PROGRAM MATERIALS
Program #36135
April 24, 2026

Springing Into "Materiality" - A Renewed Look at the False Claims Act's Requirement

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Springing Into “Materiality” - A Renewed Look at the False Claims Act's Requirement.

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April 2026

Disclaimer

The information is not meant to constitute legal advice and is current as the of the date of the initial presentation. Participants are encouraged to continually review updated case law, government website, State Bar websites and other reputable and relevant sources.

Overview

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- Post-*Escobar* Circuit Court Interpretations of Materiality
- *U.S. ex rel. Penelow et al. v. Janssen Products LP*, Case No. 25-1818 (3rd Cir.)
- March 17, 2026 DOJ Press Release – Indictment of Anchorage Doctor & Her Husband Impact on One Prong of Materiality
- Conclusion

Introduction

Recent DOJ False Claims Act Data

- $5.6 billion in total FCA settlements and judgments in FY 2021.
- $2.2 billion in total FCA settlements and judgments in FY 2022.
- $2.8 billion in total FCA settlements and judgments in FY 2023.
- $2.9 billion in total FCA settlements and judgments in FY 2024.
- **$6.8 billion in total FCA settlements and judgements in FY 2025**.
- **Healthcare continued to be the number one industry contributing to FCA recoveries (excluding Medicaid) with $5.7 billion in FY2025.**

False Claims Act Settlements and Judgements Exceed $6.8B in Fiscal Year 2025 (Jan. 16, 2026)

- What makes FY 2025 notable is that FCA settlements eclipsed FY 2024 by nearly $4 billion, 1,297 *qui tam* (whistleblower) lawsuits were filed – the highest in the FCA's history and an emphasis on "combating fraud in the federal health care system and in the government's procurement, loan, and grant programs and redressing the improper avoidance or tariffs and customs duties that are owed."
- Notably, "[t]he 1,297 qui tam suits filed in fiscal year 2025 breaks the prior record set in 2024 of 980 such cases. This past year, the Justice Department reported settlements and judgments exceeding $5.3 billion in these and earlier-filed qui tam suits."

The False Claims Act

- 31 U.S.C. §§ 3729-3733.
- 1863 – Known as the "Lincoln Law" (key amendments – 1943, 1986, 2009 and 2010)
- A case may be initiated by the Government or by an individual, who is either a lawyer or represented by a lawyer, known as a "Relator"
- The general process for Relator's counsel.
- The Seal
  - The initial seal period
  - Extensions
  - *State Farm* Case
- Government's Options (intervene, decline to intervene, or dismiss)
- Penalties and Damages
- Relator's Potential Recovery

Materiality & Holistic Approach

Escobar (2016)

Materiality under the FCA's statutory language

The FCA, 31 U.S.C. §3729(b)(4), specifically defines "**material**" as "**having a natural tendency to influence, or be capable of influencing, the payment or receipt of property**" by the government.

Universal Health Services v. U.S. ex rel. Escobar, 579 U.S. 176 (2016).

- The *Escobar* opinion impacted FCA litigation in two significant ways.
  - **First**, the Court **upheld the implied false certification theory** under certain circumstances.
  - **Second**, the Court clarified that materiality is a "demanding" standard.
- No *per se* rule on government knowledge was established.

Items to Consider

(1) whether the government explicitly identifies a requirement as a condition of payment;

(2) whether the government consistently refuses to pay based on noncompliance with a requirement;

(3) conversely, whether the government regularly pays claims despite actual knowledge of noncompliance; and

(4) whether the noncompliance goes to the “very essence of the bargain.”

3 Escobar Factors Used by Circuit Courts

- **No single factor is dispositive**.
    1. Whether the Government has expressly designated the legal requirement as a condition of payment [or if the implied theory of certification applies];
    2. Whether the alleged violation is ”minor or insubstantial” or instead goes to the “essence of the bargain” between the contractor and the Government; and
    3. Whether the Government made continued payments, or does so in the ”mine-run of cases,” despite actual knowledge of the violation.

Post-*Escobar* Circuit Court Interpretations of Materiality

Immediate Aftermath of Applying Materiality

DOJ

- Filed Statements of Interest in multiple cases arguing that *Escobar* did *not* change the materiality standard, focusing on the Court's discussion of statutory language and common law preceding its "demanding" standard discussion.

Defense Counsel

- Argued that *Escobar* raised the standard and imposed a greater burden on relators and the Government, focusing on the Court's discussion of the "rigorous" standard.

United States ex rel. Doe v. Heart Sol., PC, 923 F.3d 308 (3d Cir. 2019).

- Case involved submission of diagnostic reports to Medicare that should have been written by a specialist physician.
- The initial burden was on the government to show materiality.
- Government met its burden by asserting that, pursuant to applicable regulations, Medicare would not pay the claims in absence of a certification from a supervising neurologist and defendants made no showing that noncompliance with the supervision requirement was "minor or insubstantial" or that Medicare generally pays this type of claim in full despite its actual knowledge that certain requirements had not been satisfied.

United States ex. rel. Druding v. Care Alternatives, Case No. 22-1035 (3rd Cir. Aug. 25, 2023)

- Former employees of Alternatives, a for-profit hospice provider, sued under the False Claims Act, 31 U.S.C. 3729, alleging that Alternatives submitted claims for Medicare reimbursement despite inadequate documentation in the patients' medical records supporting hospice eligibility, under 42 C.F.R. 418.22(b)(2).
- District Court granted summary judgment in favor of the defendant, for lack of materiality based principally on the government's continued reimbursement of Care Alternatives even after being made aware of its deficient documentation required by regulation. "Because the District Court assigned dispositive weight to a single Escobar factor, government action, while overlooking the factors that could have weighted in favor of materiality – and despite an open dispute over the government's actual knowledge [citation omitted] – we will vacate the District Court's grant of summary judgment and remand for further proceedings consistent with this opinion.
- As a general matter, relators are not required to conduct discovery on government officials to demonstrate materiality — an imposition that according to the court would find no support in *Escobar's* holistic approach.

United States ex rel. Prather v. Brookdale Senior Living Communities, Inc., 892 F.3d 822 (6th Cir. 2018).

- Relator asserted that the defendants fraudulently sought reimbursements from Medicare for home health services without first obtaining a certification of need from a physician as required by federal regulations.
- Sixth Circuit held that Escobar does NOT require the relator to allege in the complaint specific prior government actions prosecuting similar claims.
- "The Supreme Court was explicit that none of the factors it enumerated were dispositive. Thus, it would be illogical to require a relator (or the United States) to plead allegations about past government action in order to survive a [MTD]."

United States ex rel. Campie v. Gilead Scis., Inc., 862 F.3d 890, 906 (9th Cir. 2017)

- The Ninth Circuit stated, that discovery may reveal "**that the government regularly pays this particular type of claim in full despite actual knowledge that certain requirements were violated, such evidence is not before us**" and
- The relator had sufficiently alleged facts supporting that the requirement at issue was material.

U.S. ex rel. Harman v. Trinity Industries, Inc., 872 F.3d 645 (5th Cir. 2017)

- Fifth Circuit reverses jury verdict in favor of relator in case involving Federal Highway Administration ("FHWA") and highway guardrails.
- The Fifth Circuit concluded that the record demonstrates FHWA continued to reimburse defendants' claims with respect to a new type of guardrail with full knowledge of the relator's claims about the product's purported deficiencies.
- While no single factor is outcome determinative, the very strong evidence of FHWA's continued payment remains unrebutted.

United States ex rel Lemon v. Nurses To Go, Inc., 924 F.3d 155,. 159 (5th Cir. 2019)

- The ONLY issue on appeal was whether or not Relator's alleged violations were material.
- A unanimous Fifth Circuit held that hospice providers "**cannot provide and charge for services without certifying that the patients are first eligible for those services under the terms of eligibility established by Congress and Medicare, which limit hospice services to a distinct class of patients.**"
- "The district court found the fraudulent claims, as alleged, immaterial. **We disagree and therefore reverse and remand for further proceedings.**"

Lemon (cont.) – Allegations

- Defendants failed to complete and maintain certifications and recertifications for hospice patients.
- Defendants failed to complete and maintained physician narratives in support of certifications for hospice patients; allowed non-medical personnel to complete certifications for hospice patients.
- Defendants allowed non-medical personnel to complete certifications for hospice patients and complete physician narratives for hospice patients.
- Permitted nurses to conduct required face-to-face encounters with hospice patients instead of a physician or nurse practitioner and at times after the allotted time periods.
- **Failed to write individualized care plans & billed for and provided services to deceased patients.**

Lemon (cont.) – Materiality Analysis

- Applied the Escobar factors: (1) conditions of payment; (2)past Government enforcement; and (3) substantial or minor.
- The Fifth Circuit concluded that all three elements had been met.
- “Because a patient must be certified as terminally ill to be eligible for Medicare, false terminally-ill certifications may lead the government to make a payment which it would not otherwise have made.”
- “We have no reason to believe that Medicare would reimburse Defendants for unnecessary hospice services.”

U.S. ex rel. Penelow et al. v. Janssen Products LP, Case No. 25-1818 (3rd Cir.)

Trial Court Procedural Background

- Case was filed in 2012 as a whistleblower FCA case - *United States ex rel. Penelow v. Janssen Products*, LP, Civil A. No. 12-07758.
- In 2017, Relators defeated Janssen's motion to dismiss (*United States ex rel. Penelow v. Johnson & Johnson, et al.*, 2017 WL 2367050 (D.N.J. May 31, 2017))
- 2021, its motion for summary judgment (*United States ex rel. Penelow v. Janssen Products, LP*, 2021 WL 6052425, *12 (D.N.J. Dec. 21, 2021))
- 2024 - ultimately prevailed at trial when a jury found in favor of the Relators and J&J's Janssen Unit was hit with a record $1.64 billion judgment.
    - The jury of eight unanimously agreed that Janssen was responsible for defrauding Medicare, Medicaid and the AIDS Drug Assistance Program.
    - The jury found that Janssen caused 159,574 false claims for reimbursement to be submitted to the government for its drugs, Prezista and Intelence, and awarded single damages of $120,004,736 on the federal False Claims Act violations and $30,001,184 on the state False Claims Act violations.

United States v. Janssen Prods., No. 25-1818 (3rd Cir. 2025). (3 Judge Panel)

- **J&J**
  - Argued there was no evidence that any false representation was material to the government's payment decision. **Judges Paul Matey and Cindy K. Chung noted materiality is an issue for a jury and questioned whether J&J was seeking to convert the continued government reimbursement factor at the center of the Supreme Court's 2016 decision in *United States v. Escobar* into a legal standard.**
- **Relators**
  - **Argued that the Government lacked actual knowledge during the relevant period; thus Escobar's continued-reimbursement analysis is inapplicable.**

Link to oral argument - https://www2.ca3.uscourts.gov/oralargument/audio/25-1818Penelow;Brancacciov.JanssenProductsL.P.mp3.

March 17, 2026 DOJ Press Release – Indictment of Anchorage Doctor & Her Husband Impact on One Prong of Materiality.

Anchorage doctor sentenced to prison in multi-million-dollar health care, tax fraud schemes.

- An Anchorage doctor was sentenced today to six and a half years in prison for executing a $12.5 million health care fraud scheme and evading over $4 million in taxes on the profits of their 15-year scheme. Her husband and co-defendant was sentenced to three years' probation, with two years to be served in home confinement for his role in the fraudulent scheme.
- Dr. Tan specialized in the treatment of autoimmune and musculoskeletal diseases, such as rheumatoid arthritis, osteoarthritis and psoriatic arthritis, and prescribed injectable medications to treat those conditions.
- Beginning in 2009 and continuing through 2024, Dr. Tan routinely and surreptitiously underdosed patients, injected them with free samples or a different medication than prescribed, injected them with expired medication, and injected them with medications purchased by other patients. Covert video recordings of Dr. Tan treating two of her patients confirmed her deceit.

March 17, 2026 Alaska Physician Indictment (cont.)

- The Tans then knowingly billed insurance plans as if Dr. Tan had provided a proper injection to each patient. Specifically, the Tans claimed to have administered 4,829 units of the medications to patients, and billed the insurance plans for that amount, despite only purchasing 369 units of medication.
- Mr. Tan assisted in executing the scheme in part by creating and submitting fraudulent insurance claims and ordering insufficient medication for the clinic. 10 insurance plans lost approx. $12.5 million and created health risks for patients.

Materiality & the Alaska Physician Indictment

DOJ

- ”For well over a decade, Dr. Tan and her husband operated a fraud scheme and squirreled away millions of dollars at the expense of their patients, callously disregarding the medical needs of those suffering from debilitating diseases so they could become rich.”

Escobar Factors (if this was a civil FCA case)

1. Whether the Government has expressly designated the legal requirement as a condition of payment [or if the implied theory of certification applies];
2. Whether the alleged violation is ”minor or insubstantial” or instead goes to the “essence of the bargain” between the contractor and the Government; and
3. Whether the Government made continued payments, or does so in the ”mine-run of cases,” despite actual knowledge of the violation.

Conclusion

Parting Thoughts

- Materiality is determined on a case-by-case basis.
- Facts and circumstances of each matter are significant considerations.
- Courts all apply the three factors (past enforcement, express condition for payment (or implied certification theory if applicable) and “minor or insubstantial” related to the government’s continued payment.
- Ensuring that an adequate compliance program that adequate addresses HIPAA and fraud, waste and abuse laws (42 CFR §483.85 is critical).

Thank You & Questions

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Resources

- *U.S. ex rel. Rose v. Stephens Institute*, 909 F.3d 1012 (10th Cir. 2019)
- *United States ex rel. Berg v. Honeywell Int'l, Inc.*, 740 Fed. Appx. 535 (9th Cir. 2018)