“Quality Meets Compliance”: An Integrated Approach to Improving Quality and Reducing Exposure in Health Care

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Agenda

• An Effective Compliance Program
• The Importance of Quality
• The Peer Review Process
• Certain Cases
• Asking the Hard Questions

AN EFFECTIVE COMPLIANCE PROGRAM
The Importance of Compliance

Compliance Program Framework

OIG Model Compliance Guidance: Elements of a Compliance Program

1) The development and distribution of written standards of conduct, as well as written policies and procedures that promote the hospital’s commitment to compliance (e.g., by including adherence to compliance as an element in evaluating managers and employees) and that address specific areas of potential fraud, such as claims development and submission processes, code gaming, and financial relationships with physicians and other health care professionals;

2) The designation of a Chief Compliance Officer and other appropriate bodies, e.g., a corporate compliance committee, charged with the responsibility of operating and monitoring the compliance program, and who report directly to the CEO and the governing body;

3) The development and implementation of regular, effective education and training programs for all affected employees;

4) The maintenance of a process, such as a compliance hotline, to receive complaints, and the adoption of procedures to protect the anonymity of complainants and to protect whistleblowers from retaliation;

5) The development of a system to respond to allegations of improper/illegal activities and the enforcement of appropriate disciplinary action against employees who have violated internal compliance policies, applicable statutes, regulations or federal health care program requirements;

6) The use of audits and/or other evaluation techniques to monitor compliance and assist in the reduction of identified problem areas; and

7) The investigation and remediation of identified systemic problems and the development of policies addressing the non-employment or retention of sanctioned individuals.

OIG Compliance Program Guidance for Hospitals
Compliance Program Framework

Affordable Care Act: Accountability Requests for Skilled Nursing Facilities

The required components of a compliance and ethics program of an operating organization are the following:

(A) The organization must have established compliance standards and procedures to be followed by its employees and other agents that are reasonably capable of reducing the prospect of criminal, civil, and administrative violations under this Act.

(B) Specific individuals within high-level personnel of the organization must have been assigned overall responsibility to oversee compliance with such standards and procedures and have sufficient resources and authority to assure such compliance.

(C) The organization must have used due care not to delegate substantial discretionary authority to individuals whom the organization knew, or should have known through the exercise of due diligence, had a propensity to engage in criminal, civil, and administrative violations under this Act.

(D) The organization must have taken steps to communicate effectively its standards and procedures to all employees and other agents, such as by requiring participation in training programs or by disseminating publications that explain in a practical manner what is required.

(E) The organization must have taken reasonable steps to achieve compliance with its standards, such as by utilizing monitoring and auditing systems reasonably designed to detect criminal, civil, and administrative violations under this Act by its employees and other agents and by having in place and publicizing a reporting system whereby employees and other agents could report violations by others within the organization without fear of retribution.

(F) The standards must have been consistently enforced through appropriate disciplinary mechanisms, including, as appropriate, discipline of individuals responsible for the failure to detect an offense.

(G) After an offense has been detected, the organization must have taken all reasonable steps to respond appropriately to the offense and to prevent further similar offenses, including any necessary modification to its program to prevent and detect criminal, civil, and administrative violations under this Act.

(H) The organization must periodically undertake reassessment of its compliance program to identify changes necessary to reflect changes within the organization and its facilities.

42 USC § 1320a-7(b)(4)

Compliance Program Framework

Established a framework for assigning penalties for organizational misconduct

Penalties may be mitigated if organization has implemented an effective internal ethics and compliance program

Compliance program must be effective in detecting criminal conduct

- must detect the offense before it is discovered outside
- must promptly report to appropriate government authorities
- no person with operational responsibility in the program can have participated in, condoned, or willfully ignored the offense

Includes 7 elements of a compliance program: written policies, procedures and standards or conduct; compliance program oversight; training and education; opening the lines of communication; auditing and monitoring; consistent discipline; corrective actions
Compliance Program Framework

Bottom Line Elements of a Compliance Program

- Designation of a Compliance Officer and compliance structure
- Written Policies and Procedures
- Training and Education
- Open lines of Communication and Reporting
- Auditing and monitoring
- Background Checks and Excluded Parties Screening
- Enforcement of Standards Through Disciplinary Guidelines
- Response and Prevention

Benefits of an Effective Compliance Program

- Demonstrates hospital’s commitment to honest and responsible conduct
- Increases likelihood of preventing, identifying and correcting unlawful and unethical behavior at an early stage
- Encourages employees to report potential problems to allow appropriate internal inquiry and corrective action
- Through early detection and reporting, minimizes any financial loss to government and taxpayers, as well as any corresponding financial loss to the hospital.

The Board’s Role in Compliance

- In the compliance arena, the Board needs to knowledgeable about compliance and the compliance program and provide reasonable oversight. Among other responsibilities the Board should understand:
  - Major risks to the Company,
  - How the Compliance Program functions, and
  - That the Compliance Program is adequate to the task

The Board’s Role in Compliance

• “Every hospital should have an effective compliance plan as well as a compliance officer on staff. Board leadership is critical for both. A successful compliance plan establishes a culture of ethical and legal standards of behavior. Compliance plans promote the prevention, detection and resolution of actions that do not conform to federal and state law, as well as the hospital’s ethical and business practices. An effective compliance program not only articulates an institution’s commitment to high standards of conduct, but sets out specific and practical steps to achieve and maintain those standards.”

• “Hospital Board’s commitment to and promotion of these ongoing efforts greatly enhance their opportunity for success. The OIG has in‐depth publications to help hospitals establish effective compliance programs.”

OIG Views on Board’s Role in Compliance

• “As appropriate, the OIG strongly encourages the participation and involvement of the hospital’s board of directors, officers (including the chief executive officer (CEO)), members of senior management, representatives from the medical and clinical staffs, and other personnel from various levels of the organizational structure in the development of all aspects of the compliance program, especially the code of conduct.”

– OIG Supplemental Compliance Guidance for Hospitals (1/31/05)

• OIG/HCCA government‐industry roundtables:
  “The OIG believes the role played by health care organizations’ Boards of Directors is a key component of an effective compliance program” (June 16, 2004)

Corporate Integrity Agreements

CIA's place additional requirements on boards. For example, Halifax & CIA requires among other things:

Board of Commissioners Compliance Obligations. The Board of Commissioners of Halifax (Board) shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements and the obligations of this CIA. The Board must include independent (i.e., non‐executive) members.

The Board shall, at a minimum, be responsible for the following:

a) meeting at least bimonthly to review and oversee Halifax’s Compliance Program, including but not limited to the performance of the Compliance Officer and Compliance Committee;

b) for the first, third, and fifth Reporting Periods, considering the results of the Compliance Program Reviews (as described in Section 111.A.4.a.v of this CIA); and

c) for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Board summarizing its review and oversight of Halifax’s compliance with Federal healthcare program requirements and the obligations of this CIA.

Board Compliance Expert. Within 60 days after the Effective Date, the Board shall retain an expert in corporate governance and compliance (Compliance Expert) to assist the Board in fulfilling the responsibilities described in Section 111.A.3 of this CIA.
The Importance of Quality

• Daniel Levinson, Inspector General:

The federal government is increasingly linking hospital payments of Medicare and Medicaid bills to the quality of patient care, both in terms of monetary rewards and penalties. All these factors have an impact on hospital finances; thus, the board’s fiduciary responsibility simply cannot be fulfilled unless trustees examine the nitty-gritty details of how hospitals are doing.

And many board members may themselves shy away from adopting such a leadership stance, particularly the many trustees who come to their board memberships without a medical background. They might be tempted, for example, to leave the hard questions about mortality rates, hospital infections or medical errors to physicians. Yet that would be a big mistake. Remember the old saw about how war is too important to leave to generals? Nonmedical professionals on boards bring an outsider’s point of view that may make them more likely, not less, to see important patterns in how hospitals are doing—provided they can get the right information.
Supplemental Compliance Program
Guidance for Hospitals

OIG has authority to exclude any individual or entity from participation in Federal health care programs if the individual or entity provides unnecessary items or services (i.e., items or services in excess of the needs of a patient) or substandard items or services (i.e., items or services of a quality which fails to meet professionally recognized standards of health care).

Supplemental Compliance Program
Guidance for Hospitals

To achieve their quality care-related goals, hospitals should continually measure their performance against comprehensive standards, including

– Conditions of Participation
– Accreditation
– Other

Supplemental Compliance Program
Guidance for Hospitals

Hospital should develop their own quality of care protocols and implement mechanisms for evaluating compliance with protocols.

In reviewing the quality of care provided,

• Hospitals must not limit their review to the quality of their nursing and other ancillary services.
• Hospitals must monitor the quality of medical services provided at the hospital by appropriately overseeing the credentialing and peer review of their medical staffs.
Supplemental Compliance Program Guidance for Nursing Facilities

- Statements reflecting importance of quality
- Standards
- Quality protocols
- Measurable resident outcome

Supplemental Compliance Program Guidance for Nursing Facilities

- Quality of Care
  - Sufficient Staffing
  - Comprehensive Resident Care Plans
  - Medication Management
  - Appropriate Use of Psychotropic Medications
  - Resident Safety
    - Promoting Resident Safety
    - Resident Interactions
    - Staff Screening

Certain OIG Skilled Nursing Facility Reports

- Skilled Nursing Facilities Often Fail To Meet Care Planning And Discharge Planning Requirements, February 2013
- Inappropriate Payments to Skilled Nursing Facilities Cost Medicare More Than a Billion Dollars in 2009, November 2012
- Questionable Billing by Skilled Nursing Facilities, December 2010
- Consecutive Medicare Stays Involving Inpatient And Skilled Nursing Facilities, June 2007
Quality CIAs

- Compliance Program
- Oversight
- Written Standards
- Policies
- Training
- Review Process
- Board of Directors

1. The payment crisis
2. The quality imperative
3. Quality meets compliance and finance
4. The role of the Board; the role of the Medical Staff
5. A roadmap for success
6. Q & A

“Is it Safe?”
The Quality Imperative
Doctors' care often deficient, study says; Proper treatment given half the time
Copyright USA Today Information Network Jun 26, 2003

On average, doctors provide appropriate health care only about half the time, a landmark study of adults in 12 U.S. metropolitan areas suggests. Such deficiencies pose serious threats to the health of the American public, that lead to tens of thousands of preventable deaths each year, researchers report in today's New England Journal of Medicine.

death beds
Dirty hospitals kill 75,000 patients a year, Unnecessarily.
By Michael J. Demens from the Chicago Tribune

Global management was wheeled into Operating Room 3 at Bridgport Hospital in Connecticut for routine coronary bypass surgery. Doctors told her she'd be back home within a week. That year, December 1999, her nursing career took off as a nurse at the hospital. She was seconded during her second attack her body, and she remained hospitalized for more than two years. After more than 900
• A 66 year old patient is hospitalized for routine orthopedic surgery.
• The patient acquires an infection.
• Her stay in the hospital is prolonged for 4 days.
• What is the effect on your bottom line? ($60,000 - $100,000)
About $9.5 billion and nearly 57,000 lives would be saved annually if all of the nation’s acute care hospitals performed as well as the country’s top hospitals, finds a new study released this week by Solucient.

Value = Quality of outcome / Unit of cost / Compliant

“R.O.I.” is not just about the income line!

• Improving systems -- beyond the “Bad Apple” approach
• Integrating attention to quality, safety, risk, and service
• Integrating quality into operations through compliance, finance
1. Focus on quality, safety and compliance
2. Dedicate time
3. Be proactive
4. Assure that quality measurement and performance improvement processes are in place
5. Understand physicians role **
6. Explicate staff and physician responsibilities
7. Ensure management’s focus (Compliance can assist)
8. Align financial resources
9. Support payment contracts aligned with this focus

Hospital Medical Staffs should develop a “quality literacy” regarding patient safety, clinical care, compliance and healthcare outcomes.

THIS IS NOT AN EASY ASSIGNMENT FOR PHYSICIANS!
As Compliance Officers:
• How are you aligned with Quality and Risk Management?
• Do you know how rigorously peer review is practiced in your hospital?
• What are the indications for external peer review?
• Are summary results presented to the Board?
• Are you assured a neutral body is reflecting the community’s interest?
• Are you assured of the fairness and consistency of the process?
• Tracking and trending process, compliance and outcome measures
• Integrating...
  – Patient safety
  – Risk management activities
  – Sentinel event reporting and analysis
• Contracting
• Compliance

“Be All That You Can Be”: A Roadmap for Success
• Commit
• Collaborate
• Align incentives
• Build structures
• Enlist patients
• Track progress
• Create identity

• Get the Board’s attention
• Must be your Institutional strategic priority
• Medical Staff priority
• Transparency keeps us honest
• Focus the workforce on value, compliance and service
  – High quality
  – Better than the national average
• Quality processes...resulting in clear and compliant, succinct report cards
• Physician outreach
• Joint Conference Quality and Audit & Compliance Committees
Board Scorecard

Health System Scorecard

Hospital Scorecard
• The “report card” concept
• You want to see the follow up
  – Quality
  – Compliance
  – Malpractice
  – Service
• Don’t be afraid to ask !!!

• Increasingly, hospitals are posturing on issues of quality and service
• Skeptical audiences, in an era of transparency, will see through posturing
• Define ourselves by our commitment

Compliance-Quality connection is vital to the essential purpose of the health care enterprise.
Hospital Medical Staffs play a vital role in monitoring and improving hospital care to ensure that it is safe, beneficial, patient centered, timely, efficient, and equitable. Indeed, hospital Medical Staffs are responsible for ensuring the quality of healthcare provided in their institutions. To fulfill their role in ensuring quality...

THE PEER REVIEW PROCESS

Effective Peer Review

- Effects: Minimizes harm to patients and potential exposure of providers
- Effective peer review requires, among other things:
  - Effective leadership
  - Supportive culture
  - Effective evaluations and reviews
  - Willingness to make potentially hard decisions
  - Accountability
Peer Review, Quality & Compliance

• Peer Review must help ensure practitioners
  — Comply with CMS requirements
  — Comply with Accreditation standards
  — Comply with patient safety and quality standards

Potential Barriers to Effective Peer Review

• Conflicts of interest
• Fear of retaliation
• Not reviewing all cases
• Effective peer review requires, among other things:
  — Effective leadership
  — Supportive culture
  — Effective evaluations and reviews
  — Willingness to make potentially hard decisions
  — Accountability

Potential Solutions

— Education and training
— Auditing & monitoring of Peer Review Process
— External Peer Review, were appropriate
— Communication among Compliance, Quality (including Risk) and Medical Staff Office
— Accountability and escalation
— Culture, culture, culture
Certain Cases

Redding Medical Center, 2003 & 2005
- Allegations: Billing for medically unnecessary cardiac procedures by two physicians
- Facts:
  - Physician and staff allegedly complained of procedures
  - Data showed a very high rate of cardiac procedures
  - FBI Raid
- Result: Tenet - $54 million plus $5.5 million
  - Hospital sold
  - Physicians
    - 4 physicians agreed to total settlement to victims of procedures and Medicare and Medical program - $32.5 million
    - 2 physicians agreed to no longer perform any services or procedures on Medicare, Medical or Tricare patients
  - Potential Lawsuit

Certain Cases

Satilla Regional Medical Center, 2011
- Allegations: Billing for medically unnecessary and worthless endovascular procedures performed by surgeon
- Facts:
  - Staff (nurses) raised complaints that doctor was a danger to patients
    - One patient died
  - Question about credentialing process
  - Questions about peer review process
- Result: Satilla paid $840,000
Certain Cases
EMH Regional Medical Center, 2013
• **Allegations**: Billing for unnecessary cardiac procedures
• **Facts**:  
  – Relator was employed in the cath lab  
  – Letters from private payor questioning procedures  
  – 2006 NY Times article, “Heart Procedure Is Off the Charts in an Ohio City”
• **Result**: EMH paid $3,863,857  
  – Physician paid $541,870

Certain Cases
Golden Living, 2013
• **Allegations**: Provided inadequate and worthless monitoring, documentation and prevention and treatment of wounds
• **Facts**:  
  – Prior 2000 and 2004 CIA  
  – Relator was medical director for one the facilities  
  – Some of the allegations include wound care, hospice care and policies
• **Result**: Paid $613,300 - 5 year CIA

Asking the Hard Questions
Asking the Hard Questions

Communication
- Are you taking complaints seriously — no matter from where they generate
- Is there any hesitation to review or act based on affiliations, high admitters and similar issues?
- Do you have any effective compliant and reporting process
- Is there effective communication among key stakeholders such as compliance, quality, the medical staff and hospital administration?

Asking the Hard Questions

Internal Controls
- Does the hospital have an effective credential process?
- Does the hospital have an effective peer review process?
- Does the hospital have an effective utilization management process?
- Does the hospital have an effective quality assurance and management function, including follow-up for adverse clients?
- What are your quality metrics? Are you tracking number of procedures? Rehospitalization?
- Who is tasked with tracking and follow-up of outcomes? What is the process for outliers?
- What is your data telling you?

Asking the Hard Questions

Level of Involvement
- Are medical staff, hospital administration, and governing board able to identify issues, and if so, are they willing to take action?
- Does the hospital offer incentives or rewards for high-quality performance?
- Is quality part of the overall compliance program, such as training, education, and auditing?
- Where, if at all, does compliance intersect with the peer review process?
Asking the Hard Questions

Connection Among Departments

- Does the hospital offer a link to communication between quality of care issues and billing processes?
- Is there effective communication between the compliance officer and other departments involved with quality of care matters?