

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



## Panel

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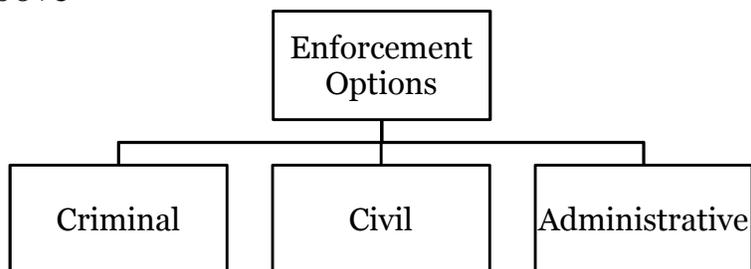
# Overview

- 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

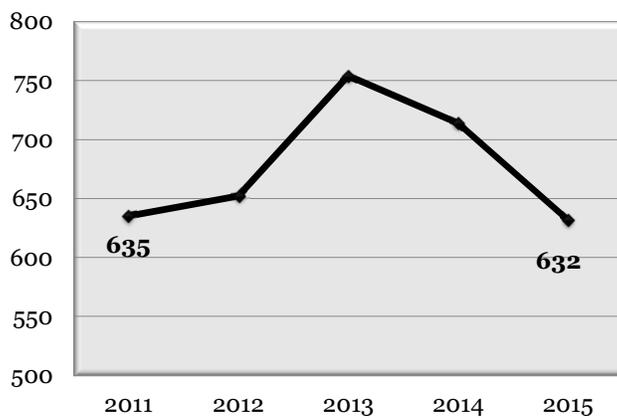
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- Government need not bind itself to a single remedy at the outset of an investigation
- Rather, it may proceed criminally, civilly, administratively, on parallel tracks, or on all of the above



## New Qui Tam Lawsuits

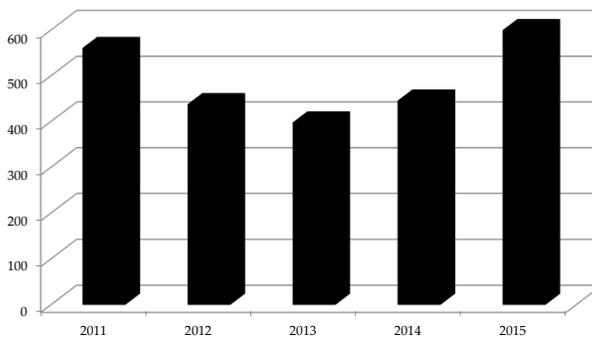
**Number of New Qui Tam Lawsuits Filed by Year (FY 2011 - 2015)**



Source: Fraud Statistics – Overview, Civil Division, U.S. DOJ

## FCA Relator Recoveries

**Relator Recoveries FY 2011-2015 (\$ in Millions)**



Source: Fraud Statistics – Overview, Civil Division, U.S. DOJ

## Era of Heightened Criminal Enforcement



THE UNITED STATES  
DEPARTMENT OF JUSTICE

Remarks by Assistant Attorney General for the Criminal Division Leslie R. Caldwell at the Taxpayers Against Fraud Education Fund Conference

United States

Wednesday, September 17, 2014

**New Qui Tam Process**

The courageous efforts by relators to bring criminal and civil misconduct to light have driven many of the largest and most important health care fraud investigations over the last several decades. And that is thanks to the work of many in this room.

I am here to tell you that the Criminal Division will redouble our efforts to work alongside you. *Qui tam* cases are a vital part of the Criminal Division's future efforts.

I know that you heard yesterday from our new Acting Associate Attorney General Stuart Delery about the Civil Division's ongoing commitment to combating fraud on the government. And I am confident that those efforts will continue in force under new Acting Assistant Attorney General for the Civil Division Joyce Branda.

We in the Criminal Division have recently implemented a procedure so that all new *qui tam* complaints are shared by the Civil Division with the Criminal Division as soon as the cases are filed. Experienced prosecutors in the Fraud Section are immediately reviewing the *qui tam* cases when we receive them to determine whether to open a parallel criminal investigation.

## 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. § 1320c-5(a)(2).
- Medicaid requires services that “are within accepted professional standards of practice.” *See, e.g., Georgia Medicaid Program Part I, 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. § 199.4(c)(1).

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# Current Trends

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

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## Current Trends

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

## Current trends

- Civil Enforcement Ramifications
- Examples
  - *Universal Health Services v. U.S. 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 psychiatrists and licensed psychologists.
  - *AseraCare* – FCA suit alleging that the provider knowingly admitted unqualified patients for hospice care (on appeal)
    - Once patients are admitted to hospice care, they are no longer entitled to receive other services related to their illnesses.
  - *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 Life Care “instituted corporate-wide policies and practices” designed to place patients in high reimbursement levels regardless of clinical needs.
  - Nearly 500 Hospitals Pay United States More Than \$250 Million to Resolve False Claims Act Allegations Related to Implantation of Cardiac Devices
    - NCD prohibits implantation during a waiting period if patient has suffered from a recent heart attack or has had bypass surgery or angioplasty.
  - *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 doctors’ orders; failure to answer resident calls; and failure to properly investigate incidents.

## Current trends

- Criminal Enforcement Ramifications – focus on responsibility
- Examples
  - The owner of skilled nursing and assisted living facility, a hospital administrator and physician's assistant were charged with conspiracy, obstruction, money laundering and health care fraud in Miami.
    - Patients not qualified for assisted living services
  - Two Georgia hospitals plead guilty to federal conspiracy to defraud the United States and to pay health care kickbacks and bribes in violation of the Anti-Kickback Statute, and forfeited more than \$145 million to the government.
    - 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.
  - 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.
    - 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
  - Watsonville Nursing Home Owners/Operators/Managers – California,
  - Allegations: overmedicated and dehydrated patients, falls, premature death.
    - 5 year agreement
    - Independent monitor at provider's expense with relevant access
    - Scope of CIA included "all owners, officers, directors, and employees"
    - Compliance Liaison designated at facility
    - Board of Directors Compliance Committee
    - 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)
    - Disclosure, reporting, and certifications

## Current trends

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

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## 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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