Medical Necessity and Civil and Criminal Liability

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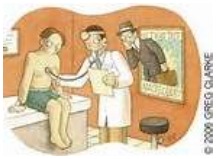
Medical Necessity — What Is It?



"Medical necessity" is a fundamental element for both the provision and payment of healthcare

- Medicare coverage is limited to items and services that are "reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. § 1395y(a)(1)(A).
- Medicare requires healthcare practitioners and providers to assure that health services ordered for government patients are "provided economically and only when, and to the extent, medically necessary." 42 U.S.C. § 1320c-5(a)(1).

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Medical Necessity — How Can It Be a False Claim?

- Providers certify that services are reasonable and necessary
- FCA liability if you "knowingly" submit or cause to submit claims for services that are not reasonable or necessary and/or for which a patient was ineligible or not entitled

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False Claims Act Penalties Ranges

False Claims Act penalty ranges adjust for inflation periodically. Both the date of violation (when the conduct occurred) and the date of assessment (when the court awards penalties) matter.

Violation After	1986	September 30, 1999	November 2, 2015 →				
Assessed After	-	-	November 2, 2015	August 1, 2016	February 3, 2017	January 29, 2018	June 19, 2020
Minimum Penalty	$5,000	$5,500	$5,500	$10,781	$10,957	$11,181	$11,665
Maximum Penalty	$10,000	$11,000	$11,000	$21,563	$21,916	$22,363	$23,331

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Criminal Health Care Fraud Statute

Criminal Health Care Fraud Statute

The Criminal Health Care Fraud Statute, 18 U.S.C. Section 1347 prohibits **knowingly and willfully** executing, or attempting to execute, a scheme or lie in connection with the delivery of, or payment for, health care benefits, items, or services to either:

- Defraud any health care benefit program
- Obtain (by means of false or fraudulent pretenses, representations, or promises) any of the money or property owned by, or under the control of, any health care benefit program

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Medical Necessity — Examples of Types of FCA cases

- Unnecessary Procedures and Tests
- Unnecessary Devices
- Unnecessary Drugs
- Unnecessary Admissions
- Ambulance Transportation
- Hospice and Home Health
- Rehabilitation Therapy/Skilled Nursing Facilities

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One Patient Does Not a Fraud Case Make

- 1X= Instance
- 5X= Occurrences
- 25X= Trend
- 50X= Pattern
- 100= Agenda

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Key Cases

United States ex rel. Polukoff v. St. Mark's Hospital

- Relator alleged that cardiologist performed medically unnecessary heart surgeries.
- District Court granted Cardiologist's motion to dismiss: medical judgment cannot be false.
- 10th Cir. reversed: "[i]t is possible for a medical judgment to be 'false or fraudulent' as proscribed by the FCA . . ."
- "a doctor's certification to the government that a procedure is 'reasonable and necessary' is 'false' under the FCA if the procedure was not reasonable and necessary under the government's definition of the phrase."

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Key Cases

United States v. Persaud

- Cardiologist convicted of health care fraud for prescribing medically unnecessary tests and performing medically unnecessary stent procedures.
- Persaud contended that his decision to prescribe additional tests was inherently subjective and thus could not support a conviction for health care fraud.
- Conviction affirmed. "A rational factfinder is entitled to rely on the government's expert testimony in concluding that Persaud's use of IVUS testing on patients whose angiograms revealed little or no arterial blockage violated this medical norm and was indicative of health care fraud."
  - Looked at standard of care

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Key Cases

United States v. AseraCare

- AseraCare allegedly admitted and retained patients not eligible to receive Medicare hospice benefit
- Court bifurcated the trial: Phase One falsity, Phase Two knowledge
  - After phase one trial, jury found 104 of 121 claims were false
  - However, the court granted summary judgment to AseraCare: mere difference of opinion between medical experts on an issue about which reasonable minds could differ is insufficient to prove falsity
  - Government must show something more than difference of medical opinion concerning prognosis
- On appeal, the Eleventh Circuit agreed with the district court than an "objective falsehood" standard is required for certifications of terminal illness
  - But rejected the proposition that claims premised on medical judgments can never be false
  - And acknowledged that its holding does not apply to claims involving "medical necessity" and is limited to the hospice context
- Case settled earlier this year for $ 1 million and no corporate integrity agreement

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Key Cases

United States ex rel. Winter v. Gardens Regional Hosp. and Med. Ctr., et al.

- Relator alleged that hospital falsely billed Medicare for medically unnecessary inpatient admissions.
- District Court: Dismissed relator's claims because they "are based on subjective medical opinions that cannot be proven to be objectively false."
- Ninth Circuit Court of Appeals reversed and remanded the case – holding that the FCA does not require proof of objective falsity
  - The Ninth Circuit stated that opinions "are not, and have never been, completely insulated from scrutiny"
    - And concluded that "[u]nder the plain language of the [FCA], the FCA imposes liability for all 'false or fraudulent claims'—it does not distinguish between 'objective' and 'subjective' falsity or carve out an exception for clinical judgments and opinions"
  - Although the Ninth Circuit noted that it does not believe that its decision in *Winter* conflicts with the Eleventh Circuit's *AseraCare* decision, the *Winter* court expressly stated that "to the extent that *AseraCare* can be read to graft any type of 'objective falsity' requirement onto the FCA, we reject that proposition"

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Key Cases

United States ex rel. Druding v. Care Alternatives

- Third Circuit rejected the argument that falsity under the FCA requires "objective falsity"
- Expressly rejected the Eleventh Circuit's *AseraCare* analysis
- Explained that a doctor's expression of his purported medical opinion can be false, in a variety of circumstances
- Held that, in the context of certifying terminal illness, "for purposes of FCA falsity, a claim may be 'false' under a theory of legal falsity, where it fails to comply with statutory and regulatory requirements," and that "a physician's judgment may be scrutinized and false"
- Defendants filed petition for writ of certiorari in Sept. 2020

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Key Cases

United States ex rel. Berntsen v. Prime Healthcare Services, Inc., et al.

- Government alleged that Prime, a hospital chain, falsely billed Medicare for medically unnecessary inpatient admissions.
- Prime moved to dismiss: Decision to admit a patient is subjective and cannot be false.
- Denied. "The fact that every decision to admit a patient was made by a doctor who was expected to use his or her judgment does not immunize Defendants from suit where the system Defendants created to make those decisions was improperly altered so as to limit the doctors' discretion."
- Case settled for $65 million + CIA

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Key Cases - Rehab in SNFs

United States ex rel. Martin v. Life Care Centers of America

- Government alleged that Life Care, a skilled nursing facility chain, falsely billed Medicare for medically unnecessary therapy services.
- Life Care moved to dismiss: Physician medical judgments cannot be false because they involve subjective clinical determinations.
- "the Medicare requirement that a physician certify services performed does not insulate Defendant from liability resulting from noncompliance with Medicare regulations."
- Case settled for $145 million

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Medical Necessity

"...no payment may be made ... for any expenses incurred for items or services which... are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member....."

Miracles made daily.

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Implied Certification

Upon submitting a claim, provider certifies that it complies with all Medicare conditions of participation and conditions of payment

Miracles made daily.

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Avoiding Liability

- Follow your bylaws
- Thorough credentialing (e.g., 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 and raw test results

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Medical Peer Review - Red Flags

- 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

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The Defense's Perspective

- First priority after learning of a potential case is to learn as much as possible
- Engage with the government to better understand scope and allegations
- Conduct internal investigation:
  - Gather as much information as possible by having robust discussions with the client
  - interview key individuals who may have relevant information (Upjohn warning)
  - Engage expert under attorney client privilege to review medical records
  - What's the standard of care in the industry?
  - Does documentation on its face support the reasonableness of the services? If not, why?
  - Can documentation deficiencies be overcome by other information?
- If government did statistically valid random sample and extrapolation, engage statistician to evaluate the SVRS
- Note – just because documentation may be insufficient doesn't necessarily mean that service was not medically necessary:
  - **DISTINCTION BETWEEN LACK OF DOCUMENTATION TO SUPPORT CLAIM THAT WAS BILLED AND PROCEDURE/SERVICE NOT BEING MEDICALLY NECESSARY**

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DOJ Civil Perspective

- Data analysis
- Obtain and analyze documents
- May draw SVRS, perform medical record review, extrapolate any loss to government
- Interview witnesses and/or testimony pursuant to Civil Investigative Demands
- Consult with agency experts
- Analyze findings of investigation as to each civil FCA element

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DOJ FCA Cooperation Policy

- In May 2019, DOJ announced new policy on cooperation by defendants in FCA investigations
- Under the policy, corporate defendants can earn credit—and a reduction in penalties and damages—by voluntarily disclosing misconduct, cooperating with our investigations, and taking remedial measures such as improving corporate compliance programs
- Even if a government FCA investigation is already underway, for example, a company may receive credit for making a voluntary self-disclosure of other misconduct—*i.e.*, misconduct outside the scope of the government's existing investigation that's unknown to the government
- Likewise, a company may earn credit by preserving relevant documents and information beyond existing business practices or legal requirements, identifying relevant individuals, and facilitating review and evaluation of data or information that requires access to special or proprietary technologies
- Cooperation means more than "paper" compliance programs
- Justice Manual Section 4-4.112

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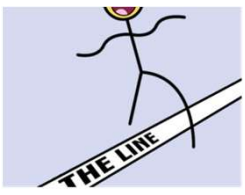
When Does a Civil FCA Fraud Become Criminal?

Hypothetical Example: Unnecessary chest x-rays v. unnecessary chemotherapy

- Both unnecessary
- Both cause patient harm
- Both cost government money



Question: civil, criminal or both?

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Civil v. Criminal- Some Considerations:

- Preponderance of evidence v. beyond a reasonable doubt standard
- Parallel intake/referral to Criminal Division
- Violate FCA, Criminal HCF Statutes
- Size of fraud/scope of conduct/loss to government
- Patient harm
- Egregiousness
- Repeat offender
- DOJ enforcement priority
- Defendant's explanation- reckless or worse

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Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Friday, July 10, 2015

Detroit Area Doctor Sentenced to 45 Years in Prison for Providing Medically Unnecessary Chemotherapy to Patients

A Detroit area hematologist-oncologist was sentenced today to serve 45 years in prison for his role in a health care fraud scheme that included administering medically unnecessary infusions or injections to 553 individual patients and submitting to Medicare and private insurance companies approximately $34 million in fraudulent claims.

Assistant Attorney General Leslie R. Caldwell of the Justice Department's Criminal Division, U.S. Attorney Barbara L. McQuade of the Eastern District of Michigan, Special Agent in Charge Paul M. Abbate of the FBI's Detroit Field Office, Special Agent in Charge Lamont Pugh III of the U.S. Department of Health and Human Services Office of Inspector General (HHS-OIG) Chicago Regional Office and Chief Richard Weber of the Internal Revenue Service – Criminal Investigation (IRS-CI) made the announcement.

Farid Fata, M.D., 50, of Oakland Township, Michigan, pleaded guilty in September 2014 to 13 counts of health care fraud, one count of conspiracy to pay or receive kickbacks and two counts of money laundering. U.S. District Judge Paul D. Borman of the Eastern District of Michigan imposed the sentence and ordered Fata to forfeit $17.6 million.

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Examples of Civil FCA cases which sometimes are—and sometimes are not—Criminal cases

- Pain medications/opioids
- Telehealth
- DME
- Stents
- Tox Screening
- Compound Pharmacies
- BUT MOST FCA CASES HAVE POTENTIAL TO BECOME CRIMINAL

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What Makes a Good Medical Necessity Case from Whistleblower's Counsel's Perspective?

- Is it really fraud?
- How pervasive?
- Patient harm?
- Kids?
- Will it interest DOJ?
- Loss to government?
- Reported Internally? Response?
- Documents?
- Data?
- Collectible?
- Whistleblower have clean hands?

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