed by clinicians or clinical committees that have relatively limited enforcement capability. The self-policing abilities of Peer Review and Medical Staff is frequently affected by political and relationship considerations. The result of these functional impediments is that quality programs are usually less effective than quality managers would prefer. In short, quality initiatives in many health care organizations do not have the 'teeth' a robust compliance process enjoys through application of the FCA and other Federal and State laws and regulations.

Many believe the fundamental difference between a traditional hospital quality program and a compliance based quality program is that compliance driven quality programs have a better chance of positively influencing behavioral change in the organization, from the top down. Over time, the OIG, CMS and DOJ will continue to pursue and implement their interest in monitoring, measuring, and enforcing quality. This will likely take the form of additional quality-related Corporate Integrity Agreements, and compliance investigations that consider quality of care as a component of false claims. To date, the OIG and DOJ, along with State Departments of Health, have already conducted quality focused reviews of industry segments such as long term care, home health, and hospice.

Clearly, the Tenet CIA puts compliance officers on notice that hospitals and medical practices will be the next focus of such reviews. Under the Deficit Omnibus Reconciliation Act of 2005 (DRA) States are expected to implement their own False Claims Acts, and may enjoy the opportunity to retain part of the funds collected by State FCA investigators.

Ahead of the curve?

Are compliance officers who seek to implement quality and compliance processes too far ahead of the ‘curve’ to win support and acceptance from Administration and their clinical colleagues? In this case, it is better to be ahead of the curve than behind it. The Tenet CIA serves as a reminder that the OIG, CMS, and DOJ are increasingly quality-focused organizations. The quality actions of the OIG in the new Tenet CIA represent a regulatory agency approach to quality of care in a major US hospital system. This quality focus has been seen during investigations in some health care industry segments, but not to such a large degree in hospitals and medical practices. Many experts are convinced that a combined quality and compliance focus will be seen in the regulatory and investigative future at both the State and Federal level.

For hospitals and medical practices, the new Tenet CIA represents a great learning opportunity. A review of the CIA and the related appendices reveals a number of lessons. Hospitals and Physicians should be alerted to the implications of a quality agenda in Corporate Integrity Agreements. This agenda will not only affect the CIA organization, but has the potential to impact the health care industry as a whole across all segments of care. Given this information, compliance officers now have a perfect opportunity to consider future quality and compliance actions of the OIG, DOJ and CMS. They must act decisively to prepare compliance programs to review quality as well as billing, documentation, and reimbursement.

Compliance officers who choose to wait with regard to implementing quality of care standards have another consideration. DRA 2005 calls for States to develop their own False Claims Act, and allow states to retain a portion of recoveries from investigations. This is a powerful incentive for State Departments of Health and Attorneys General to move forward with their own quality and compliance investigations.

When convincing administration to properly fund quality, risk and compliance, we would do well to paraphrase Philip Crosby, one of the early leaders in American quality thinking:

“Quality is Free. Every dollar we don’t spend doing something over or correcting something done wrong is a dollar that goes straight to the bottom line.”

About AHPIS

American Healthcare Providers Insurance Services (AHPIS) is a full service management company serving professional liability insurance reciprocals in Pennsylvania, Maryland, and New Jersey. Through its' service subsidiary, Health Care Providers Insurance Services (HCP), it also provides risk management, claims management, and insurance consulting services nationwide.

AHPIS is a subsidiary of Duane Morris, LLP, one of the nations' top 100 legal firms. Duane Morris is an international law firm, and operates offices around the globe and across the United States.

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