

HCCA Healthcare Enforcement Compliance Conference

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Medical Necessity and the False Claims Act: Investigating, Proving, and Defending FCA Cases Involving Issues of Medical Necessity

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Agenda

- Medical Necessity and the FCA
 - Legal Theory and Basics
- Recent Case Law
- Hypothetical — medical necessity case
 - Facts
 - Filing of Qui Tam case
 - Investigation
 - Defending Against Medical Necessity Cases
 - Government and Relator's Response
- Additional Discussion and Questions

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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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Medical Necessity — Examples of Types of FCA cases



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



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Opinions Can Be Actionable False Statements

*United States ex rel. Harrison v.
Westinghouse Savannah River Co.*, 176
F.3d 776, 792 (4th Cir. 1999)

- “an opinion or estimate carries with it an implied assertion, not only that the speaker knows no facts which would preclude such an opinion, but that he does know facts which justify it.”



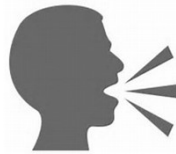
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Opinions Can Be Actionable False Statements

United States ex rel. Loughren v. Unum Group, 613 F.3d 300, 310 (1st Cir. 2010)

- Even if “the fact that an allegedly false statement constitutes the speaker’s opinion,” it still “may qualify as a false statement for purposes of the FCA where the speaker knows facts which would preclude such an opinion.”



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Opinions Can Be Actionable False Statements

Hooper v. Lockheed Martin Corp., 688 F.3d 1037 (9th Cir. 2012)

- FCA liability may be premised on false estimates



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Opinions Can Be Actionable False Statements

Restatement (Second) of Torts § 525

- There can be fraudulent misstatements of opinion, and so “a statement that a . . . person . . . is of a particular opinion . . . is a misrepresentation if the person in question does not hold the opinion.” § 525 cmt. c
- A statement taking the form of an opinion is often “reasonably understood as implying that there are facts that justify the opinion.” § 539 cmt. a
- Identifying as fraudulent “a statement that a bond is a good investment” when the speaker knows that the interest is in default and the issuer is in receivership. § 539 cmt. a



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Opinions Can Be Actionable False Statements

Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund,
135 S. Ct. 1318, 1326-27 (2015).

- The Supreme Court has recognized that an opinion can qualify as a “false statement” for purposes of liability under the securities laws.



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Recent Cases/Litigation



United States v. Paulus, 894 F.3d 267 (6th Cir. 2018)

- Jury convicted cardiologist for healthcare fraud and false statements for performing and billing for medically unnecessary cardiac procedures - stenting.
- United States argued that cardiologist systematically exaggerated amount of blockage he saw on angiograms in order to justify stent procedure.
- District court entered judgment of acquittal, reasoning that angiogram interpretations are opinions and cannot be false.

[11]

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Recent Cases/Litigation



Paulus

- 6th Circuit reversed. “[t]he degree of stenosis is a fact capable of proof or disproof. A doctor who deliberately inflates the blockage he sees on an angiogram has told a lie; if he does so to bill a more expensive procedure, then he has also committed fraud.”
- “it is up to the jury – not the court – to decide whether the government’s proof is worthy of belief.”

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Recent Cases/Litigation



Paulus

- “opinions may trigger liability for fraud when they are not honestly held by their maker, or when the speaker knows of facts that are fundamentally incompatible with his opinion.”
- Proof included doctor’s astronomical billing numbers, enormous salary, injured patients’ testimony, and expert testimony explaining that doctor recorded severe blockages where none existed.
- Judgment of acquittal vacated, jury verdict reinstated.

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Recent Cases/Litigation

United States ex rel. Polukoff v. St. Mark’s Hospital, et al., 895 F.3d 730 (10th Cir. 2018)



- 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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Recent Cases/Litigation



Polukoff

- Surgery to repair hole in heart
- Medicare Program Integrity Manual: Furnished in accordance with accepted standards of medical practice
- Accepted practice: a closure is not medically necessary unless patient had 2 strokes
- Doctor claimed to believe procedure appropriate to prevent stroke
- Doctor falsely represented that procedures being performed on basis of guidelines.

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Recent Cases/Litigation



United States v. Persaud, 866 F.3d 371 (6th Cir. 2017)

- 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."



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Recent Cases/Litigation



Hospice

United States v. AseraCare, et al., __ F.3d __ (11th Cir. 2019)

- Government: AseraCare admitted and retained patients not eligible to receive Medicare hospice benefit.
- Court bifurcated the trial,
 - Phase One falsity
 - Phase Two knowledge
- Jury found 104 of 121 claims were false
- 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.

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Recent Cases/Litigation



Hospice

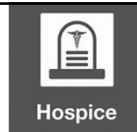
AseraCare

- 11th Cir.: To prove that a hospice claim is false, must show that the physician's clinical judgment reflects an objective falsehood.
 - physician failed to review patient's records or familiarize herself with patient's condition,
 - physician did not believe patient was terminally ill
 - no reasonable physician could have concluded that a patient was terminally ill given the records.
- Government must show something more than difference of medical opinion concerning prognosis.

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Recent Cases/Litigation



AseraCare

- Reverses summary judgment for Aseracare
- Court should consider falsity based on entirety of the evidence linked to false claims (time and place)
 - deliberate practice of not giving physicians relevant, accurate, and complete info about patients
 - certifying doctors not provided with any clinical information, rather just signing a stack of papers
 - auditors criticizing company because certifying doctors not adequately involved in making eligibility determinations and did not consistently receive medical information
 - Testimony of former physician that employees did not defer to his clinical judgment that certain patients were not entitled to hospice prior to initial certification
- Affirmed new trial

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Recent Cases/Litigation



United States ex rel. Graves v. Plaza Medical Centers Corp., 276 F.Supp.3d 1335 (SD Fla. 2017)

- Relator alleged that doctor knowingly submitted false diagnosis codes to a Medicare Advantage Organization
- Doctor moved for summary judgment contending that relator could not show that the diagnoses were “objectively false.”
- Denied: doctor’s “exercise of his clinical judgment does not preclude FCA liability for the diagnoses that he has not admitted were unsupported.”

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Recent Cases/Litigation



Graves

- “Material issues of fact exist as to whether the diagnoses that are refuted by the medical record were a valid exercise of [doctor’s] clinical judgment or made to achieve a desired result” of higher reimbursement.
- Specific methodology used to obtain predetermined result
- Contradictory information in medical record
- Doctor diagnosed patient without testing or treating patient

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Recent Cases/Litigation



United States ex rel. Tra v. Fesen, et al., 2019 WL 3453801 (D. Kan. July 31, 2019)

- Government alleged that medical oncologist prescribed medically unnecessary chemotherapy drugs.
- Oncologist moved to dismiss: complaint failed to allege any basis to find drugs were not appropriate.
- Denied: “the government has specifically identified why the treatments amounted to unnecessary care.”

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Recent Cases/Litigation



United States v. Adams, et al., 371 *F.Supp.3d* 1195 (N.D. Ga. 2019)

- Government alleged that physician submitted claims for medically unnecessary lead poisoning treatment
- Doctor moved to dismiss: Difference in medical opinion about therapy cannot be false
- Denied: “a physician’s subjective medical opinions or judgments can be false for purposes of the FCA.”
- Medical consensus that therapy not appropriate for the conditions for which physician administered it
- Experimental therapy excluded from Medicare coverage by NCD

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Recent Cases/Litigation



United States ex rel. Dildine v. Pandya, et al., 2019 WL 3074076 (N.D. Ga. July 9, 2019)

- Government alleged that ophthalmologist performed medically unnecessary surgical and laser procedures, and diagnostic tests.
- Doctor moved to dismiss: Difference in subjective opinion cannot be false
- Denied: “allowing physicians to avoid allegations of fraud by simply subjectively asserting the services were medically necessary cannot be the standard for determining falsity.”

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Recent Cases/Litigation



United States ex rel. Lutz, et al. v. Berkeley Heartlab, Inc., 2017 WL 4803911 (D. S.C. Oct. 23, 2017)

- Government alleged that blood lab performed and billed for medically unnecessary blood tests.
- Lab moved for summary judgment: US fails to prove scienter because there is a difference of medical opinion on whether the blood tests had value.
- Denied: “Even if there were a difference of opinion between the parties’ experts, it is the province of the jury to weigh the credibility of those opinions.”
- Jury found lab violated the FCA

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Recent Cases/Litigation

United States ex rel. Hayward, et al. v. Sava Senior Care LLC, et al., 2016 WL 5395949 (M.D. Tenn. Sept. 27, 2016)

- Government alleges that Sava, a skilled nursing facility chain, falsely billed Medicare for medically unnecessary rehabilitation services.
- Sava moved to dismiss: No objectively false claim because nothing more than clinical disagreements.
- Denied. “Presumably, even under the objectively false standard a claim can be false, notwithstanding a clinician’s prescription. For example, a clinician who prescribes therapy because he or she has mandated goals and not because it is in the patient’s best interest is not prescribing objectively reasonable or necessary care.”



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Recent Cases/Litigation

United States ex rel. Martin v. Life Care Centers of America, 2014 WL 11429265 (E.D. Tenn. Mar. 26, 2014)



- Government alleges 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.
- Denied. Complaint alleges that “the physicians’ medical judgment was affected by corporate pressure by Life Care, resulting in Life Care filing false or fraudulent claims.”
- “the Medicare requirement that a physician certify services performed does not insulate Defendant from liability resulting from noncompliance with Medicare regulations.”

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Recent Cases/Litigation

United States ex rel. Berntsen v. Prime Healthcare Services, Inc., et al., Case No. CV-11-8214 (C.D. Cal. January 13, 2017)



- Government alleges 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.”

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Recent Cases/Litigation

United States ex rel. Winter v. Gardens Regional Hosp. and Med. Ctr., et al., 2017 WL 8793222 (C.D. Cal. Dec. 29, 2017)

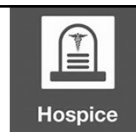


- Relator alleged that hospital falsely billed Medicare for medically unnecessary inpatient admissions.
- District Court: Dismissed relator's claims because they "are based on subjective medical opinions that cannot be proven to be objectively false."
- On appeal. *Winter ex rel. US v. Gardens Regional Hosp. and Med. Ctr., Inc.*, No. 18-55020 (9th Cir.).

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Recent Cases/Litigation



United States ex rel. Druding v. Care Alternatives, Inc., 346 F. Supp. 3d 669 (D.N.J. 2018)

- Relator: Care Alternatives admitted and retained patients not eligible to receive Medicare hospice benefit.
- District Court: Granted summary judgment to defendant on basis that the diverging opinions of the relator's and the defendant's medical experts preclude a finding of objective falsity.
- On appeal. *US ex rel. Druding v. Care Alternatives, Inc.*, No. 18-3298 (3d Cir.).

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Hypothetical — Qui tam case

- Large Cardiology Practice
 - Well-trained, board certified MDs
 - No malpractice claims
 - No fraud allegations,
 - No suspension of privileges
 - At every annual exam most patients, 65 and older, regardless of diagnoses, symptoms or previous exams, undergo:
 - EKG
 - Echocardiogram
 - Stress Test*
 - Carotid Doppler Exam
- *Performed at hospital (out-patient)



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Hypothetical — Qui tam case

- Medical Guidelines state that these tests should not be routinely performed in the absence of symptoms (excluding EKG)
- CMS requires tests be reasonable and necessary
- Recent Clinical Study suggests regular screening using these tests **may** detect impending heart attacks and strokes
 - Small study
 - Not randomized, blind or peer-reviewed
- No Adverse Incidents, Complications or Patient Complaints
- Most test results were within normal limits
- Some tests diagnosed asymptotic blockages which were then treated



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Hypothetical — Evaluation of Qui Tam Case

Relator's counsel considerations:

- Compelling issue?
- How pervasive?
- How egregious?
- Patient harm?
- Relator documents?
- Medical records?
- Reported to organization? Response?
- Strong evidence/provability?
- Chart review/expert review
- Amount at Stake?
- Who to sue — physician, hospital, system?
- Collectability



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Hypothetical — Government Investigation

Government investigation:

- Parallel intake with criminal
- Gathers agents and team
- Evaluates relator/relator's information
- Confers with agencies
- Materiality analysis
- Data run and analytics
- CIDs (charts and other documents)
- Engages with defense counsel



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Hypothetical — Government Investigation



- Consults with agency experts
- Retains independent expert
- Generates a sample and review charts
- Interview witnesses
- Document review

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Hypothetical — Defense Response

- Produce what is requested
- Engage with the government and ask questions
- Do an internal investigation
- Speak to physician and other employees-remember Yates Memo
- Retain an expert
- Analyze medical necessity issue
- Analyze materiality and other legal issues
- Challenge sample if appropriate

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Hypothetical — Defense Response

- Medical Guidelines are out of date
- Physician is practicing cutting edge medicine and has the support of clinical study
- Physicians are well qualified experts in Cardiology
- Expert witness will testify that it's not only reasonable and necessary but also beneficial to screen patients— so not objectively false
- Review is retrospective by a hired gun, and not by the treating physician whose hands were on the patient
- Hospital did not make medical judgments and shouldn't be liable
- DOJ lawyers should not make clinical judgments

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Hypothetical — Govt/Relator Responses

- Medical guidelines are evidence of what is reasonable and necessary
- Physicians did not use medical judgment before ordering tests
- No reasonable physician could have concluded reasonable and necessary
- Clinical study said MAY benefit — only a possibility and only one trial
- No evidence that the standard of care has changed
- Medical opinions can be false

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Hypothetical — Govt/Relator Responses

- Must have a way to reign in outlier physicians and enforce Medicare rules
- Patient harm
- Hospital has knowledge of and benefits from treatment decisions and can be liable
- Retrospective review by independent well trained physician is the only way to have oversight
- It is the role of the jury to weigh expert evidence

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Medical Necessity — Final Questions/Issues to Discuss

- Should Government bring FCA cases regarding medical necessity and under what circumstances?
- Should the Government be able to sample and extrapolate for the purposes of liability and/or damages?
- Should the government be able to present knowledge evidence along with falsity?
- Aren't these really medical malpractice cases?
- Can differences of physicians' opinions result in a meritorious FCA case?
- Is that an issue for a jury?

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QUESTIONS?

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