IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA, *et al.*, *ex rel.* CHRISTOPHER PIACENTILE,	)	
	)	No. 1:14-cv-3988
v.	)	
SNAP DIAGNOSTICS, LLC, *et al.*,	)	Hon. Charles R. Norgle
Defendants.	)	

OPINION

On May 29, 2014, Plaintiff Christopher Piacentile ("Plaintiff") filed his complaint, on behalf of the United States of America and California, Colorado, Connecticut, Delaware, Florida, Georgia, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Washington, Wisconsin, and the District of Columbia, pursuant to the *qui tam* provisions of the False Claims Act, as codified by 31 U.S.C. § 3730(b)(2). Plaintiff's complaint alleges that Defendants Snap Diagnostics LLC ("Snap"), Gil Raviv, Ph.D. ("Raviv"), Stephen Burton, ("Burton"), Leslie Gardea ("Gardea"), Apria Healthcare Group, Inc., Lincare Holdings, Inc., DME Does, Physician Does (collectively, "Defendants") were involved in a scheme to, *inter alia*, defraud the United States through the filing of false and fraudulent Medicare and Medicaid claims.

Following a years long investigation into Plaintiff's allegations, the United States filed its Complaint in Intervention of the United States of America (the "Complaint") on December 18, 2017. The civil Complaint alleges: Defendants filed false claims with Medicate for payments of federal funds, Count I; made false statements to agents of the United States in connection with their claims for payment of federal funds, Count II; and paid illegal kickbacks, bribes, or rebates

to treating physicians and independent sales representatives to induce patient referrals, Count III, in violation of the False Claims Act, as codified at 31 U.S.C. § 3729. Before the Court is Defendants' motion to dismiss the Government's Complaint. For the following reasons, the motion is denied.

BACKGROUND

Snap is a provider of home sleep diagnostic testing. Their product, in conjunction with an evaluation by a medical professional, is used in the diagnosis of Obstructive Sleep Apnea ("Sleep Apnea"). Snap, following a physician's order and referral, would ship a proprietary Type 3[1] sleep machine to the patient who would be trained by a Territory Manager, the referring physician, or a member of his staff on the machines use. After the taking the test, the patient or physician would return the data cartridge(s) to Snap for analysis. Snap would then analyze and process the data, interpret the results, and generate a report for the referring physician.

The Scheme

In an effort to drive up profits, Defendants orchestrated a scheme where they would deploy their product and conduct multiple nights of Sleep Apnea tests—where only one night was required. Moreover, Defendants allowed the prescribing physicians to bill their patient's insurance a carrier for the professional components of the tests, necessary and unnecessary.

False Claims

Founded in 1994, Snap provides home sleep tests to individuals to diagnose Sleep Apnea. In 2009, following lobbying from Raviv, Medicare began to cover the cost of home sleep tests for the diagnosis of Sleep Apnea. In a letter Raviv sent to Medicare, he indicated that it was

[1] "Home sleep monitors are typically classified into three categories: (i) Type 2, a full unattended polysomnography device with seven or greater channels for collecting sleep data; (ii) Type 3, a limited channel device (with between four and seven channels); and (iii) Type 4, a one- or two-channel device, usually using oximetry (a measurement of oxygen in the blood) as one of the parameters." Compl. In Intervention of the United States of America, ¶ 23.

routine practice for patients to undergo only a single night of home sleep testing to diagnose Sleep Apnea. Indeed, Snap's promotional documents aver that a diagnosis can almost always be made in a single session. Compl. In Intervention of the United States of America [hereinafter, "Compl."], ¶ 71. However, the Complaint alleges that in an effort to drive up profits Snap began conducting two nights of testing per patient—allowing them to bill the patient and the patients insurance twice. Compl. ¶ 80-82.

Snap's new procedure of analyzing both nights of data was not a blanket policy. Instead Snap's procedure was to analyze and bill for both nights of testing, only when the patient was either covered by Medicare or self-pay. The decision to analyze and bill both nights of data was not based on a clinical determination of the specific patient's needs—i.e. whether multiple nights of testing were medically necessary. The Complaint alleges that since October 2010, Snap has and continues to analyze and bill two or more data sets to Medicare while analyzing only a single night's test when a patient has private insurance. Compl. ¶ 87.

Burton herself stated: "For the vast majority of patients releasing all three nights would not provide any more clinical value than one night… Sometimes there are important differences that force the release of multiple reports. Yet, often there is no value to releasing multiple nights as the data are consistent. It would simply cost more." Compl. ¶ 111. The Complaint provides six examples of patients who were double billed (individually and to Medicare) for multiple nights of unnecessary and duplicative testing. Compl. ¶¶ 114-119.

Kickbacks

The Complaint alleges that the most egregious violation of the anti-kickback provision of the False Claims Act was Snap's "offering and encouraging referring physicians to bill for the

professional component[2] of the test, although SNAP physicians were performing the professional component." Compl. ¶ 122. The Complaint further alleges that Territory Managers would highlight the opportunity to bill private insurers for the professional component of the test because typically private insurers would not have educational or certification requirements for evaluating home sleep tests. The Complaint details conversations and correspondence between the individual defendants discussing this business model and the anticipated increase in volume of physician referrals.

The Complaint also alleges that the Defendants' false claims were driven, at least in part, by the inducements and commissions paid to their Territory Managers. The Complaint is replete with allegations that Raviv and Defendants constructed a sales program that encouraged Territory Managers to push medically unnecessary procedures to generate commissions and win "challenges" where they would be rewarded for clients completing additional nights of testing. The Complaint argues that because Territory Managers were paid on a per-test basis and were encouraging the filing of false claims, all of the Medicare Payments made to Snap were paid as the result of false claims.

Lastly, the complaint alleges that Snap provided free or no-copay tests to referring physicians, their families, and key staff members in an effort to induce patient referrals. These tests and services rendered by Snap were internally valued in excess of $1,000.00 per test. The Government alleges that these inducements, like the commissions and kickbacks paid to other actors, promoted referrals and encouraged prescriptions for medically unnecessary tests.

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[2] Diagnostic tests are separated into two components: technical and professional. For a home sleep test, providing the recorder, analyzing the data, and generating a report to be reviewed by a physician constitute the "technical component" of the test, while physician review and interpretation of the report constitute the "professional component." Defs. Snap Diagnostics, LLC, Gil Raviv, and Stephen Burton's Mem. Of L. in Supp. of their Mot. To Dismiss [hereinafter, "Motion to Dismiss"], 2.

ANALYSIS

Standard Of Decision

A motion under Rule 12(b)(6) tests the sufficiency of the complaint under the plausibility standard, Bell Atlantic Corporation v. Twombly, 550 U.S. 544, 570 (2007), not the merits of the suit. Gibson v. City of Chicago, 910 F.2d 1510, 1520 (7th Cir. 1990) (citation omitted). "[A] plaintiff's claim need not be probable, only plausible: 'a well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable, and that a recovery is very remote and unlikely.'" Indep. Trust Corp. v. Stewart Info. Servs. Corp., 665 F.3d 930, 935 (7th Cir. 2012) (quoting Twombly, 550 U.S. at 556). "'A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.' To rise above the 'speculative level' of plausibility, the complaint must make more than '[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements.'" Oakland Police & Fire Ret. Sys. v. Mayer Brown, LLP, 861 F.3d 644, 649 (7th Cir. 2017) (citing Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009)). In deciding a Rule 12(b)(6) motion, the Court accepts as true all well-pleaded facts in a plaintiff's complaint, and draws all reasonable inferences in his favor. Burke v. 401 N. Wabash Venture, LLC, 714 F.3d 501, 504 (7th Cir. 2013) (citations omitted). "[A] a plaintiff is not required to plead facts in the complaint to anticipate and defeat affirmative defenses. But when a plaintiff's complaint nonetheless sets out all of the elements of an affirmative defense, dismissal under Rule 12(b)(6) is appropriate." Indep. Trust Corp., 665 F.3d at 935.

Defendants Argue that the Complaint Fails to Allege an Objective Falsity

In their motion, Defendants make a number of arguments. The first is that the Complaint fails to allege an objective falsity. Defendants argue that "[a] claim is not objectively false when

reasonable persons can read the government's guidance and disagree about whether the service was properly billed to the government." Motion to Dismiss, 7 (citing United States ex rel. Lamers v. City of Green Bay, 168 F.3d 1013, 1018 (7th Cir. 1999)). Defendants continue to argue that: (1) they relied on a reasonable interpretation of vague language in the Centers for Medicare & Medicaid Services National Coverage Determination for Sleep Testing for Obstructive Sleep Apnea ("Medicare Guidance"); (2) a disagreement about whether a test is medically necessary fails to satisfy the objective falsity required by the False Claims Act; and (3) that the Government failed to meet the heightened pleading standard of Rule 9(b)—"[t]he absence of allegations addressing why the claims were medical unnecessary mandates the Complaint be dismissed." Motion to Dismiss, 13.

Defendants' arguments about a reasonable interpretation of the Medicare Guidance and disagreements about medical necessity are inappropriate at this stage of litigation. Each of these arguments asks the Court to make a factual determination at the motion to dismiss stage, which the Court cannot do. A motion to dismiss pursuant to 12(b)(6) looks only to weather the complaint satisfies the plausibility standard, not the merits of the suit. Gibson, 910 F.2d at 1520. Here, Defendants ask the Court to make a factual determination about: the reasonableness of its statutory interpretation; whether it knowingly submitted false claims to Medicare; and whether the tests were medically necessary. Because these arguments are inappropriate for a motion to dismiss, they are disregarded.

As to the argument that the pleadings fail to satisfy the heightened pleading standard articulated in Rule 9, the Court disagrees. The Complaint provides numerous examples of multiple nights of tests being billed. Paragraphs 103, 114-119 allege that Medicare was billed for at least one duplicative night of testing, the patient, the date or dates, and the amounts paid.

Defendants' argument that the Government needs to allege why he tests were unnecessary—beyond the Medicare Guidance's determination that only one night of testing is medically necessary—is without merit. This case is readily distinguishable from United States ex rel. Presser v. Acacia Mental Health Clinic, LLC, where the plaintiff simply averred that the care rendered was unnecessary, but was unable to point to "policies or practices at other medical clinics, regulations, or other publications which call [defendant's] policies into question." 836 F.3d 770, 779 (7th Cir. 2016). Here, the Government repeatedly refers to Medicare Guidance and Snap's own past practices and literature. Accordingly, the Court finds that the Complaint does satisfy the heightened pleading standard for fraud, pursuant to Rule 9(b).

Defendants Argue That The Complaint Fails To Allege Materiality

Next, Defendants argue that the Complaint fails to satisfy the materiality requirements articulated in Universal Health Servs., Inc. v. United States and Massachusetts, *ex rel.* Julio Escobar and Carmen Correa, 136 S. Ct. 1989 (2016) (hereinafter, "Escobar"). They argue that a complaint must do more than show the Government had the option to decline payment, and that the Government's and that regular payment of certain types of claims is strong evidence that a requirement is not material. Moreover, Defendants urge the Court to shift the burden to the Government to show: (1) had the Government been aware of the duplicative billing it would not have paid the claims; (2) the Government warned Snap that duplicative billing was prohibited; and (3) the Government made prior efforts to recoup payments made.

First, the Court disregards the argument that the Government's routine payment of duplicative claims is strong evidence that the requirements were not material. This is an argument unfit for the motion to dismiss stage. Moreover, Defendants' argument is based on the logical falsity of *post hoc ergo propter hoc* and misstates the Supreme Court's position in

Escobar. Second, Defendants cite United States v. Sanford-Brown, Ltd., which the Court finds persuasive. 840 F.3d 445, 447 (7th Cir. 2016).

Sanford-Brown requires "two conditions [be] met: 'first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths.'" Sanford-Brown, Ltd., 840 F.3d at 447 (7th Cir. 2016) (citing Escobar, 136 S. Ct. at 2001). Here, the Complaint alleges that, according to Medicare Guidance, Medicare would only cover a second or third night of Sleep Apnea testing where it was medically necessary. Thus, by submitting subsequent nights of testing, Snap represented that those tests were medically necessary. Therefore, by routinely submitting claims for unnecessary second and third nights of testing, Defendants mislead the Government. Accordingly, the Court finds that the Complaint satisfies the materiality requirement as articulated in Sanford-Brown and states claims for violations of the False Claims Act.

Defendants Argue that the Complaint Fails to Allege Kickbacks

Defendants argue that the Complaint fails to plead violations of anti-kickback statute with requisite particularity and that no inappropriate conduct took place. As an initial matter, the Court finds Defendants' Rule 9(b) argument without merit. The Complaint outlines numerous instances of alleged kickbacks being distributed, the individuals involved, the method used, and the time frame in which they took place. Accordingly, the Court finds the Complaint contains the requisite particularity.

As to Defendants' arguments that the billing of the professional component, free tests, and commissions are not sufficient to allege fraud are without merit. Defendants' argue, first,

that allowing physicians to bill for the professional component is not enough to show a violation of the anti-kickback provision of the False Claims Act. This argument is unfounded. The Complaint explicitly quotes Raviv and Burton discussing their "business model" wherein referring physicians were able to bill of the professional component of the test saying that it "drove volume[,]" Compl. ¶ 127, and "the doctor's making the money off the professional component... So they're—so we don't have to pay, because we've given them, we're giving them... a billing." Compl. ¶ 132. Moreover, the following allegations quote Raviv discussing the success of this inducement model. Compl. ¶ 134.

Second, Defendants argue that because the IRS deemed Snap's Territory Managers as employees in the years prior to their internal classification as such, there can be no anti-kickback statute violation. This is not an argument fit for a motion to dismiss.

Finally, Defendants argue that because no alleged false claims can be shown to result from the free tests given to staff members, the Complaint cannot satisfy the heightened pleading standard for fraud claims. The Court disagrees. The Complaint alleges that Territory managers were encouraged to seek out an office champion—a nurse or office manager—and provide them a free test because they would be a person "most valuable to Snap[.]" Compl. ¶ 161 (quoting Gardea). Additionally, the Complaint alleges the necessary who, what, and when required by Rule 9. Accordingly, the Court finds the Complaint alleges violations of the anti-kickback provisions of the False Claims Act with the requisite particularity.

Defendants Argue the Complaint Fails to Allege Claims Against Individual Defendants

Defendants' final argument for dismissal is completely baseless. Defendants argue that the communications within the Compliant are insufficient to infer more than the possibility of misconduct by Burton or Raviv (the "Individual Defendants") or that the Individual Defendants

acted knowingly. However, this argument ignores the numerous quotations within the Complaint. The Complaint alleges the Individual Defendants orchestrated a scheme where: individual Territory Managers were given illegal incentives, Medicare was being wrongfully billed for multiple nights of testing, and doctors were given effort-free billing opportunities. The Complaint directly quotes Individual Defendants discussing the "business model" and how their kickback scheme would drive the volume of tests given and their duplicative billing would drive up revenues. See Compl. ¶¶ 79-81 & 84-90 (discussing multi-night testing, analyzing, and billing); ¶¶ 97-98 & 105 (quoting Raviv discussing profitability of multi-night billing); ¶¶ 127-129 & 131-132 (discussing generating revenue and giving doctors an effort-free billing). Accordingly, the Court finds the Complaint does state claims against the Individual Defendants for violations of the False Claims Act.

CONCLUSION

Because the Complaint satisfies the plausibility standard articulated by Bell Atlantic Corporation v. Twombly and Ashcroft v. Iqbal; and because the Complaint satisfies the heightened pleading standard of Rule 9(b) for fraud claims, Defendants' motion to dismiss is denied.

IT IS SO ORDERED.

ENTER:

CHARLES RONALD NORGLE, Judge
United States District Court

DATE: June 5, 2018