

IN THE UNITED STATES DISTRICT COURT
 FOR THE DISTRICT OF SOUTH CAROLINA
 COLUMBIA DIVISION

United States of America,)	
)	C/A No. 3:14-382-MBS
Plaintiff,)	
)	
ex rel. Catherine A. Schaefer,)	
)	
Plaintiff-Relator,)	
)	
vs.)	ORDER AND OPINION
)	
Family Medicine Centers of South)	
Carolina, LLC; Stephen F. Serbin, M.D.;)	
and Victoria Serbin,)	
)	
Defendants.)	
_____)	

Plaintiff United States of America filed a complaint in intervention on May 5, 2016, alleging Defendants Family Medical Centers of South Carolina, LLC (FMC); Stephen F. Serbin, M.D.; and Victoria Serbin (together, “Defendants”) submitted false claims to Medicare, TRICARE, and the Federal Employees Health Benefits Program (FEHBP). The United States alleges that Defendants had employment arrangements with physicians that included compensation directly attributable to the volume or value of the employed physician’s referrals, in violation of the Stark Law, 42 U.S.C. § 1395nn. The United States further alleges that claims for reimbursement based on referrals generated by physicians who received compensation based on these terms comprises a violation of the False Claims Act (FCA), 31 U.S.C. § 3729 et seq. In addition, the United States alleges that, in order to maximize revenue, Defendants devised a variety of schemes, including: creating custom laboratory panels comprised of diagnostic tests not appropriate for routine measurement; implementing standing orders to assure custom panels were performed with defined frequency rather

than in reaction to clinical needs; and programming billing software to misrepresent services provided by referencing improper Current Procedural Terminology (CPT) codes; ordering unnecessary laboratory tests; and billing for office visits when a patient presented only for a blood-drawing procedure. See Complaint in Intervention, ECF No. 57, 2-3. The United States asserts causes of action for presenting false claims, as prohibited by the FCA, 31 U.S.C. § 3729(a)(1) and (a)(1)(A) (First Cause of Action); and for making false statements material to false claims, as prohibited by the FCA, 31 U.S.C. § 3729(a)(1)(B) (Second Cause of Action). The United States also asserts state law causes of action for payment by mistake and unjust enrichment. The government proceeds under a theory of express false certification. See United States ex rel. Conner v. Salina Reg'l Health Ctr., 543 F.3d 1211, 1217 (10th Cir. 2008) (“An express false certification theory applies when a government payee ‘falsely certifies compliance with a particular statute, regulation or contractual term, where compliance is a prerequisite to payment.’”) (quoting Mikes v. Straus, 274 F.3d 687, 698 (2d Cir. 2001), abrogated on other grounds by Universal Health Svcs., Inc. v. United States, 136 S. Ct. 1989 (2016)).

This matter is before the court on Defendants’ motion to dismiss pursuant to Fed. R. Civ. P. 8(a), 9(b), 12(b)(1), and 12(b)(6), which motion was filed on July 11, 2016. The United States filed a response in opposition on August 4, 2016, to which Defendants filed a reply on August 15, 2016. Defendants also filed a motion to stay discovery on August 15, 2016, to which the United States filed a response in opposition on September 1, 2016, and Relator Catherine A. Schaeffer, M.D. also filed a response in opposition on September 1, 2016.

DISCUSSION

“Defendants may challenge subject-matter jurisdiction of an FCA claim through a Rule 12(b)(1) motion to dismiss by contending ““that a complaint simply fails to allege facts upon which subject matter jurisdiction can be based.”” United States ex rel. Szymoniak v ACE Sec. Corp., C/A No. 0:13-cv-00464-JFA, 2014 WL 1910876, *3 (D.S.C. May 12, 2014) (quoting Adams v. Bain, 697 F.2d 1213, 1219 (4th Cir. 1982)). If a defendant facially attacks a complaint for lack of subject-matter jurisdiction, ““all the facts alleged in the complaint are assumed to be true and the plaintiff, in effect, is afforded the same procedural protection as he would receive under a Rule 12(b)(6) consideration.”” Id. (quoting Adams, 697 F.2d at 1219).

To survive a motion to dismiss under Rule 12(b)(6), a complaint must contain sufficient facts to state a claim to relief that is plausible on its face. United States ex rel. Garzione v. PAE Gov’t Svcs., Inc., No. 16-1349, 2016 WL 6518439, *1 (4th Cir. 2016) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). Thus, the United States must allege sufficient facts to support a claim for relief under the FCA.

The FCA prohibits any person from knowingly presenting or causing to be presented a false or fraudulent claim for payment, or knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim. 31 U.S.C. § 3729(a)(1)(A), (B). ““To state a claim under the FCA, the plaintiff must prove: (1) that the defendant made a false statement or engaged in a fraudulent course of conduct; (2) such statement or conduct was made or carried out with the requisite scienter; (3) the statement or conduct was material; and (4) the statement or conduct caused the government to pay out money or to forfeit money due.”” Garzione, 2016 WL 6518439 at *1 (quoting United States ex rel. Harrison v. Westinghouse Savannah River Co., 352

F.3d 908, 913 (4th Cir. 2003)).

As to scienter, a plaintiff must establish that there was intent on the part of the defendant to present a false claim. United States ex rel Garzione v. PAE Gov't Svcs., Inc., 164 F. Supp. 3d 806, 816 (E.D. Va. 2016)(citing 32 U.S.C. § 3729(a)(1); United States ex rel. Owens v. First Kuwaiti Gen. Trading & Contracting Co., 612 F.3d 724, 728 (4th Cir. 2010)). A plaintiff need not show “specific intent to defraud,” but at a minimum, must establish that a defendant acted with “reckless disregard of the truth or falsity of the information.” Id. (citing cases)). As to materiality under the FCA, the materiality of a false statement or conduct “turns on whether the false statement has a natural tendency to influence agency action or is capable of influencing agency action. Materiality does not look to whether the false statements actually influenced agency action, but rather whether the statements are capable of having such an influence.” United States ex rel. Hedley v. Abhe & Svoboda, Inc., Civil Action No. RDB-14-2935, 2016 WL 4060738, *6 (D. Md. July 29, 2016) (internal citations omitted).

In addition, Rule 9(b) requires an FCA plaintiff to, ““at a minimum, describe the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby.”” Id. (quoting Smith v. Clark/Smoot/Russell, 796 F.3d 424, 432 (4th Cir. 2015)). ““These facts are often referred to as the who, what, when, where, and how of the alleged fraud.”” Id. (quoting United States ex re. Wilson v. Kellogg Brown & Root, Inc., 525 F.3d 370, 379 (4th Cir. 2008)).

A. The Stark Law Claims

The Stark Law, 42 U.S.C. § 1395nn, ““was enacted to address overutilization of services by physicians who stood to profit from referring patients to facilities or entities in which they had a

financial interest.” Philips v. North Carolina State, No. 5:15-CV-95-F, 2015 WL 9462095, *4, n.2 (E.D.N.C. Dec. 28, 2015) (quoting United States ex rel. Drakeford v. Tuomey Healthcare Sys., Inc., 675 F.3d 394, 397 (4th Cir. 2012)). Defendants assert that the Stark Law claims fail because the United States has not pleaded with particularity the materiality and scienter requirements. The court disagrees.

The United States alleges that Dr. Serbin executed multiple certification statements in Section 15 of Form CMS-855B indicating that he would adhere to the requirements of Medicare laws, regulations, and program instructions, including, but not limited to, the Stark Law. The United States alleges that named physicians employed by FMC were encouraged to refer laboratory tests associated with Medicare beneficiaries to FMC. FMC then submitted claims to Medicare for reimbursement. The United States alleges that the claims were false because of the improper financial relationship between FMC and the physicians. According to the United States, when FMC’s claims were reimbursed by Medicare, FMC would pass along a percentage of the improper reimbursement to the physician who made the referral. The United States further alleges that Defendants encouraged physicians to refer testing and other services to FMC, or be subject to lesser compensation under the employment agreements. According to the United States, Defendants engaged in an improper compensation structure over nearly ten years and obtained reimbursement from Medicare in an amount representing millions of dollars.

In the court’s view, the United States has adequately pleaded scienter and materiality so as to state a claim under the FCA for violations of the Stark Law, and that the United States has pleaded scienter and materiality with sufficient particularity as to establish the “who, what, when, where, and how” of the alleged Stark Law fraudulent conduct.

B. The Medical Necessity Claims

Defendants next assert that the United States' claims regarding laboratory panels and standing orders fail to state a claim under the FCA. According to Defendants, the United States' allegations regarding laboratory panels and standing orders merely reflect a mere difference of opinions between physicians. See United States ex rel. Prevenslik v. University of Washington, No. Civ. A. MJG-02-80, 2003 WL 23573424 (D. Md. June 20, 2003) (noting that a difference in the interpretation of research results and data not an appropriate basis for a FCA claim). The court disagrees.

Contrary to Defendants' contentions, the United States' allegations regarding laboratory panels and standing orders present facts to support over-utilization of laboratory services in order to generate revenue. The United States alleges that Defendants created and utilized custom disease-oriented panels that included more diagnostic tests than typical for screening or routine testing. The United States alleges that Defendants stressed to the physicians with whom FMC had a contractual relationship to utilize the laboratory panels designed by Defendants, regardless of whether all components of the panel were medically necessary. The United States alleges that, between 2008 and 2015, FMC was paid over \$4 million for unnecessary lipid tests, over \$1.6 million for unnecessary chemistry panel tests; over \$500,00 for unnecessary hepatic function tests; and over \$1 million for unnecessary thyroid panel tests. The United States further alleges that Defendants devised a set of "Lab Standing Orders" that required staff to automatically perform certain diagnostic tests or provide certain services, whether or not ordered by a physician. According to the United States, Defendants submitted or caused the submission of tens of thousands of claims for services that were not medically necessary. For purposes of a motion to dismiss, the court cannot say that

allegedly routine testing made without reference to the patient's needs or a physician's request constitutes a difference of opinion so as not to state a claim under the FCA.

Defendants further assert that the United States' allegations regarding laboratory tests and standing orders are not pleaded with sufficient particularity as required by Rule 9(b). However, the gravamen of the United States' allegations is that tests were performed as a matter of course by FMC employees with reference to the guidelines developed by Dr. Serbin. The complaint in intervention adequately sets forth the "who, what, when, where, and how" of the FCA claim.

Defendants next assert that the United States' allegations regarding "flipping" the a CPT code to a diagnostic test covered by Medicare is not adequately substantiated. The court disagrees.

The United States alleges that, prior to October 5, 2015, Medicare did not pay for High-Sensitivity C-Reactive Protein testing (HsCRP) (CPT 86141) in South Carolina. Medicare paid only for standard sensitivity C-Reactive Protein testing (CPT 86140) to detect the presence of an inflammatory process. HsCRP was, however, a component of FMC's custom lipid panel, which, according to the United States, was required to be run for multiple diagnoses regardless of medical necessity. The United States alleges that Victoria Serbin manipulated FMC's billing software so that and entry for CPT 86141 became CPT 86140. According to the United States, Medicare paid for a test that was neither medically necessary nor clinically relevant. The United States alleges that Medicare paid approximately \$298,500 for improper standard sensitivity CPR testing. Although the United States provides only one example of Defendants' alleged wrongdoing, the court finds that the United States' allegations state a claim that is plausible on its face.

Next, Defendants assert that the United States fails to substantiate its allegation that Defendants fraudulently billed venipuncture procedures. The court disagrees.

The United States contends that, when a patient presented to have blood drawn, Defendants instructed office staff to bill Medicare for an office visit as well as for the venipuncture. The United States contends that the systematic billing practice resulted in approximately \$96,485 in overpayment to Defendants. The court concludes that the allegations set forth in the complaint in intervention are sufficient to state a claim that is plausible on its face.

Finally, Defendants assert that the United States failed to establish materiality because the government has continued to pay all claims submitted for payment. The court disagrees.

The Fourth Circuit has determined that materiality of a false statement turns on whether the false statement has a natural tendency to influence agency action or is capable of influencing agency action. United States ex rel. Berge v. Bd. of Trustees, 104 F.3d 1453, 1460 (4th Cir. 1997). The natural tendency test properly focuses upon the presentment of a false or fraudulent claim, rather than actual payment on that claim. United States ex rel. A+ Homecare, Inc. v. Medshares Management Group, Inc., 400 F.3d 428, 445 (6th Cir. 2005). Although the government's knowledge of an alleged false claim can negate the scienter element of a FCA violation, United States ex rel. Burlbaw v. Orenduff, 548 F.3d 931, 951 (10th Cir. 2008), the court concludes that the proper focus with respect to materiality is the influence of the false statement at the time of presentment.

C. Common Law Claims

Defendants argue that the United States' common law claims of payment by mistake and unjust enrichment must be dismissed because they are dependent on the FCA claims. For the reasons stated, Defendants' motion to dismiss is denied as to these claims.

CONCLUSION

For all these reasons, Defendants' motion to dismiss (ECF No. 73) is **denied**. Defendants'

motion to stay discovery pending a ruling on the motion to dismiss (ECF No. 88) is **denied as moot**.

/s/ Margaret B. Seymour
Senior United States District Judge

Columbia, South Carolina

November 8, 2016