E. False Claims Act: Materiality

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1. False Claims Amendments Act of 2021 (S.2428)

- The Senate Committee on the Judiciary has approved for the Senate's full consideration an amendment to the FCA that would explicitly provide that "the [g]overnment's decision to forego a refund or to pay a claim despite knowledge of fraud or falsity is not dispositive" on the issue of materiality.

***Yates v. Pinellas Hematology & Oncology, P.A.*, No. 20-10276, 2021 WL 6133175, at *6 (11th Cir. Dec. 29, 2021)**

- On appeal from a jury verdict rendered against it, defendant argued that, because a certificate required by the Clinical Laboratory Improvement Amendments of 1988 ("CLIA") was not a condition of payment, lacking the required certificate number could not be a material, actionable violation of the FCA.

- Citing *Escobar*, the Eleventh Circuit disagreed, holding that the lack of an explicit label on the certificate stating that it is a condition of payment was not dispositive to the question of materiality.

- Further, the Eleventh Circuit found that the fact that the laboratory had a certificate prior to an ownership change did not render the lack of certificate at the time of claim submission immaterial. Although the government did not sanction defendant or seek reimbursement of the claims, it had originally denied the claims lacking a certificate number. That fact, in combination with the defendant's conduct in attempting to hide the lack of certificate by re-filing the claims using another facility's location and certificate number, as well as the fact that the Florida agency that regulated the CLIA program within the state closed the facility in October of 2015 upon learning that it had been operating without a certificate, were dispositive of materiality.

***Druding v. Care Alternatives, Inc.*, No. CV 08-2126, 2021 WL 5923883 (D.N.J. Dec. 15, 2021)**

- After the district court awarded summary judgment to defendant in 2018 based on relators' failure to demonstrate falsity, the Third Circuit reversed and remanded in 2020, finding falsity was met and requiring consideration of the other elements.

- On remand from the Third Circuit, the district court again granted defendant summary judgment, this time finding that relators failed to prove that hospice documentation deficiencies were material to the government's payment decision because the government continued to pay the provider despite being aware of the poor documentation.

- The court found in defendant's favor despite acknowledging that defendant "had longstanding problems with maintaining necessary and proper documentation and that it was well aware of those problems," as "it is incumbent upon the Relators to present **some** evidence suggesting the Government's apparent disregard of the inadequacies in Care Alternatives' billing documentation was not the result of its having concluded those inadequacies were immaterial to its decision to make those payments anyway."

Cases Included in August 2021 Submission[47]

***United States v. Molina Healthcare of Illinois, Inc.*, 17 F.4th 732 (7th Cir. 2021)**[48]

- The United States District Court dismissed the complaint, finding that relator's allegations that the defendant knew services were material were too conclusory.

- The Seventh Circuit reversed, holding that the district court failed to give proper weight to the defendant's status as a "highly sophisticated member of the medical-services industry," and, further, that the complaint included "ample detail to support a finding that Molina either had actual knowledge that the government would view skilled nursing services as a critical part of the Nursing Facility rate cell (*i.e.*, as material), or that it was deliberately ignorant on this point."

- The Seventh Circuit further concluded that defendant's arguments regarding the government's continued payment and renewal of contracts with the defendant even after the relator brought the lawsuit were "better saved for a later stage, once both sides have conducted discovery."

***U.S. ex rel. Int'l Bhd. of Elec. Workers Loc. Union No. 98 v. Farfield Co.*, 5 F.4th 315 (3d Cir. 2021)**

- The United States District Court for the Eastern District of Pennsylvania entered judgment against defendant construction contractor, awarding $1,055,320.62 in treble damages and statutory civil penalties based on claims that defendant misclassified workers in its payroll invoices.

- On appeal, the Third Circuit affirmed, finding that the falsely certified payrolls were material.

- The Third Circuit rejected defendant's arguments based on the purportedly small value of the contract, the discretionary nature of the government's contractual ability to withhold payment, and the government's failure to take action against defendant while the suit was pending.
- Rather, the Court held that the government's undisputed right to withhold payment, regardless of whether the power was discretionary, in combination with evidence of the defendant's actual knowledge that the condition was material even if not expressly called a condition of payment, and a lack of evidence that the government would overlook misclassification demonstrated materiality.

***U.S. ex rel. Jehl v. GGNSC Southaven, LLC*, No. 3:19-cv-00091-MPM-JMV, 2021 WL 2815974, at *1 (N.D. Miss. July 6, 2021)**

[47] One case previously included in a prior submission dated back to December 2020. That case has been removed from this submission.

[48] The opinion Bradley cited in August 2021 was been amended and superseded by the above opinion on November 15, 2021. The holding on materiality did not change.

- The United States District Court for the Northern District of Mississippi, facing the possibility of trial on what the Court termed a "novel theory of liability" based on a "rather minor licensing issue," *sua sponte* ordered plaintiff to show cause why the case should not be dismissed.

- The Court suggested that the matter should be dismissed because the matter was better left to state and federal regulators to police given that "[t]he mandatory penalties and treble damages which exist in FCA claims are much too strong medicine for the conduct alleged."

- Particularly, the Court concluded that the FCA was an inappropriate enforcement mechanism under the circumstances, because evidence developed during discovery suggested that "actual Medicaid regulators would not have regarded the alleged violation in this case as something worthy of their time."

- The Court similarly found CMS guidance "clearly tends to reduce the importance of the licensing issues."

- After the close of discovery, relator sought to introduce an affidavit from a Mississippi state Medicaid official declaring the licensing violation would have been material to his office. The Court determined "the opinion of a single state official, offered in support of litigation, to be much less reliable than formal guidance issued by CMS to its surveyors."

- On August 12, 2021, Judge Michael P. Mills, author of the *sua sponte* order, recused himself due to friendship (and, seemingly, book club membership) with plaintiff's counsel. He stated in his recusal order that he was "completely undecided regarding whether [the] case should go to trial or not." The matter has now been assigned to Senior Judge Neal B. Biggers for ultimate determination.

***United States v. Wal-Mart Stores E., LP*, 858 F. App'x 876 (Mem), 2021 WL 2287488, at *1 (6th Cir. June 4, 2021)**

- The United States District Court for the Eastern District of Michigan dismissed relator's complaint and declined to reconsider dismissal. Relator appealed to the Sixth Circuit.

- On appeal, the Sixth Circuit affirmed the district court, holding that, because the government had access to the same knowledge as the defendant regarding the allegedly high doses of opiates prescribed, the government's decision to pay claims relating to the prescriptions was strong evidence that the dosage amounts were not material.

***Dan Abrams Company LLC v. Medtronic Inc.*, 850 F. App'x 508 (Mem), 2021 WL 1235845, at *1 (9th Cir. Apr. 2, 2021)**

- The United States District Court for the Central District of California dismissed relator's claims, and the Ninth Circuit affirmed in part and reversed in part.

- The Court separated relator's fraud claims into two distinct buckets: "Extra-Use" device claims and "Contraindicated-only" device claims and found that only the latter could meet the materiality requirement.

    - With respect to the "Extra-Use" devices, which had valid U.S. Food and Drug Administration (FDA) approval but were being used off-label, the Court affirmed dismissal and held that relator could not establish materiality because the federal government historically "allow[ed] reimbursement for off-label and even contraindicated uses."

    - With respect to the "Contraindicated-only" devices, which were "not properly cleared for any use" by the FDA and could only be used in a contraindicated fashion, the Court found that the complaint established plausible fraud in several areas which were "precisely those that the FDA considers in granting Class II certification." For that reason, the Court found that the fraud went "'to the very essence of the bargain'" between defendant, the FDA, and Medicare, and reversed the district court, reinstating the claim for those devices.

***U.S. ex rel. Bibby v. Mortgage Investors Corp.*, 987 F.3d 1340, 1343 (11th Cir. 2021)**

- As a prerequisite to obtain a Veteran's Administration (VA) loan guaranty, lenders are required to certify compliance with various VA regulations, including limitations on the fees charged to veterans. In *Bibby*, former mortgage brokers who specialized in originating VA mortgage loans alleged that defendant charged veterans unallowable fees and failed to disclose its practices.

- The United States District Court for the Northern District of Georgia granted defendant's motion for summary judgment on materiality grounds because the government continued making payments even after learning of defendant's allegedly fraudulently fee practices.

- The Eleventh Circuit reversed, holding that the government had established a sufficient basis for a jury to find the misrepresented fee compliance was material. In a seeming departure from sister circuits and traditional understandings of *Escobar*, rather than emphasizing the decision of the government to continue payment, the Court instead noted that "the significance of continued payment may vary."

    - Because the VA was required by law to continue its payments and hold its guaranties, the Eleventh Circuit held that the VA's other efforts to curb noncompliance (sending notice letters and auditing more regularly) were enough

to establish the requisite materiality for the purposes of surviving summary judgment.

***United States v. Kindred Healthcare, Inc.*, 517 F.Supp.3d 367 (E.D.Pa. Feb. 5, 2021)**

- The former director of a skilled nursing facility (SNF) operated by defendants alleged, among other things, that defendants understaffed the SNF to such a degree that the needs of residents could not be met in violation of federal and state regulations. Such understaffing purportedly made defendants' certifications with such regulations false.

- Although it ultimately granted defendants' motion to dismiss in part on other grounds, the United States District Court for the Eastern District of Pennsylvania rejected defendants' materiality argument.

- Because relator's complaint included two examples of CMS denying payments to SNFs purportedly "found to have significant and pervasive staffing violations" of a similar nature, relator adequately alleged materiality.

- Defendants argued that they could not have known that staffing levels were material to the government based on relator's stated examples of the government's prospective refusal to pay SNFs not affiliated with defendants.

    - Defendants argued that relator instead had to allege that CMS retroactively denied or recouped claims from facilities based on findings that they were understaffed

    - However, the Court held that the FCA "does not draw a distinction between prospective denial of payments and retroactive recoupment of payments."