Update on FCA Case Law

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Recent Trends

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Universal Health Services, Inc. v. U.S. ex rel. Escobar

- On June 16, 2016, the U.S. Supreme Court published a unanimous opinion in *Universal Health Services, Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989 (2016), recognizing the "implied false certification" theory of FCA liability.
- The Court decision sought to resolve disagreement among the courts of appeals about the viability and scope of the implied false certification theory.
  - The Seventh Circuit had rejected the theory outright.
  - The Second Circuit had held that the theory was viable only when the relevant legal requirement was expressly stated to be a condition of payment.
- Relators alleged that a mental health facility submitted false claims to the Massachusetts Medicaid program by billing for caregivers who were not properly licensed to provide the services for which reimbursement was claimed.

The Supreme Court's Holding in *Escobar*

- The Court held that the implied false certification theory can be a basis for liability "at least where two conditions are satisfied:"
  1. The "claim does not merely request payment but also makes specific representations about the goods or services provided;" and
  2. The "defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths."
- The Court held that these conditions were met because the facility billed Medicaid using billing codes and provider numbers that were tied to specific qualification and supervision requirements that relators alleged the facility knowingly failed to meet.

The *Escobar* Materiality Requirement

- The Court rejected an "express condition of payment" requirement in favor of a "rigorous" and "demanding" materiality standard.
- FCA liability can arise from violation of a legal requirement only if the non-compliance with that requirement actually matters to the government's payment decision to pay, and the defendant knew that it would.
- "[U]nder any understanding of the concept, materiality 'looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.'"
  - In order to state a claim for relief under the implied false certification theory, it is not enough to allege that non-compliance *could* have had an effect on a payment decision; instead, the plaintiff must allege that non-compliance *would actually* have had an effect on the government's payment decision.
- Minor regulatory missteps remain outside of the purview of the FCA.

Post-*Escobar* Jurisprudence: the "Two-Part Test"

- The court in *U.S. ex rel. Rose v. Stephens Institute*, No. 09-CV-05966-PJH (N.D. Cal. Sept. 20, 2016), denied summary judgment on the grounds that "Escobar did not establish a rigid two-part test for falsity that must be met in . . . every single implied certification case."
  - Two part falsity test is not mandatory; the Supreme Court explicitly limited its holding: "We need not resolve whether all claims for payment implicitly represent that the billing party is legally entitled to payment." *Escobar*, 136 S. Ct. at 2000.
  - Specific representations need not directly relate to undisclosed noncompliance.
  - Misstatements may be material under the FCA even if the government didn't deny payments when it was aware of them.

Post-*Escobar* Jurisprudence: the "Two-Part Test"

- Seventh Circuit reaffirmed summary judgment for the defendant in *U.S. v. Sanford–Brown, Ltd.*, No. 14-2506 (7th Cir. Oct. 24, 2016), holding that neither condition of *Escobar* was met:
  - Relator "offered no evidence that defendant made any representations at all in connection with its claims for payment, much less false or misleading representations," and
  - Relator offered no evidence of materiality.
- Courts holding that complaint must allege both prongs of falsity test:
  - *U.S. ex rel. Handal v. Ctr. for Employment Training* (E.D. Cal. Aug. 8, 2016)
  - *U.S. ex rel. Doe v. Health First, Inc.* (M.D. Fla. July 22, 2016)
  - *U.S. ex rel. Creighton v. Beauty Basics Inc.* (N.D. Ala. June 28, 2016)

Post-*Escobar* Jurisprudence: Materiality

- As expected, the materiality standard has generated diverging opinions because there is no clear legal definition of what constitutes materiality—it is all fact-based. Some courts have enforced a "rigorous" and "demanding" standard:
  - *U.S. ex rel. Ferris v. Afognak Native Corp.* (Alaska Sept. 28, 2016)
  - *U.S. ex rel. Lee v. Northern Adult Daily Health Care Ctr.* (E.D.N.Y. Sept. 7, 2016)
  - *U.S. ex rel. Knudsen v. Sprint* (N.D. Cal. Sept. 1, 2016)
  - *U.S. ex rel. Voss v.* Monaco (E.D. Wash. July 1, 2016)
- Others continue to apply a flexible standard based on the facts:
  - *U.S. ex rel. Rose v. Stephens Inst.*:
    - Dep't of Ed. decision not to take action against university despite its awareness of the FCA allegations was "not terribly relevant to materiality"
    - Dep't of Ed. failure to enforce Title IV Incentive Compensation Ban does not undermine materiality

Sampling and Extrapolation

- *The issue:* Statistical sampling is a relatively uncontroversial means to calculate *damages* in an FCA action where claim-by-claim analysis is impractical. But can it be used to establish FCA *liability*?
- *Definition:* Statistical sampling is a set of quantitative techniques used to draw generalizations about a population of data from a sample, or subset, of those data.
- *Contours of the debate*
  - Relators and the government say:
    - Sampling is an accepted form of evidence.
    - Limiting its use means immunizing large-scale frauds from prosecution.
  - Defendants say:
    - Sampling = “trial by formula” based on insufficient proof.
    - Relator’s/government’s burden to prove FCA elements for each claim.
    - Extrapolation violates due process.

Sampling and Extrapolation

- *U.S. ex rel. Martin v. Life Care Ctrs. of Am., Inc.*, 114 F. Supp. 3d 549 (E.D. Tenn. 2014)
  - Nursing home company accused of billing Medicare for medically unnecessary services. Government sought to establish falsity by extrapolating from an analysis of 400 admissions to 50k+ admissions and 150k+ claims. On summary judgement, Defs. maintained sampling could not establish liability.
  - "[T]here is no explicit prohibition against the use of statistical sampling" in the FCA's text.
    - Point of sampling is to extrapolate from a smaller sample to a larger heterogeneous group, making it suited to determining medical necessity where individualized clinical judgment underlies each claim.
    - For "the Government [to] specify in detail the specific claims [] it alleges are false . . . would require the devotion of more time and resources than would be practicable for any single case."
    - Due process satisfied through cross-examination & def's ability to offer contradictory evidence.
  - "The purpose of the FCA as well as the . . . expansion of government programs as to which it may be employed support the use of statistical sampling . . . where a claim-by-claim review is impracticable."

Sampling and Extrapolation

- Other cases permitting sampling to establish liability
  - *United States ex rel. Guardiola v. Renown Health*, No. 3:12-cv-00295, 2014 U.S. Dist. LEXIS 157410 (D. Nev. Nov. 5 2014).
  - *United States v. Aseracare Inc.*, No. 2:12-CV-245, 2014 U.S. Dist. LEXIS 167970 (N.D. Ala. Dec. 4, 2014).
  - *United States v. Robinson*, No. 13-cv-27 (E.D. Ky. Mar. 31, 2015).
  - *United States ex rel. Ruckh v. Genoa Healthcare, LLC*, No. 11-cv-01303, 2015 U.S. Dist. LEXIS 55384 (M.D. Fla. Apr. 28, 2015).

Sampling and Extrapolation

- *United States ex rel. Michaels v. Agape Senior Cmty., Inc.*, No. 0:12-3466, 2015 U.S. Dist. LEXIS 82379 (D.S.C. June 25, 2015)
  - Relators alleged provider submitted to false claims. Proposed to examine sample and extrapolate % of false claims to 61k+ payment requests.
  - The court denied Relators' request.
    - "[E]ach and every claim at issue in this case is fact-dependent and wholly unrelated to each and every other claim."
    - Sampling might be OK if evidence is gone; here, records are "intact and available for review."
  - Recent hearing in the Fourth Circuit. Most observers doubt panel will decide sampling issue.
    - Novel materiality argument: *Escobar*'s materiality standard cannot be reconciled with the use of statistical sampling, since it assumes all claims contain identical misstatements and every misstatement is equally material to government reimbursement.

Sampling and Extrapolation

- Direction from SCOTUS? *Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036 (2016)
  - Workers alleged failure to pay overtime for time spent donning and doffing protective equipment. Proof at trial extrapolated from an expert's estimate of the amount of time the activities take. Defendant sought categorical exclusion of statistical evidence as means to establish FLSA liability.
  - A "statistical sample, like all evidence, is a means to establish or defend against liability."
    - Courts should consider:
      - The sample's reliability;
      - The purpose for which it's introduced;
      - The elements of the underlying cause of action;
      - Whether the "remedial nature" of the underlying statute "militate[s] against making the burden of proving [liability] an impossible hurdle";
      - The harm to a defendant's ability to assert individual defenses; and
      - The availability of substitute evidence, including direct proof.

Sampling and Extrapolation

- *U.S. ex rel. Wall v. Vista Hospice Care, Inc.*, No. 07-cv-00604 (N.D. Tex. June 20, 2016)
  - Relator alleged hospice provider submitted claims for ineligible patients. A statistician sampled 291 patients out of 12k. A clinician then reviewed medical records to opine on their eligibility.
  - Extrapolation inappropriate to establish liability in this case.
    - Reads *Tyson* restrictively: Sampling is "not the only practicable means" to establish liability.
    - Sampling inappropriate because hospice-eligibility determinations are subjective.
    - Proof of liability is a problem of relator's own making.
    - *But* sampling may be appropriate if "defendant's objective approach was similar in all cases, making the sample a reasonable basis for extrapolation to the whole."

Medical Necessity and Clinical Judgment

- *U.S. ex rel. Paradies v. Aseracare, Inc.* (N.D. Ala. 2016), *appeal pending* (11th Cir.)
  - Government and Relators allege that Aseracare billed Medicare for ineligible hospice patients.
  - Court initially found that material factual disputes precluded entry of summary judgment.
  - Court bifurcated the case into falsity (expert opinion as to eligibility based on chart reviews) and scienter (improper business practice evidence) phases.
  - In falsity phase, jury determined that 104 of 123 claims submitted by AseraCare were false.
  - After the verdict, the court granted motion for a new trial based on reversible error in the jury instructions: court held it should have instructed the jury that the FCA requires proof of an "objective" falsehood, and that a difference of opinion between doctors, without more, is insufficient to show that a Medicare hospice claim is false.
  - Court *sua sponte* re-opened summary judgment, and, on March 31, 2016, granted summary judgment on all remaining counts, holding that mere difference of clinical judgment is not enough to show that the claims are objectively false.
  - On appeal, AseraCare argues that the government's self-imposed limits on falsity evidence undermined its ability to adduce evidence to create a jury question.

Rule 9(b)—the Circuit Split Remains

- "Particular details of a scheme" paired with "reliable indicia that lead to a strong inference that claims were actually submitted."
  - *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009)).
  - *U.S. ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 854-55 (7th Cir. 2009)
  - *U.S. ex rel. Ebeid v. Lungwitz*, 616 F.3d 993, 998 (9th Cir. 2010)
- "Representative examples" of actual false claims.
  - *U.S. ex rel. Nathan v. Takeda Pharm.*, 707 F.3d 451, 457-58 (4th Cir. 2013)
  - *U.S. ex rel. Bledsoe v. Cmty. Health Sys.*, 501 F.3d 493, 504 (6th Cir. 2007)
  - *U.S. ex rel. Joshi v. St. Luke's Hosp.*, 441 F.3d 552, 557 (8th Cir. 2006)

Rule 9(b)—Some Circuits Show Flexibility

- Circuits that straddle the fence:
  - *Cf. U.S. ex rel. Hopper v. Solvay Pharm.*, 588 F.3d 1318, 1326-27 (11th Cir. 2009) (specific examples) *with U.S. ex rel. Mastej v. Health Mgmt. Associates, Inc.*, 591 F. App'x 693, 703 (11th Cir. 2014) (someone with "first-hand knowledge of billing practices" can provide the required "indicia of reliability that a false claim was actually submitted"); *Hill v. Morehouse Med. Assocs., Inc.*, 2003 WL 22019936 at *4 (11th Cir. Aug. 15, 2003) ("heightened pleading standard may be applied less stringently … when specific factual information about the fraud is peculiarly within the defendant's knowledge or control."); *U.S. ex rel. Walker v. R & F Properties of Lake County, Inc.*, 433 F.3d 1349 (2005) (in case involving corporate insider, Rule 9(b) can be satisfied without identifying any individual false claims.); U.S. *ex rel. Matheny v. Medco Health Solutions, Inc.*, 2012 WL 555200, at *10 (11th Cir. 2012) ("we are more tolerant toward complaints that leave out some particularities of the submissions of a false claim if the complaint also alleges personal knowledge or participation in the fraudulent conduct.");
  - *Cf. U.S. ex rel. Kelly v. Novartis Pharmaceuticals Corp.,* 827 F.3d 5, 13 (1st Cir. 2016)*, with U.S. ex rel. Duxbury v. Ortho Biotech*, 579 F.3d 13, 29 (1st Cir. 2009)
  - *Cf. U.S. ex rel. Lemmon v. Envirocare of Utah, Inc.*, 614 F.3d 1163 (10th Cir. 2010), *with U.S. ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 727 (10th Cir. 2006)

Enforcement of Qui Tam Procedural Requirements

- *State Farm Fire & Casualty v. United States ex rel. Rigsby*
  - Supreme Court granted cert to resolve an emerging circuit split regarding the standard for dismissal of a qui tam complaint where the relator has violated the FCA's seal provision, 31 U.S.C. § 3730(b)(2)
  - Allegations by insurance adjustors against State Farm alleging that the insurance company fraudulently misclassified claims related to flood policies in order to get them paid by the federal government in the aftermath of Hurricane Katrina.
  - State Farm contended relators violated the seal by disclosing the suit to media outlets on three occasions.
  - District court ruled that the seal violations were not "severe" and did not warrant dismissal because there was no evidence they "had led to a public disclosure in the news media that this action had been filed," had impeded the government's investigation, or were in bad faith.
    - Fifth Circuit affirmed, relying in part on Ninth Circuit test: (1) whether and to what extent the seal violation caused harm to the government; (2) the relative severity or nature of the disclosure; and (3) whether the disclosure occurred in bad faith.
    - Second and Fourth Circuits have adopted an "incurable frustration" test: whether the violations "incurably frustrate" the interests protected by § 3730(b)(2) : (1) allowing the government time to investigate and decide whether to intervene; (2) protecting defendants from having to answer complaints without knowing whether the government or relators will pursue the litigation; (3) protecting a defendant's reputation from meritless qui tam actions; and (4) incentivizing defendants to settle to avoid the unsealing of a case.
    - Sixth Circuit has rejected the balancing tests, and instead applies a per se rule.