2021-2022
SOUTHERN ILLINOIS UNIVERSITY
NATIONAL HEALTH LAW MOOT COURT COMPETITION

Transcript of Record
Docket No. 21-1967

United States ex rel. Keegan Mason,
Petitioner,

v.

Southern American Metropolitan Clinics, Inc.,
Respondent.

COMPETITION PROBLEM

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF LINCOLN

UNITED STATES ex rel. KEEGAN MASON, Plaintiff-Relator, v. SOUTHERN AMERICAN METROPOLITIAN CLINICS INC, Defendants.	)	Civil action no. 1:20-cv-2697-AG

MEMORANDUM OPINION

Garrett Andrew, District Judge

Plaintiff-Relator Keegan Mason, a citizen of the State of Lincoln, filed this proceeding *qui tam* under seal on November 22, 2019, against Defendant Southern America Metropolitan Clinics, Inc. ("SAM Clinics"), a collection of wound care centers across the state of Lincoln. Ms. Mason alleges that SAM Clinics violated the False Claims Act (FCA), 31 U.S.C. § 3729(a)(1), by knowingly submitting false certifications of the medical necessity of Hyperbaric Oxygen (HBO) therapy in order to receive Medicare or Medicaid reimbursements. Having been given proper notice and opportunity, the United States declined to intervene or seek dismissal of Mason's claims.[1] Mason's complaint was unsealed on January 24, 2020, and on January 30, 2020, SAM Clinics filed two motions to dismiss under the Federal Rules of Civil Procedure, a 12(b)(1) motion asserting the Court lacked subject matter jurisdiction to hear this claim under the FCA's first-to-file rule, 31 U.S.C. § 3730(b)(5), because there was already another pending FCA action alleging the same essential facts, and a 12(b)(6) motion asserting the plaintiff failed to

[1] Nothing in this problem is intended to raise issues about the United States' right to intervene in a False Claims Act proceeding or whether the proper procedural steps were followed other than what is stated in the Supreme Court's grant of the writ of certiorari.

plausibly allege SAM Clinics' Medicare certifications were false because she established only a reasonable difference of opinion regarding the medical necessity of the treatment provided. The other FCA action pending when Mason filed her action was brought by Dr. Elizabeth Cobb, who filed under seal on October 14, 2019. Cobb's complaint was unsealed on December 16, 2019, and Cobb's complaint was dismissed for failure to state a claim on January 20, 2020.

Facts and Relevant Procedural History

The following facts, as well-pleaded in the complaint, are treated as undisputed for purposes of the instant motion to dismiss. SAM Clinics operates fourteen wound care centers in Lincoln. In addition to their own clinics, SAM Clinics contracts with two different hospital systems: Lincoln Memorial Hospital System and Jefferson Community Hospital System. SAM Clinics is the largest for-profit provider of wound care services in Lincoln and treats various chronic and non-healing wounds, including among others venous ulcers, pressure ulcers, arterial ulcers, necrotizing infections, surgical wounds and burns, and diabetic lower extremity ulcers, as well as associated conditions such as osteomyelitis (infection of the bone). SAM Clinics obtains approximately seventy-five percent of its revenue from reimbursements from Medicare and Medicaid. SAM Clinics has been in operation since 1956 but has seen considerable expansion in the past decade.

SAM Clinics has a particular specialty in treating chronic wounds. A chronic wound is defined as one that is unresponsive to initial therapy or persistent in the face of appropriate care. Robert Frykberg & Jaminelli Banks, *Challenges in the Treatment of Chronic Wounds,* Advances in Wound Care, Aug. 3, 2015, at 560, *available at* https://doi.org/10.1089/wound.2015.0635. The most common types of chronic wounds of the lower extremity are described by their cause or etiology: 1) vascular (e.g., arterial, venous, or mixed ulcers); 2) pressure ulcers; and 3) neuropathic (e.g., diabetic ulcers). *Id.* Most wounds are treated using conservative, non-surgical

interventions, but when those are not successful, debridement of the wound may be conducted. *Id.* Debridement is defined as the removal of unhealthy tissue from a wound in order to promote healing. Daniel R. Levinson, "Medicare Payments for Surgical Debridement Services in 2004" Dep't. of Health and Human Serv., May 2007, 1, *available at* https://oig.hhs.gov/oei/reports/oei-02-05-00390.pdf. There are currently two types of debridement which are reimbursable under the Center for Medicare and Medicaid Services (CMS) guidelines: selective and surgical/excisional debridement.[2] *Id.* SAM Clinics performs both procedures.

SAM Clinics also provides Hyperbaric Oxygen (HBO) therapy at their wound care clinics, used mainly with patients who have not responded to other conventional and surgical interventions. HBO therapy involves the inhalation of 100 percent oxygen at increased atmospheric pressures. Gowri Raman et. al., *A Horizon Scan: Uses of Hyperbaric Oxygen Therapy,* Technology Assessment Rep., Oct. 5, 2005. HBO therapy is used to treat several conditions including selected diabetic wounds, intracranial abscesses, necrotizing soft tissue infections, osteoradionecrosis, osteomyelitis (chronic refractory), and thermal burns. Medicare Policies and Guidelines, LCD Determination ID: 10220-03.2, Original Determination Effective date of 04-03-2017 with the latest effective date of 11-17-2018. Medicare and Medicaid will pay for HBO therapy but generally requires other interventions be tried first. *Id.* CMS guidelines use the Meggitt-Wagner system, also known as the Wagner grade, to determine whether the treatment can be reimbursed. *See id; see also* Gowri Raman et. al., *A Horizon Scan: Uses of Hyperbaric Oxygen Therapy,* Technology Assessment Rep., Oct. 5, 2005 (describing how the Wagner grade system is used to assess diabetic foot wounds and provide a guideline for

[2] The main difference between a selective debridement and a surgical debridement is the type of tissue removed. *Id.* Selective debridement does not involve removal of subcutaneous fat, muscle tissue or bone, while surgical debridement does. *Id.*

measuring the severity of the wound). CMS approves HBO therapy for treating wounds classified as a Wagner grade III and higher. LCD Determination ID: 10220-03.2.[3]

Mason started working for SAM Clinics as a clinical nurse specialist in the State of Lincoln in 2017. Under Lincoln law, clinical nurse specialists can supervise HBO therapy that has been ordered by a physician but cannot diagnosis and order the treatment themselves. Mason had previously worked in a state that permitted clinical nurse specialists to diagnose and order the therapy. She relocated to Lincoln for family reasons. Mason sees patients at various SAM Clinics' facilities in and around Washington City, a large metropolitan area within the State of Lincoln, and also at certain satellite clinics in nearby communities. Mason is familiar with CMS's criteria for reimbursement of HBO therapy.

The current CEO of SAM Clinics is John O'Keefe, who was hired in January, 2019. In February 2019, Mason began noticing an unexpected increase in the number of HBO therapy treatments at each of the clinics where she was assigned, both in cases where she was asked to supervise the treatment and cases where it was performed under others' supervision. Many of those cases appeared questionable, either because the patient's underlying diagnosis did not seem to support it, the patient appeared to be responding to conventional treatment just fine, or Mason questioned the Wagner grading of the wound. Most of these patients were on Medicare and

[3] This system has six grades of lesions, with the first four grades based on the depth of the lesion and the last two based on the extent of gangrene and lost perfusion in the foot. *Id.* A Wagner grade III wound is an ulcer with abscess, osteomyelitis, joint sepsis, or bone involvement. Robert G. Frykberg, *Diabetic Foot Ulcers: Pathogenesis and Management,* Am. Family Physician 1655, 1655 (Nov. 1, 2002) https://www.aafp.org/afp/2002/1101/p1655.html; Dr. Amit C. Jain, *A New Classification of Diabetic Foot Complications: A Simple and Effective Training Tool,* 4 J. of Diabetic Foot Complications 1, 1-5 (2012). Wounds classified as a Wagner grade II have an ulcer extension to ligament, tendon, joint capsule, or deep fascia without abscess or osteomyelitis. Robert G. Frykberg, *Diabetic Foot Ulcers: Pathogenesis and Management,* Am. Family Physician 1655, 1655 (Nov. 1, 2002) https://www.aafp.org/afp/2002/1101/p1655.html. When the patient has a diagnosis of diabetes and an abscessed wound classified as a Wagner grade III that has not responded to standard treatment, that patient is eligible for HBO therapy under Medicare. However, a wound that did not have an abscess or osteomyelitis would be classified as a Wagner grade II wound and not be eligible.

Mason was aware that SAM Clinics had certified to CMS that these treatments were medically necessary as part of seeking Medicare reimbursement.

Part of the reason Mason was concerned was that she had heard talk that clinic management was "pushing" physicians to meet some kind of "quota system." At one point during this time, Mason had observed a physician change the Wagner grade of a wound after O'Keefe called her in for a meeting. Mason raised her concerns about this with another clinical nurse specialist, who suggested it was best to just do what they were told.

On September 24, 2019, Mason alleges she was at the nurse's station finalizing patient files at the SAM Clinic on Adams Street in Washington City when she overheard O'Keefe and one of the doctors, Dr. William R. Drake, having a discussion about the number of HBO therapy procedures Dr. Drake had been performing at the clinic. She heard O'Keefe say, "Got to keep those numbers up." Dr. Drake laughed and said, "I'm good. Almost got that Tesla down payment." O'Keefe then said, "Yep, CMS approves, you get that fancy new car, and the patients are happy. It's a win-win-win."

The conversation confirmed for Mason that her suspicions about false medical certifications were correct, and that there was some kind inappropriate scheme in place. Mason then contacted an attorney to assist with filing a *qui tam* case under the FCA.

Meanwhile, on October 14, 2019, Dr. Elizabeth Cobb, a plastic surgeon at the SAM Clinic on Madison Street in Washington City, also filed a *qui tam* FCA complaint under seal in the District Court for the State of Lincoln. Dr. Cobb alleged she had been fired by O'Keefe because she refused to perform a medically unnecessary surgical debridement on a patient while working at SAM Clinics. She alleged that O'Keefe had pressured her to certify the medical necessity of the surgical procedure for a Medicare patient, and that after she refused, O'Keefe got another doctor to do it. The district court dismissed her case on January 20, 2020, for failure

to plead fraud with specificity as required under Federal Rule of Civil Procedure 9(b). *Cobb v. Southern America Metropolitan Clinic Inc.,* No. CV-2019-213 *3 (D. Linc. Jan. 20, 2020) (concluding that FCA complaints must plead fraud with particularity as required under Rule 9(b)).[4] The court reasoned that Rule 9(b) prevents "[s]peculative suits against innocent actors for fraud," explaining that under Rule 9(b) allegations of fraud "must include facts as to time, place, and substance of the defendant's alleged fraud." *Id.* (quoting *United States ex rel. Cooper v. Blue Cross & Blue Shield of Fla.,* 19 F.3d 562, 566-67 (11th Cir. 1994)). The court concluded that although Dr. Cobb's complaint alleged generally that she had felt pressure from O'Keefe to perform a medically unnecessary surgical debridement, she had not alleged with any particularity facts showing specific instances in which SAM Clinics knowingly submitted to CMS false certifications of medical necessity. Therefore, the court ruled her complaint failed to meet Rule 9(b). *Id.* at *4.

Mason's complaint alleges a scheme similar to that alleged in the Cobb complaint but involving HBO therapy. She alleges SAM Clinics knowingly submitted Medicare claims falsely certifying HBO therapy as medically necessary when those treatments were contradicted by the information within each patient's chart as well as the general criteria used by CMS to determine when treatments are necessary and will be covered. Despite CMS's guideline that "[t]he use of HBO therapy is covered as adjunctive therapy only after there are no measurable signs of healing for at least 30 days of treatment with standard wound therapy and must be used in addition to standard wound care,"[5] Mason alleges she observed several instances where that standard was

[4] Hypothetical case citation. May be cited as listed in the problem.

[5] National Coverage Determination (NCD) for HYPERBARIC Oxygen Therapy § 20.29 (12/18/2017) *available at* https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=12&ncdver=4&KeyWord=hyperbaric&KeyWordLookUp=Title&KeyWordSearchType=Exact&bc=CAAAAAAAAAAA

not met. She also noted instances where the patient's diagnosis did not seem to match her own observations of the patient's condition. Mason included the following specific instances of patients who received HBO therapy for which they were not qualified but for which SAM Clinics submitted certification of medical necessity:

> Patient 1: March 2019. Patient has type I diabetes and a lower extremity ulcerated wound due to diabetes. The physician classified the wound as Wagner grade II and ordered treatment that did not include HBO therapy. After O'Keefe pulled the patient's chart and spoke to the treating physician, the physician upgraded the wound to Wagner grade III. The patient was subsequently treated with HBO therapy.
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> Patient 2: April 2019. Patient B has type II diabetes and developed osteomyelitis in one of her lower extremities. The osteomyelitis was responding after a short course of conventional treatment. Nonetheless, HBO therapy was ordered and administered several times. The CMS medical certification stated a diagnosis of chronic refractory osteomyelitis, which is required to show HBO therapy is medically indicated.[6]
>
> Patient 3: July 2019. Patient C has end stage vascular disease in patient's toes and is not diabetic. Amputation was indicated for patient's condition but patient was treated with HBO therapy multiple times before amputation performed. When Relator asked the physician about what indicators supported HBO therapy, the physician responded by telling Relator to "talk to O'Keefe about it."
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> Patient 4: October 2019. Patient D has type I diabetes and a lower extremity wound due to diabetes. The medical certification classified the wound as Wagner grade III, but the patient has no record of osteitis, abscess, or osteomyelitis.

Complaint, Mason v. Southern Am. Metropolitan Clinics, No. 21-2358-G (D. Linc. Dec. 4, 2019). Mason's complaint also references an affidavit from a medical expert[7] who concluded the identified treatments contradict CMS guidelines. Mason alleges those facts along with the conversation between O'Keefe and Dr. Drake shows a scheme to defraud Medicare by falsely

[6] Chronic refractory osteomyelitis is a bone infection that persists or recurs despite appropriate treatment. *See* Mary E. Hanley, Stephen Hendriksen and Jeffrey S. Cooper, Hyperbaric Treatment of Chronic Refractory Osteomyelitis, StatPerls (last updated Sept. 17, 2020), https://www.ncbi.nlm.nih.gov/books/NBK430785/.

[7] The medical expert met all requirements to testify as a medical expert in the State of Lincoln.

certifying the medical necessity of HBO therapy for unqualified patients in exchange for the physicians receiving a monetary payment based on their number of procedures.

In its 12(b)(1) motion, SAM Clinics argues that the District Court of Lincoln does not have subject matter jurisdiction over this case because Cobb's complaint, which was pending when Mason filed her complaint, deprives the court of that jurisdiction under the FCA's "first-to-file rule." The False Claims Act provides that when a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action. *See* 31 U.S.C. § 3730(b)(5). Whether this "first-to-file" rule is a jurisdictional bar to hearing the later-filed action, however, is a matter of first impression within this circuit. SAM Clinics urges this Court to adopt the approach from the Fourth and Sixth Circuits, which find that the rule is one of subject matter jurisdiction. *See United States ex rel. Carter v. Halliburton Co.*, 710 F.3d 171, 181 (4th Cir. 2013), *aff'd in part, rev'd in part and remanded sub nom. Kellogg Brown & Root Servs., Inc. v. United States ex rel. Carter*, 575 U.S. 650 (2015); *United States ex rel. Poteet v. Medtronic, Inc.*, 552 F.3d 503, 516 (6th Cir. 2009). Those circuits conclude that if a later-filed action is based on the same essential facts or elements of fraud as a pending earlier-filed action, the later filed action is jurisdictionally barred. *See, e.g., Poteet*, 552 F.3d at 516. The later allegation is barred even if it incorporates somewhat different details. *Id.* The Sixth Circuit has explained that once the government knows the essential facts of a fraudulent scheme, it has enough information to discover other related facts and the purpose of the False Claims *qui tam* provision has been satisfied. *See id.* at 516. Therefore, SAM Clinics argues that Mason's action is jurisdictionally barred under the first-to-file rule because it is based on the essential facts of the action brought by Dr. Cobb, which was pending at the time Mason filed.

SAM Clinics additionally argues that even if this Court does find it has jurisdiction, under Rule 12(b)(6), Mason has failed to plausibly allege that SAM Clinics presented any false claims under the FCA. The FCA does not define false within the Act, and that question is also one of first impression within this circuit. SAM Clinics argues that a physician's medical opinion regarding the medical necessity of a treatment cannot be objectively "false." It urges the Court to adopt the objective falsehood standard articulated by the Eleventh Circuit and require the relator to show "more than the mere difference of reasonable opinion concerning the prognosis of a patient." *United States v. AseraCarea, Inc.*, 938 F.3d 1278, 1297 (11th Cir. 2019). SAM Clinics argues that Mason has not plead anything more than a mere difference in medical opinion, because while Mason and her expert may question these patients' care, SAM Clinics' physicians exercised their best medical judgment that HBO therapy was indicated for these patients.

This Court, having considered each of these arguments and Mason's responses, concludes that although the first-to-file rule does not bar Mason's claim, she has not plausibly plead that SAM Clinics submitted to CMS false certification of the medical necessity of HBO therapy in violation of the FCA.

ANALYSIS

The FCA imposes civil liability on any person who knowingly presents or causes to be presented a false or fraudulent claim for payment to the federal government. *See* 31 U.S.C. § 3729. The FCA permits *qui tam* suits by private parties, known as relators, on behalf of the United States against anyone submitting a false claim to the government. *See United States ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262, 267 (5th Cir. 2010). The relator files the complaint under seal and serves a copy of the complaint and an evidentiary disclosure on the United States. *See* 31 U.S.C. § 3730(b)(2). The United States can elect to intervene and assume

primary responsibility for the action, but even if declines to do so, the relator may proceed on the action. *See id.* § 3730(b)(4)(B). A successful *qui tam* relator is entitled to a share of the award. *See id.* § 3730(d).

Mason asserts the "'certification theory' of liability, which is predicated upon a false representation of compliance with a federal statute or regulation or a prescribed contractual term." *Mikes v. Straus*, 274 F.3d 687, 696–97 (2d Cir. 2001), *abrogated on other grounds by Universal Health Servs., Inc. v. United States*, 136 S. Ct. 1989 (2016) (quoting Lisa Michelle Phelps, Note, *Calling off the Bounty Hunters: Discrediting the Use of Alleged Anti–Kickback Violations to Support Civil False Claims Actions*, 51 Vand. L.Rev. 1003, 1014–15 (1998)). The essential elements of a false certification claim are: "(1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due." *United States ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1174 (9th Cir. 2006). Only the first element is at issue in SAM Clinics' 12(b)(6) motion to dismiss.

The false certifications alleged in Mason's complaint occurred in conjunction with claims submitted for reimbursement from the Medicare program. Medicare provides basic health insurance for individuals who are 65 or older, disabled, or have end-stage renal disease. 42 U.S.C. § 1395(c) (2018). "[N]o payment may be made ... for any expenses incurred for items or services ... [that] are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member[.]" 42 U.S.C. § 1395y(a)(1)(A) (2018). Medicare reimburses providers for inpatient hospitalization only if "a physician certifies that such services are required to be given on an inpatient basis for such individual's medical treatment, or that inpatient diagnostic study is medically required and such

services are necessary for such purpose[.]" 42 U.S.C. § 1395f(a)(3) (2018). A provider such as SAM Clinics violates the FCA when it knowingly submits a false certification that services are medically necessary in order to obtain reimbursement from federal benefits programs such as Medicare. *See Universal Health Servs., Inc. v. United States*, 136 S. Ct. 1989, 1996 (2016) (noting that a "claim" under the FCA "includes direct requests to the Government for payment as well as reimbursement requests made to the recipients of federal funds under federal benefits programs").

I. THE FIRST-TO-FILE RULE DOES NOT BAR THIS FCA PROCEEDING.

SAM Clinics argues that the first-to-file rule precludes Mason's action because Cobb's action was pending at the time Mason filed her action. Mason acknowledges that Cobb's action was pending when she filed but argues that the first-to-file rule would merely bear on whether she has stated a claim. Even if the rule is a jurisdictional bar, Mason argues Cobb's claim was legally insufficient to state an FCA claim and therefore does not count as a pending action. In any case, Mason argues the two cases do not share the same essential facts such that Mason's case is not preempted by Cobb's.

The purpose of the FCA's first-to-file rule is to prevent opportunistic plaintiffs from filing repetitive *qui tam* actions. *See U.S. ex rel. LaCorte v. SmithKline Beecham Clinical Lab'ys, Inc.,* 149 F.3d 227, 233 (3d Cir. 1998) (describing § 3730's purpose to encourage citizen whistleblowers while discouraging opportunistic suits). Congress amended the FCA more than once before it struck the current balance found in § 3730(b)(5). *Id*. As the Third Circuit recognized, "duplicative claims do not help reduce fraud or return funds to the federal fisc, since once the government knows the essential facts of a fraudulent scheme, it has enough information to discover related frauds." *LaCorte,* 149 F.3d at 234.

The Supreme Court has interpreted this rule as not preventing a later filed FCA action when it was filed after the prior FCA action had been dismissed. *Kellogg Brown & Root Services, Inc., v. United States ex rel. Carter*, 575 U.S. 650, 664 (2015). That decision, however, left open the question presented in this case, namely whether the rule applies if the previous FCA action is pending when the later action filed but then is later dismissed. The question has created a split within the federal courts, with the majority of circuits to consider it finding the first-to-file rule is a jurisdictional bar to any case filed while a previous FCA claim is pending. *See, e.g.*, *United States ex rel. Carter v. Halliburton Co.*, 866 F.3d 199, 203 (4th Cir. 2017) (concluding the first-to-file rule is jurisdictional where if a later allegation states the essential facts or elements of a previously filed claim, then the action is jurisdictionally barred)*; United States ex rel. Branch Consultants v. Allstate Ins. Co.*, 560 F.3d 371, 377 (5th Cir. 2009) (same); *United States ex rel. Poteet v. Medtronic, Inc.*, 552 F.3d 503, 516 (6th Cir. 2009) (same). In these circuits, the fact the earlier case was later dismissed is irrelevant. *See Carter*, 866 F.3d at 210 (reasoning that dismissal of the earlier filed FCA action did not alter defect that later filed action was brought while that earlier action was pending).

Other circuits have held that it is not an issue of subject matter jurisdiction but only bears on whether the relator has stated a claim. *See e.g.*, *United States v. Millenium Laboratories, Inc.*, 923 F.3d 240, 248 (1st Cir. 2019) (reversing prior precedent and finding § 3730(b)(5) does not speak in jurisdictional terms); *United States ex rel. Hanks v. U.S.*, 961 F.3d 131, 137 (2d Cir. 2020) (holding the first-to-file rule is not jurisdictional and instead bears on the merits of whether a plaintiff has stated a claim); *In re Plavix Mktg., Sales Practices and Products Liab. Litig. (No. II)*, 974 F.3d 228, 234 (3d Cir. 2020) (concluding that if Congress wanted the first-to-file bar to reach more broadly, it would have said so). Because the Fifteenth Circuit has not yet

weighed in on the issue, this Court must determine if the rule is jurisdictional and if it is, whether it applies on the facts of this case.

This Court agrees with the circuits that find § 3730(b)(5) lacks language supporting a jurisdictional standard. The plain language of the first-to-file rule "does not speak in jurisdictional terms or refer in any way to the jurisdiction of the district courts," while other provisions of the FCA do. *See United States ex rel. Hayes v. Allstate Ins. Co.*, 853 F.3d 80, 86 (2d Cir. 2017). The Supreme Court has indicated that in order "[t]o ward off profligate use of the term 'jurisdiction,' [the Court] adopted a 'readily administrable bright line' for determining whether to classify a statutory limitation as jurisdictional." *See Sebelius v. Auburn Reg'l Med. Ctr.,* 568 U.S. 145, 153 (2013) (quoting *Arbaugh v. Y&H Corp.*, 546 U.S. 500, 516 (2006)). The Court directed courts to "inquire whether Congress has 'clearly stated' that the rule is jurisdictional; absent such a clear statement, . . . 'courts should treat the restriction as nonjurisdictional in character.'" *Id.* (quoting *Arbaugh*, 546 U.S. at 515-16).

Congress included jurisdictional language in some provisions of the False Claims Act but did not provide any jurisdictional language in the first-to-file provision. *See, e.g.*, 31 U.S.C. § 3730(e)(1) ("No court shall have jurisdiction over an action brought by a former or present member of the armed forces ... against a member of the armed forces arising out of such person's service in the armed forces."). The Supreme Court has directed that "where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Kucana v. Holder*, 558 U.S. 233, 249 (2010). Because the plain language of the first-to-file provision does not include jurisdictional language, this Court declines to read in such a requirement where none exists.

This Court therefore holds that the first-to-file rule is not jurisdictional. Even if this Court were to find that the rule is jurisdictional, the Court agrees with Mason that the first filed proceeding is preemptive only if it was legally sufficient under Rule 9(b) to state a claim for fraud. The Sixth Circuit has concluded that "[a]lthough not expressly required by the statutory language, . . . a complaint alleging violations of the False Claims Act must allege the circumstances surrounding the fraud with particularity as required by Rule 9(b)." *Walburn v. Lockheed Martin Corp.*, 431 F.3d 966, 972 (6th Cir. 2005). The Supreme Court seems to agree, noting in a footnote that FCA plaintiffs "must . . . plead their claims with plausibility and particularity under Federal Rules of Civil Procedure 8 and 9(b)." *See Universal Health Servs., Inc. v. United States*, 136 S. Ct. 1989, 2004 n. 6 (2016). As the Sixth Circuit persuasively noted, to accord preemptive effect to a "fatally-broad complaint" does not further the purpose of the first-to-file rule, which is to encourage whistleblowers with knowledge of the fraud to come forward and provide the government with notice of the potential fraud. *See Walburn*, 431 F.3d at 973. A contrary rule would encourage a run to the courthouse by individuals with limited or no knowledge of the fraud in an attempt to obtain a right to "shar[e] in any bounty eventually recovered." *Id.*

The Court recognizes that some courts have refused to apply Rule 9(b) to FCA claims or examine the earlier filed complaint for legal sufficiency. The District of Columbia Circuit expressed concern that such a rule would require courts to review the sufficiency of pleadings file in other courts, possibly resulting in contradictory rulings. *See United States ex rel. Batiste v. SLM Corp.*, 659 F.3d 1204, 1210 (D.C. Cir. 2011) (declining to apply Rule 9(b) heightened pleading standards to FCA claims). Here, however, we have a ruling from the prior court that

Cobb's complaint failed to state a FCA claim with any particularity[8] and this Court does not need to conduct its own evaluation of Cobb's pleadings. Because that court found Cobb's complaint legally insufficient to state an FCA claim, that action does not preempt a properly plead later action.

Regardless, § 3730(b)(5) only prohibits later actions that are "related" to the pending action. Courts have interpreted this to mean that the essential facts of the earlier action must allege all the same essential facts as the later complaint. *See United States ex rel. Duxbury v. Ortho Biotech Prod., L.P.,* 579 F.3d 13, 32 (1st Cir. 2009) (noting that "[a]ll courts that have addressed the issue have interpreted § 3730(b)(5) to bar 'a later allegation [if it] states all the essential facts of a previously-filed claim' or 'the same elements of a fraud described in an earlier suit.'" (citations omitted). To the extent she alleged any FCA claim, Cobb alleged that while working at the Madison Street Clinic, she was encouraged to submit false certification of the medical necessity of a surgical debridement for one of her patients. By contrast, Mason alleges a multi-clinic scheme involving altered medical records and improper incentive payments to doctors to certify cases for HBO therapy. Cobb's claim would not have put the United States on notice of the grand scheme that Mason has alleged. This is sufficient to conclude that the Cobb proceeding does not preempt Mason's action. *See United States ex rel. Heath v. AT & T, Inc.*, 791 F.3d 112, 121 (D.C. Cir. 2015) (finding the plaintiff's complaint not preempted when it alleged "a different and more far-reaching scheme to defraud").

Therefore, the first-to-file rule does not bar Mason's complaint and SAM Clinics' 12(b)(1) motion to dismiss is DENIED.

[8] The prior proceeding was within this district but assigned to a different judge.

II. THE FALSE CLAIMS ACT REQUIRES THE PLAINTIFF TO PLAUSIBLY ALLEGE MORE THAN A MERE DIFFERENCE OF MEDICAL OPINION REGARDING THE MEDICAL NECESSITY OF A PROCEDURE.

SAM Clinics then turns to its second argument, that the Court should regardless dismiss Mason's claims because she failed to plead that SAM Clinics submitted objectively false medical certifications to CMS that HBO therapy was medically necessary and therefore eligible for Medicare reimbursement. CMS defines a "reasonable and necessary" service as one that "meets, but does not exceed, the patient's medical need," and is furnished "in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition ... in a setting appropriate to the patient's medical needs and condition[.]" CMS, Medicare Program Integrity Manual § 13.5.4 (2019). CMS further describes "medically necessary" as health care services "needed to diagnose or treat an illness, injury, condition, disease, or its symptoms and that meet accepted standards of medicine." CMS, Medicare & You 2020: The Official U.S. Government Medicare Handbook 114 (2019), *available at https://www.medicare.gov/Pubs/pdf/10050-Medicare-and-You.pdf*.

The False Claims Act defines "knowing" and "claim," but does not provide a definition for "false." *See* 31 U.S.C. § 3729. The Fifteenth Circuit has not addressed this question. There is currently a split among the circuits regarding what must be shown for the certification to be considered 'false.' *Compare United States v. AseraCarea, Inc*., 938 F.3d 1278, 1281 (11th Cir. 2019) (requiring plaintiffs to plead an objective falsehood in the certification of medical necessity) *with Winter ex. rel. United States v. Gardens Reg'l Hosp. & Med. Ctr., Inc*., 953 F.3d 1108, 1117-118 (9th Cir. 2020) (finding that a doctor's assertion of clinical judgment regarding medical necessity can be false).

The medical necessity issue in this case focuses on whether the doctors at the SAM Clinics exercised proper clinical judgment regarding what Wagner grade certain wounds should be assigned and their proper treatment moving forward. Mason argues that it is sufficient at the pleading stage to allege that the physician's opinion as to medical necessity was false based on her medical expert's opinion that proper standards were not followed, relying on *Winter ex. rel. United States v. Gardens Reg'l Hosp. & Med. Ctr., Inc.* Alternatively, even if she is required to show that the defendants' certifications were based on objective falsehood, she has made a plausible case such that her claim should survive a motion to dismiss. *See Ashcroft v. Iqbal*, 556 U.S. 662 (2008) (setting out the plausibility test under FRCP 8(a)).

This Court adopts the Eleventh Circuit's standard that requires the plaintiff to allege the defendant's certification of medical necessity was objectively false, and this requires more than merely showing reasonable disagreement between medical experts. *See United States v. AseraCarea, Inc*., 938 F.3d 1278, 1297 (11th Cir. 2019). In *AseraCarea*, the government alleged the defendant submitted false certifications of patients' eligibility for hospice care. *Id.* at 1281. The government argued that it created an issue for the jury on falsity by producing expert testimony showing the patient's medical records did not support the terminal illness prognosis required to qualify for hospice care. *Id.* at 1291. The Eleventh Circuit disagreed, finding that did not give sufficient deference to the doctor's clinical judgment, as required by the CMS regulations regarding certification of hospice eligibility. *Id.* at 1295. Instead, the court adopted a standard that asked whether the doctor's clinical judgment reflected an obvious falsehood. *Id.* at 1296-97. The court suggested objective falsehood could be established in a number of ways:

> Where, for instance, a certifying physician fails to review a patient's medical records or otherwise familiarize himself with the patient's condition before asserting that the patient is terminal, his ill-formed "clinical judgment" reflects an objective falsehood. The same is true where a plaintiff proves that a physician did

> not, in fact, subjectively believe that his patient was terminally ill at the time of certification. A claim may also reflect an objective falsehood when expert evidence proves that no reasonable physician could have concluded that a patient was terminally ill given the relevant medical records. In each of these examples, the clinical judgment on which the claim is based contains a flaw that can be demonstrated through verifiable facts.

Id. at 1297.

This objective falsity standard allows healthcare providers to continue to make clinic judgments without fear that the government will come knocking for every case with a challenging call. Mason's approach, to the contrary, would force physicians to get second opinions on their diagnoses and make it more difficult for them to quickly respond to the patient's needs without fear of liability. Nothing in the statutory or regulatory framework suggests that a physician's clinical judgment should be second-guessed just because an unaffiliated physician came to a different conclusion based on a medical chart.

Accordingly, in order for the relator to properly state a claim under the FCA, the relator must identify facts and circumstances surrounding the certification that show more than a difference of clinical opinion about the proper course of treatment, but rather show the defendant's certification contained an objective falsehood. When no such facts are shown, the claim must fail as a matter of law. Put more simply, in this case, Mason must allege something more than the fact another medical expert disagrees with the wound grade and use of HBO therapy in a particular patient.

Here, Mason has not pointed to any facts or circumstances surrounding the treatment of the patients at SAM Clinics that show the medical certifications for HBO therapy were based on objective falsehood. She has not alleged the physicians had failed to review the patients' medical charts or otherwise familiarize themselves with the patient's condition before grading their wounds, or that the physicians subjectively did not believe the therapy was medically

necessary. While she provides the opinion of one medical expert that the treatments were not medically indicated under CMS guidelines, she has not shown that "no reasonable physician would conclude" the Wagner grades assigned to the wound were correct or that the patient was insufficiently benefitting from conventional medical treatments. What we have here is a difference of clinical opinion regarding whether HBO therapy was medically necessary for some patients. That cannot support a FCA claim. *See AseraCarea, Inc*., 938 F.3d at 1297.

For the above reasons, while I **DENY** SAM Clinics' 12(b)(1) motion to dismiss, I **GRANT** SAM Clinics' 12(b)(6) motion to dismiss Mason's claim for failure to state a FCA claim.

It is so ordered.

March 31, 2020

UNITED STATES COURT OF APPEALS FOR THE FIFTEENTH CIRCUIT

UNITED STATES EX REL. KEEGAN MASON
Appellant,

v.

SOUTHERN AMERICA METROPOLITIAN CLINICS INC.
Appellee.

No. 21-2386
June 21, 2021

Before: Ralston, Holmes, and Adkins, Circuit Judges.

OPINION

Ralson, C.J. delivered the opinion of the Court in which Holmes, C.J., joined.

Adkins, C.J., filed an opinion dissenting.

This appeal comes to us from the United States District Court for the District of Lincoln, which dismissed Appellee Mason's False Claims Act (FCA) action for failure to state a claim. The lower court granted Appellant SAM Clinics' F.R. Civ. P. 12(b)(6) motion to dismiss, finding that Appellee Mason had failed to plausibly state an FCA claim. The lower court denied Appellant's 12(b)(1) motion that asserted the court lacked subject matter jurisdiction under the FCA to hear this action because there was at the time it was filed, another pending FCA action alleging the same essential facts. Mason appealed the dismissal of her complaint. For the reasons set forth below, we reverse and remand on the district court's decision on the jurisdictional issue and do not address Mason's argument that the lower court applied the incorrect standard of falsity.

We review a motion to dismiss for failure to state a claim de novo. Because the facts of this case are well set out in the District Court's opinion, we only recite facts of the case where necessary to proceed with the legal analysis.

I. THE FIRST-TO-FILE RULE IS A JURISDICTIONAL BAR THUS PRECLUDING APPELLANT'S CLAIM FROM PROCEEDING.

As the lower court properly noted, whether a court has subject matter jurisdiction can be raised at any time. Although SAM Clinics did not appeal this issue, this Court raises the issue *sua sponte*. *See Fed. Dep. Ins. Corp. v. Four Star Holding Co*., 178 F.3d 97, 100 n. 2 (2d Cir.1999) ("Although the parties did not brief the issue in their original submissions on appeal, the Court may examine subject matter jurisdiction, *sua sponte*, at any stage of the proceeding."). We rule that the district court lacked subject matter jurisdiction to consider Mason's FCA claim. The lower court erred in scrutinizing whether the first filed action met the standards of Federal Rule of Civil Procedure 9(b). The lower court also erred in finding that Mason's action is not related to the underlying pending action. The Cobb action would have been sufficient to put the United States on notice that SAM Clinics may be submitting fraudulent certifications of medical necessity, such that if the government investigated the fraud Cobb alleged, it would have discovered it was part of a broader scheme that related to what Mason alleged. Accordingly, the district court should have dismissed this action without reaching the question of what amounts to a "false" claim under the FCA.

In the present case, Dr. Cobb filed a FCA action against SAM Clinics under seal in October, 2019, alleging she was fired for refusing to perform surgical debridement when it was not medically necessary. The purpose of requiring the relator to file her complaint under seal and to serve a copy of it along with an evidentiary disclosure on the government is to allow the government an opportunity to investigate the case and decide whether it will take over the relator's action or allow the relator to litigate it in the government's place. *See Smith v. Clark/Smoot/Russell*, 796 F.3d 424, 430 (4th Cir. 2015); *see also* 31 U.S.C. § 3730(b)(4) (setting out possible government responses). *Qui tam* proceedings and the first-to-file rule serve the

FCA's dual purpose by incentivizing whistleblowers to report fraud while preventing parasitic lawsuits based on previously disclosed fraud. *See United States ex rel. Beauchamp v. Academi Training Ctr.*, 816 F.3d 37, 39 (4th Cir. 2016). Thus, the United States received notice in October, 2019, regarding the potential fraud in Medicare reimbursement claims being submitted by SAM Clinics, and after an opportunity to investigate, declined to intervene in that action.

The first-to-file provision of the FCA provides that "no person other than the Government may intervene or bring a related action based on the facts underlying the *pending* action." *See* 31 U.S.C. § 3730(b)(5) (emphasis added). The Supreme Court has defined "pending" to mean "[r]emaining undecided; awaiting decision," thereby finding that the first-to-file rule bars later actions if their earlier-filed counterparts are pending. *See Kellogg Brown & Root Services, Inc. v. United States ex rel. Carter*, 575 U.S. 650, 663 (2015) (quoting *Black's Law Dictionary* 1314 (10th ed. 2014)). There is no dispute that Dr. Cobb's claim was still pending in the district court when Mason filed her FCA claim. The only question is whether this deprived the district court of jurisdiction to hear Mason's FCA action.

We agree with the Fourth, Fifth and Sixth Circuits that the first-to-file rule is jurisdictional. *See United States. ex rel. Carter v. Halliburton Co.*, 866 F.3d 199, 203 (4th Cir. 2017) (articulating that the first-to-file rule is jurisdictional)*; United States ex rel. Branch Consultants v. Allstate Ins. Co.*, 560 F.3d 371, 377 (5th Cir. 2009) (same); *United States ex rel. Poteet v. Medtronic, Inc.*, 552 F.3d 503, 516 (6th Cir. 2009) (same). As the Fifth Circuit explained in *Branch Consultants*, this jurisdictional bar is the result of "repeated attempts by Congress to balance" the two competing goals of the FCA, namely to encourage whistleblowers with valuable information but also discourage parasitic lawsuits. *Branch*, 560 F.3d at 376. "To promote the latter goal, Congress has placed a number of jurisdictional limits on the FCA's qui

tam provisions, including § 3730(b)(5)'s first-to-file bar." *Id.* Therefore, when there is a pending action related to the plaintiff's later filed action, the court does not have subject matter jurisdiction to consider the later filed action and must dismiss it.

The only question for the court to determine before dismissing the later filed action is whether the two actions are "related." The lower court was correct to use the "essential facts" test, but it should have given the bar a broader interpretation. *See Branch*, 560 F.3d at 377 (explaining that an overly narrow bar would not advance the purpose of excluding relators with little significant information to contribute). The later allegation is barred even if it incorporates somewhat different details. *See, e.g., United States ex rel. Poteet v. Medtronic, Inc.*, 552 F.3d 503, 516 (6th Cir. 2009). Once the government is put on notice of its potential fraud claim, the purpose behind allowing the *qui tam* proceeding has been satisfied. *Grynberg v. Koch Gateway Pipeline Co*., 390 F.3d 1276, 1279 (10th Cir. 2004). As the Tenth Circuit in *Grynberg* reasoned, "so long as a subsequent complaint raises the same or a related claim based in significant measure on the core fact or general conduct relied upon in the first qui tam action, the § 3730(b)(5)'s first-to-file bar applies." *Id.*

Looking at Dr. Cobbs and Mason's claims together, Dr. Cobb put the government on notice of SAM Clinics potential fraudulent Medicare certification scheme. Mason's claim alleges a similar scheme by SAM Clinics to pressure physicians to falsely certify the medical necessity of procedures, with a similar actor (John O'Keefe) responsible for that pressure, albeit involving a different procedure and more details about how that pressure was being applied. Mason's claim did not provide additional or new information about SAM Clinics' practices that could not have been discovered by the government when it investigated Dr. Cobb's allegation.

Therefore, Mason's claim was jurisdictionally barred by the first-to-file provision of the FCA and should have been dismissed by the district court because it lacked subject matter jurisdiction.

Mason argues that the bar should not apply because Cobb's claim was dismissed for failure to meet Federal Rule of Civil Procedure 9(b)'s requirements for pleading fraud with particularity. It is not clear whether the court should permit an FCA action only if it meets the heightened pleading standards of Rule 9(b). Although as the district court noted, the Supreme Court in a footnote suggested that 9(b) applies, that case related to the FCA's materiality standard and it is not clear if and how it might apply to the first-to-file bar. *See Universal Health Services, Inc. v. U.S.,* 136 S. Ct. 1989, 2003 n. 6 (2016). *Universal Health Services* addressed § 3729(a)(1)(A)'s materiality requirement, which the Court characterized as "demanding." *See id.* We think the District Court for the District of Columbia was correct that under § 3730(b)(5), the question is only whether the first filed action provided sufficient notice for the government to initiate an investigation into the alleged fraud. *See United States ex rel. Batiste v. SLM Corp.*, 659 F.3d 1204, 1210 (D.C. Cir. 2011). The government may have sufficient information to launch its investigation even if the complaint does not meet Rule 9(b)'s heightened standards.

That Dr. Cobb's claim was dismissed for failing to plead fraud with particularity as required by Rule 9(b) does not preclude the government having been put on notice of the need to investigate. Dr. Cobb alleged that her employer was encouraging false certifications of the medical necessity of procedures for which it was seeking Medicare reimbursement. The details may have been scarce but if her claim was true, there was enough to trigger the government's further investigation of SAM Clinics' Medicare reimbursement certifications, if it chose to do so.

Mason next argues that regardless of a 9(b) analysis, the essential facts of her claim are not the same as Dr. Cobb's and therefore the first-to-file bar does not apply. We disagree. Both

Dr. Cobb's claim and Mason's claim alleged SAM Clinics was defrauding Medicare by prescribing patients certain wound treatments when they were not medically necessary. Both complaints identified John O'Keefe as involved in the alleged false certifications. While each claim contained different procedures and Mason's provided much more detail, that does not preclude finding the earlier action equipped the government on its own to find the broader scheme. *See United States ex rel. Folliard v. CDW Tech. Servs., Inc.*, 722 F. Supp. 2d 37, 43 (D.D.C. 2010) (reasoning that allegations of fraud in one type of procurement contract "equipped [the government] on its own to discover the extent to which defendants had other federal procurement contracts" and whether any wrongdoing occurred in regard to those contracts (internal quotation omitted)).

Because we resolve that the district court lacked jurisdiction to hear this case, the lower court should not have considered Mason's second argument regarding the standard of falsity that is applied to FCA claims. Albeit for different reasons, we AFFIRM the decision of the court below dismissing Mason's cause of action.

Judge Askins, dissenting.

I would find that the district court was correct to find the first-to-file rule is not jurisdictional and that the cases do not allege the same essential facts, which means Dr. Cobb was not the first-to-file the FCA claims raised in Mason's case. I would reach the second issue and hold the district court erred in limiting the scope of the falsity element to whether the defendant made an objective falsehood.

More specifically, I would hold that the district court erroneously determined that it was not enough to allege that a physician's clinical medical judgment was false based on the

assessment of another medical expert. By adopting this "objective falsehood" standard, the district court created an additional element not found in the language of the FCA. The plain language of the FCA imposes liability for presenting "false or fraudulent claims for payment or approval," making a "false record or statement material to a false or fraudulent claim," or conspiring to do either. 31 U.S.C. § 3729 (2018). Because Congress did not define "false or fraudulent," we should presume Congress intended to use the common-law definition, including the rule that a statement does not need to contain an "express falsehood" to satisfy the element of the statute. *See Universal Health Services, Inc. v. United States,* 136 S. Ct. 1989, 1999 (2016) (applying the common law definition to hold that in some cases, misrepresentation by omission can violate the FCA). The Ninth Circuit has properly concluded that the plain language of the statute does not distinguish between "objective" and "subjective" falsity or create an exception for clinical medical judgments. *Winter ex. rel. United States v. Gardens Reg'l Hosp. & Med. Ctr., Inc.*, 953 F.3d 1108, 1117 (9th Cir. 2020). That court distinguished the Eleventh Circuit's decision in *AseraCare* in part because it involved hospice certification, for which the CMS guidelines establish considerable deference to the physician's judgment. *See id.* at 1119 (distinguishing *United States v. AseraCarea, Inc*., 938 F.3d 1278 (11th Cir. 2019)). The Eleventh Circuit itself acknowledged the objective falsehood standard might not apply to a physician's certification of medical necessity. *AseraCarea, Inc*., 938 F.3d at 1300 n. 25; *see also Winter*, 953 F.3d at 1119 (discussing Eleventh Circuit's reasoning).

The Ninth Circuit additionally rejected concerns such as those raised by the district court regarding the impact on physician decision-making if their clinical judgments can be found to be fraudulent. *Winter*, 953 F.3d at 1117. As the court explained, policy concerns cannot trump the plain language of the statute. *Id.* Moreover, because the Supreme Court has established a

demanding standard for the materiality and scienter elements of an FCA claim, there was no reason for a circumscribed view of what is false or fraudulent. *Id.*

In order to state a claim under the FCA, Mason only needed to assert that a physician's certification that HBO therapy was 'medically necessary' was false or fraudulent for the same reasons that any opinion can be false or fraudulent. Mason alleged facts that, if true, demonstrate the treatments for which SAM Clinics sought reimbursement were improperly certified as medically necessary. She provided a qualified medical expert who concluded HBO therapy was not medically necessary for the identified patients. If that difference in medical opinion about medical necessity is enough to create a jury question, it is enough to survive a motion to dismiss. *Cf. United States ex rel Druding v. Care Alternatives,* 952 F.3d 89, 98 (3d Cir. 2020) (concluding a jury can consider whether a certification of medical necessity was false based on an expert's testimony challenging the certifying physician's medical opinion). Mason had more than merely a difference in medical opinion; she also had other information about a scheme to intentionally defraud Medicare by performing medically unnecessary treatments. She had shown a plausible claim under the FCA and the lower court should have denied the motion to dismiss.

But, even if the standard requires objective falsity, as noted, Mason has more than a mere difference in medical opinion; she had alleged a scheme by doctors and administrators of SAM Clinics to defraud the government by altering patient diagnoses to meet CMS reimbursement thresholds. She points to at least five patients who did not meet the CMS standards for medically necessary HBO therapy. She also alleges her own observations about altered diagnoses and pressure from an administrator to submit false Wagner grades. These are objective facts that would render the medical certifications objectively false under the standard identified by the

district court. Thus, even under the majority's standard, Mason is entitled to remand of her case for further considerations.

I respectfully dissent.

IN THE SUPREME COURT OF THE UNITED STATES

Keegan Mason,
Petitioner,

v.

Southern American Metropolitan Clinics, Inc.,
Respondent.

No. 21-1967

Petition for writ of certiorari to the United States Court of Appeals for the Twelfth Circuit is granted limited to the following Questions:

1) Does the FCA's first-to-file rule establish a rule of subject matter jurisdiction and was Petitioner's case barred by that rule?
2) Can certification of a medical opinion be false under the FCA or must the relator show the certification was objectively false, and did Petitioner in this case meet the requisite standard?