United States District Court
District of Massachusetts (Springfield)
CIVIL DOCKET FOR CASE #: 3:17−cv−30038−MGM

United States of America et al v. Cleanslate Centers, Inc. et al
Assigned to: Judge Mark G. Mastroianni
Cause: 31:3729 False Claims Act

Date Filed: 04/05/2017
Jury Demand: Plaintiff
Nature of Suit: 376 Qui Tam (31 U.S.C. § 3729(a))
Jurisdiction: U.S. Government Plaintiff

Date Entered	#	Docket Text
09/27/2021	111	Judge Mark G. Mastroianni: ELECTRONIC ORDER entered GRANTING IN PART and DENYING IN PART Motions to Dismiss the Amended Complaint by 83 Defendant Dr. Amanda Louise Wilson, 84 the Cleanslate Defendants, and 86 Defendant Apple Tree Partners ("Apple Tree"). Relator's 115−page Amended Complaint ("AC") alleges that Defendants' for−profit opioid−addiction treatment centers impermissibly billed Medicare and Medicaid for unnecessary medical tests and inadequately supervised doctor visits, essentially operating as "pill mills." Relator Dr. Wendy Welch brings claims on behalf of the U.S., Indiana, and Massachusetts under the False Claims Act, 31 U.S.C. § 3729(a)(1), and state analogs. Relator also brings individual employment claims. The Commonwealth of Massachusetts filed an Intervenor Complaint, and the parties are in the process of settling those claims. (Dkt. No. 107.) The court does not, therefore, address Relator's claims under Massachusetts law (counts 6, 7) or FCA claims on behalf of Massachusetts Medicaid and Medicare patients. "[L]iability under the False Claims Act requires a false claim.... A health care provider's violation of government regulations or engagement in private fraudulent schemes does not impose liability under the FCA unless the provider submits false or fraudulent claims to the government for payment based on these wrongful activities." *U.S. ex rel. Karvelas v. Melrose−Wakefield Hosp.*, 360 F.3d 220, 232 (1st Cir. 2004) (internal citation omitted). Moreover, "[b]ecause the FCA is a fraud statute, a complaint alleging the submission of a false claim must comply with Fed. R. Civ. P. 9(b)." *U.S. ex rel Collins v. Molina Healthcare, Inc.*, 2019 WL 11816475, at *6 (D. Mass. July 17, 2019). Specifically, "[r]elators are required to set forth with particularity the 'who, what, when, where, and how' of the alleged fraud." *U.S. ex rel Ge v. Takeda Pharm. Co.*, 737 F.3d 116, 123 (1st Cir. 2013) (internal quotation marks omitted). Relator adequately alleges FCA claims and Indiana analog claims against the Cleanslate Defendants and Cleanslate founder Dr. Wilson for submission of false claims, false statements/records, and reverse false claims. *See D'Agnostino v. ev3, Inc.*, 845 F.3d 1, 10 (1st Cir. 2016) (noting relator may satisfy pleading standard by alleging examples of false claims "with particularity"). Relator alleges that the Cleanslate Defendants and Dr. Wilson violated the Anti−Kickback Statute and Stark Law by ordering medically unnecessary tests and sending them to the Cleanslate lab, which Dr. Wilson owned. (AC 117−124, 128, 135−38, 142−43, 152−54, 162.) Defendants then submitted these medically unnecessary and impermissibly self−referred claims to Medicare and Medicaid for reimbursement in violation of the FCA. *See Guilfoile v. Shields*, 913 F.3d 178, 190 (1st Cir. 2019) (anti−kickback statute violation is per se false claim under FCA). According to Relator, the Cleanslate Defendants mandated that clinicians both conduct frequent, unnecessary drug tests and that the testing be self−referred to the Cleanslate lab. (AC 135−38, 159.) Relator alleges that clinicians did not review the test results upon receipt or use them in patient care decisions. (*Id.* 132−33, 164−66, 220.) According to the Amended Complaint, Defendants' policy was an integral and acknowledged part of the Cleanslate Defendants' revenue stream. (*Id.* 116, 125−126, 131, 144.) Despite knowing that they had submitted false claims, Defendants accepted unwarranted payments from Medicaid and Medicare for which they did not reimburse the government. (*Id.* 204, 239, 242−44.) Defendants'

		affirmative defense to the Stark Law claims is unavailing; on a motion to dismiss, Defendants must show "inevitable success" to prevail on an affirmative defense, which they cannot. *See Nisselson v. Lernout*, 469 F.3d 143, 150 (1st Cir. 2006). Relator likewise pleads FCA claims based on the Cleanslate Defendants' failure to supervise nurse practitioners and physician assistants who provided the majority, and sometimes all, of the patient care at Defendants' clinics including prescription of controlled substances, in violation of Medicare policy and policies of the states. (AC 171−74, 186−98, 206.) Between 2009 and 2016, Relator alleges, the Cleanslate Defendants submitted claims to Medicare and Medicaid using a billing code that falsely indicated direct physician supervision of mid−level practitioners. (*Id.* 181−82.) Around 2017, Defendants switched billing codes, but still used one that falsely represented the actual level of supervision occurring at their clinics. (*Id.* 183.) According to Relator, this structure was key to Dr. Wilson's and the Cleanslate Defendants' profit−maximizing strategy of serving the most patients with the least amount of costly physician involvement. (*Id.* 193, 203−207, 214.) Relator does not, however, sufficiently plead Defendant Apple Tree's FCA liability to satisfy Rule 9(b). *See D'Agnostino*, 845 F.3d at 10. Relator alleges, at most, that Defendant Apple Tree saw a profitable investment in Defendant Cleanslate's centers and sought to capitalize on it. Relator, likewise, does not plead an FCA conspiracy claim (or Indiana analog claim) with sufficient specificity to satisfy Rule 9(b) against any of the Defendants. Relator admits that Dr. Wilson and the Cleanslate Defendants cannot conspire among themselves and her strongest allegation of Apple Tree's involvement is that Apple Tree knew that the Cleanslate Defendants' Medicare and Medicaid patients were potentially profitable and that Apple Tree approached Dr. Wilson about the investment opportunity. Relator's individual employment claims, for FCA retaliation and breach of contract, are barred by her binding and broadly worded arbitration agreement. *See U.S. ex rel. Hagerty v. Cyberonics, Inc.*, 146 F. Supp. 3d 337, 347 (D. Mass. 2015) (applying "presumption of arbitrability" to dismiss FCA retaliation claim), *aff'd on other grounds sub nom. by Hagerty ex rel U.S. v. Cyberonics, Inc.*, 844 F.3d 26 (1st Cir. 2016). For the foregoing reasons, the Amended Complaint's counts 4 (FCA conspiracy), 8 (FCA retaliation), and 9 (breach of contract) are dismissed as to all Defendants; and counts 1 (FCA false claims), 2 (FCA false statements), 3 (FCA reverse false claims), and 5 (Indiana False Claims) are dismissed as to Defendant Apple Tree Partners. Counts 1, 2, 3, and 5 survive as to Defendant Dr. Wilson and the Cleanslate Defendants. (Lindsay, Maurice) (Entered: 09/27/2021)