

## HCCA Healthcare Compliance Enforcement Institute

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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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## Can Opinions Be False?



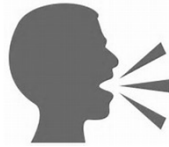
*Mechanic: Your car needs a new transmission.*

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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 (4<sup>th</sup> 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 (1<sup>st</sup> 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

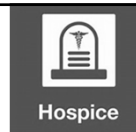
*Hooper v. Lockheed Martin Corp.*, 688 F.3d 1037, 1048 (9<sup>th</sup> Cir. 2012)

- 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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## Recent Cases/Litigation



*United States ex rel. Landis v. Hospice Care Kan., LLC*, 2010 WL 5067614 (D. Kan. Dec. 7, 2010)

- Government alleged that Hospice Care admitted and retained patients not eligible to receive the Medicare hospice benefit.
- Hospice Care moved to dismiss: “a medical opinion regarding whether a patient is terminally ill – a life expectancy of less than six months – is a subjective medical opinion that cannot be false.”
- Denied: “by submitting Medicare claims, defendants represented that that the patients were terminally ill; that defendants’ intentional, reckless business practices lead physicians to inaccurately certify patients as terminally ill; and that defendants submitted claims even though they knew, or had reckless disregard for the fact, that the patients were not terminally ill.”

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## Recent Cases/Litigation



Hospice

### *United States ex rel. Fowler v. Evercare Hospice, Inc.*, 2015 WL 5568614 (D. Colo. Sept 21, 2015)

- Government alleged that Evercare admitted and retained patients not eligible to receive the Medicare hospice benefit.
- Evercare moved to dismiss: Clinical decisions of certifying physicians cannot be objectively false.
- Denied: Defendant's "business practices created an environment in which physicians could not legitimately exercise their medical judgment because defendants provided false information on which the physicians relied."

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## Recent Cases/Litigation



Hospice

### *United States ex rel. Hinkle v. Caris Healthcare, L.P., et al.*, 2017 WL 3670652 (E.D. Tenn. May 30, 2017)

- Government alleged that Caris admitted and retained patients not eligible to receive the Medicare hospice benefit.
- Caris moved to dismiss: Difference in subjective opinion cannot be false
- Denied: "facts that rely upon clinical judgment are not automatically excluded from liability under the FCA."
- "the scheme described by the government sufficiently alleges that the 'physicians could not legitimately exercise their medical judgment because defendants provided false information on which the physicians relied.'"

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## Recent Cases/Litigation



Hospice

### *United States v. AseraCare*, 2016 U.S. Dist. LEXIS 42986 (N.D. Ala. Mar. 31, 2016)

- Government alleged that AseraCare admitted and retained patients not eligible to receive the Medicare hospice benefit.
- Court bifurcated the trial, with Phase One focusing on falsity only and Phase Two focusing on knowledge and other elements.
- Following conclusion of Phase One where the jury found 104 of 121 were false, Court granted a new trial and then summary judgment to AseraCare, finding that government had failed to point to any admissible evidence to prove falsity beyond the testimony of the government's expert.
- Court held that mere difference of opinion between physicians and medical experts on an issue about which reasonable minds could differ is insufficient to prove falsity.
- Currently on appeal to the 11<sup>th</sup> Circuit

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## Recent Cases/Litigation



Hospice

### *United States ex rel. Wall v. Vista Hospice Care, Inc., et al.*, 2016 WL 3449833 (N.D. Tex. June 20, 2016)

- Relator alleged that Vista Hospice Care admitted and retained patients not eligible to receive the Medicare hospice benefit.
- Summary judgment for Vista
- "A testifying physician's disagreement with a certifying physician's prediction of life expectancy is not enough to show falsity."
- Court recognized that evidence that certifying physician was not exercising clinical judgment could establish falsity, but relator failed to present such evidence.

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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 v. Persaud*, 866 F.3d 371 (6<sup>th</sup> 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.”



## Medical Necessity Cases Going Forward

- AseraCare case on appeal to the 11<sup>th</sup> Circuit; oral argument was in March
- Several have followed this reasoning and/or cited it; others have not
- From Government and Relator prospective — Aseracare conclusion CANNOT be the answer
- Many issues in medical necessity cases- best illustrated by a hypothetical

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## Hypothetical — the Facts



- FDA approved a drug in 2005 to treat symptoms for a genetic disease; no other on-label indication
- Very expensive drug prescribed for a disease presenting in Medicare age patients
- Drug must be administered intravenously monthly, as an in-patient
- Hospital gets paid under Part A for admission including lucrative mark-up on the drug
- Patient requires frequent exams, labs, and imaging—lucrative Part B reimbursement
- Medicare Rule- NCD — circa 2007 — regarding drug: says you can't prescribe drug unless patient is symptomatic
- Clinical trial, circa 2012: shows evidence that drug, when given before symptoms appear, may slow or prevent onset of symptoms

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## Hypothetical — the Physician



- Physician prescribes more of this drug than anyone else in the nation
- He has historically treated a large number of symptomatic patients
- After the 2012 clinical trial, he treats a huge number of new patients prophylactically, in violation of the NCD
- This physician is Chief of Medicine for his hospital and for the entire health system
- He implements the prophylactic treatment systemwide
- Health system actively markets for patients with this genetic condition whether symptomatic or not

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## Hypothetical — Qui tam case

- Many “prophylactic” patients develop toxicity to the drug
- One patient hires a medical malpractice lawyer who hires an expert (similarly trained as a treating physician) who opines that it’s below the standard of care to treat a patient who doesn’t have symptoms
- Medical malpractice lawyer attends a qui tam seminar . . . and approaches a qui tam lawyer



## Hypothetical — Evaluation of Qui Tam Case

### Relator's counsel considerations:

- Compelling issue?
- NCD violation
- Off label issue
- 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

- Medicare NCD is out of date and didn't keep pace with medicine
- Physicians are permitted to prescribe off-label
- Physician is practicing cutting edge medicine and has the support of clinical trial
- Physician is preeminent expert in treatment of this disease
- Expert witness will testify that it's not only reasonable and necessary but also beneficial to treat patients prophylactically — 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

- An NCD is the determination of what is reasonable and necessary
- Clinical trial said MAY benefit — only a possibility and only one trial
- No evidence that the standard of care has changed
- NCD has not 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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