

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

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THOMAS FOGLIA, in the name	:	
of the United States	:	
Government pursuant to the	:	
False Claims Act, 31 U.S.C.	:	Civ. A. No. 09-1552 (NLH) (AMD)
Section 3730; the State of	:	
New Jersey False Claims Act,	:	
Title 2A of the New Jersey	:	
Statutes and amending	:	
3 P.L. 1968, c.413; the State	:	<b>OPINION</b>
of Texas pursuant to	:	
TEX.HUM.RES.CODE Sec.	:	
36.001-36.117 and individually:	:	
pursuant to the New Jersey	:	
Conscientious Employee	:	
Protection Act, N.J.S.A.	:	
34:19-1 et seq.,	:	
	:	
Relator/Plaintiff,	:	
	:	
v.	:	
	:	
Renal Ventures Management,	:	
LLC,	:	
	:	
Defendant.	:	

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**HILLMAN, District Judge:**

This matter involves a qui tam claim under the False Claims Act ("FCA"), 31 U.S.C. § 3729 et seq., arising out of allegedly fraudulent claims for Medicare funds. Presently before the Court is a motion for partial judgment on the pleadings pursuant to

Fed. R. Civ. P. 12(c) filed by Defendant, Renal Ventures Management, LLC.<sup>1</sup> The Court has considered the parties' submissions, and for the reasons that follow Defendant's motion for partial judgment on the pleadings is granted in part and denied in part.

## **I. BACKGROUND**

Defendant is a dialysis care services company that provides all forms of dialysis care for patients with end-stage renal disease. (Am. Compl. ¶ 2.) Defendant's services include in-hospital and outpatient hemodialysis, peritoneal dialysis, home dialysis and a transplant referral program. (Id.) Defendant operates numerous dialysis centers in New Jersey, Texas, Iowa, Arkansas, and Pennsylvania. (Id.) Defendant is responsible for "all management, and training, including the acquisition of all equipment, technology, supplies, employee benefits and administrative services, including all back-office operations, which include all billing and collection functions." (Id. at ¶ 3.) One of Defendant's dialysis centers is known as the Renal Center of Sewell, LLC and is located in Sewell, New Jersey. (Id.

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1. Defendant filed a motion seeking entry of a protective order limiting discovery or, in the alternative, entry of partial judgment on the pleadings. The Court, by Order dated April 6, 2011, denied the motion without prejudice insofar as Defendant sought a protective order, and directed Relator to respond to Defendant's motion for partial judgment on the pleadings. (Order 2, Apr. 6, 2011.)

at ¶ 2.)

Relator Thomas G. Foglia alleges that he was a registered nurse who began employment at Defendant's Sewell, New Jersey dialysis center on March 13, 2007. (Id. at ¶ 1.) Relator's employment was terminated on November 7, 2008, allegedly in retaliation for Relator's complaints about purported illegal conduct by Defendant. (Id. at ¶¶ 1, 40-41.) Relator contends that during his employment he observed a number of violations of state law as set forth herein. (Id. at ¶ 8.)

In the amended complaint, Relator avers that Defendant was required, pursuant to certain administrative regulations promulgated by the State of New Jersey, to staff its dialysis centers with at least one registered nurse for every nine patients receiving dialysis services on the premises and at least one registered nurse, licensed practical nurse or trained patient care technician for every three patients receiving dialysis services. (Am. Compl. ¶¶ 6-7.) Relator alleges that he observed on a "recurring and routine" basis that the ratio of registered nurses to patients failed to comply with the New Jersey administrative regulations,<sup>2</sup> and that Defendant failed to comply

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2. Plaintiff identifies the following dates on which there was purportedly an insufficient number of registered nurses on premises: March 12, 2008, March 26, 2008, April 14, 2008, August 20, 2008, September 29, 2008, and October 29, 2008. (Am. Compl. ¶ 8.)

with other state regulations such as an illegal staff-to-patient ratio.<sup>3</sup> (Id. at ¶ 8.) The other alleged violations Plaintiff observed include Defendant's failure to check a reverse osmosis water system on May 30, 2008, a patient receiving dialysis on August 22, 2008 without having been medically cleared by a doctor, patients having received dialysis on August 25, 2008 and October 1, 2008 with unarmed air detectors, and an unlicensed person administering medications on October 17, 2008.<sup>4</sup> (Id.) Additionally, Relator contends that the dialysis unit in Sewell is mandated and licensed to operate with a maximum of eighteen patients but purportedly routinely operates with twenty-two to twenty-three patients on the floor. (Id.)

In addition to the foregoing, Relator contends that Defendant improperly used and billed for a drug called Zemplar, a prescription medication administered by injection, which is a "metabolically active form of Vitamin D used for the prevention and treatment of secondary hyperparathyroidism associated with chronic kidney disease[.]" (Am. Compl. ¶¶ 9, 17, 26.) Relator

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3. Plaintiff lists the following dates on which there was purportedly an insufficient number of staff members on premises: May 26, 2008, July 21, 2008, August 1, 2008, August 18, 2008, August 29, 2008, September 5, 2008, October 22, 2008, October 24, 2008, October 27, 2008, October 29, 2008, and November 7, 2008. (Am. Compl. ¶ 8.)

4. Although Plaintiff does not identify the year of this alleged violation, it appears based on the time period of the other alleged violations that this event occurred in 2008.

avers that Zemplar is available as a sterile, colorless aqueous solution for intravenous injection in 2 mcg, 5 mcg or 10 mcg vials, and Defendant purportedly orders and stocks only the 5 mcg vials. (Id. at ¶ 10.) Relator asserts that both the drug manufacturer and the Food and Drug Administration “clinically recommend[] and direct[]” that when the contents of a vial are not completely used, the remaining drug should be discarded. (Id. at ¶ 12.) Relator contends that Defendant has disregarded this recommendation and administers leftover Zemplar to patients rather than using a new vial of Zemplar each time the drug is administered. (See id. at ¶ 26.)

On April 1, 2009, Plaintiff brought suit in this Court individually and in the name of the United States, the State of New Jersey, and the State of Texas under the federal FCA and the qui tam provisions in 31 U.S.C. § 3730(b). On September 23, 2009, the State of Texas declined to intervene in this matter. The United States declined to intervene on September 24, 2009, and the State of New Jersey declined intervention on November 4, 2009. Relator filed an amended, redacted complaint on May 12, 2010. The amended complaint contains four counts: Count I alleges a violation of the federal FCA, Count II alleges a violation of the New Jersey False Claims Act, Count III alleges a violation of the Texas Medicaid Fraud Prevention Act, and Count IV alleges a violation of the New Jersey Conscientious Employee

Protection Act, N.J.S.A. 34:19-1 et seq., based on Relator's alleged retaliatory discharge for complaining about Defendant's purported illegal conduct.

Relator has three theories of liability underlying his false claim allegations. One theory of liability is predicated on Relator's contention that Defendant received government funds but failed to comply with applicable New Jersey regulations concerning adequate staffing of dialysis facilities. A second, related theory of liability is that Defendant receives government funds but failed to comply with certain quality of care drug use standards requiring one time use of vials containing Zemplar. Relator's third theory of liability is also based on Defendant's administration of Zemplar, as Relator contends that Defendant gave patients unused portions of previously-opened vials of the drug but sought reimbursement for each vial that should have been or could have been used based on the prescribed doses. According to Relator, Defendant submitted claims for reimbursement to federal payors, such as Medicare or Medicaid, for up to fifty vials of Zemplar per day when only twenty-nine to thirty-five vials were actually used. (Am. Compl. ¶ 20.)<sup>5</sup>

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5. As noted supra, Relator also asserts a claim under the New Jersey Conscientious Employee Protection Act, but this claim is not at issue on the motion presently before the Court.

## II. DISCUSSION

### A. Subject Matter Jurisdiction

This Court has jurisdiction over Relator's federal claims under 28 U.S.C. § 1331, and may exercise supplemental jurisdiction over Relator's related state law claim under 28 U.S.C. § 1367.

### B. Standard for Judgment on the Pleadings

A Rule 12(c) motion for judgment on the pleadings may be filed after the pleadings are closed. Fed. R. Civ. P. 12(c); Turbe v. Gov't of V.I., 938 F.2d 427, 428 (3d Cir. 1991). In analyzing a Rule 12(c) motion, a court applies the same legal standards as applicable to a motion filed pursuant to Federal Rule of Civil Procedure 12(b)(6). Turbe, 938 F.2d at 428.

When considering a motion to dismiss a complaint for failure to state a claim upon which relief can be granted pursuant to Rule 12(b)(6), a court must accept all well-pleaded allegations in the complaint as true and view them in the light most favorable to the plaintiff. See Evancho v. Fisher, 423 F.3d 347, 350 (3d Cir. 2005). A complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2).

A district court, in weighing a motion to dismiss, asks "not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims."



Bell Atl. Corp. v. Twombly, 550 U.S. 544, 563 n.8, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007) (quoting Scheuer v. Rhoades, 416 U.S. 232, 236, 94 S. Ct. 1683, 40 L. Ed. 2d 90 (1974)); see also Ashcroft v. Iqbal, 556 U.S. 662, 129 S. Ct. 1937, 1953, 173 L. Ed. 2d 868 (2009) (“Our decision in Twombly expounded the pleading standard for ‘all civil actions[.]’”) (citation omitted). The Third Circuit has instructed district courts to conduct a two-part analysis in deciding a motion to dismiss. Fowler v. UPMC Shadyside, 578 F.3d 203, 210 (3d Cir. 2009).

First, a district court “must accept all of the complaint’s well-pleaded facts as true, but may disregard any legal conclusions.” Fowler, 578 F.3d at 210-11 (citing Iqbal, 129 S. Ct. at 1949). Second, a district court must “determine whether the facts alleged in the complaint are sufficient to show that the plaintiff has a ‘plausible claim for relief.’” Id. at 211 (quoting Iqbal, 129 S. Ct. at 1950). “[A] complaint must do more than allege the plaintiff’s entitlement to relief.” Id. “[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged – but it has not ‘show[n]’ – ‘that the pleader is entitled to relief.’” Id. (quoting Iqbal, 129 S. Ct. at 1949); see also Phillips v. County of Allegheny, 515 F.3d 224, 234 (3d Cir. 2008) (“The Supreme Court’s Twombly formulation of the pleading standard can be summed up thus: ‘stating . . . a claim

requires a complaint with enough factual matter (taken as true) to suggest' the required element. This 'does not impose a probability requirement at the pleading stage,' but instead 'simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of' the necessary element.") (quoting Twombly, 550 U.S. at 556).

A court need not credit "'bald assertions'" or "'legal conclusions'" in a complaint when deciding a motion to dismiss. In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1429-30 (3d Cir. 1997). The defendant has the burden of demonstrating that no claim has been presented. Hedges v. United States, 404 F.3d 744, 750 (3d Cir. 2005) (citing Kehr Packages, Inc. v. Fidelcor, Inc., 926 F.2d 1406, 1409 (3d Cir. 1991)).

In this case, the amended complaint alleges violations of the federal FCA and the false claim statutes of New Jersey and Texas. Because these claims implicate fraud statutes, Relator's allegations with respect to these claims must satisfy the heightened pleading requirements of Fed. R. Civ. P. 9(b). See United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc., 149 F.3d 227, 234 (3d Cir. 1998) (noting that Rule 9(b) "requires plaintiffs to plead fraud with particularity, specifying the time, place and substance of the defendant's alleged conduct[,]" and thus "provides sufficient deterrence against overly broad allegations" under the False Claims Act).

Accordingly, Relator must plead "with particularity the circumstances constituting fraud[,] " but "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). The Third Circuit has held that "Fed.R.Civ.P. 9(b) requires plaintiffs to plead the circumstances of the alleged fraud with particularity to ensure that defendants are placed on notice of the 'precise misconduct with which they are charged, and to safeguard defendants against spurious charges' of fraud." Craftmatic Sec. Litig. v. Kraftsow, 890 F.2d 628, 645 (3d Cir. 1989) (quoting Seville Indus. Mach. Corp. v. Southmost Mach. Corp., 742 F.2d 786, 791 (3d Cir. 1984), cert. denied, 469 U.S. 1211, 105 S. Ct. 1179, 84 L. Ed. 2d 327 (1985)).

### **C. Analysis**

Defendant moves to dismiss the amended complaint insofar as Relator attempts to assert a False Claim Act violation based on a "false certification" theory, as well as any allegation that Defendant submitted false claims to the State of Texas. Defendant contends that the claims based on the "false certification" theory must be dismissed as the Third Circuit has not recognized such a cause of action. (Br. in Supp. of Def.'s Mot. for Protective Order or, in the Alternative, for Partial J. on the Pleadings ("Def.'s Br.") 17.) Defendant alternatively asserts that Relator failed to plead this theory with the

requisite specificity. (Id.) Additionally, to the extent Relator alleges that Defendant submitted false claims to the State of Texas, Defendant asserts that such allegations must be dismissed because Relator fails to identify a single false claim submitted for payment to the State of Texas, any Texas regulations alleged to have been violated that were material to payment, and facts sufficient to satisfy the specificity requirements of Fed. R. Civ. P. 9(b). (Id. at 17-18.)

Relator responds that he has properly pled his false claim allegations. Relator argues that the complaint states that Defendant submitted false claim information on which payment is based by "failing to adhere to the requirements of federal and state law and violation of public policy concerning the public health, safety or welfare such [as] the staffing requirements set forth in Title 8:43A-24.7(c) . . . and Subparagraph d of Title 8:43A-24.7[.]" (Pl.'s Reply to Def.'s Mot. for Protective Order or, in the Alternative, Mot. for Partial J. on the Pleadings ("Pl.'s Opp. Br.") 10-11.) Relator also asserts that the complaint properly pleads that Defendant submits false claims for reimbursement by submitting claims for payment for Zemplar based on the full use of each vial even though Defendant gives patients unused portions of vials and thus does not administer as much Zemplar as Defendant claims. (Pl.'s Opp. Br. 11.) Further, Relator argues that the complaint properly pleads that

Defendant's reuse of single dose Zemplar vials violates the quality of care standards notwithstanding Defendant's representation to the government that it complies with the applicable quality of care standards. (Id. at 12.)

Relator also contends that because Defendant did not file a motion to dismiss under Fed. R. Civ. P. 12(b)(6), it waived the right to object to the sufficiency of the allegations in the amended complaint. (Id. at 20.) Relator cites no authority to support this argument, and the Court notes that the Rule 9(b) objection, although not raised in Defendant's answer, was asserted in a motion filed relatively early in this case. See 2 James Wm. Moore et al., Moore's Federal Practice ¶ 9.03 [5] (2009) ("If the failure to plead with particularity under Rule 9(b) is not raised in the first responsive pleading or in an early motion, the issue will be deemed waived."). Relator further asserts that even if the Court considers its amended complaint under Fed. R. Civ. P. 9(b), Relator meets the sufficiency requirements and need not identify a specific claim that was made to the government. (Id. at 20-21.) Relator argues that he need only assert "that there was a material nexus between the wrongful conduct and the government's decision to expend funds." (Id. at 29.)<sup>6</sup>

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6. Relator also addresses the merits of Defendant's protective order motion. However, as noted above, the Court already denied

## 1. Federal False Claims Act Claim

The federal False Claims Act prohibits the submission of false or fraudulent claims for payment to the United States and authorizes qui tam actions, by which private individuals may bring a lawsuit on behalf of the government in exchange for the right to retain a portion of any resulting damages award.

Schindler Elevator Corp. v. U.S. ex rel. Kirk, \_\_\_ U.S. \_\_\_, 131 S. Ct. 1885, 1889, 179 L. Ed. 2d 825 (2011); U.S. ex rel. Wilkins v. United Health Group, Inc., \_\_\_ F.2d \_\_\_, No. Civ. A. 10-2747, 2011 WL 2573380, at \*1 n.1 (3d Cir. June 30, 2011). "The primary purpose of the FCA 'is to indemnify the government-through its restitutionary penalty provisions-against losses caused by a defendant's fraud.'" Wilkins, 2011 WL 2573380, at \*6 (quoting Mikes v. Straus, 274 F.3d 687, 696 (2d Cir. 2001)).

Prior to 2009, the FCA provided in relevant part:

Any person who—

(1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;  
[or]

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the motion for a protective order and directed Relator to respond to the alternative relief sought in the motion, that is, judgment on the pleadings. Accordingly, the Court at this time does not address the arguments raised by Relator concerning discovery issues.

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;

. . .

is liable to the United States Government for a civil penalty . . .[.]

31 U.S.C. § 3729(a) (1)-(2).

On May 20, 2009, Congress enacted the Fraud Enforcement and Recovery Act of 2009 ("FERA"), which amended the FCA and now imposes liability on:

[A]ny person who--

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim[.]

31 U.S.C. § 3729(a) (1). Pursuant to the amendment, Section 3729(a) (2) of the pre-FERA statute was renumbered as Section 3729(a) (1) (B) and expanded liability to anyone who submitted statements which are material to receipt of government funds, even if such statements were not made to induce the government directly to pay the funds.

In this case, Relator filed a complaint on April 1, 2009 -- prior to the enactment of FERA -- which details conduct that Relator observed from March 12, 2008 through November 7, 2008. The amended complaint is dated December 21, 2009 -- following

enactment of FERA -- and was filed in May 2010. Even though the original complaint was filed prior to the enactment of FERA, FERA contains a retroactivity provision as to Section 3729(a)(1)(B), which states that this clause "'take[s] effect as if enacted on June 7, 2008 and appl[ies] to all claims under [the FCA] that are pending on or after that date.'" Wilkins, 2011 WL 2573380, at \*5 (citation omitted). Relator cites to Section 3729(a)(1)(B) with respect to certain claims in the amended complaint (see Am. Compl. ¶¶ 27, 30), although he primarily relies on the pre-FERA version of this subsection. (Id. at ¶¶ 27, 30.) Neither party addresses which version of the statute applies in this case.<sup>7</sup>

The word "claim" as phrased in the relevant provision of Section 3729(a)(1)(B) refers to a "defendant's request for payment" and not to "civil actions for FCA violations." United States v. Sci. Applications Int'l Corp., 653 F. Supp. 2d 87, 107 (D.D.C. 2009); see also United States v. Albinson, No. Civ. A. 09-1791, 2010 WL 3258266, at \*9 (D.N.J. Aug. 16, 2010) (Section 3729(a)(1)(B) "applies retroactively in place of unamended §

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7. Relator apparently attempts to address the issue by representing that the complaint was filed on July 10, 2008 "but clearly alleged a time period were [sic] claims would be pending on June 7, 2008." (Pl.'s Opp. Br. 26 n.8.) The Court notes that this statement is identical to a footnote contained in a relator's appellate brief in a separate qui tam action, U.S. ex rel. Wilkins v. United Health Group, Inc., No. Civ. A. 08-3425. See 2010 WL 4057996, at n.17. Relator's counsel in this case also served as counsel in the Wilkins matter. Relator does not address why claims in this case were pending on June 7, 2008.



3729(a)(2) only when a defendant's false claims for payment were pending on or after June 7, 2008." ). In this case, the amended complaint does not allege the date on which any claims were made by Defendant and the Court at this time is unable to determine which version of the FCA applies.

Nonetheless, the Court finds that it need not resolve this issue to decide the present motion because under either the former or amended version of the statute, the analysis will be the same. As stated in U.S. ex rel. Loughren v. Unum Group, 613 F.3d 300, 307 n.7 (1st Cir. 2010), the FERA amendment primarily addressed an "intent requirement" that the Supreme Court found in the pre-FERA Section 3729(a)(2):

The primary difference between the former and amended versions of the provision is the replacement of the phrase "to get" with the word "material." . . . [T]he FERA amendments to the FCA were responding, in part, to the Supreme Court's suggestion in Allison Engine Co., Inc. v. United States ex rel. Sanders, 553 U.S. 662, 128 S. Ct. 2123, 170 L. Ed. 2d 1030 (2008), that section 3729(a)(2) contained an intent requirement, and by striking the words "to get," Congress intended to eliminate that requirement. S. Rep. No. 111-10, at 11 (2009). That change is not particularly relevant here. The "intent requirement" which Allison Engine read into section 3729(a)(2) was in the context of a party submitting a false statement not directly to the government, but to a private third party (as in the case of a subcontractor and prime contractor). The Court explained that the subcontractor would only violate section 3729(a)(2) if it had the intent that the statement be used by the

prime contractor to get the Government to pay its claim. Id. at 2130. There is no question in this case that [Defendant] caused the statements at issue to be made directly to the government; thus Allison Engine's intent requirement and its abrogation by FERA, are not relevant here.

U.S. ex rel. Loughren v. Unum Group, 613 F.3d 300, 307 n.7 (1st Cir. 2010). As in Unum Group, this case does not concern whether Defendant caused false statements to be made directly to the government, and the intent requirement addressed by FERA is not relevant here. The Third Circuit, in Wilkins, concluded that it need not decide whether the earlier or amended version of the FCA was applicable to the relators' claims in that case because the claims could not survive under either version of the statute. Wilkins, 2011 WL 2573380, at \*6. The Third Circuit decided the case under the pre-FERA version of the statute, and the Court here will likewise cite to the pre-FERA version of the FCA.

To assert a claim under either subsection of the federal FCA, a relator must allege that the defendant submitted a legally fraudulent or false claim. See U.S. ex rel. Conner v. Salina Reg'l Health Ctr., Inc., 543 F.3d 1211, 1217 (10th Cir. 2008) (citing Mikes, 274 F.3d at 695-96). Two categories of false claims are recognized under the federal FCA: factually false claims and legally false claims. Wilkins, 2011 WL 2573380, at \*7 (citing Conner, 543 F.3d at 1217). A claim is factually false when a government payee "has submitted 'an incorrect description

of goods or services provided or a request for reimbursement for goods or services never provided.’” Conner, 543 F.3d at 1217 (quoting Mikes, 274 F.3d at 697). A claim is legally false when a government payee has “‘certifie[d] compliance with a statute or regulation as a condition to government payment,’ yet knowingly failed to comply with such statute or regulation.” Id. “A legally false FCA claim is based on a ‘false certification’ theory of liability.” Wilkins, 2011 WL 2573380, at \*7 (citing Rodriguez v. Our Lady of Lourdes Med. Ctr., 552 F.3d 297, 303 (3d Cir. 2008), overruled in part on other grounds by U.S. ex rel. Eisenstein v. City of New York, 556 U.S. 928, 129 S. Ct. 2230, 173 L. Ed. 2d 1255 (2009)).<sup>8</sup>

The category of legally false claims is further divided into two categories: express false certifications and implied false certifications. Wilkins, 2011 2573380, at \*7. “Under the ‘express false certification’ theory, an entity is liable under the FCA for falsely certifying that it is in compliance with

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8. Although not addressed by the parties, it appears that one aspect of Relator’s claim concerning the overbilling for Zemplar falls within the category of factually false claims and will remain in the case after the disposition of the pending motion. We do not read Defendant’s motion to assert that it may, for example, bill the government for fifty vials when it only used thirty vials. However, as this claim is not the subject of the motion for partial judgment on the pleadings, the Court does not address this category further. The claims at issue in the pending motion fall within the legally false category and are based on the “false certification” theory of liability.

regulations which are prerequisites to Government payment in connection with the claim for payment of federal funds.” Id. (citing Rodriguez, 552 F.3d at 303). Under the “implied false certification” theory, a claimant “seeks and makes a claim for payment from the Government without disclosing that it violated regulations that affected its eligibility for payment.” Id. Under either an express or implied false certification theory, to plead a claim a plaintiff “must show that compliance with the regulation which the defendant allegedly violated was a condition of payment from the Government.” Id. at \*11.<sup>9</sup>

As noted above, the majority of Defendant’s argument relies on the district court’s decision in Wilkins and focuses on the assertion that the Third Circuit has never adopted the “false certification” theory. However, the Third Circuit recently issued a precedential opinion in Wilkins on express and implied false certification liability. In its opinion, the Third Circuit clarified that it does recognize express false certification liability under the FCA. Wilkins, 2011 WL 2573380, at \*8 (citing U.S. ex rel. Kosenske v. Carlisle HMA, Inc., 554 F.3d 88, 94 (3d

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9. “Express false certification” claims may arise under any subsection of § 3729(a), but “implied false certification” claims can arise only under § 3729(a)(1) and not under § 3729(a)(2). U.S. ex rel. Lemmon v. Envirocare of Utah, Inc., 614 F.3d 1163, 1168 (10th Cir. 2010). This is because subsection (a)(1) requires “‘only the presentation of a false or fraudulent claim for payment or approval’” without the additional requirement of a “‘false record or statement’” under subsection (a)(2). Id.

Cir. 2009)). Further, in Wilkins the Third Circuit adopted the implied false certification theory of liability under the federal FCA. Id. Subsequent to the decision in Wilkins, Defendant submitted a letter stating that even though the Third Circuit now recognizes the false certification theory, the amended complaint nonetheless fails to state a claim and remains subject to dismissal.

Relator states that the FCA claims in this case are based on both express and implied certification theories of liability. (See Letter from Marc M. Orlow, Esq. 1, July 13, 2011.) Relator contends that Paragraph 16 of the amended complaint specifically sets forth both theories of liability. (Id.) Paragraph 16 states as follows:

The submission of false information regarding the type of care that was provided, and by whom and whether it was performed by an authorized person directly impacts the type and amount of the payment. Defendant represents that it is in compliance with State regulations regarding quality of care and staffing as described above, which is, both expressly and by implication, a condition of payment by the Federal Payors. Each claim that Defendant submits for payment contains an express certification that Defendant is in compliance with all Federal and State Regulations related to the operational requirements set forth by the appropriate regulatory authorities including, inter alia, the regulations set forth above.

(Am. Compl. ¶ 16) (emphasis supplied). This language, Relator argues, in addition to asserting an express certification theory,

invokes the implied certification theory because it pleads that "implied certification is a 'condition of payment.'" (Letter from Marc M. Orlow, Esq. 2, July 13, 2011.)

The Court rejects Relator's argument that Paragraph 16 asserts an implied certification theory of liability. The phrase "expressly and by implication," as used in Paragraph 16, modifies the phrase "conditions of payment." Thus, Paragraph 16 as phrased asserts that Defendant represented that it was in compliance with New Jersey's regulations regarding quality of care and staffing, and that compliance with such regulations was both an express and implied requirement for Defendant to obtain payment by the federal government.<sup>10</sup>

The theory of implied certification adopted by the Third

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10. Relator fails to identify a rule, regulation or other source that expressly requires compliance with New Jersey's quality of care and staffing regulations to obtain payments from the federal government. Relator, in Paragraph 16, thus alternatively alleges that even though there is no express requirement set forth in a rule, regulation or other source, compliance with New Jersey's quality of care and staffing regulations is an implied condition for payment. The parties do not address, and the Court does not resolve herein, the issue of whether preconditions for payment must be expressly set forth by rule, statute, or other source, or whether such preconditions may be implied. Compare, e.g., U.S. ex rel. Hutcheson v. Blackstone Medical, Inc., 647 F.3d 377, 388 (1st Cir. 2011) (rule that "only express statements in statutes and regulations can establish preconditions of payment is not set forth in the text of the FCA.") and Mikes, 274 F.3d at 700 ("implied false certification is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies expressly states the provider must comply in order to be paid.") (emphasis in original).

Circuit, however, does not focus on whether the conditions for payment are express or implied. Rather, the relevant inquiry is whether the defendant's conduct implies compliance with all conditions required for payment and, thus, entitlement to payment. As stated in Wilkins, "an implied false certification theory of liability is premised 'on the notion that the act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a precondition to payment.'" Wilkins, 2011 WL 2573380, at \*7 (citations omitted). In other words, when a person must meet certain preconditions before he can receive government funds, and such person then accepts the government funds, that person impliedly certifies that he is in compliance with all preconditions for payment.

The language contained in Paragraph 16 of the amended complaint does not allege that Defendant implied that it was entitled to payment. Paragraph 16 clearly alleges that Defendant made an express claim for payment. The paragraph states: "Each claim that Defendant submits for payment contains an express certification that Defendant is in compliance with all Federal and State Regulations related to the operational requirements set forth by the appropriate regulatory authorities, including, inter alia, the regulations set forth above." (Am. Compl. ¶ 16.) Accordingly, the Court construes Paragraph 16 as alleging liability only under the express certification theory of

liability.

Notwithstanding the foregoing, Relator does assert an implied certification theory of liability in the amended complaint. Paragraph 16 of the amended complaint concerns Relator's claim that Defendant made a claim for government funds but failed to adequately staff its facility in accordance with applicable New Jersey regulations. As noted above, however, Relator also asserts a separate claim concerning Defendant's alleged reuse of Zemplar vials purportedly in violation of government regulations requiring single use of containers for injectable medications, and it is this claim that implicates the implied certification theory. Specifically, as set forth in Paragraph 26 of the amended complaint, Relator alleges:

"Defendant's re-use of single dose Zemplar containers for injectable medications violates the quality of care standards that Defendant represents and certifies that it provides, both in an implied and express manner . . . [.] Defendants [sic] implied and express representations are material conditions to the Government's decision to reimburse or pay for the Zemplar . . . [.]" (Am. Compl. ¶ 26) (emphasis supplied). The Court thus construes the amended complaint as asserting both the express certification and the implied certification theories of liability.

As noted above, "to plead a claim upon which relief could be



granted under a false certification theory, either express or implied, a plaintiff must show that compliance with the regulation which the defendant allegedly violated was a condition of payment from the Government.” Wilkins, 2011 WL 2573380, at \*11. Courts must distinguish between conditions of participation in government programs and conditions of payment of government funds. Id. As noted in Wilkins, “[c]onditions of participation . . . are enforced through administrative mechanisms, and the ultimate sanction for violation of such conditions is removal from the government program,’ while ‘[c]onditions of payment are those which, if the government knew they were not being followed, might cause it to actually refuse payment.’” Id. (citing Conner, 543 F.3d at 1220).

With respect to Relator’s claim that Defendant violated the federal FCA by accepting federal funds notwithstanding its staffing deficiencies and other isolated violations of New Jersey law,<sup>11</sup> Relator documents several instances in which he purportedly personally observed Defendant violate its obligations under the New Jersey Administrative Code, Title 8 Chapter 43A. Relator details the alleged violative activity, the dates on

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11. These incidents include the failure to check the reverse osmosis water system on one day, a patient receiving dialysis on August 22, 2008 without having been medically cleared by a doctor, patients having received dialysis on August 25, 2008 and October 1, 2008 with unarmed air detectors, and an unlicensed person administering medications on October 17, 2008.

which the alleged violations occurred, and the regulation allegedly violated. Relator, however, does not cite any facts to support his contention that the federal government, had it been aware of the purported violations of Title 8 Chapter 43A of the New Jersey Administrative Code as set forth in the amended complaint, may have refused payment of federal funds to Defendant. The state regulations cited by Relator "provide[] standards for the licensure and operation of ambulatory care facilities" in New Jersey. (Am. Compl. ¶ 6). Relator asserts in merely conclusory fashion that compliance with these licensing regulations is a condition of payment by the federal government. (Id. at ¶ 16.) The amended complaint is devoid of reference to any rule, regulation, or other source that would provide factual support for Relator's assertion.

Thus, in this case, as in Wilkins, the fundamental flaw in Relator's claim concerning staffing violations is that Relator "does not cite to any regulation demonstrating that a participant's compliance" with Title 8, Chapter 43 of the New Jersey Administrative Code "is a condition for its receipt of payment from the Government." Wilkins, 2011 WL 2573380, at \*12. Nor does Relator "cite examples, in case law or otherwise, of the Government seeking recovery of Medicare payments for services that a provider actually performed on the basis that its lack of compliance" with the New Jersey regulations "rendered those

services fraudulent.” Id. As such, Relator’s federal FCA claim based on an alleged failure to comply with Title 8 Chapter 43A of the New Jersey Administrative Code is legally insufficient and is subject to dismissal.

Relator’s FCA claim based on Defendant’s alleged reuse of Zemplar vials is similarly deficient. Relator alleges that Defendant was required to discard unused portions of Zemplar vials and not administer remaining portions of the drug to another patient. (Am. Compl. ¶ 12.) Unlike his claim concerning insufficient staffing, where he described the dates and details of the alleged violations of the New Jersey Administrative Code, Relator’s claim here fails to set forth with any specificity even a single occasion on which a vial containing leftover Zemplar was administered to a patient.<sup>12</sup>

Even assuming that the amended complaint does contain such facts, however, Relator fails to cite a particular rule or

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12. In connection with the allegation that Defendant seeks reimbursement for more Zemplar than actually administered, Relator alleges that for forty patients a total of fifty vials of Zemplar should have been used per day, based on the amount of Zemplar prescribed for each patient, the amount of Zemplar given to each patient, and the amount of Zemplar vials that should have been used if Defendant used only 5 mcg vials of Zemplar. (Am. Compl. ¶ 22.) Defendant purportedly used only thirty vials on one day and Relator thus assumes that Defendant reused Zemplar vials. (Id.) While these alleged facts may imply that Zemplar vials were reused, Relator does not allege a single instance in which a vial containing leftover Zemplar was actually administered to a patient.

regulation that prohibits the reuse of Zemplar. The amended complaint states only that “[i]t is clinically recommended and directed by the manufacturer and Food and Drug Administration” that unused portions of Zemplar be discarded. (Id.) More importantly, Relator fails to cite any rule, regulation, contract, or other facts to demonstrate that the single vial use of injectable drugs was a condition precedent to the receipt of government funds. The only assertion in this regard is Relator’s wholly conclusory allegation that “Defendants [sic] implied and express representations are material conditions to the Government’s decision to reimburse or pay for the Zemplar[.]” (Am. Compl. ¶ 26.) The amended complaint contains no facts to support Relator’s contention that the government, had it been aware of Defendant’s alleged reuse of Zemplar vials, may have refused payment of federal funds to Defendant. Accordingly, the Court concludes that Relator’s federal FCA claim concerning Defendant’s alleged reuse of Zemplar vials is subject to dismissal for failure to state a claim.

In so finding, the Court notes Relator’s argument that Defendant was prohibited as of 2001 from using leftover Zemplar. Defendant argues that the Center for Disease Control recommended single-use administration but did not require such administration as a condition for receiving Medicare payment until June 30,

2009.<sup>13</sup> (Def.'s Br. 13.) The Court does not resolve whether Defendant was required to use new vials of Zemplar each time it administered the drug because even taking as true the allegation that Defendant was prohibited from using leftover Zemplar, Relator fails to cite in the amended complaint to a single fact supporting his allegation that compliance with this requirement was a precondition for payment.

Additionally, the Court notes Defendant's argument that Relator's express certification claim fails on the ground that Relator does not aver a specific claim for payment. (Def.'s Br. 17.) After briefing on the motion to dismiss was closed, the parties submitted letters to the Court disputing whether allegations of a specific claim for payment are necessary at the pleading stage. The Third Circuit in Wilkins noted that "we have never held that a plaintiff must identify a specific claim for payment at the pleading stage of the case to state a claim for relief," but "a plaintiff, at the pleading stage, must identify representative examples of specific false claims that a defendant made to the Government in order to plead an FCA claim properly .

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13. According to Defendant, the Center for Disease Control in 2001 recommended that all single-use injectable medications be dedicated for use on a single patient, but such recommendation did not become a condition for receipt of Medicare payments for outpatient dialysis services until October 14, 2008. (Def.'s Br. 13.) The deadline for compliance with this recommendation was then purportedly extended to June 30, 2009. (Id.)

. . . under the more particular pleading standards of Rule 9(b).” Wilkins, 2011 WL 2573380, at \*10 (citation omitted) (emphasis in original). Having found that Relator’s claims under either an express or implied certification theory fail because the amended complaint does not assert facts concerning the preconditions for payment of federal funds, the Court need not address whether Relator’s express certification claims should also be dismissed for failure to allege representative examples of specific false claims.

## **2. State FCA Claims**

Relator further alleges violations of the New Jersey False Claims Act and the Texas Medicaid Fraud Prevention Act. (Am. Compl. ¶¶ 33-35, 36-38.) Relator contends that Defendant maintains, operates and manages nine dialysis centers in the State of New Jersey and ten centers in the State of Texas. (Id. at ¶¶ 34, 37.) Relator alleges that Defendant’s conduct constituted the making of false claims to the State of New Jersey because Defendant “services patients in their centers in New Jersey who are beneficiaries of Medicaid and/or other programs in which the State is a payor.” (Id. at ¶ 35.) Similarly, Relator avers that Defendant’s conduct constituted the making of false claims to the State of Texas because Defendant “services patients in their centers in Texas who are beneficiaries of Medicaid and/or other programs in which the State is a payor.” (Id. at ¶

38.)

Defendant moves to dismiss the claim under the Texas Medicaid Fraud Prevention Act because none of the factual allegations of the complaint support any wrongful conduct vis-a-vis the State of Texas. With respect to the New Jersey False Claims Act cause of action, Defendant does not expressly seek dismissal of this claim, although it generally seeks dismissal of Relator's "qui tam claims based upon a false certification theory . . .[.]" (Proposed Order ¶ 4.) It thus appears that Defendant, through this statement, seeks dismissal of all claims to the extent they assert a false certification theory.

The Court finds that the causes of action under either the New Jersey or Texas statutes are deficient, particularly in light of the heightened pleading standard for these claims of fraud under Fed. R. Civ. P. 9(b). Relator does not specify which provisions of the New Jersey False Claims Act or the Texas Medicaid Fraud Prevention Act were allegedly violated by Defendant. Certain provisions of the New Jersey statute are essentially identical to the pre-FERA version of the federal FCA. See N.J.S.A. § 2A:32C-3(a), (b). It appears, based on the factual recitation in the amended complaint, that Relator's claims are based on these provisions.<sup>14</sup> It appears that

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14. Specifically, N.J.S.A. § 2A:32C-3(a) and (b) prohibit a person from "knowingly present[ing] or caus[ing] to be presented

Relator's claims under the Texas statute are based on an alleged violation of Tex. Hum. Res. Code § 36.002.<sup>15</sup> The laws of both states require a defendant to have acted wrongfully in obtaining State funds or benefits. As detailed below, Relator fails to allege any attempt to wrongfully obtain monies or benefits from the State of New Jersey or the State of Texas.

The only allegations in the amended complaint concerning Texas are that Defendant operates ten centers in the state and services patients in Texas who are beneficiaries of Medicaid funds. (Am. Compl. ¶¶ 2-3, 37-38.) The amended complaint alleges no facts demonstrating that Defendant made false

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to an employee, officer or agent of the State, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment" or "knowingly mak[ing], us[ing], or caus[ing] to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State[.]" As defined by the statute, "State" means "any of the principal departments in the Executive Branch of State government, and any division, board, bureau, office, commission or other instrumentality within or created by such department; and any independent State authority, commission, instrumentality or agency." N.J.S.A. § 2A:32C-2.

15. Under the statute, a person commits an unlawful act if he, inter alia, "knowingly makes or causes to be made a false statement or misrepresentation of a material fact to permit a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized," or "knowingly conceals or fails to disclose information" that permits a payment or benefit under the Medicaid program that is not authorized or is greater than the amount authorized. Tex. Hum. Res. Code § 36.002. The "Medicaid program" referred to in the statute means "the state Medicaid program." Tex. Hum. Res. Code § 36.001(6).



statements or misrepresentations, or concealed or failed to disclose information, in seeking to obtain an unauthorized payment or benefit under the Texas Medicaid program. Moreover, Relator was employed at Defendant's Sewell, New Jersey location, and the specific facts in the complaint relate to his observations in Sewell, New Jersey. Relator cannot support an allegation that Defendant violated the laws of other states based solely on an alleged violation of New Jersey regulations at a New Jersey facility.<sup>16</sup> The amended complaint lacks facts alleging with specificity that Defendant made a claim for or otherwise caused the wrongful payment of Texas Medicaid funds or benefits.

Relator's claim under the New Jersey False Claims Act is likewise deficient. Although the amended complaint details alleged violations of New Jersey regulations, Relator does not aver with any specificity that Defendant fraudulently attempted to cause New Jersey to pay state funds. The only averment in the amended complaint concerning the New Jersey Medicaid program states that Defendant "services patients in their centers in New Jersey who are beneficiaries of Medicaid and/or other programs in which the State is a payor." (Am. Compl. ¶ 35.) An allegation that Defendant provides services to patients who receive state

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16. The Court notes that Relator alleges in the amended complaint that Defendant also operates facilities in Iowa, Arkansas and Pennsylvania (Am. Compl. ¶ 2), but Relator does not seek to assert claims under the fraud statutes of these states.

funds, however, is not the same as an allegation that Defendant sought payment of state funds through false or fraudulent means. The Court notes that Relator alleges that "Defendant treats patients who are eligible for Medicare and Medicaid and routinely submits claims for payment to them," but Relator also alleges that he "believes that Defendant is submitting claims for reimbursement to Federal payors such as Medicare and Medicaid." (Am. Compl. ¶¶ 20, 23) (emphasis supplied). Relator therefore does not clearly allege that false or fraudulent claims were submitted to New Jersey or Texas state payors and these causes of action thus fail, particularly in light of the heightened pleading standard under Rule 9(b).

Consequently, the amended complaint is devoid of sufficient facts to place Defendant on notice of the precise violations of the New Jersey and Texas fraud statutes with which it is charged. These state claims in the amended complaint are dismissed.

### **3. Amendment of the Complaint**

Having determined that dismissal of Relator's FCA claims in Counts I, II and III is warranted, the Court must determine whether the dismissal should be with prejudice. Fed. R. Civ. P. 15(a)(2) provides that the Court should "freely give leave" to amend the complaint "when justice so requires." Defendant seeks dismissal with prejudice, arguing that amendment of the complaint would be futile because Relator has provided disclosures and

responded to Defendant's discovery requests and has still failed to provide further specification concerning the alleged false claims in this case. (Reply Br. in Further Supp. of Def.'s Mot. for Partial J. on the Pleadings 2.) Relator has not sought to amend the complaint in light of the arguments raised in the motion for judgment on the pleadings.

Although Relator does not move to amend the complaint, the Third Circuit has held that "if a complaint is vulnerable to 12(b)(6) dismissal, a district court must permit a curative amendment, unless an amendment would be inequitable or futile." Phillips v. Cty. of Allegheny, 515 F.3d 224, 236 (3d Cir. 2008) (citations omitted). The record at this time does not demonstrate that amendment of the complaint would be inequitable or futile and, consequently, leave to amend will be granted.

### **III. CONCLUSION**

Defendant's Motion to Dismiss will be granted insofar as Defendant seeks dismissal of the claims in the amended complaint based on the false certification theory and the state law claims concerning false or fraudulent claims, but denied to the extent Defendant seeks dismissal of such claims with prejudice. An Order consistent with this Opinion will be entered.

Dated: November 23, 2011 \_\_\_\_\_ /s Noel L. Hillman  
NOEL L. HILLMAN, U.S.D.J.  
At Camden, New Jersey