Peer Review and the False Claims Act: Avoiding Civil and Criminal Liability

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Presenter(s): Erin L. Muellenberg, JD
PEER REVIEW AND THE FALSE CLAIMS ACT: Avoiding Civil and Criminal Liability

Erin L. Muellenberg
Partner
Arent Fox, LLP
Los Angeles, CA
Erin.Muellenberg@ArentFox.com
213.443.7595

Where we are going today?

Conditions of Payment & Participation
False Claims Act
United Memorial Hospital
Redding Hospital
Azmat
OIG Position
Whistleblower Actions
Government Investigations
Compliance & Medical Staff

Primary Federal Criminal Statutes

The Anti-Kickback Statute 42 U.S.C. § 1320a-7b(b)
The Health Insurance Portability and Accessibility Act:
42 U.S.C. § 1320d-6
Federal All-Payer Statutes: 18 U.S.C. §§ 1035 and 1347
False Claims: 18 U.S.C. § 287
Primary Federal Criminal Statutes
• Obstruction of a Criminal Health Care Investigation: 18 U.S.C. § 1518
• Mail and Wire Fraud: 18 U.S.C. §§ 1341 and 1343
• False Statements: 18 U.S.C. § 1001

Primary Federal Civil Statutes
– Amended in 2009 Fraud Enforcement and Recovery Act

Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a

Conditions of Payment or Participation
• Payment – Conditions which must be met to be paid
• Participation – Conditions which must be met to participate in a Federal health care program
Conditions of Participation and the False Claims Act

- **Express Certification**
  - Complied with all conditions of payment
- **Implied Certification**
  - Submission of claim certifies that complies will all conditions of participation and conditions of payment

Expansion of FCA Liability

*Universal Health Services, Inc. v. United States ex. rel. Escobar (Escobar)*
June 16, 2016

- Violations of the FCA on the implied false certification theory permitted
  - Relators alleged UHS failed to provide sufficient licensed staff to render competent mental health services

Implied False Certification

- Claim requests payment and makes specific representations about the goods or services provided; and
- Failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths
Implied False Certification

- FCA liability for failure to comply with regulatory, statutory or contractual requirements
- Affirmative misrepresentation not required
- Must be material to the Government's payment decision
  - Appointments/Reappointments?
  - Privileges?
  - Attestations?

False Claims Act
31 U.S.C. §§3729-3733
Enacted 1863
Civil War Supplies
Knowingly submitting false claims
Claims = any demand for payment

False Claims Act
31 U.S.C. §§3729-3733

Knowledge of Falsity
  - Actual knowledge
  - Deliberate ignorance of the truth or falsity of the information
  - Reckless disregard of the truth or falsity of the information
Penalties – Aug. 1, 2016 Interim Rule increase
  - $11,000 - $21,563 for each claim
  - Treble damages
  - Double damages in some circumstances for self reporting
**Conspiracy & Knowledge**

- Actual knowledge
- Deliberate ignorance
- Reckless disregard
- Depraved indifference

**Overview of Potential Civil & Criminal Liability Exposure**

**Federal & State**

- False Claims Act
- Stark
- HIPAA
- Drug Enforcement Agency
- Sexual Misconduct
- Manslaughter plus
- Fraud
- Unlicensed Practice of Medicine

**Hospital Exposure**

- Know or should have know
- Reckless disregard for the truth
Doctor Arrests = Notice

Dr. Richard Kaul – anesthesiologist performing spine surgery
Dr. Abubakar Durrani – unnecessary spine surgery
Dr. Cully White – spine surgery monitoring
Dr. Robert Hadden – ob/gyn sexual assault
Dr. Kristen Howard – DUI
Dr. Don Wagoner – narcotic prescribing
Dr. Brett Whatcott – possession of controlled substance
Dr. John Christensen – 1st degree murder – unnecessary drugs
Dr. Anthony Garcia – murder
HEAT: Healthcare Fraud and Abuse Enforcement Action Team

Mission
Prevent waste, fraud, and abuse
“Crack down” on people and organizations
Reduce costs and improve care
Highlight best practices to reduce fraud
To build upon existing relationships with HHS and DOJ to reduce fraud

Healthcare Fraud is a DOJ Priority

“The Medicare Fraud Strike Force is one of this country’s most productive investments. We are not only putting hundreds of criminals who steal from Medicare into prison, but also stopping their theft in its tracks, recovering missions of dollars for taxpayers, and deterring potential criminals who ultimately decide the crime isn’t worth it.”

Acting Assistant Attorney General Mythili Raman
Criminal Division, Department of Justice
January 27, 2014
OIG Accomplishments for 2015

Expected recoveries of more than $3 billion
- $1.13 billion in audit receivables
- $2.22 billion in investigative receivables

4112 exclusions of individuals and entities
925 criminal actions for crimes against HHS
682 civil actions (FCA, CMP settlements, self-disclosure)

OIG 2015 Recoveries

$3.5 Billion in False Claims Act recoveries

"Of the $3.5 billion recovered last year, $1.9 billion came from companies and individuals in the health care industry for allegedly providing unnecessary or inadequate care, paying kickbacks to health care providers to induce the use of certain goods and services, or overcharging for goods and services paid for by Medicare, Medicaid, and other federal health care programs."

Department of Justice
Office of Public Affairs
December 3, 2015

OIG Work Plan 2015

Oversight of hospital privileging

"We will determine how hospitals assess medical staff candidates before granting initial privileges, including verification of credentials and review of the National Practitioner Databank."
OIG Work Plan 2016

Right heart catheterizations and endomyocardial biopsies during the same operative session
Kwashiorkor (severe protein malnutrition)
Bone marrow or stem cell transplants
Intensity modulated radiation therapy
Medical device credits for replaced medical devices
Inpatient rehabilitation – adverse events
Long term care – adverse events

Hospital response and preparedness to high risk infectious disease
Electronic health record contingency plans
CMS validation of hospital quality data
Continued evaluation of credible whistleblower claims and protection of the whistleblower
What We Struggle With

Medicare Fraud Strike Force – Its Mission

Partnership between the Departments of Justice and Health and Human Services called HEAT (Health Care Enforcement and Prevention Action Team)

Composed of coordinated teams of investigators and prosecutors from the DOJ, USAO, HHS, and the FBI for geographic areas and providers demonstrating unusually high levels of Medicare billing

Federal and state authorities collaboratively investigate Medicaid and CHIP program fraud

“Low-Hanging Fruit” Is Not the Touchstone

“And rest assured, the defendants who are being charged are not just the low-hanging fruit. The strike force has charged almost 140 licensed doctors – individuals who have breached the public trust and their professional duties of care, selling out their medical licenses for the lure of easy money, often by preying on vulnerable Medicare beneficiaries.”

Assistant Attorney General Leslie Caldwell
Criminal Division, Department of Justice
Taxpayers Against Fraud Education Fund Conference
September 17, 2014
Corporations are Smack in the Middle of the Target Zone

"We also are stepping up our prosecutions of corporations involved in health care fraud. Corporate health care fraud cases are a natural fit for us in light of our health care fraud expertise and our prosecutions of corporate cases in the financial fraud and foreign bribery arenas. We have numerous ongoing corporate health care fraud investigations, and we are determined to bring more."

Assistant Attorney General Leslie Caldwell
Criminal Division, Department of Justice
Taxpayers Against Fraud Education Fund Conference

Recent Hospital False Claims Act Settlements

April 2015 - $20 million Medical Center of Central Georgia – inpatient services should have been billed as outpatient
April 2015 - $21 million – Citizens Medical Center Texas – payment to ER physicians for cardiology referrals
April 2015 - $1.5 million and 10 years in prison billing for services not provided or unnecessary

Broward Health - $118 million for inappropriate referrals
Dec. 2015 – 32 hospitals settle for $28 million for unnecessary overnight stays for kyphoplasty
July 2016 - $17 million settlement with Lexington Hospital for improper contracts for purchase of physician practice. Whistleblower MD received $4.5 million
July 2016 – Evercare Hospice and Palliative Care settles for $18 million for services to people who were not terminally ill
Recent Hospital False Claims Act

May 25, 2016 – Prime Healthcare charged with FCA violations for unnecessary admissions from ED
March 8, 2016 – Century Oncology settles for $34.7 million for alleged unnecessary treatments
Feb. 17, 2016 – 51 hospitals in 15 states settle for $23 million for unnecessary implantable cardiac devices
Jan. 15, 2016 – Tri-City settles for $3.2 million for violations of Stark laws with physician contracts

Whistleblowers – fiscal 2015

“Most false claims actions are filed under the Act’s whistleblower, or qui tam, provisions that allow individuals to file lawsuits alleging false claims on behalf of the government. If the government prevails in the action, the whistleblower, also known as the relator, receives up to 30 percent of the recovery. Whistleblowers filed 638 qui tam suits in fiscal year 2015 and the department recovered $2.8 billion in these and earlier filed suits this past year. Whistleblower awards during the same period totaled $597 million.”

Department of Justice
Office of Public Affairs
December 3, 2015
Whistleblowers Make a Difference

Penalties 63% higher

Prison terms 2.5 times longer

The Impact of Whistleblowers on Financial Misrepresentation Enforcement Actions
December 8, 2014
Available at SSRN: http://ssrn.com/abstract=2506418
Medical Necessity/FCA

Social Security Act
“Section 1862 (42 U.S.C. 1395) – (a) Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services (I) (A) which, except for items and services described in a succeeding paragraph, are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member…..”
Medical Necessity/False Claims Act

(a)(1)(A) any person who knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval...is liable to the United States...for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted...plus three times the amount of damages which the Government sustains because of the act of that person”

Worthless Services

“...the performance of the service is so deficient that for all practical purposes it is the equivalent of no performance at all.”

Mikes v. Straus (2001)

What We Struggle With

“Tam right there in the room, and no one even acknowledges me.”
United Memorial Hospital, MI
Settled: January 7, 2003

FT Anesthesiologist recruited
Granted privileges limited to anesthesia
Anesthesiologist started pain service
No training or experience and no privileges
Approved his own privileges

United Memorial Hospital, MI
Settled: January 7, 2003

Dramatic increased in procedures performed
Staff complained it was a mill
Hospital moved out of the red in one year
Nurses complaints ignored
Physicians complaints ignored
Patient complaints ignored
No peer review

United Memorial Hospital

Board directed chair of QAC to conduct review
No response from QAC
Anesthesiologist formed partnership with Chief of Staff
and Chief of E.D.
CEO told complaining doctors that comments not welcomed
United Memorial Hospital

Patient death started investigation
Anesthesiologist indicted
Chief of Staff indicted
Chief of E.D. indicted
CEO indicted
Hospital settled with Board admitting inadequate supervision of peer review process

Redding Medical Center

Medically unnecessary heart caths and open heart surgery
Inadequate peer review
Profit over patients
$54 million settlement to avoid criminal liability for corporation

Redding Medical Center
Congressional Report

How Peer Review Failed
Dr. Campbell, new internist on staff assigned to MR Comm.
Moon suspended every day of 1992
Referred a patient for consult and young surgeon disagreed with need for surgery
Patient had surgery anyway
Discrepancies between radiology reports and cath reports
How Peer Review Failed

May 1997 meeting between 5 internists and CEO requesting external review
Review never occurred
Moon bragged of having more power than CEO
1999 more doctors c/o unnecessary procedures and requested review
Review never occurred

Redding Medical Center
Congressional Report

How Peer Review Failed
1999 - Joint Commission cited for inadequate peer review of cardiovascular cases
Deficiencies continued
Multiple resurveys (4)
Plans of Correction approved by DHS
No peer review – no complications forwarded
Complaints filed with MBC not pursued
Whistleblower
FBI Raid 10/22/02

Lessons from Redding

PEER REVIEW
PEER REVIEW
PEER REVIEW
Privileges?

"Nurse, get on the internet, go to SURGERY.COM, scroll down and click on the "Are you totally lost?" icon."

United States v. Azmat
June 2011

Worthless Services – False Claims Act
Alleged Endovascular Services were “Worthless”
Relator – Cath Lab Nurse
Alleged Dr. Azmat lacked the education, training and experience to perform procedures
Nurse refused to work with Dr. Azmat and was fired

United States v. Azmat

Because physician was not qualified, competent or credentialed to perform the services they were “worthless.”
Hospital knew or should have known the physician was not competent.
Unnecessary stents.
United States v. Azmat

The Hospital knowingly allowed the physician to provide services and then billed Medicare and Medicaid for the services. Hospital settled for $1.5 million. Hospital knew, recklessly ignored or deliberately ignored. Complication rate in endovascular exceedingly high.

Azmat Complaint

Privileges at prior hospital were restricted. Three medical malpractice suits. Repeated complaints about competence and safety. Allowed to perform procedures for which privileges were not granted.

Azmat Lessons

Ongoing peer review documented in regular meetings of medical staff. Privileges granted based on training, education and experience. Complaints of poor care are promptly investigated. Physicians not allowed to perform procedures without privileges.
What Prompts a Medical Necessity Investigation?

- Whistleblower/qui tam
- Review of utilization data
- DOJ/OIG/CMS
- Identify leads and trends
- Look for known patterns of abuse

Medical Necessity Investigation

- Claims data
- Subpoena
  - Medical records
  - Credentials file
  - Peer review/quality assurance/utilization review
  - Complaints, incident reports, etc.
  - Medical Staff Committee minutes

Two key elements for medical necessity investigation

- Falsity
  - Misrepresentation, concealment or nondisclosure
  - Prove that the service in question was not payable, i.e., prove that the service was not medically necessary
- Knowledge
  - Actual knowledge, deliberate ignorance, reckless disregard
  - Provide that the provider who billed for the service knew or should have known that the services were not medically necessary
DOJ Decision to Prosecute or Pursue

Nature of the procedure/service at issue
Patient harm, potential for patient harm
Error rate based on expert review – patterns
Nature of errors – worthless
Amount at issue
Evidence of knowledge
Evidence of revenue driven scheme

Whistleblowing: A profitable profession

UC OKs paying surgeon $10 million in whistleblower-retaliation case
April 22, 2014 Los Angeles Times
Orthopedic surgeon recruited to be chair of UCLA’s
orthopedic surgery department in 2009
Stepped down as Chair in 2010
Filed lawsuit in 2011
Alleged failure to act on complaints of conflict of
interest & retaliation
– Ties to medical device makers and other companies that influenced care
– UCLA claimed ties were for research and teaching

Dept. chair selects all the cases for peer review
Complaints of incompetence or unnecessary procedures are ignored
High volume producers are not subjected to meaningful peer review
Patterns with significant deviations are not addressed
Avoiding Liability

Follow your bylaws
Thorough credentialing
  – NPDB
  – Licensing Boards
Take peer review/quality assurance seriously
  – Consider possible advantages of external review
    • Get specialist that you need
    • Objective assessment
    • Don’t take records at face value – review images/raw test results

Avoiding Liability

Don’t ignore complaints and tips!
Refund money for unnecessary procedures/service
Medical necessity often goes hand-in-hand with other issues
  – Medical malpractice
  – Miscoding
  – Quality of care

Documenting Minutes

a. “The committee concluded that the procedure was not indicated.”

b. “The committee concluded that there was insufficient documentation to fully support the indications for the procedure.”

c. “A member of the committee commented that the only reason this patient had the surgery was so the surgeon could bill the insurance.”
**Documenting Correspondence**

Dear Doctor:

Documentation in the record must include the medical decision making process rather than just the medical decision.

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**Documenting Attorney Advice**

Attorney Client Communication
General terms
Have attorney review before finalized

*Less is more*

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**Credentialing**

Thorough background checks of all new applicants
Privileges only granted based on demonstrated current competence
No shortcuts
Conflicts of interest forms
Confidentiality agreements
When & How to Involve Compliance

Issue arises that may require compliance investigation
Refer to compliance officer in general terms to permit reasonable assessment
No initial sharing of peer review
Attorney involvement
Separate investigations

Case Studies

You have just taken over the Medical Staff Office of a 180 bed hospital with 400 medical staff members. The prior Medical Staff Director had retired early after an illness. As you begin to sift through the office you start to find files stashed in varying locations and you cannot find minutes for many of the meetings. The credentials files are in a disarray. You call the prior director and learn that she is too ill to talk. You soon find that many reappointments have not been processed and that at least 38 have expired appointments ranging for several months. What are your exposures and how do you handle?

Case Studies

As you continue assessing the Medical Staff Office you find that the new appointment application packages do not include the Medicare Attestation. This prompts you to do an audit and you find that all applicants for the past year have not completed or submitted a form. What are your exposures and how do you handle?
Case Studies

Dr. Pain is an anesthesiologist who is a specialist in pain. He comes to your hospital and starts a pain program where he is doing invasive procedures on multiple patients. Many patients receiving multiple procedures. You receive a call that one of his patients was driving after a procedure and hit and severely injured a child. What are your exposures?

Case Studies

Dr. Jon has increased his volume of spinal surgeries by 30% in the past year. There are also increasing complications with infections and returns to the OR. The OR Supervisor is concerned that Dr. Jon is using a new device manufacturer and is implanting a significant amount of hardware and is "stabilizing" levels that don’t show any pathology. The head of purchasing has let you know that Dr. Jon is now using the new device manuf. exclusively and it is rumored he is an investor in the company. How do you handle?

The Challenges We Face

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