Appeal No. 15-14231

UNITED STATES COURT OF APPEALS
ELEVENTH CIRCUIT

UNITED STATES OF AMERICA,
ex. rel. MARGARET JALLALI,

Appellant,

VS.

SUN HEALTHCARE GROUP, et al.,

Appellees

An Appeal from the United States District Court

in and for the Southern District of Florida

LT. No. 0:12-cv-61011-KMW

INITIAL BRIEF OF APPELLEES

HALL BOOTH SMITH, P.C.
191 Peachtree Street, NE, Suite 2900
Atlanta, Georgia 30303
Telephone: (404) 954-5000
Facsimile: (404) 954-5020

By: 
T. Andrew Graham
Attorney-in-Charge
Georgia Bar Number: 304777
Attorneys for Appellees

JACKSON LEWIS, LLP
501 Riverside Avenue, Suite 902
Jacksonville, Florida 32202
Telephone: (904) 638-2655
Facsimile: (904) 638-2656

By: 
Benjamin D. Sharkey
Florida Bar Number: 0389160
sharkeyb@jacksonleweis.com
Colin A. Thakkar
Florida Bar Number: 0010242
colin.thakkar@jacksonlewis.com
Attorneys for Appellees

CERTIFICATE OF INTERESTED PERSONS

US, ex rel., Margaret Jallali v. Sun Healthcare Group, et.al.,

Appeal Number: 15-14231-C
District Court Docket No: 0:12-cv-61011-KMW

In addition to the list of parties and entities which may have an interest in the outcome of this appeal, Appellee sets forth the following parties and entities:

As to SunDance Rehabilitation, LLC

1. SunDance Rehabilitation, LLC is a limited liability Company ("LLC") and non-governmental party to this civil action.
2. SunDance Rehabilitation, LLC's parent company is currently Genesis ElderCare Rehabilitation Services, LLC.
3. SunDance Rehabilitation, LLC is an indirect subsidiary of Genesis Healthcare, Inc.® which is a publicly-traded company. No publicly held corporation owns 10% or more of SunDance Rehabilitation, LLC. As a LLC, SunDance Rehabilitation, LLC has no stock.

As to SunDance Rehabilitation Agency, LLC

1. SunDance Rehabilitation Agency, LLC is a limited liability company ("LLC") and non-governmental party to this civil action.
2. SunDance Rehabilitation Agency, LLC's parent company is SunDance Rehabilitation, LLC.

US, ex rel., Margaret Jallali v. Sun Healthcare Group, et.al.,

Appeal Number: 15-14231-C
District Court Docket No: 0:12-cv-61011-KMW

3. SunDance Rehabilitation Agency, LLC is an indirect subsidiary of Genesis Healthcare, Inc.®, which is a publicly-traded company. No publicly held corporation owns 10% or more of SunDance Rehabilitation Agency, LLC. As a LLC, SunDance Rehabilitation Agency, LLC has no stock.

As to Sun Healthcare Group, Inc., incorrectly named Sun HealthCare Group

1. Sun Healthcare Group, Inc. is a non-governmental party to this civil action.
2. Sun Healthcare Group, Inc.'s parent company is presently Genesis Healthcare, Inc.®
3. Genesis Healthcare, Inc.® is a publicly-traded company, and Genesis Healthcare, Inc.® currently owns 10% or more of Sun Healthcare Group, Inc.'s stock.

STATEMENT REGARDING ORAL ARGUMENT

Appellees-Defendants respectfully submit that oral argument is unnecessary because the district court's clear and thorough decision dismissing Appellant-Plaintiff's Complaint was based on a straightforward application of this Court's precedent. Furthermore, Appellees-Defendants respectfully submit that oral argument would be duplicative of the written arguments made by the parties in their respective briefs.

TABLE OF CONTENTS

TABLE OF CITATIONS

CASES

STATUTES

RULES

STATEMENT OF THE ISSUE

Whether the district court properly dismissed the Amended Complaint for Relator's failure to plead fraud with particularity, as required by Federal Rule of Civil Procedure 9(b), and in accordance with well-established Eleventh Circuit precedent interpreting the heightened pleading standard under Rule 9(b) in the context of False Claims Act complaints.

STATEMENT OF THE CASE

A. Procedural History

1. On May 25, 2012, Relator initially filed a three-count Complaint (the "Original Complaint") under seal against Defendants in the United States District Court for the Southern District of Florida, alleging claims for (1) violations of the False Claims Act under 31 U.S.C. §3729a, (2) conspiracy to violate the False Claims Act under 31 U.S.C. §3729(a)(1)(C), and (3) violations of the Anti-Kickback Statute under 42 U.S.C. §1320a-7b(b). (DE #1).

2. On January 30, 2013, the United States filed a Notice of Election to Decline Intervention. (DE #10). The following day, January 31, 2013, the district court signed an Order unsealing the Original Complaint and the government's notice declining intervention. (DE #11).

3. On April 3, 2013, Defendants filed a Motion to Dismiss Relator's Complaint for failing to plead with particularity and failure to allege the existence of any false claims. (DE #32).

4. On February 6, 2014, the district court held a hearing on Defendants' Motion to Dismiss and related matters, and granted the Defendants' Motion to Dismiss and dismissed the Original Complaint on the same date. (DE #85, 86).

5. On February 14, 2014, Defendants filed their Notice of Pending, Refiled, Related or Similar Actions. (DE #90), and filed a Supplemental Notice on September 19, 2014. (DE #95).[1]

6. On March 18, 2014, Relator filed her First Amended Complaint (the "Amended Complaint"). (DE #91).

7. On April 7, 2014, Defendants filed their Motion to Dismiss the Amended Complaint. (DE # 92).

8. Relator responded to the Motion to Dismiss on April 22, 2014 (DE #93), and Defendants filed a Reply to Relator's Response on April 29, 2014 (DE #94).

9. On August 28, 2015, the district court held a hearing on Defendants' Motion to Dismiss the Amended Complaint (DE #100).

10. On September 17, 2015, the district court issued its Order granting Defendants' Motion to Dismiss with Prejudice. (DE #101).

---

[1] The district court noted that this case was the second case that Jallali had brought in the Southern District of Florida against Defendant Sun Healthcare Group, and summarized the procedural history of the first case in its Order. (DE #101, p.1 at n.1). The record in this case also includes a summary of a number of related litigation and administrative complaint matters arising from the first and present case, including a complaint filed by Jallali against two employees (Barbara Cuff, Physical Therapist, and Aleksandra Sarmiento, Physical Therapist Assistant) of Defendant with a State of Florida licensing agency, a complaint filed by Jallali in a Florida state court against the attorneys representing Defendant Sun Healthcare Group in the first case, and a complaint filed by Jallali against the same counsel with the State Bar of Florida. (DE #90, #95).

11. On the same date, Relator filed her Notice of Appeal to the United States Court of Appeals for the Eleventh Circuit. (DE #102).

B. Summary of Relator's Allegations in the Amended Complaint

1. Background

The Amended Complaint filed by Relator alleges the following counts: (i) false or fraudulent claims under the federal False Claims Act ("FCA"), 31 U.S.C. §3729(a)(1)(A) ("Count I") (DE #91 ¶¶91-104); (ii) false statements under the FCA, 31 U.S.C. §3729(a)(1)(B) ("Count II") (DE #91 ¶¶105-109); (iii) conspiracy to violate the FCA, 31, U.S.C. §3729(a)(1)(C) ("Count III") (DE #91 ¶¶110-121); (iv) violation of the Anti-Kickback Statute, 42 U.S.C. §1320a-7b(b) ("Count IV") (DE#91 ¶¶122-132); (v) unjust enrichment ("Count V") (DE#91 ¶¶133-134); (vi) payment by mistake ("Count VI") (DE #91 ¶¶135-138); and (vii) conversion ("Count VI") (DE#91 ¶¶139-141).

Relator identifies herself as "a Therapy Program Manager ("TPM") and/or a Director a Director of Rehab and Therapy ("DRT")" at Sun HealthCare Group. (DE #91 ¶ 35). The Defendants are identified as Sun HealthCare Group, a corporation authorized to do business in Florida, Sundance Rehabilitation Agency, a Delaware corporation, and Sundance Rehabilitation Corporation, a Connecticut corporation. (DE #91 ¶¶9-11). Throughout the Amended Complaint, the Relator

refers to the Defendants collectively as "Sun Group" or "Defendants", but does not otherwise distinguish among or between them. (DE#91 ¶33).

Under the Amended Complaint, Relator generally alleges that Defendants engaged in a scheme under which certain employees of Defendants altered patient medical records "after-the-fact" and engaged in other improper documentation practices, that Defendants improperly induced certain employees to alter such medical records in violation of the Anti-Kickback Statute, and that Defendants presented false claims for payments under the Medicare program.

2. Summary of Allegations under the False Claims Act (Counts I-III)

With respect to False Claim Act allegations (Counts I, II and III) under the Amended Complaint, Relator alleges that Defendants presented claims for payment by Medicare "flowing from late entries in patient charts, usage of white-out to alter treating physician dates; cutting and pasting signatures that were absent on treating orders or patient evaluations; [and] in some incidents pasting with clear tape directly on the notes." (DE #91 ¶34). Relator further alleges that Defendants violated the False Claims Act by "generating billing from unsigned treatment orders and unsigned clarification orders", "billing for services rendered that were not actually rendered", and billing Medicare for dates of service where the "patient chart shows no notes present [for] the day billed." (DE #91 ¶34).

Relator alleges that she has "personal knowledge of the fraud committed by Defendants." (DE #91 ¶32). Relator alleges that, "as a Therapy Program Manager for Defendant, having reviewed each of the patient files that are stated in the complaint, [she] has a personal knowledge regarding false claims for payments by Defendant" and "personal knowledge of billing logs and medical records of patients and also had interactions with patients." (DE #91 ¶ 53, 55). While the Relator also claims that she had "firsthand information about the billing practice of the [D]efendants", the district court correctly found that the Relator focused primarily on the allegedly deceptive record keeping, alteration of charts, and falsified physician approvals without elaborating on the alleged "fraudulent billing schemes." (DE#101, p.3; DE #91 ¶¶58-59). The district court further observed that the Relator, throughout her allegations of the Amended Complaint, "appears to conflate the internal processes for maintaining patient records with the separate act of billing the government." (DE #101, p.3; DE #91 ¶¶61-83).

In support of her claims under the False Claims Act (Counts I and II) of the Amended Complaint, Relator makes the same or substantially similar allegations of improper practices by Defendants: that the Defendants "altered patient charts"; "generated billing statements for claims for Medicare payments based upon unsigned treatment orders"; "forged, reproduced, [and] cut-and-pasted" physician signatures; "performed illegal acts in an effort to create records"; "caused"

physicians to execute improper referrals (DE#91 ¶¶95-100); and "concealed the fact of recreating patient treatment records after-the-fact of billing." (DE#91 ¶108). These same or substantially similar allegations are also pleaded as allegations "[i]n furtherance of the conspiracy" pursuant to the conspiracy claim (Count III) under the False Claims Act of the Amended Complaint. (DE#91 ¶113-119).

Notwithstanding Relator's contention that she "had a reliable indication that claims were fraudulently submitted to Medicare for payments by Defendant[s]" (DE #91 ¶61), the district court properly found that Relator's "statement is not supported by any specific factual allegations." (DE #101, p.3). The district court also found that, throughout the Amended Complaint, "specific allegations that Defendants actually submitted false claims to the government or that the government made any payments were notably lacking." (DE #101, p.3-4).

3. Summary of Allegations under the Anti-Kickback Statute (Count IV)

With respect to the alleged violations under the Anti-Kickback Statute (Count IV), Relator alleges that certain actions by employees of Defendants caused improper referrals prohibited by the Anti-Kickback Statute. Relator alleges that, as a general practice, Defendants would treat patients despite not having timely obtained a physician's written evaluation order or clarification order approving the course of treatment. (DE #91¶¶ 85-87). More specifically, Relator alleges that two of Defendants' employees (Barbara Cuff, Physical Therapist, and Aleksandra

Sarmiento, Physical Therapist Assistant)[2] were instructed by their supervisor to back-date patient records, and were paid "[a] sizable number of billable hours" for "back-dating patient medical records." (DE #91 ¶¶127-130). As with the alleged violations pursuant to the False Claims Act, the district court properly found that "there are no specific factual allegations supporting the conclusory assertion that the Defendants 'violated the Anti-Kickback Statute,' and then submitted a claim to the government for payment arising from an unlawful referral." (DE #101, p.4; DE#91 ¶125).

4. Allegations under Common Law Claims (Counts V-VII)

In her Initial Brief, Relator-Appellant fails to address the district court's dismissal of Relator's common law claims for unjust enrichment (Count V), payment by mistake (Count VI), and conversion (Count VII) for lack of standing to assert common law claims on behalf of the United States. (DE# 101, p.21-23). Therefore, the Defendants-Appellees respectfully submit that Relator-Appellant has abandoned her appeal with respect to Counts V, VI and VII of the Amended Complaint.

---

[2] In her Amended Complaint and Initial Brief in this Appeal, Relator-Appellant identifies Barbara Cuff as a "Physician Therapist" and Aleksandra Sarmiento as a "Physician Therapist Assistant" (DE #91¶ 37-38; Initial Brief of Appellant, p.7 n.4). However, these licensed professional titles are erroneous references based on the deposition testimony of Barbara Cuff and Aleksandra Sarmiento. (DE #83, 84).

STANDARD OF REVIEW

This Court reviews *de novo* the grant of a motion to dismiss. *Ironworkers Local Union 68 v. AstraZeneca Pharm., LP,* 634 F.3d 1352, 1359 (11th Cir. 2011).

SUMMARY OF THE ARGUMENT

The district court properly dismissed Relator's claims under the False Claims Act (Counts I-III) for failure to allege fraud with particularity, as required by Federal Rule of Civil Procedure 9(b). Rule 9(b) requires that "a party must state with particularity the circumstances constituting fraud." Citing to and relying upon well-established Eleventh Circuit precedent addressing the heightened pleading standard under Rule 9(b) in the context of False Claims Act complaints, the district court correctly determined that Relator failed to plead with particularity that any claims arising from the allegedly back-dated files, post-dated approvals, improperly signed authorizations and orders, or deceptively described services were in fact submitted to the government or paid as a result of the scheme. In short, Relator has failed to plead with sufficient particularity in her Amended Complaint as to the "who", "what", "where", "when" and "how" of the alleged fraudulent submission of claims to the government or payment by the government.

For a relator who lacks direct evidence that false claims were actually submitted to the government, alternate means are available to present sufficient

indicia of reliability that a false claim was actually submitted. However, such alternate means nevertheless impose strict requirements on qui tam relators and do not constitute a "relaxation" of the standards set forth by well-established Eleventh Circuit precedent. After a careful and thorough review of Relator's allegations under the Amended Complaint, including the various exhibits submitted in support of Relator's Amended Complaint, the district court properly determined that Relator has failed to plead with particularity, and failed to provide the required indicia of reliability, that any claims were actually submitted to the government and reimbursed as a result of the scheme.

For similar reasons, the district court also properly dismissed Relator's claim under the Anti-Kickback Statute (Counts IV) for failure to plead fraud with particularity, as required by Federal Rule of Civil Procedure 9(b). Relator failed to identify any claims submitted to the government, or specific certifications made to the government, and therefore failed to connect the scheme to particular instances of fraud or misrepresentations. In addition to the district court's ruling, none of the alleged conduct or actions of the Defendants or their employees is prohibited by the Anti-Kickback Statute. Furthermore, even assuming that the allegations under Count IV somehow included conduct which is prohibited by the Anti-Kickback Statute, such allegations clearly fall within the "Employment Exception" of the Anti-Kickback Statute. Stated differently, even viewing the facts in a light most

favorable to Relator, the Anti-Kickback Statute allegations as pled by Relator under the Amended Complaint against the Defendants and their employees clearly meet the "Employment Exception" under the Anti-Kickback Statute. Therefore, in addition to the pleading deficiencies under Rule 9(b) as set forth by the district court, Defendants are entitled to dismissal of Count IV of the Amended Complaint as a matter of law.

ARGUMENT/CITATIONS OF AUTHORITY

I. The District Court Properly Dismissed Relator's Claims Under the False Claims Act (Counts I-III) For Failure To Allege Fraud With Particularity, As Required By Federal Rule Of Civil Procedure 9(b), And In Accordance With Well-Established Eleventh Circuit Precedent Addressing The Heightened Pleading Requirements Under Rule 9(b) In The Context Of False Claims Act Complaints.

A. The Heightened Pleading Standard Under Rule 9(b)

The district court issued a clear and thorough order dismissing the Relator's claims under the False Claims Act (Counts I, II and III) for failure to allege fraud with particularity, as required by Federal Rule of Civil Procedure 9(b). The starting point of any analysis under Rule 9(b) is a discussion of the Eleventh Circuit precedent addressing the heightened pleading requirements under Rule 9(b) in the context of FCA complaints.[3]

---

[3] Before discussing the standard under Rule 9(b), the district court first summarized the standards for a motion to dismiss under Rule 12(b)(6):

> To survive a Rule 12(b)(6) motion to dismiss, a plaintiff must plead sufficient facts to state a claim that is "plausible on its face." *Ashcroft v. Iqbal,* 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly,* 550 U.S. 544, 570 (2007)). The court's consideration is limited to the allegations presented. *See GSW, Inc. v. Long Cnty., Ga.,* 999 F.2d 1508, 1510 (11th Cir. 1993). All factual allegations are accepted as true and all reasonable inferences are drawn in plaintiff's favor. *See Speaker v. U.S. Dep't of Health & Human Servs. Ctrs. For Disease Control & Prevention,* 523 F.3d 1371, 1379 (11th Cir. 2010); *see also Roberts v. Fla. Power & Light,* 146 F.3d 1305, 1307 (11th Cir. 1998). Nevertheless, while a plaintiff need not provide "detailed factual allegations," the allegations must contain more than "a formulaic recitation of the elements of a cause of action." *Twombly,* 550 U.S. at 555 (internal citations and quotations omitted). Additionally, "conclusory allegations, unwarranted factual deductions and

In addition to the plausibility criteria under *Twombly* and *Iqbal*, and the other pleading requirements under Federal Rules of Civil Procedure 8(a) and 12(b)(6), the district court recognized that claims asserted under the False Claims Act (as well as other fraud claims) are subject to the heightened pleading standards of Federal Rule of Civil Procedure 9(b), citing *United States ex rel. Clausen v. Laboratory Corp. of Am., Inc.*, 290 F.3d 1301, 1309-10 and *United States ex rel. Keeler v. Eisal, Inc.*, 568 F. App'x 783, 798-99 (11th Cir. 2014). (DE #101, p.5). Accordingly, a False Claims Act complaint must "state with particularity the circumstances constituting fraud or mistake." *Fed. R. Civ. P. 9(b)*.

In the context of the False Claims Act, Rule 9(b) requires, and the district reiterated, that "the complaint must set forth 'facts as to time, place, and substance of the defendant's alleged fraud' and 'the details of the [defendant's] allegedly fraudulent acts, when they occurred, and who engaged in them.' *Clausen*, 290 F.3d at 1309-10 (quotations omitted); *accord United States ex rel. Sanchez v. Lymphatx, Inc.*, 596 F.3d 1300, 1302 (11th Cir. 2010)". (DE #101, p.6); *see also Garfield v. NDC Health Corp.*, 466 F. 3d 1255, 1262 (11th Cir. 2006) (requiring relators to

---

legal conclusions masquerading as facts will not prevent dismissal." *Davila v. Delta Air Lines, Inc.*, 326 F.3d 1183, 1185 (11th Cir. 2003); *United States ex rel. Keeler v. Eisai, Inc.*, 586 F. App'x 783, 792-93 (11th Cir. 2014). The "[f]actual allegations must be enough to raise a right of relief above the speculative level." *Watts v. Fla. Int'l Univ,*. 495 F.3d 1289 (11th Cir. 2007) (quoting *Twombly,* 550 U.S. at 545).

(DE #101, p.5).

detail the "who, what, when, where and how" of their claims). The district court concluded: "'Underlying schemes and other wrongful activities that result in the submission of fraudulent claims are included in the 'circumstances constituting fraud or mistake' that must be pled with particularity pursuant to Rule 9(b).'" (DE #101, p.6) (citing *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 232 (1st Cir. 2004)).

Before discussing the adequacy of the Amended Complaint under heightened pleading standards of Rule 9(b), the district court made several important observations:

> Whether submission of the claim or payment by the government are sufficiently established are different questions than whether the scheme has been sufficiently pleaded. *See Keeler*, 568 F. App'x at 798 (citing *Corsello v. Lincare, Inc.*, 428 F. 3d 1008, 1014 (11th Cir. 2005)); *see also Britton v. Lincare, Inc.*, Case No. 2:13-cv-00742-SGC, 2015 WL 1487134, at *4 (N.D. Ala. March 30, 2015) ("[T]he relevant inquiry for purposes of determining whether a complaint has pled the actual submission of a claim sufficiently is whether the relator purports to have direct, first-hand knowledge of the defendant's *billing practices*.") (emphasis in original). As discussed below, the Eleventh Circuit has recognized that while these requirements of Rule 9(b) may, in practice, make it difficult for a qui tam relator to bring an action, they are necessary to prevent "[s]peculative suits against innocent actors for fraud" and charges of guilt by association. *Clausen,* 290 F.3d at 1308 (quoting *United States ex rel. Cooper v. Blue Cross & Blue Shield of Fla.*, 19 F. 3d 562, 566-67 (11th Cir. 1994)(per curiam)).

(DE #101, p.6-7); *accord United States ex rel. Nathan v. Takeda Pharmaceuticals North America,* 707 F.3d 451, 548 (4th Cir. 2013), cert. denied (March 31, 2014) (acknowledging the "practical challenges that a relator may face" in meeting Rule

9(b) standards, such as where a relator may not have independent access to records such as invoices, but Rule 9(b) pleading requirements "do not permit a relator to bring action without pleading facts that support all the elements of a claim.")

B. Improper Practices and Alleged Violations of Medicare Laws or Regulations, Standing Alone, Are Insufficient to Create False Claims Act Liability

After reviewing the purposes and requirements of the False Claims Act[4], the district court outlined the inherent limitations of False Claims Act liability pursuant to Eleventh Circuit precedent and other Circuit decisions. "The False Claims Act does not deal with all non-compliance and '[t]he fact that that there may have been a violation of the laws governing Medicare…is not enough, standing alone, to sustain a cause of action under the False Claims Act.' *United States ex rel. Ortolano v. Amin Radiology,* Case No. 5: 10-CV-583-OC-PRL, 2015 WE 403221, at *3 n.3 (M.D. Fla. January 28, 2015) (citing *Mikes v. Straus,* 274 F. 3d 687, 697 (2nd Cir. 2001))." (DE #101, p.8). Instead, there must be a falsehood that affects the government's willingness to pay, because "[i]mproper practices standing alone are insufficient." (Id.) (citing *Hopper v. Solvay Pharm., Inc.,* 588 F. 3d 1318, 1328 (11th Cir. 2009)). To prevail, according to the district court, "a relator must

[4] The False Claims Act imposes liability on any person who, *inter alia*: (a)(1)(A) "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" (the "presentment" provision); (a)(1)(B) "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim" (the "make-or-use" provision); or (a)(1)(C) "conspires to commit a violation of subparagraph (A), (B), (D), (E), (F) or (G)." 31 U.S.C. §3729.

provide details of a link between improper practices and the submission of false claims. (Id.) (citing *United States ex rel. Klusmeier v. Bell Constructors, Inc.*, 469 F. App'x 718, 721 (11th Cir. 2012)).

As with the district court, a number of Circuit courts have admonished that the False Claims Act liability should not be invoked lightly; it is "not a vehicle to police technical compliance." *See, e.g., United States ex rel. Hobbs v. MedQuest Assocs., Inc.*, 711 F. 3d 707, 717 (6th Cir. 2013) (quoting *United States ex rel. Williams v. Renal Care Grp, Inc.*, 696 F. 3d 518, 532 (6th Cir. 2012)). The district court further explained the limitations of liability under the FCA:

> Accordingly, "[t]he False Claims Act does not create liability merely for a health care provider's disregard of Government regulations or improper internal policies unless, as a result of such acts, the provider knowingly asks the Government to pay amounts it does not owe." *Clausen,* 290 F.3d at 1311. The Eleventh Circuit recently reiterated that liability under the False Claims Act does not arise solely from the "failure to maintain proper internal procedures." *Urquilla-Diaz v. Kaplan Univ.*, 780 F. 3d 1039, 1045, 1051-52 (11th Cir. 2015) (quoting *Corsello,* 428 F.3d at 1012); *see also Jallali v. Nova Se. Univ., Inc.*, 486 F. App'x 765, 766 (11th Cir. 2012)(same). And the Second Circuit admonished that the False Claims Act is not a "blunt instrument" to be used for every false certification of compliance" with the vast and complicated Medicare program. *Mikes,* 274 F. 3d at 699 (cited with approval by *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F. 3d 295, 307 (3d Cir. 2011).

(DE #101, p.8-9).

C. Liability Under the False Claims Act May Only Be Triggered By the Submission of an Actual False Claim to the Government for Payment

As the Eleventh Circuit has made clear, the submission of an actual claim to the government for payment is "the *sine qua non*" of a False Claims Act violation. *Clausen,* 290 F.3d at 1311. Therefore, the "central question" in a claim brought under the False Claims Act is "whether the defendant ever presented a 'false or fraudulent claim' to the government." *Hopper*, 588 F.3d at 1326 (quoting *Clausen,* 290 F.3d at 1311). Rule 9(b) does not permit a relator "merely to describe a private scheme in detail but then to allege simply and without any stated reason for his belief that claims requesting illegal payments *must have been submitted, were likely submitted or should have been submitted to the Government*." *Clausen*, 290 F.3d at 1311 (emphasis added). Instead, Rule 9(b) requires "some indicia of reliability… in the complaint to support the allegation of *an actual false claim* for payment being made to the government." *Id.* (emphasis in original); *see also United States ex rel. Mastej v. Health Mgmt. Assocs., Inc.* 591 F. App'x 693, 703 (11th Cir. 2014) (internal citations and quotations omitted; italics in original) ("Because the submission of an actual claim to the government is the *sine quo non* of an FCA violation, a plaintiff-relator must plead the submission of a false claim with particularity."); *see also Nathan,* 707 F.3d at 456 ("the critical question is whether the defendant caused a false claim to be presented to the government,

because liability under the Act attaches only to a claim actually presented to the government for payment, not to the underlying fraudulent scheme.").

D. Relator Failed to Plead with Particularity the Submission of An Actual False Claim Under the Amended Complaint As Required by Rule 9(b) and Well-Established Eleventh Circuit Precedent

The district court properly found that the Relator failed to plead with particularity the submission of an actual false claim under the Amended Complaint as required by Rule 9(b) and well-established Eleventh Circuit precedent. Citing applicable Eleventh Circuit case law, the district court specifically found:

> Relator has failed to plead with particularity that any claims arising from the allegedly back-dated files, post-dated approvals, improperly signed authorizations and orders, or deceptively described services were in fact submitted to the government or paid as a result of the scheme. *See Hooper*, 588 F. 3d at 1325 (requiring a plaintiff to link the fraudulent scheme to the submission of false claims); *United States ex rel. Atkins v. McInteer*, 470 F. 3d 1350, 1359 (11th Cir. 2006) (holding that the defendants must "provide the next link in the FCA liability chain: showing that the defendants *actually submitted reimbursement claims* for the services he describes"); *Corsello v. Lincare, Inc.*, 428 F. 3d 1008, 1013-14 (11th Cir. 2005) (affirming dismissal where complaint "did not alleged that a specific fraudulent claims was in fact submitted to the government"); *Clausen*, 290 F. 3d at 1311 (calling the submission of a claim to the government the "*sine qua non*" of a False Claims Act violation); *Urquilla-Diaz*, 780 F.3d 1052 (quoting *Hopper*, 588 F. 3d at 1329) ("[T]he relator has to allege with particularity that the defendant's 'false statements ultimately led the government to pay amounts it did not owe.'").

(DE# 101, p.10).

Relator argued at the district court (and now on appeal) that the exhibits submitted in connection with the Amended Complaint[5] provide documentation of "billing events" which are sufficient to meet the heightened pleading requirements under Rule 9(b). (DE #101, p.10). The district court specifically addressed the Relator's argument:

> Relator argues that the exhibits submitted with the original complaint document "billing events." (DE 93 ¶ 12 (citing DE 2). They do not. They contain, for example, patient progress summaries (DE 2-1 at 3), plans of treatment (*id.* at 4), medical notes (*id.* at 7), treatment record charts (*id.* at 10) and clarification orders (DE 2-2 at 9). Relator characterizes the treatment record charts as "billing entries," but there is no evidence that claims were submitted to the government based on the procedures or patient visits reflected by those entries. Since the filing of the original sealed appendix, the treatment record charts have been augmented with hand-written notations of dollar amounts corresponding to billing codes. (*See, e.g.*, DE 93 at 21). Even taking these unauthenticated additions as true, the notations do not covert the treatment records into claims.

(DE #101, p.10).

[5] In support of the Amended Complaint, Relator attached certain exhibits: (i) a so-called "Patient Billing List", a document created by Relator which purports to summarize procedure codes, frequency and charges for certain patients (DE #91, Exhibit A); (ii) declaration of a former patient (DE #91, Exhibit B); (iii) affidavit of Relator (DE #91, Exhibit C); (iv) deposition transcript of Barbara Cuff, Physical Therapist (DE #91, Exhibit D); and (v) deposition transcript of Aleksandra Sarmiento, Physical Therapist Assistant (DE #91, Exhibit E). In addition, Relator attached certain "Patient Monthly Record[s] of Treatment" to Relator's Response to Defendants' Motion to Dismiss. (DE #93, Appendix A).

At the district court (and now on appeal), Relator cites to these exhibits as a "mountain of evidence (including billing and patient records)"[6] which provides sufficient support for the Amended Complaint to survive dismissal. However, the district court properly found that "Fed. R. Civ. P. 9(b) tests for quality, not quantity." (DE #101, p.9) (citing *Keeler,* 568 F. App'x at 794 ("Relator's complaint – however prolix – fails to provide the requisite particularity to survive dismissal."); and *Liaros v. Vaillant*, Fed. Sec. L. Rep. P 99093, at *10 (S.D.N.Y. 1996) ("[O]f course, Rule 9(b) requires quality – or as the rule puts it, 'particularity' – not quantity; and plaintiffs' allegations are anything but particular."). (DE #101, p.9)

In its decision, the district court reinforced that "the 'stringent requirements of Clausen' and its progeny remain the law in the Eleventh Circuit." (DE #101, p.9) (citing *Keeler*, 568 F. App'x at 797 n. 19). According to the district court, "[t]he particularity requirement directs a relator not only to describe the details

[6] The district court noted that the "mountain of evidence" includes "self-generated summaries and scrawled notations that are bereft of any indication of when bills were submitted or paid and lack 'facts as to time, place, and substance of the defendant's alleged fraud, specifically, the details of the defendants' allegedly fraudulent acts, when they occurred and who engaged in them.' *Keeler*, 658 F. App'x at 801 (quoting *Clausen*, 290 F. 3d at 1310). The patient notes, including handwritten commentary, cited by Relator do not provide 'the next link in FCA liability chain.' *Id.*" (DE #101, p.9 at n.10). The district court also noted that the records that Relator "refers to (DE #91 at 2-16) are not actual business records as contemplated by the Federal Rules of Evidence, but are merely a summary of unattributed and uncorroborated information that she has created for this case." (DE #101, p.3 at n.4).

about how the scheme operated (however well that might be pleaded), but to also cite specific occurrences of actual fraud." (DE #101 p.11) (citing *Clausen*, 290 F. 3d at 1305, 1311-12 & n.21). As the district court more fully explained:

> As recognized by the court in *Corsello*, a relator's pleading is insufficient if he "provided the 'who', 'what', 'where', 'when' and 'how' of improper practices, but he failed to allege the 'who', 'what', 'where', 'when' and 'how' of fraudulent submissions to the government." *Corsello*, 428 F. 3d at 1014. Thus, for at least some of the claims, a relator must provide the following: "details concerning the dates of the claims, the content of the forms or bills submitted, their identification numbers, the amount of money charged to the government, the particular goods or services for which the government was billed, the individuals involved in the billing, and the length of time between the alleged fraudulent practices and the submission of claims based on those practices." *Karvelas*, 360 F. 3d at 232-33 (quoting *Clausen*, 290 F. 3d at 1312 n.21).

(DE #101, p.11).

The Relator has failed to provide any of these required billing details in her Amended Complaint. The district court specifically addressed this failure: "Relator has provided none of those details about the billing at issue; all of her allegations concern charting and coding and are premised on the assumption that those charts and codes ultimately translated into particular bills for particular treatments on particular patients that were submitted to the government." (DE #101, p.11). The district court further determined that "Relator's allegation that '[t]he Patient Billing codes demonstrate that Defendants submitted billings for payments,' is insufficient." (DE #101, p.11). In False Claims Act cases, the district court properly found that "the submission of a specific claim is a critical element

and not merely a 'ministerial act.'" (DE #101, p.12) (citing *Clausen*, 290 F. 3d at 1311). *See Atkins*, 470 F. 3d at 1357 (where this Court has refused to "make assumptions about a False Claims Act defendant's submission of actual claims to the Government," because doing so would "strip[] all meaning from Rule 9(b)'s requirement for specificity."); *see also Clausen*, 290 F.3d at 1313 ("[W]e cannot be left wondering whether a plaintiff has offered mere conjecture or a specifically pleaded allegation on an essential element of the lawsuit.").

Based on the foregoing analysis, the district court rejected the Relator's expansive interpretation of Rule 9(b) under the False Claims Act:

> Under Relator's proposed interpretation of the law, merely alleging that a relator has seen patient charts that contained improper billing codes suffices to state a claim. But taking this argument to its logical conclusion would entirely eliminate the presentment and governmental payment requirements of §§ 3729(a)(1)(A) and (B) claims. This expansive interpretation is not supported by the case law. Thus, facts alleging placement, or even alteration, of billing codes do not establish a sufficient predicate unless Relator can link those activities to claims submitted or she can reliably aver the specific facts of who, what, where, when and how the claims were submitted.

(DE#101, p.12).

E. Based Upon this Court's Seminal Decision in *Clausen* and its Progeny, including *Mastej*, the District Court Properly Dismissed the Amended Complaint for Failure to Provide the Required Indicia of Reliability that a False Claim was Actually Submitted to the Government

In her brief on appeal, the Relator-Appellant cites and relies on the recent

Eleventh Circuit decision in *Mastej* to support her argument that the district court erred in dismissing the Amended Complaint for failure to meet the heightened pleading requirements under Rule 9(b).[7] However, the district court's decision was based upon, and consistent with, this Court's seminal decision in *Clausen* and its progeny, including *Mastej*, and the district court properly dismissed the Amended Complaint for failure to provide the required indicia of reliability that a false claim was actually submitted to the government.

In its decision, the district court acknowledged and discussed this Court's decision in *Mastej*. The district court recognized that a relator could survive a 9(b) challenge, without direct evidence of claims submitted to the government, "by showing that she held a position and performed a work function that allowed her to allege – again, with specificity and from personal knowledge – that false claims were submitted." (DE # 101, p.12). The district court stated:

> As the court in *Mastej* explained, "[a]though there are no bright-line rules, our case law has indicated that a relator with direct, first-hand knowledge of the defendants' submission of false claims gained through her employment with defendants may have a sufficient basis for asserting that the defendants actually submitted false claims." *Id.*, 591 F. App'x at 704. Relator argues

[7] Relator also cites to this Court's decision in *Mastej* to support her request for oral argument: "There appears to be confusion over the application of *Clausen* to Rule 9(b), Federal Rules of Civil Procedure, to *qui tam* cases after the *Mastej* decision." (Appellant's Initial Brief at p. i) (footnotes omitted), and includes numerous excerpts from the district court's hearing below in which the *Mastej* decision was discussed. (Id. at pp. 15-21). For the reasons set forth herein, Defendants-Appellants respectively submit that there is no such confusion and the district court discussed and clearly distinguished the *Mastej* decision from the present case.

> that *Mastej* announced a dramatic shift in Eleventh Circuit False Claims Act jurisprudence toward a more relaxed pleading standard that is akin to notice pleading. It did not and subsequent cases have not construed it as such. *See, e.g. Britton*, 2015 WL 1487134, at *4 (citing *Mastej*, 591 F. App'x at 704, 709) ("[A]llegations that false claims 'must have been, were likely submitted or should have been submitted' without more are insufficient to satisfy Rule 9(b).")

(DE #101, p.13).

As the district court explained, this Court in both *Mastej* and *Keeler* discussed an alternate means by which a relator who lacks evidence of actual claims submitted "can lend credibility to [her] claims and propel [them] over pleading hurdles." (DE #101, p.13) (quoting *Keeler*, 568 F. App'x at 801 and citing *Mastej*, 591 F. App'x at 704 ("[O]ther means are available to present the required indicia of reliability that a false claim was actually submitted.")). The district court reiterated that "[t]hose alternate means nevertheless impose strict requirements on qui tam relators and do not constitute a 'relaxation' of the standards set forth in *Clausen*, *Corsello*, *Atkins*, and *Hopper*." (DE #101 p.13) (citing *Mastej,* 591 F. App'x at 704, 707-11).

The *Mastej* court found that "a plaintiff-relator without first-hand knowledge of the defendants' billing practices is unlikely to have a sufficient basis for such an allegation." *Mastej,* 591 F. App'x at 704 (citing *Atkins*, 470 F.3d at 1359 (holding that Rule 9(b) was not satisfied where the relator was a doctor who did not allege first-hand knowledge of the hospital's submission of false claims)). The district court explained:

> For example, it is not enough for a relator simply to have held a title such as "office manager;" fraud claims are properly dismissed when the relator's experience does not equip them to provide sufficient detail and indicia of reliability. *Sanchez*, 596 F.3d at 1302-03. At the very least, a "relator must explain the basis for her assertion that fraudulent claims were actually submitted." *Mastej*, 591 F. App'x at 704. Thus, the role played by Relator and her level of involvement in Defendants' billing practices or receipt of payments are significant. *Id.* (citing *Atkins*, 470 F. 3d at 1359) (quotation omitted).

(DE #101, p.13).

To illustrate the differences in a relator's employment position and having first-hand knowledge of a defendant's billing practices or procedures, the district court started its discussion with the relator's employment position in *Mastej*:

> In *Mastej*, the court found that sufficient indicia of reliability were provided by a relator who acted as both vice president and CEO of defendants, accessed information about billings, revenues, and payor mix, and attended management meetings where Medicare patients and submission of claims were discussed. *Mastej*, 591 F. App'x at 708. Likewise, the Eighth Circuit in *United States ex rel. Thayer v. Planned Parenthood of the Heartland*, 765 F. 3d 914, 919 (8th Cir. 2014), found that 9(b) was satisfied where relator's role as "center manager gave her access to Planned Parenthood's centralized billing system," and her complaint included "specific details about Planned Parenthood's billing systems and practices," based on "personal knowledge of Planned Parenthood's submission of false claims."
>
> ****
>
> In contrast, the Eleventh Circuit found, in *Atkins*, that a "psychiatrist responsible for the provision of medical care, [who was] not a billing and coding administrator responsible for filing and submitting the defendants' claims for reimbursement," could not provide sufficient indicia of reliability to survive dismissal. *Atkins*, 470 F. 3d at 1359. Consequently, it is not enough that a relator "could point to dates of services, name the patients that received the services, and identify the records that would prove his claim;" a pleading is insufficient if the relator cannot "show that any claims were actually submitted to the Government." *Keeler*, 568 F. App'x at 797 n.19

> (citing *Atkins*, 470 F. 3d at 1357); *see also United States ex rel. Gravett v. Methodist Med. Ctr. of Illinois*, 82 F. Supp. 3d 835, 843-44 (C.D. Ill. 2015) (dismissing emergency room physician's claims where "his involvement was in the area of filling out patient charts [and] there [wa]s no indication that he was responsible for or has other first-hand knowledge of Defendants' actual billing practices, submission of claims for payment, or receipt of payments from the Government payors.") Here, while Relator has first-hand knowledge of patient treatment records, she does not have first-hand knowledge of billing practices or procedures.

(DE #101, pp.14-15).

Likewise, the various documents submitted with the Amended Complaint do not provide the required indicia of reliability that a false claim was actually submitted to the government. In its decision, the district court specifically addressed each of these documents:

> Relator argues that that the depositions of Aleksandra Sarmiento and Barbara Cuff, Relator's affidavit, her own summary of patient treatment, and a largely irrelevant patient declaration attesting that the patient reviewed a Medicare explanation of benefits with Relator add "enough meat" to the complaint to survive dismissal. (DE 93 at 11-12, 15). Relator's typed summary is unpersuasive for the same reasons that the hand-written version of the same information does not bolster Relator's allegations. (DE 91-1 at 3-16). Moreover, Relator's affidavit conflates the treatment records with "billing statements" and does not link Defendants' allegedly improper practices with false claims. (*Id.* at 20-21). And, in submitting a patient's declaration, Relator asks the Court to infer that because a single patient asked to review a Medicare explanation of benefits, false claims must have been submitted to the government. (*Id.* at 18). This conclusory leap is contrary to the clear directive of the Eleventh Circuit that courts must not make "assumptions about a False Claims Act defendant's submission of actual claims to the Government." *Clausen*, 290 F. 3d at 1312 n.21.

(DE #101, p.15-16).

The district court also specifically addressed the depositions of Relator's former co-workers, Barbara Cuff, Physical Therapist, and Aleksandra Sarmiento, Physical Therapist Assistant, as potential indicia of reliability that a false claim was actually submitted to the government for payment:

> Citations to Relator's former co-workers' depositions are similarly unpersuasive. Relator's knowledge, whether gained through her own observation or based on therapists Aleksandra Sarmiento and Barbara Cuff, is limited to patient interactions and charting of services rendered. (DE 91 ¶¶ 53-57). Sarmiento's deposition cannot remedy the lack of detail in the complaint: "I don't really bill the Medicare so I really don't know…I'm really not sure about the strict procedures of billing." June 17, 2013 Aleksandra Sarmiento Deposition DE 91-1 at 121:18-20 [footnote omitted]. "I'm mostly a clinician and I assist my therapist in the clinical part more than with the billing. (*Id.* at 123:8-10).
>
> Likewise, Cuff's deposition is heavily laden with exhaustive questioning regarding the tracking of patient treatment but lends no support to Relator's billing claims. In response to questions regarding Medicare billing, Cuff responded "I don't know….I do the eval[uation], put in my charges for the eval[uation], whatever codes apply to that day. It goes into the computer system. What happens to it after that - …I don't deal with it." (June 17, 2013 Barbara Cuff Deposition DE 91-1 at 119:1-17 (attorney questions omitted); *see also id.* at 160: 16-20 ("I'm assuming, but I do not know [if Sundance was reimbursed by Medicare for services rendered.]")). Cuff consistently answered that she had no knowledge regarding claims submission, and when bluntly asked whether the government billed the government "for services that were not rendered," she responded "I don't know that." (*Id.* at 170:9-11; *see also id.* at 171:22-23 ("I have no way of knowing if Medicare paid them for anything. I don't do that.")).

(DE #101 p.16-17)

Based on a full review of the deposition testimony of Barbara Cuff, the district court found that "Cuff's job responsibilities had, at most, a tenuous connection with billing or claims submission; 'I don't know if they billed Medicare

or how they did that. What I did was the services that I delivered on a clinical basis with the charges that I entered into the computer.' (Id. at 148:17-20)." (DE #101, at p.17). Accordingly, the district court properly concluded that the "Relator has failed to plead with particularity that any claims were submitted to the government and reimbursed as a result of the scheme." (DE 101, p. 17-18) (citing, *e.g., Hopper*, 588 F. 3d at 1325).

F. The District Court Properly Rejected Relator's False Certification Theory Under the Same Rule 9(b) Analysis

In reaching its decision to dismiss the Amended Complaint for its pleading deficiencies under Rule 9(b), the district court similarly rejected Relator's theory of false certification for failure to redress these same deficiencies. To plead a claim under the false certification theory, the district court found that the Relator must "allege facts that, if true, would show (1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, causing (4) the government to pay our moneys or forfeit moneys due." (DE #101, p.18) (quoting *Urqullia – Diaz,* 780 F.3d at 1052). The district court addressed Relator's argument that where a complaint raises a theory of implied false certification, a False Claims Act count is adequately pleaded by showing a defendant submitted claims for Medicare reimbursement. The district court properly concluded:

> Relator is partially correct, but the government payment element is lacking and the Court cannot assume that it has been satisfied. *See Clausen*, 290 F. 3d at 1312 n.21; *see also Wilkins*, 659 F. 3d at 307 ("[T]he implied

> certification theory of liability should not be applied expansively."). Ultimately, "[i]t is not enough for the plaintiff-relator to baldly state that [s]he was aware of the defendant' billing practices, to base h[er] knowledge on rumors, or offer only conjecture about the source of h[er] knowledge." *Mastej*, 591 F. App'x at 704-05 (collecting cases) (internal quotations and citations omitted). This is precisely what Relator has done here and why her claims must fail.

(DE #101, p.18)

G. The District Court Properly Dismissed the Conspiracy Claim Under the Amended Complaint[8]

The district court properly dismissed the conspiracy claim (Count III) for the same pleading deficiencies and for an additional reason. First, the district court found that "[t]he requirements of 9(b) are also applicable to conspiracy claims under the False Claims Act and the amended complaint lacks sufficient detail regarding conspiracy. *See Corsello*, 428 F. 3d at 1014." (DE #101, p.18)[9]. Second, citing Fed. R. Civ. P. 8(a)(2), the district court also found that courts dismiss conspiracy claims:

---

[8] Similar to the common law claims (Counts V, VI and VII), Relator-Appellant has also failed to address the district court's dismissal of the conspiracy claim (Count III) in her Initial Brief. Therefore, the Defendants-Appellees respectfully submit that Relator-Appellant has abandoned her appeal with respect to Count III of the Amended Complaint. In an abundance of caution, Defendants-Appellees will briefly address the conspiracy claim in this brief.

[9] To state a claim for conspiracy under Section 3729(a)(1)(C), a relator must show "(1) that the defendant conspired with one or more persons to get a false or fraudulent claim paid by the United States; (2) that one or more conspirators performed any act to effect the object of the conspiracy; and (3) that the United States suffered damages as a result of the false or fraudulent claim." (DE #101, p. 18-19) (quoting *Corsello,* 428 F.3d at 1014).

> when relators fail to plead sufficient facts supporting the assertion that defendants agreed to violate the False Claims Act. *see e.g., id.; United States ex rel. Graves v. Plaza Med. Centers Corp.*, Case No. 10-23382 –CIV, 2014 WL 5040284 at *3 (S.D. Fla. Oct. 8, 2014 ("The bare assertion that the Defendants conspired' to violate the False Claims Act was entirely conclusory, and legal conclusions are insufficient under Fed. R. Civ. P. 8(a)(2) and certainly under the heightened Rule 9(b) standard."). Relator concludes, without any support, that "Defendants herein did knowingly and intentionally combine, conspire, confederate and agree with persons known and unknown to" violate the False Claims Act. (DE 91 ¶112). This is plainly insufficient. *See* Fed. R. Civ. P. 9(b); Fed. R. Civ. P. 8(a); *Corsello*, 428 F. 3d at 1014.

(DE #101, p.19).

Based on the foregoing, the district court properly dismissed the conspiracy claim (Count III) of the Amended Complaint.

H. The Relator's False Claims Act Claims under the Amended Complaint Were Properly Dismissed under Rule 9(b) Based on a More Detailed Analysis under the Eleventh Circuit's Recent Decision in *Mastej*

As previously noted, the Relator-Appellant cites and relies on the recent Eleventh Circuit decision in *Mastej* to support her argument that the district court erred in dismissing the Amended Complaint for failure to meet the heightened pleading requirements under Rule 9(b). In addition to the discussion of the *Mastej* decision by the district court, the Defendants-Appellants respectfully submit that the fraud allegations under the *Mastej* case are clearly distinguishable from the fraud allegations in the present case. Therefore, this Court's decision in *Mastej* fails to support Relator's arguments in this appeal.

To more fully understand the holding of the *Mastej* decision, it is important to understand the factual background and the specific fraud allegations under this relator's complaint. Relator Mastej was the former Vice President of Acquisitions and Development of the defendant parent company of a hospital system ("HMA") from 2001 to February 2007, and from February 2007 to October 2007, became the Chief Executive Officer ("CEO") of the defendant HMA hospital ("Medical Center"). *Mastej,* 591 Fed.. Appx. at 695. The underlying bases for Mastej's False Claims Act claims are his allegations that: (1) the defendants made "on call" payments to six neurosurgeons for emergency neurosurgery coverage pursuant to "call coverage" contracts from 2007-2009 and provided a free golf trip to four other physicians in 2008 to induce them to refer, or to reward them for referring, Medicare patients to the Medical Center; (2) those ten physicians referred Medicare patients to the Medical Center for medical services, which were provided; (3) the Medical Center submitted "interim claim forms" and annual "hospital cost reports" requesting payment for the referred patients' medical treatment, which Medicare paid; (4) the defendants violated the Stark Law and Anti-Kickback Statute by seeking any Medicare reimbursement at all for the treatment of patients referred by the physicians to whom the defendants had given improper benefits; and (5) the defendants then falsely certified to the government in the hospital cost reports that the services were provided in compliance with

applicable laws, including the Stark Law and the Anti-Kickback Statute. *Id. at 697.*

In the context of these fraud allegations, the *Mastej* Court summarized the well-established law for the application of *Rule 9(b)* in False Claims Act cases and reaffirmed its seminal decision in *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301 (11th Cir. 2002).[10] The *Mastej* Court explained that it evaluates "whether the allegations of a complaint contain sufficient indicia of reliability to satisfy *Rule 9(b)* on a case-by-case basis." *Id.* at 704. (citing *United States ex rel. Atkins v. McInteer,* 470 F.3d 1350, 1358 (11th Cir. 2006)). Under this case-by-case approach, the *Mastej* Court noted that "other means are available to present the required indicia of reliability that a false claim was actually submitted" and recognized that "[Eleventh Circuit] case law has indicated that a relator with direct, first-hand knowledge of the defendants' submission of false claims gained through her employment with the defendant may have a sufficient basis for asserting that the defendants actually submitted false claims." *Id.*

[10] The *Mastej* court reiterated that *Rule 9(b)* "does not permit a False Claim Act plaintiff merely to describe a private scheme in detail but then to allege simply and without any stated reason for his belief that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government." *Clausen,* 290 F.3d at 1311. Instead, "some indicia of reliability must be given in the complaint to support the allegation of an actual false claim for payment being made to the Government." *Id.* at 703-704.

By contrast, the *Mastej* Court recognized that a plaintiff-relator without first-hand knowledge of billing practices (i.e. claims submission process) is unlikely to have a sufficient basis for such an allegation. Id. (citing *Atkins,* 470 F. 3d at 1359). According to the Court's decision in *Mastej*:

> At the minimum, a plaintiff-relator must explain the basis for her assertion that fraudulent claims were actually submitted. See *Corsello v. Lincare, Inc.,* 428 F.3d 1008, 1013-14 (11th Cir. 2005) (finding insufficient indicia of reliability after noting that the relator "did not explain why he believes fraudulent claims were ultimately submitted.") It is not enough for the plaintiff-relator to state baldly that he was aware of the defendants' billing practices, see *id.* at 1014, to base his knowledge on rumors, see *Atkins,* 470 F. 3d at 1359, or offer only conjecture about the source of his knowledge, see *United States ex rel. Sanchez v. Lymphatx, Inc.,* 596 F. 3d 1300, 1303 n. 4 (11th Cir. 2010).

Id. at 704-705.

Based on the Eleventh Circuit's heightened pleading standard, and given the type of fraud alleged in the complaint, this Court concluded: "Mastej's complaint contains sufficient indicia of reliability for his personal knowledge that the Defendants actually submitted interim claims to Medicare for patient referred to the Medical Center as part of the on-call incentive scheme during 2007" because, as HMA Vice President and then Medical Center CEO from February 2007 until October 2007, "he had direct information about [the Medical Center's] billings, revenues, payor mix, and he was in the very meetings where Medicare patients and the submission of claims to Medicare were discussed." *Id.* at 707.

Importantly, in performing the Rule 9(b) analysis on a case-by-case basis, the Court reasoned that the type of information which would be sufficient indications of reliability that actual claims were submitted would depend on the type of fraud allegations in the complaint. The *Mastej* Court stated:

> Critical to this conclusion is also the fact that the type of fraud alleged here does not depend as much on the particularized medical or billing content of any given claim form. In other FCA cases, the allegation is that a defendant's Medicare claim contained a false statement because the claim sought reimbursement for particular medical services never rendered to the patient, see *Atkins,* 470 F.3d at 1354*; Corsello,* 428 F.3d at 1011*; Sanchez,* 596 F.3d at 1302; or for medical services that were unnecessary, overcharged, or miscoded, see *Clausen,* 290 F.3d at 1302*; Corsello,* 428 F.3d at 1011*; Atkins,* 470 F.3d at 1354; or for improper prescriptions, see *Hopper,* 588 F.3d at 1322; or for services not covered by Medicare, see *Sanchez,* 596 F.3d at 1302 & n.2. In those types of cases, representative claims with particularized medical and billing content matter more, because the falsity of the claim depends largely on the details contained within the claim form – such as type of medical services rendered, the billing code or codes used on the claim form, and what amounts was charged on the claim form for the medical services.

Id. at 708.

In her Amended Complaint, Relator fails to identify a single specific *claim* that she alleges was *presented to or paid* by the federal government. She fails to allege any *services* that were actually *presented* in a claim to the federal government or *paid* by the federal government. She fails to allege the *date* any claim was actually presented to or paid by the federal government. She fails to allege the *amount* of any claim that was actually presented to or paid by the federal

government. She also fails to allege *who submitted* any claim to the federal government.

In short, at no point in her Amended Complaint does Relator state which entity of the three named Defendants actually submitted any claim to Medicare, what date(s) any claim was actually submitted to Medicare, the services or the amounts allegedly billed to Medicare on any claim form, and whether any payment or how much payment was ever received any Defendant based on any submitted claim. Accordingly, Relator's action is subject to dismissal for its failure state facts as to time, place and substance of the Defendants' alleged fraudulent submission to the government or payment by the government. *See Hopper,* 588 F.3d at 1324*; see also Corsello,* 428 F.3d at 1014.

With respect to the type of fraud allegations in the Amended Complaint, the underlying theme of Relator's case is that the Defendants engaged in a purported scheme under which certain employees of Defendants (i.e. Physical Therapist and Physical Therapist Assistant) allegedly altered certain patient records "after-the-fact" and engaged in other improper documentation practices. Under the *Mastej* Court's analysis, it is clear that these type of fraud allegations warrant the Amended Complaint to include representative claims with particularized medical and billing content because the falsity of the claim depends largely on the details contained within the claim form as well as the existence and timing of the claim

submission – such as whether any claim was actually submitted for the patient in question; if so, on what date was a claim actually submitted for payment after the services and applicable medical records were provided; what were the billing code or codes used on the actual claim form as compared to the applicable medical records for the services; and what amounts were charged on the actual claim form for the services in question as compared to the applicable medical records.

By contrast, the type of fraud allegations in Mastej's complaint did not depend on any information in the claim form or the precise timing of any claim submission – if Mastej's allegations of the illegal on-call referral incentive scheme were true, then *every* claim submitted by the defendants for services rendered to patients by these neurosurgeons after the alleged Stark and Anti-Kickback violations occurred would be "false" within the meaning of the False Claims Act. Stated differently, Mastej's fraud allegations in his Complaint were *not* "claim-specific" for purposes of applying the "indicia of reliability" standard under *Rule 9(b)* and therefore did not require representative claims to meet this standard. Unlike the fraud allegations in Mastej's complaint, the fraud allegations in the Relator's Amended Complaint are, by definition, "claim-specific". Therefore, this Court should require representative claims with particularized medical and billing content to be attached to the Amended Complaint for purposes of applying the "indicia of reliability" standards under Rule 9(b).

As explained by the *Mastej* Court, this Court must evaluate whether the allegations of a complaint contain sufficient "indicia of reliability" to satisfy *Rule 9(b)* on a case-by-case basis. *Id.* at 703 (citing *Atkins,* 470 F.3d at 1358). As more fully described above, Relator has failed to attach any representative claim that was actually submitted to the government and therefore fails to meet Rule 9(b) based on the fraud allegations in the Amended Complaint. With respect to other indications of reliability in the Amended Complaint, Relator has made only bare conclusory allegations that Relator has personal knowledge of Defendants' "internal billing practices" and has failed to plead with particularity and with sufficient indicia of reliability that Relator has personal knowledge of any fraudulent claim that was actually submitted or presented to the government by Defendants or that the government paid any fraudulent claim. And for the reasons clearly set forth by the district court in its Order, the exhibits submitted by Relator in support of the Amended Complaint likewise fail to provide the required indicia of reliability that false claims were actually submitted to the government or paid by the government.

I. Conclusion

Based on the foregoing, the district court properly dismissed Relator's claims under the False Claims Act (Counts I, II and III) for failure to plead fraud with particularity, as required by Rule 9(b), and in accordance with well-

established Eleventh Circuit precedent interpreting the heightened pleading requirements under Rule 9(b) in the context of False Claims Act complaints.

II. The District Court Properly Dismissed Relator's Claim Under the Anti-Kickback Statute (Counts IV) For Failure To Plead Fraud With Particularity, As Required By Federal Rule Of Civil Procedure 9(b)

A. The District Court's Decision Dismissing Relator's Claim Under the Anti-Kickback Statute

Generally speaking, the Anti-Kickback Statute prohibits a person from financially inducing another person to refer a Medicare patient. *See 42 U.S.C. §1320a-7b(b)*. More specifically, the Anti-Kickback Statute forbids knowingly "offer[ing] or pay[ing] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person…to refer an individual [for medical services] for which payment may be made in whole or in part under a Federal health care program" such as Medicare. *42 U.S.C. §1320a-7b(b)(2)(A)*; *see Mastej*, 591 F. App'x at 698; *see also 42 U.S.C. §1320a-7b(b)(3)* (providing exceptions to the general rule).

It is well-established in the Eleventh Circuit that allegations of kickbacks can create potential liability under the False Claims Act where compliance with the Anti-Kickback is a prerequisite for payment. (DE #101, p.20) (citing *Keeler*, 568 F. App'x at 799 and *McNutt v. Haleyville Med. Supplies, Inc.*, 423 F. 3d 1256, 1259-60 (11th Cir. 2005)). It is equally well-established that, as with any basis for liability under the False Claims Act, claims under the Anti-Kickback Statute are

subject to Rule 9(b)'s heightened pleading requirements. (DE #101, p.20) (citing *Keeler*, 568 F. App'x at 799).

After outlining the Eleventh Circuit standard for an Anti-Kickback Statute claim in the context of the False Claims Act, the district court made the following findings:

> Despite some discussion of improper referrals, the gravamen of Relator's kickback claim is that Defendants, through Area Manager Heidi Kreikemeier, violated 42 U.S.C. §1320a-7b(b) when they paid Cuff and Sarmiento for three work days spent "back-dating and recreating patient records." (DE 91 ¶ 129). However, there are few details to support a conclusion that any patient record allegedly modified by Defendants – assuming [footnote omitted] paying Cuff and Sarmiento for this work constitutes a kickback – resulted in a submission of a claim to the government
>
> As discussed above, Relator has not identified any claims submitted to the government for payment or specific certifications of compliance made and thus fails to connect the scheme to particular instances of fraud or misrepresentation.... *Keeler,* F. App'x at 800; *McNutt*, 423 F. 3d at 1260 (holding that dismissal was not appropriate where the government identified "numerous specific claims" submitted by defendants "for reimbursement knowing that they were ineligible for the payments demanded in those claims.").

(DE #101, p.20-21).

Based on the foregoing, the district court properly dismissed Relator's claim under the Anti-Kickback Statute (Counts IV) for failure to plead fraud with particularity, as required by Federal Rule of Civil Procedure 9(b).

B. The Relator's Allegations under Count IV Did Not Include Any Conduct Which is Prohibited by the Anti-Kickback Statute

In addition to the rationale of the district court to dismiss the Anti-Kickback Statute claim, Relator's allegations under Count IV of the Amended Complaint fail as a matter of law for other reasons. As a starting point, Relator fails to allege any patient who was *unlawful referred* by any physician to any Defendant which resulted in the submission of any false claim. Moreover, Relator's claims under Count IV do not include any allegations that the Defendants engaged in any conduct which is statutorily proscribed by the terms of the Anti-Kickback Statute, as such conduct is defined in the Anti-Kickback Statute (hereinafter, collectively, the "Prohibited Referral Conduct"). Under Count IV, Relator does not allege that any of the Defendants or their employees, including the Area Manager, Physical Therapist ("PT") and Physical Therapist Assistant ("PTA"), engaged or performed any of the Prohibited Referral Conduct as described under the Anti-Kickback Statute.

More specifically, the Amended Complaint merely alleges a "sizable number of billable hours" were paid to the PT and the PTA by Defendants to conduct certain activities which are outside the scope of the Anti-Kickback Statute, specifically alleging that the PT and PTA were paid "to back-date and perform after-the fact edits of patient notes, evaluations and records." (See DE #91 ¶ 128). Stated differently, none of the allegations under Count IV of the Amended

Complaint include any Prohibited Referral Conduct as described under the Anti-Kickback Statute, including the payment of "any remuneration…to any person to induce such person to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service…[or] to purchase, lease, order or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal healthcare program…." 42 U.S.C. § 1320a-7b(b)(2)(A), (B). The payment of compensation by Defendants to their employees for allegedly "back-dating" certain patient records or otherwise altering any records does not, under any reasonable interpretation of the Anti-Kickback Statute, fall within the scope of prohibited conduct defined under the Anti-Kickback Statute.

C. Even Assuming the Relator's Allegations Under Count IV Describe Conduct Prohibited by the Anti-Kickback Statute, Such Allegations Clearly Fall within the Employment Exception to the Anti-Kickback Statute

Assuming *arguendo* that the allegations somehow describe conduct that is prohibited by the Anti-Kickback Statute, Count IV of the Amended Complaint fails to state a claim upon which relief can be granted because the allegations clearly fall within a statutory exception under the Anti-Kickback Statute. This Anti-Kickback Statute exception, known as the "Employment Exception", extends to "any amount paid by any employer to any employee (who has a bona fide employment relationship with such employer) for employment in the provision of

covered items or services." *42 U.S.C. § 1320a-7b(b)(3)(B)*. Accordingly, any compensation paid by an employer to an employee for the provision of covered services under the Medicare program[11] is expressly exempt by Congress from the application of the Anti-Kickback Statute.

In Count IV of the Amended Complaint, Relator simply alleges that Defendants violated the Anti-Kickback Statute by directing certain employees (PT and PTA) to improperly alter medical records of patients under the Medicare program, in exchange for compensation as employees of Defendants. Taking her allegations of the Amended Complaint as true, and even without applying the applicable "heightened pleading" standard under Federal Rules of Civil Procedure 9)(b), Relator's allegations under Count IV fail to "state a claim to relief that is plausible on its face". *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1953, 173 L.Ed. 2d 868 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570, 127 S.Ct. 1955, 1974, 167 L. Ed. 2d 929 (2007)).

In a recent decision, a district court within the Eleventh Circuit applied this "employment exception" under the Anti-Kickback Statute in the context of a *qui tam* complaint in the health care setting. *United States ex rel. Baklid-Kunz v.*

---

[11] Outpatient therapy services (e.g. physical and occupational therapy) are covered services under the Medicare program. Relator alleges in the Amended Complaint that services of physical and occupational therapists are covered by Medicare Part B. (DE #91 ¶ 18); See also 42 U.S.C. § 1395k(a)(2)(C).

Halifax Hospital Medical Center and Halifax Staffing, Inc., 2014 U.S. Dist. LEXIS 1950 (M.D. Fla. January 8, 2014). In *Baklid-Kunz,* the defendants moved for summary judgment based on the "Employment Exception" under the Anti-Kickback Statute. The background of the *Baklid-Kunz* case included a dispute in discovery as to whether the physicians at issue who allegedly made improper referrals – certain oncologists, neurosurgeons and psychiatrists – were independent contractors of defendant Halifax Hospital, rather than employees. Based on the facts in that case, the district court found that the relator failed to establish a genuine issue of material fact as to whether the physicians at issue had a bona fide employment relationship with defendant Halifax Hospital for purposes of the Anti-Kickback Statute. *Id.* Accordingly, the district court found that the "Employment Exception" under the Anti-Kickback Statute applied, and granted summary judgment in favor of the defendants as to the relator's claims under the Anti-Kickback Statute.

Under this Amended Complaint, Relator has alleged that the PT, PTA and the Area Manager are employees of Defendants who engaged in certain acts which allegedly violate the Anti-Kickback Statute. Specifically, Relator alleges that "Defendants, through employees PT, PTA and Kreikemeier violated the Anti-Kickback Statute…." (DE# 91 ¶125), and further alleges that PT and PTA were paid for altering patient records (DE#91 ¶128).

As such, and accepting the allegations of the Amended Complaint as true for purposes of Defendants' Motion to Dismiss, Defendants clearly meet the "Employment Exception" under the Anti-Kickback Statute since the PT and PTA are specifically alleged to be employees of the Defendants. The payment of compensation by Defendants to their employees (PT and PTA) in connection with the provision of therapy services as a covered service under the Medicare program is precisely the type of employment activities entitled to protection under the "Employment Exception" of the Anti-Kickback Statute. As the *Baklid-Kunz* court found, the "[t]he '[i]llegal remuneration' section of the Anti-Kickback Statute states that the prohibitions against providing compensation in exchange for referrals shall not apply to 'any amount paid by any employer to any employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services.' 42 U.S.C. § 1320a-7b(b)(3)(B)". *Id. at 13-14.* Accordingly, Defendants are entitled, as a matter of law, to the dismissal of Count IV of the Amended Complaint.

D. Conclusion

The district court properly dismissed Relator's claim under the Anti-Kickback Statute (Count IV) for failure to plead fraud with particularity, as required by Federal Rule of Civil Procedure 9(b). In addition, none of the alleged conduct or actions of the Defendants or their employees is prohibited by the Anti-

Kickback Statute. Furthermore, even assuming that the allegations under Count IV somehow included conduct which is prohibited by the Anti-Kickback Statute, such allegations clearly fall within the "Employment Exception" of the Anti-Kickback Statute. Stated differently, even viewing the allegations in a light most favorable to Relator, the Anti-Kickback Statute allegations as pleaded under the Amended Complaint against the Defendants and their PT and PTA employees clearly meet the "Employment Exception" under the Anti-Kickback Statute. Therefore, in addition to the pleading deficiencies under Rule 9(b) set forth by the district court, Defendants are entitled to dismissal of Count IV of the Amended Complaint as a matter of law.

CONCLUSION

For the reasons set forth herein, the district court's order dismissing the Amended Complaint with prejudice should be affirmed.

CERTIFICATE OF COMPLIANCE

I certify that this brief complies with the type-volume limitations set forth in FRAP 32(a)(7)(B). This brief contains 12,729 words.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 16th day of December, 2015, a copy of the foregoing was filed and served by electronic ECMC notice upon:

Franklin G. Monsour, Jr., United States Attorney's Office
Email: Franklin.Monsour@usdoj.gov

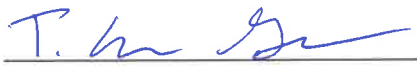
Benjamin David Sharkey, Esquire
Email: sharkeyb@jacksonlewis.com

Colin A. Thakkar, Esquire
Email: colin.thakkar@jacksonlewis.com

T. Andrew Graham, Esquire
Email: agraham@hallboothsmith.com

Robert O. Saunooke, Esquire
Email: ndnlawyer@hotmail.com

HALL BOOTH SMITH, P.C.
191 Peachtree Street, NE, Suite 2900
Atlanta, Georgia 30303
Telephone: (404) 954-5000
Facsimile: (404) 954-5020

By: 

T. Andrew Graham
Attorney-in-Charge
Georgia Bar Number: 304777
Attorneys for Appellees

JACKSON LEWIS, LLP
501 Riverside Avenue, Suite 902
Jacksonville, Florida 32202
Telephone: (904) 638-2655
Facsimile: (904) 638-2656

By: 
Benjamin D. Sharkey
Florida Bar Number: 0389160
sharkeyb@jacksonleweis.com
Colin A. Thakkar
Florida Bar Number: 0010242
colin.thakkar@jacksonlewis.com
Attorneys for Appellees