Patient Safety and Medical Peer Review: An update in Government Enforcement

Panel

Jeffrey W. Dickstein
Phillips & Cohen LLP
(former Assistant U.S. Attorney, Miami)
jdickstein@phillipsandcohen.com

Lisa S. Rivera
Member, Bass Berry Sims
(former Assistant U.S. Attorney, Nashville)
lrivera@bassberry.com

Overview

• Current trends in medical necessity and quality of care cases
• Ramifications of quality measurements and enforcement
• Sufficiency of patient safety compliance procedures
• Peer review protections and limitations
Government Enforcement Options

- Government need not bind itself to a single remedy at the outset of an investigation
- Rather, it may proceed criminally, civilly, administratively, on parallel tracks, or on all of the above

New Qui Tam Lawsuits

Number of New Qui Tam Lawsuits Filed by Year (FY 2011 - 2015)

FCA Relator Recoveries

Relator Recoveries
FY 2011-2015 ($ in Millions)
Era of Heightened Criminal Enforcement

Current trends
How does a medical necessity or quality of care issue become a government enforcement issue?

• Failure to follow regulations
• Failure to follow guidance
• Failure to implement and enforce compliance measures
• Failure to implement and enforce quality measures
• Failure to take appropriate and timely corrective measures
• Failure to disclose/reimburse the government

Current trends
Quality of care = Compliance

• Medicare requires submission of claims that are “of a quality which meets professionally recognized standards of health care.” In addition, each claim must be supported by evidence that it is medically necessary and of the appropriate quality. 42 U.S.C. § 13906(a).

• Medicaid requires services that “are within accepted professional standards of practice.” See, e.g., Georgia Medicaid Program Part 1, section 106(k). Practices vary by state.

• TRICARE regulations require that “professional services be provided in accordance with good medical practice and established standards of quality.” 32 C.F.R. § 199.46(b)(1).
Current Trends

• Quality Requirements:
  o Medicare Conditions of Participation
  o Medicare Conditions of Payment
  o State regulatory requirements
  o Joint Commission Hospital Accreditation Standards
  o Health Care Quality Improvement Act
  o Federal False Claims Act
  o State False Claims Act
  o Affordable Care Act
  o Federal Criminal Statutes

Current Trends

• Types of Cases:
  o Unnecessary procedures;
  o Worthless services;
  o Ambulance transportation;
  o Hospice;
  o Negligent credentialing resulting in improper care;
  o Improper calibration of laboratory equipment/testing equipment;
  o Reporting of inaccurate quality data linked to payment;
  o Risk adjustment cases;
  o US ex rel. Duffy v. Laurence Memorial
  o U.S. ex rel. Absher v. Momence Meadows Nursing Center

Current trends

• Civil Enforcement Ramifications
  • Examples
    o Universal Health Services, Inc. v. United States ex rel Escobar – FCA suit alleges that the patient died at a mental health facility because caregivers were not properly supervised, and the facility lacked board-certified or qualified psychologists.
    o AmericaCare – FCA suit alleging that the provider knowingly admitted unqualified patients to hospices for improper gain.
      • Once patients are admitted to hospice care, they are no longer entitled to receive other services related to their illnesses.
    o LifeCare Centers of America – $145 million settlement for submission of alleged false claims for rehabilitation services that were not reasonable, necessary or skilled.
      • The government alleged that LifeCare “maintained corporate-wide policies and practices” designed to place patients in high reimbursement levels regardless of clinical needs.
    o Daybreak Partners, LLC, a holding company for subsidiaries that manage skilled nursing facilities in Texas, paid $5.3 million to resolve claims of substandard nursing.
      • Failure to follow proper protocols for falls, pressure ulcers and infection control; failure to follow dietary orders; failure to answer resident calls; and failure to properly investigate incidents.
Current trends

• Criminal Enforcement Ramifications – focus on responsibility

• Examples
  o The owner of skilled nursing and assisted living facility, a hospital administrator and physician's assistant were charged with conspiracy, obstruction, money laundering and healthcare fraud in Miami.
  o Patients not qualified for assisted living services
  o Two Georgia hospitals plead guilty to federal conspiracy to defraud the United States and to pay healthcare kickbacks and bribes in violation of the Anti-Kickback Statute, and forfeited more than $145 million to the government.
  o The allegations asserted that expectant Medicaid mothers were told at certain prenatal clinics that Medicaid would only cover the costs of delivery and care if the women went to the specific hospital defendants. Some travelled long distances to the hospitals.
  o Kentucky cardiologist was convicted of health care fraud in October for performing invasive heart procedures on patients who did not need them. He falsified patient charts to exaggerate the patients’ medical conditions.
  o Ten cardiologists testified against him, but the procedures were performed during a period of more than 5 years. The medical center settled with the government by paying more than $40 million.

Current trends

• Administrative Ramifications – Quality of Care

Corporate Integrity Agreements (CIA)

• Example
  o Watsonville Nursing Home Owners/Operators/Managers – California
  o Allegations: overmedicated and dehydrated patients, falls, premature death.
  o 5 year agreement
  o Independent monitor at provider's expense with relevant access
  o Scope of CIA included "all owners, officers, directors, and employees"
  o Compliance Liaison designated at facility
  o Board of Directors Compliance Committee
  o Written standards, policies and procedures; training (8 hours general; 4 hours on quality of care related to case; plus 2 additional hours for Board members)
  o Disclosure, reporting, and certifications

Current trends

• Administrative Ramifications – Quality of Care

Corporate Integrity Agreements (CIA)

• Example
  o Parkland Memorial Hospital – Dallas. Allegations included inappropriate supervision of resident physicians during procedures, upcoding, and inadequate support for rehabilitation stays.
  o Compliance officer and a Chief Quality and Safety Officer during term of CIA
  o Quality, Safety and Performance Improvement Department – responsible for monitoring clinical quality at Parkland; the improvement program; physician credentialing, privileging, and peer review program; evidence-based medicine programs; standards of clinical excellence; and utilization management and review.
  o Board retained corporate governance and compliance expert
  o Board Audit and Compliance Committee – oversight of CIA
  o Certifications by: compliance officer, Chief Quality and Safety Officer.
  o Agreement that material breach constitutes a basis for exclusion.
**Patient Safety Compliance Procedures**

- Are you doing enough?
  - Government guidance is the minimum standard
  - Industry guidance
    - The Joint Commission Accreditation Standards
    - "The hospital’s governing body has the ultimate authority and responsibility for the oversight and delivery of health care rendered by licensed independent practitioners..."

- What are the factors to consider?
- Use of data
- Witnesses
- Intent

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**Patient Safety Compliance Procedures**

- How can DOJ lawyers determine what is reasonable and necessary?

- Even if DOJ could make those determinations, shouldn’t physicians—and not the government—make medical decisions?

- How could this be FRAUD, especially when reasonable minds can differ?

- Why should facilities be liable for— and in the position of second guessing— clinical decisions made by physicians?

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**Peer Review**

- **Protections:**
  - State peer review privileges
  - Health Care Quality Improvement Act (HCQIA) - federal
    - Immunity from civil monetary damages when conducting peer review activities pursuant to its standards
    - Requires a reasonable effort to learn the facts
  - Procedures and limited disclosure

- **Limitations:**
  - There is no federal peer review privilege
  - Government is not prevented from reviewing if relevant to the investigation.
  - Negotiate disclosure and scope.

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