Peer Review is a Compliance Issue: Medical Necessity, Quality, & False Claims Act Liability

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Presented by Terri D. Keville, Esq., Partner, Davis Wright Tremaine LLP
Terence O., Executive Director of Compliance, Huntington Hospital (Pasadena, CA)

I. Objectives of Session

- Understand What Is Involved in Peer Review
- Understand What Medical Necessity Is and How It Relates to Peer Review
- Be Aware of Major Government Enforcement Actions, and Potential Consequences of Ignoring Compliance Issues in Peer Review—and Vice Versa
- Understand How Compliance Should Interact with the Medical Staff and Quality Management

II. Introduction

The Office of Inspector General of the federal Department of Health and Human Services (DHHS) warned hospitals more than 15 years ago, in compliance program guidance, that their compliance programs must include processes for ensuring that the services they provide are medically necessary and the care is high-quality.
II. Introduction (cont’d)

Recent government enforcement actions demonstrate that regulators will indeed go after hospitals when they have billed for services that whistleblowers allege were performed by medical staff members who knew the services were unnecessary, or who provided substandard care.

II. Introduction (cont’d)

Other laws also expose hospitals to liability and/or regulatory sanctions resulting from physician noncompliance—for example, the federal Health Insurance Portability and Accountability Act (HIPAA), the California Confidentiality of Medical Information Act (CMIA), the federal Emergency Medical Treatment and Active Labor Act (EMTALA), and laws governing the conduct of medical research.

II. Introduction (cont’d)

- Although errant physicians can get themselves and their hospitals into serious compliance trouble, in many hospitals peer review information is not typically part of the compliance process, and vice versa.
- A hospital must integrate peer review into its culture of compliance to reduce the risk of false claims and other liability for unnecessary or substandard care or medical staff physician misconduct.
III. Interrelated Hospital Peer Review, Confidentiality, and Reimbursement Obligations

A. Medicare Conditions of Participation (CoP)
B. Joint Commission Hospital Accreditation Standards
C. Common Law of Hospital Corporate Liability
D. State Hospital Licensure Requirements
E. Health Care Quality Improvement Act (HCQIA)
F. State Statutory Protection of Peer Review Information
G. False Claims Act (FCA)
H. Affordable Care Act (ACA)

A. Medicare Conditions of Participation

Governing Body (42 Code of Federal Regulations (CFR) § 482.12)

- The governing body must be effective and responsible for the conduct of the hospital.
- The governing body must “[e]nsure that the medical staff is accountable to the governing body for the quality of care provided to patients.”

A. Medicare Conditions of Participation (cont’d)

Medical Staff (42 CFR § 482.22)

- The medical staff is responsible—and accountable to the governing body—for the quality of medical care provided to patients by the hospital.
- The medical staff must periodically conduct appraisals of its members.
**B. Joint Commission Standards**

The governing body must work with the medical staff, but final decisions are always the responsibility of the governing body, and the medical staff is accountable to the governing body. *(Comprehensive Accreditation Manual for Hospitals (CAMH), Introduction to Leadership Structure, Standards LD (Leadership).01.01.01 through LD.01.07.01; LD.01.05.01, Element of Performance (EP) 6)*

**B. Joint Commission Standards (cont’d)**

The governing body must establish processes:

1. for making decisions when a leadership group, e.g., the Medical Executive Committee, “fails to fulfill its responsibilities and/or accountabilities” (LD.01.02.01, EP 2);

2. for addressing conflicts of interest that could affect safety and/or quality of care (LD.01.03.01, EP 7; LD.02.01.01, LD.02.04.01, LD.04.02.01);

**B. Joint Commission Standards (cont’d)**

3. for evaluating patient safety and implementing effective improvement measures based on available data (LD.03.01.01 through LD.03.06.01);

4. for ensuring compliance with applicable laws and regulations (LD.04.01.01); and

5. ensuring that services provided through contracts are provided safely and effectively (LD.04.03.09).
B. Joint Commission Standards (cont’d)

- “The hospital’s governing body has the ultimate authority and responsibility for the oversight and delivery of health care rendered by licensed independent practitioners...” (CAMM, Overview to Medical Staff (MS) chapter)
- “The organized medical staff oversees the quality of patient care, treatment, and services provided by practitioners privileged through the medical staff process.” (MS.03.01.01)

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B. Joint Commission Standards (cont’d)

Focused Professional Practice Evaluation (FPPE) evaluates new members, e.g., via initial proctoring, and specific aspects of performance for existing members with issues, e.g., when a question is identified regarding a currently privileged practitioner’s ability to provide “safe, high quality patient care.” (MS.08.01.01)

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B. Joint Commission Standards (cont’d)

Joint Commission’s Ongoing Professional Practice Evaluation (OPPE) standards mandate that the medical staff evaluate each practitioner’s performance in six clinical and behavioral categories continually, to identify and address performance problems promptly. (MS.08.01.03)
B. Joint Commission Standards (cont’d)

- Six areas for assessing OPPE data and other peer review information:
  1. Patient care
  2. Medical and clinical knowledge
  3. Practice-based learning and improvement
  4. Interpersonal and communications skills
  5. Professionalism
  6. Systems-based practice

(Areas of competency developed by Accreditation Council for Graduate Medical Education and the American Board of Medical Specialties)

C. Common Law of Hospital Corporate Liability (cont’d)

- Example: Darling v. Charleston Community Memorial Hospital is the seminal case nationally on hospital corporate liability. (33 Ill. 2d 326, 211 N.E. 2d 253 (1965).)
- A young patient with a broken leg came to the emergency department. The leg was improperly set, and the patient lost his lower leg as a result. The doctor settled, but the case continued against the hospital. The Illinois Supreme Court held the hospital could be liable for the negligence of its medical staff physicians—including independent contractors.
- At least 30 states recognize the tort of negligent credentialing. Only two, Maine and Pennsylvania, have actually rejected it.

C. Common Law of Hospital Corporate Liability (cont’d)

- Example: Elam v. College Park Hospital is the leading California case on hospital corporate liability: the hospital is accountable for “negligently screening the competency of its medical staff to insure the adequacy of medical care rendered to patients at its facility.” (132 Cal. App. 3d 332, 266 (1982).)
- After a bad outcome from foot surgery, the patient sued the hospital and her doctors. In the course of the litigation, the hospital acknowledged that it had learned of another malpractice suit against her doctor several months before her surgery.
- The trial court had ruled that the hospital could not be liable, but the court of appeal reversed, because (depending upon facts to be decided at trial) the hospital might be liable for negligently allowing the doctor to continue practicing in the facility unrestricted.
D. State Licensure Requirements

Example: California Code ofRegs. Title 22

- The hospital’s governing body is responsible for ensuring that the medical staff reviews the clinical performance of members and complying with federal, state, and local laws. (22 Cal. CodeRegs. § 70701)
- The hospital’s organized medical staff is responsible to the governing body for the adequacy and quality of the care rendered to patients. (22 Cal. CodeRegs. § 70703)
- Note: Examples of similar licensure requirements from other jurisdictions include WAC 246-320-131, WAC 246-320-161.

E. Health Care Quality Improvement Act (HCQIA)

- HCQIA provides immunity from damages for peer review actions taken in accordance with its procedural standards (and reported in accordance with its requirements, if applicable).
- However, to qualify for HCQIA protection a professional review action must be taken (among other requirements):
  - “(2) after a reasonable effort to obtain the facts of the matter.” (42 United States Code (USC) Section 11111)

F. State Protection of Peer Review Information

- For example, California and Hawaii protect the “proceedings” and “records” of peer review committees from discovery. (Cal. Evid. Code § 1157; Haw. Rev. Stat. § 624-25.5.)
- Merely labeling documents created in the ordinary course of hospital business as peer review documents is not sufficient.
- There is no federal peer review privilege.
F. State Protection of Peer Review Information (cont’d)

- Protection of peer review records from discovery by outsiders does not mean non-physicians who perform quality review and compliance functions within a hospital (e.g., risk management personnel, the hospital’s compliance officer) cannot review peer review documents.
- The medical staff must participate in hospital-wide performance improvement activities to meet Medicare and Joint Commission requirements, and peer review data must be used in those activities where relevant, with appropriate safeguards to prevent wider disclosure.
- Note: Another example of state peer review record protection is Mass. Gen’l Laws Ch. 111, § 204.

G. False Claims Acts (FCA)

- The federal False Claims Act allows the government to go after organizations and individuals that have improperly—and knowingly—billed the federal government for goods or services. (31 USC § 3729 et. seq.)
- The FCA also allows a whistleblower, known as a qui tam “relator,” to sue under the FCA and collect a portion of the government’s recovery if the suit is successful. In some instances, relators have collected millions of dollars, so this is a very strong incentive to “blow the whistle.”

G. False Claims Acts (FCA) (cont’d)

- Whistleblowers may use information from peer review (see the Halifax Hospital case discussed below.)
- State peer review protections do not apply in federal courts.
- Many states have their own false claims statutes, e.g., California Government Code Section 12650 et seq., which also provides for qui tam actions by private individuals who can receive a portion of any recovery, in addition to actions by the California Attorney General.
H. Patient Protection and Affordable Care Act (ACA)

- The ACA established a new section of the Social Security Act entitled “Reporting and Returning of Overpayments,” also known as the “60-Day Repayment Rule.” (42 USC § 1320a-7k(d))
- This law requires providers to report and repay identified overpayments from Medicare or Medicaid within 60 days (or the date when any corresponding cost report is due, if applicable, whichever is later).
- Failure to report and return an overpayment by the deadline causes it to become an obligation to the United States (US) government, resulting in FCA liability for a reverse false claim.

H. Patient Protection and Affordable Care Act (cont’d)

- The government may assert that a hospital “identified” an overpayment for medically unnecessary or substandard services as soon as the issue came to its attention, long before a peer review process to evaluate that issue could have been completed.
- The hospital will be in a worse position to defend an FCA case if the peer review process should have alerted the medical staff to the improper physician conduct, but did not—or if the evidence did surface, but was ignored by the medical staff or never communicated to hospital compliance personnel.
- Effective peer review, and timely communication between the medical staff and compliance personnel about these issues, are essential to minimize exposure.

Questions So Far?
Case Law Review: Active FCA Enforcement Activity With Some Multi-Million Dollar False Claims Settlements

Case 1: United Memorial Hospital

- **Date:** January 8, 2003—hospital pleads guilty to criminal charges following criminal conviction of the physician whose conduct led to the allegations against the hospital.
- **Terms of Hospital Plea Agreement:** Payment of a $1,050,908 fine, restitution of all payments for medically unnecessary procedures (more than $750,000), payment to US Attorney’s Office of prosecution costs, 3-year probation/compliance plan including independent auditing of hospital’s billing and coding processes—but no federal program exclusion.

United Memorial Hospital (cont’d)

- **Facts:** United Memorial Hospital (UMH) in Greenville, Michigan recruited an anesthesiologist with no pain management training or experience, who rapidly changed his practice so that the number of pain procedures he was performing increased tenfold within a year, and he was responsible for approximately one-third of the hospital’s income.
- As Chair of the Anesthesia Department, the anesthesiologist approved his own clinical privileges.
- Nurses who complained about the anesthesiologist’s “assembly line” pain management practice were told to keep their concerns to themselves or go elsewhere.
- Two physicians who expressed concerns about the anesthesiologist’s pain practice were subject to adverse peer review action afterward; another lost referrals.
United Memorial Hospital (cont’d)

- The Medical Staff President and the Chief of Emergency Medicine entered into financial relationships with the anesthesiologist, but continued to participate in “review” of his practice despite being asked to recuse themselves; they subsequently were prosecuted criminally also, and pled guilty, with resulting restitution, fines, and community service penalties.
- The situation did not change until a patient died following a pain procedure (one of more than 20 she underwent in a year), which triggered a government investigation and the anesthesiologist’s resignation—but the hospital continued to collect reimbursement for the anesthesiologist’s pain procedures for several years after he resigned.
- The medical staff and hospital had essentially ignored two outside reviews (one prior to the patient death and one after) that expressed concerns about the anesthesiologist’s pain practice, e.g., the lack of evaluation or documentation to support many of his procedures, including identical procedures on the same patients despite lack of demonstrated efficacy.

Case 2: Tenet Healthcare Corporation – Redding Medical Center

- **Date:** August 4, 2003
- **Settlement:** $54 million
- **Facts:** Two cardiologists at Redding Medical Center in Northern California allegedly performed unnecessary cardiac surgeries and other procedures on hundreds of patients over a period of approximately five years. There was evidence that hospital leaders knew about this but did nothing for economic reasons.
- **Note:** To date, this settlement is the largest in a case involving medical necessity fraud, i.e., billing the government programs for tests and treatments that patients did not need.

Case 3: Lafayette General Medical Center

- **Date:** January 11, 2008
- **Settlement:** $1.9 million
- **Facts:** Lafayette General Medical Center in Louisiana allegedly defrauded federal and state health care programs by billing them for medically unnecessary cardiology procedures.
- **Note:** The settlement was made under the FCA. A cardiologist claimed that another cardiologist was routinely endangering patients by subjecting them to unnecessary and inappropriate medical procedures. Government investigators found that the allegations had merit and decided to intervene and litigate the matter.

Case 4: St. Joseph’s Medical Center

- **Date:** November 10, 2010
- **Settlement:** $22 million
- **Facts:** Three physician whistleblowers, cardiac surgeons who practiced together, claimed that St. Joseph Medical Center in Maryland had contracted with a cardiology group and paid kickbacks in return for referrals of lucrative cardiovascular cases, some of which allegedly involved unnecessary procedures.
- **Note:** As a result of the settlement, the three cardiologist whistleblowers received a portion of the federal share of the recovery.


- **Timeframe:** July 12, 2004 (original complaint filed) through March 6, 2013 (hospital dismissed; case continued for the physician defendants)
- **Facts:** The whistleblowers sued under the federal FCA and the Illinois whistleblower statute, alleging violations of the Medicare Part B requirement that an attending physician be "immediately available" to supervise medical residents during simultaneous surgeries, or that an equivalent "back-up" physician be on hand.


- "Relators claim that Rush knew the surgeries being billed by [defendant] doctors were not being properly supervised, but they allowed and assisted the scheduling of concurrent surgeries and obtained reimbursement from the government for surgeries that they knew did not comply with the Medicare Rules and Regulations.” (929 F. Supp. 2d 807, 813 [N.D. Ill. 2013].)
- In other words, the relators’ legal theory of hospital liability was that the hospital scheduled numerous simultaneous surgeries, and was paid by Medicare for its component of those procedures, knowing that the attending physician supervision of those surgeries could not possibly have met the Medicare requirement—because doctors can’t be in multiple places at once.

- **Result:** The hospital ultimately convinced the judge to dismiss the hospital from the case because the allegations of the complaint showed only that the physician defendants violated Medicare law, not the hospital—but that took almost nine years, and the hospital’s defense was very costly.

- **Note:** This case illustrates the trend of actions alleging fraud based upon how physicians provide care.

Case 6: United States ex rel. Rogers v. Azmat

- **Date:** January 19, 2012
- **Settlement:** $840,000
- **Facts:** The government intervened in a *qui tam* action brought by a cath lab nurse who alleged that Medicare and Medicaid claims for endovascular services provided by a medical staff physician constituted false claims. The claims focused on the physician’s alleged incompetence to perform cath lab procedures and the hospital’s failure to address serious quality issues with his care.

US ex rel. Rogers v. Azmat (cont’d)

- **Government’s Theories:**
  - Because the physician was unqualified and had not been credentialed for endovascular privileges, the procedures at issue “were not reasonable and necessary, were incompatible with standards of acceptable medical practice, were worthless and of no medical value…” (emphasis added)—and thus the Medicare/Medicaid claims for his endovascular procedures were false and fraudulent.
  - The government also argued that the hospital knew or should have known the physician was not competent to perform the cath lab procedures, and failed to address that through either the credentialing process or corrective action.
Case 7: KentuckyOne Health Inc.

- **Date:** January 29, 2014
- **Settlement:** $16.5 million
- **Facts:** A Kentucky hospital’s parent company agreed to pay $16.5 million to resolve claims that the hospital billed government programs for unnecessary heart procedures. The unnecessary procedures allegedly cost between $10,000 and $15,000 each, and included diagnostic catheterizations, placements of stents and pacemakers, and coronary artery bypass graft surgeries.
- **Note:** The settlement resulted from a whistleblower suit and also the hospital’s voluntary disclosure of some medically unnecessary coronary stent operations by one of its cardiologists in an earlier matter. The whistleblowers split more than $2 million from the settlement, and the State of Kentucky recovered $366,000 for Medicaid payments to the hospital.

Case 8: Halifax Hospital Medical Center

- **Timeline:** This case was filed by the relator in 2009, but all claims were not resolved until 2014.
- **Facts:** The relator, a former director of physician services and long-time employee at the Florida hospital, alleged that (among other things) employed oncologists routinely admitted patients to the hospital for unnecessary overnight stays for which federal programs were billed. The government intervened and prosecuted the case.
- **Procedure:** According to the relator’s attorneys, hundreds of millions of dollars were at stake in the case, which was in litigation for five years. The judge dismissed some anti-kickback claims against the hospital, but ruled that a trial was required to decide the unnecessary-admissions allegations against the hospital.

Halifax Hospital Medical Center (cont’d)

- **Settlement:** The case was split into two parts, and resolution of all claims cost the hospital approximately $120 million.
  - The first part of the case focused on Stark allegations of improper incentive compensation arrangements with physicians, and settled in March 2014 for $85 million plus $29.5 million in legal fees—the largest Stark settlement to date.
  - The second part focused on inappropriate admissions, and settled in July, 2014 for $1 million plus $4.5 million in legal fees.
Case 9: King’s Daughters Medical Center

- Date: May 28, 2014
- Settlement: $40.9 million (for medically unnecessary procedures and alleged anti-kickback violations, i.e., cardiologist salaries above fair market value, paid to induce referrals)
- Facts: DOJ had alleged the hospital knowingly or recklessly billed for numerous unnecessary coronary stents and diagnostic catheterizations between 2006 and 2011, and that physicians falsified medical records to support the bogus claims.
- Note: The prosecuting US Attorney stated that “These cases are not just about dollars and cents. They are also about patient safety and quality of medical care.”

Case 10: Sacred Heart Hospital of Chicago

- Date: March 19, 2015
- Criminal Convictions: Sacred Heart’s former CEO, CFO, and COO were convicted on numerous counts of conspiracy and paying direct kickbacks to physicians (CEO-27 counts, CFO-17 counts, COO-11 counts) for Medicare and Medicaid patient referrals, with each count carrying a maximum penalty of 5 years in prison.
- Facts: Prosecutors proved a scheme involving kickbacks disguised as, e.g., teaching contracts, leases, free office staff, etc., in exchange for referrals that included improper patient transfers from nursing homes, and unnecessary services provided to frail, elderly patients.

Case 10: Sacred Heart Hospital of Chicago (cont’d)

- Notes:
  - The jury was not persuaded by defense arguments that as a business, “[e]verything a hospital does is designed to attract doctors and patients,” which is not improper.
  - Four defendants pleaded guilty, including two doctors.
  - The hospital closed in 2013.
2016: $23 Million DOJ Settlement with 51 Hospitals

- In mid-February 2016, the DOJ reached settlements with 51 hospitals for a total of $23 million. The government’s claims involved Medicare payments for cardiac implant devices that allegedly were implanted too soon after heart attacks, cardiac bypass procedures, or angioplasties.
- One hospital alone paid $4.8 million, and one system paid $5.9 million on behalf of numerous affiliates.
- The government’s lengthy investigation of this issue yielded settlements totaling $250 million with more than 450 hospitals.

The Intersection of Peer Review and Compliance

- **Peer Review**: addresses clinical and other patient care concerns through confidential processes (in part to maintain state-law protection of the information).
- **Compliance**: promotes openness so that information needed to identify problems and improve care will be shared, but the compliance program cannot address issues that never come to its attention.

A. Peer Review Contrasted with Compliance

*There must be a mechanism for compliance personnel to learn about medical necessity and other compliance issues that arise in the peer review context, or the essential compliance processes will not occur.*
8. Examples of Other Laws that Expose a Hospital to Substantial Liability/Sanctions for Physician Misconduct

HIPAA Privacy Rule ([5 CFR § 164.500, et seq.])
- State Privacy Laws, e.g.,
California Confidentiality of Medical Information Act (CMIA, Cal. Civ. Code § 56, et seq.)
  - Violation of federal and state patient privacy laws can result in substantial fines for hospitals, both for the violations themselves, and for failure to report privacy breaches where required.
  - The CMIA includes a private right of action and the possibility of civil damages—including actual damages as well as "nominal damages" of $1,000 per individual, which can add up to huge sums if thousands of patients were affected by a privacy breach.

Examples of Other Laws thatExpose a Hospital to Substantial Liability/Sanctions for Physician Misconduct (cont'd)

EMTALA (42 USC § 1395dd; 42 CFR § 489.24)
- Imposes federal obligations for on-call coverage, appropriate medical screening examinations, stabilizing treatment for patients with emergency medical conditions, appropriate transfer of patients who cannot be stabilized, acceptance of appropriate transfers from other hospitals, etc. Physician compliance is absolutely essential.
- Consequences for violations include fines of up to $50,000 per violation; termination of Medicare participation; strict liability for personal harm to patient; liability for financial loss to another hospital because of an improper transfer.

Examples of Other Laws that Expose a Hospital to Substantial Liability/Sanctions for Physician Misconduct (cont'd)

Federal and State Laws Governing Clinical Research
- Hospitals with clinical research programs are required to comply with detailed FDA and DHHS requirements governing research on human subjects. (See, e.g., 21 CFR Part 50; 42 CFR Part 46)
- Additionally, states have statutes governing the conduct of clinical research, e.g., California Health and Safety Code Sections 24170 – 24179.5.
Examples of Other Laws that Expose a Hospital to Substantial Liability/Sanctions for Physician Misconduct (cont’d)

Federal and State Laws Governing Clinical Research (cont’d)

- Hospitals must ensure that medical staff physicians who conduct clinical research in their facilities also comply with the federal and state regulatory requirements—including (but not limited to) requirements involving conflicts of interest, and research subjects’ informed consent to participation in research—even if all that’s involved is review of paper medical records, but particularly where there are risks to subjects from participating.
- Violations can result in (among other potential sanctions) demands from the government for repayment of research funding, and debarment from conducting research.

C. Strategies for Integrating Peer Review and Compliance Processes

- Develop and implement a written policy for compliance personnel to receive relevant peer review data (or incorporate this process into an existing policy, such as a hospital peer review policy), and for investigations to be coordinated, while maintaining 1157 protection.
- Build a functioning relationship among the medical staff, quality management, and hospital compliance personnel to ensure that issues of fraud or other regulatory exposure are identified and addressed early—and facilitate effective communication among the participants.
- Designate those responsible for maintaining that relationship.
- Ensure that the Conflict of Interest Policy covers both leaders and other medical staff members, and is followed.

Strategies for Integrating Peer Review and Compliance Processes (cont’d)

- Educate medical staff leaders as well as hospital compliance and risk management personnel on the relationship of quality, medical necessity, and peer review to compliance.
- Educate hospital governing body members about their peer review responsibilities and related conflicts of interest.
- Ensure that hospital and medical staff personnel involved in recruiting, credentialing, and re-credentialing of physicians are aware of and consider compliance issues such as criminal convictions, Medicare exclusions, etc.
Strategies for Integrating Peer Review and Compliance Processes (cont’d)

- Ensure that the medical staff and hospital evaluate the effectiveness of these processes regularly, the results are reported to the MEC and the governing body, and changes are implemented as needed.
- Document, document, document!

Questions?

Terri D. Keville  
Partner  
terrikeville@dwt.com  
213.633.8660

Terence Ou  
Executive Director  
Terence.Ou@huntingtonhospital.com  
626.397.5335