# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA, et al.,	)
<u>ex rel.</u> TINA D. GROAT,	)))))
Plaintiffs,	)
v.	)
BOSTON HEART DIAGNOSTICS CORPORATION,	)))))
Defendant.	)

Civil Action No. 15-487 (RBW)

# **MEMORANDUM OPINION**

The plaintiff/relator, Tina D. Groat, M.D., brings this <u>qui tam</u> action against the defendant, Boston Heart Diagnostics Corporation ("Boston Heart"), under the federal False Claims Act, 31 U.S.C. § 3729 (2012), and various analog state false claims statutes. <u>See</u> Relator's Second Amended Complaint Pursuant to the Federal False Claims Act, 31 U.S.C. §§ 3729 <u>et seq.</u> and Pendent State False Claims Acts ("2d Am. Compl.") ¶ 1. Currently before the Court are the Relator's Motion for Judicial Notice ("Relator's Mot.") and Boston Heart Diagnostics Corporation's Motion to Dismiss Relator's Second Amended Complaint ("Def.'s Mot."), which seeks dismissal of the plaintiff's Second Amended Complaint pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6). <u>See</u> Def.'s Mot. at 2. Upon careful consideration of the parties' submissions,<sup>1</sup> the Court concludes that it must grant the relator's motion for judicial notice and grant in part and deny in part Boston Heart's motion to dismiss.

<sup>&</sup>lt;sup>1</sup> In addition to the filings already identified, the Court considered the following submissions in rendering its decision: (1) the Memorandum of Law in Support of Boston Heart Diagnostics Corporation's Motion to Dismiss (continued . . . )

## I. BACKGROUND

## A. Statutory Background

A brief overview of the Medicare program will help elucidate the relator's allegations in this case. Medicare is a federal health insurance program for the elderly and people with disabilities. <u>See</u> 42 U.S.C. § 1395c (2012). Medicare Part B, which provides outpatient coverage for, among other things, diagnostic laboratory tests, <u>see</u> 42 C.F.R. § 410.32 (2016), only covers medical services that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member," 42 U.S.C. § 1395y(a)(1)(A). "[Laboratory t]ests that are performed in the absence of signs, symptoms, complaints, personal history of disease, or injury are not covered except when there is a statutory provision that explicitly covers tests for screening as described." Medicare Claims Processing Manual: Chapter 16—Laboratory Services § 120.1, <u>available at</u> https://www.cms.gov/ Regulations-and-Guidance/Guidance/Manuals/downloads/clm104C16.pdf (last visited May 16, 2017).

Medicare establishes its national payment policy for covered items or services through national coverage determinations, which are formal decisions by the Secretary of Health and Human Services regarding whether, and under what circumstances, Medicare covers a particular item or service. <u>See</u> 42 U.S.C. § 1395ff(1); 42 C.F.R. § 405.1060(a). National coverage determinations are binding on both Medicare contractors and administrative law judges, who preside over Medicare coverage appeals. <u>See</u> 42 U.S.C. § 1395ff(1)(A)(i); 42 C.F.R

<sup>(...</sup> continued)

Relator's Second Amended Complaint ("Def.'s Mem."); (2) the Relator's Oppos[i]tion to Defendant's Motion to Dismiss Relator's Second Amended Complaint ("Relator's Opp'n"); and (3) Boston Heart Diagnostics Corporation's Reply in Support of its Motion to Dismiss Relator's Second Amended Complaint ("Def.'s Reply").

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§ 405.1060(a). Medicare contractors process and pay Medicare claims within a specified jurisdiction on behalf of the Centers for Medicare and Medicaid Services ("CMS"), and have authority to issue local coverage determinations for that jurisdiction. See 42 U.S.C. § 1395ff(f)(2); see also id. § 1395m-1(g)(noting that Medicare contractors may issue local coverage determinations regarding clinical diagnostic laboratory tests under the same process). Local coverage determinations, like national coverage determinations, govern Medicare coverage for a particular item or service. See id. § 1395ff(f)(2)(b). Administrative law judges "give substantial deference" to local coverage determinations, but they are not bound by them. 42 C.F.R. § 405.1062.

An entity seeking reimbursement for services provided to Medicare patients must submit a CMS-1500 form to the Medicare contractor. <u>See United States ex rel. Hobbs v. MedQuest</u> <u>Assocs., Inc.</u>, 711 F.3d 707, 711 (6th Cir. 2013). "The[ CMS-1500] form[] reflect[s] the treatment or services provided and identif[ies] the [entity that] provided them. Tests, supplies, and services are correlated to a series of unique numbers, called CPT codes, which quickly convey to the [claims processor] what reimbursable expenses the [entity] has incurred." <u>Id.</u> at 711. The CMS-1500 form requires the entity to certify that, among other things, "the services on this form were medically necessary." Health Insurance Claim Form ("CMS-1500") at 2, <u>available at https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf</u> (last visited May 16, 2017).

## **B.** Factual Background and Procedural History

The relator is a medical doctor and the National Medical Director of Women's Health and Genetics at United Healthcare ("United"), 2d Am. Compl. ¶ 6, which is a health insurance company that offers Medicare and Medicaid insurance coverage, TriCare health insurance

coverage, as well as employer-sponsored and individual health insurance coverage, <u>id.</u>  $\P$  23. The relator alleges the following in her Second Amended Complaint.

Boston Heart is a clinical laboratory located in Framingham, Massachusetts, which "provides diagnostic testing related to cardiovascular health," 2d Am. Compl. ¶ 24, by "conducting laboratory tests that are ordered by doctors and other healthcare providers," <u>id.</u> ¶ 50.<sup>2</sup> "To facilitate the ordering of those tests, [Boston Heart] supplies doctors with pre-printed test requisition forms which that doctor fills out and sends to the [Boston Heart] laboratory along with the patient's specimen that is to be tested." <u>Id.</u>

These test requisition forms include a list of the tests that the lab[oratory] performs for the doctor to select based on the doctor's examination of the patient and subsequent diagnosis. The form also groups certain tests together in test panels, which allows the doctor to easily order several tests at once simply by checking one box on the form.

<u>Id.</u> ¶ 51. "After the lab[oratory] conducts the tests ordered, it bills the government [or government intermediary] . . . for tests performed for Medicare [and other government health insurance] patients." <u>Id.</u> ¶ 55.

The relator alleges that various genetic and non-genetic tests<sup>3</sup> performed by Boston Heart are not medically necessary for patients with the following four diagnostic codes: (1) routine general medical examination at a health care facility; (2) essential hypertension (high blood pressure); (3) other and unspecified hyperlipidemia (high cholesterol); and (4) other malaise and

<sup>&</sup>lt;sup>2</sup> For simplicity's sake, the Court will refer to these health care providers only as "doctors."

<sup>&</sup>lt;sup>3</sup> The specific genetic tests at issue are: (1) prothrombin, coagulation factor II; (2) coagulation factor V; (3) 5, 10-methylenetetrahydrofolate reductase; (4) cytochrome P450, family 2, subfamily C, polypeptide 19; (5) genotyping to determine cytochrome p450, family 2, subfamily C, polypeptide 19 and vitamin K epoxide reductase subunit C1 genetic polymorphisms for the purpose of managing the administration and dosing of warfarin; and (6) molecular pathology procedure, Level 2, used for apolipoprotein E genotyping. 2d Am. Compl. at 18–19. The specific non-genetic tests at issue are: (1) additional cholesterol particles testing for LDL and HDL subspecies; (2) high-sensitivity c-reactive protein; (3) fibrinogen; (4) FFA/NEFA; (5) cystatin-c; (6) omega 3; and (7) AspirinWorks. Id. at 19.

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fatigue (collectively, "the four diagnostic codes"). See id. ¶¶ 57–59. Specifically, the relator alleges:

when any of these four [] diagnostic codes are given to a patient in the absence of other diagnostic codes, the tests set forth above are . . . known to be medically unnecessary because they (1) do not and cannot predict the patient's risk of future heart disease, (2) do not and cannot screen for any currently existing heart disease in the patient, and (3) provide no additional information regarding the cardiovascular-related diagnoses sometimes used to justify these tests, such as hypertension, hyperlipidemia, or malaise and fatigue, and (4) have no bearing on any potential treatments for those diagnoses.

Id. ¶ 59. According to the relator, when these tests are ordered for patients with some or all of the four diagnostic codes, they are used solely for screening purposes on adults who do not exhibit "signs, symptoms, complaints, or personal history of heart disease," and thus are not covered by Medicare or other government health care programs. Id. ¶ 70; see also id. ¶ 67. To support her allegation, the relator relies on the Guideline for Assessment of Cardiovascular Risk in Asymptomatic Adults in November 2010 (the "Guideline"), jointly published by the American Heart Association and the American College of Cardiology, id. ¶¶ 61–62 (noting that the Guideline "specifically recommends against certain of these tests to assess the risk of developing heart disease"), as well as various national and local coverage determinations made by the government and its contractors, respectively, id. ¶¶ 67–69, 73–74.

The relator also relies on the data examined by her team at United, which, in order to "evaluat[e] the drivers of increased costs in women's care and genetic testing[,]... examined the volume and type of genetic testing purportedly related to cardiac risk performed for thousands of patients by hundreds of laboratories that bill to United." <u>Id.</u> ¶ 119. "Because [United] provides and services [health insurance plans that] are funded by Medicare and Medicaid dollars, [the r]elator received and evaluated [United] data that showed that Boston Heart submitted claims to [United] on behalf of patients insured under [government health insurance plans] for the tests at

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issue here." Id. ¶ 136. "[B]y examining data for the year 2013," id. ¶ 120, the relator "identified a combination of seven tests that are frequently performed and billed by Boston Heart and specifically compared Boston Heart's billing of that combination to other laboratories," id. ¶ 121. According to the relator, the comparison revealed that "Boston Heart was an extreme outlier in the frequency of billing this combination of seven tests," id. ¶ 122, and that examination "of specific claims submitted to United [] show that Boston Heart was billing for medically unnecessary tests to screen for cardiac-related issues and predict future cardiac risk," id. ¶ 124. The relator alleges that "Boston Heart encourages providers to order these medically unnecessary tests," id. ¶ 132, through marketing materials and test panels on pre-printed test requisition forms, see id. ¶¶ 52, 94, 127, 132, and that "General Practitioners and other non-cardiology physicians are Boston Heart's primary target" for its allegedly false marketing statements regarding the medical necessity of its tests, id. ¶ 127, and their ability "to predict cardiac risk," id. ¶ 131. Ultimately, the relator met with Boston Heart's CEO and its Vice President of Payer Innovation and Strategy on August 15, 2014, and told them "that their test panels included many unnecessary tests." Id. ¶ 128–30; see also Relator's Opp'n at 35 (identifying the Boston Heart meeting attendees as the CEO and Vice President of Payor Innovation and Strategy).

Based on these factual allegations, the relator filed her original complaint under seal on February 3, 2015.<sup>4</sup> See Relator's Complaint Pursuant to the Federal False Claims Act, 31 U.S.C. §§ 3729 et seq. and Pendent State False Claims Acts at 1, ECF No. 1. On May 11, 2015, the relator filed her first amended complaint. See Relator's Amended Complaint Pursuant to the Federal False Claims Act, 31 U.S.C. §§ 3729 et seq. and Pendent State False Claims Acts at 10,

<sup>&</sup>lt;sup>4</sup> The relator originally filed her Complaint in the United States District Court for the Eastern District of Virginia, which subsequently transferred the case to this Court on the United States' motion to change venue. <u>See</u> Civil Docket for Case #: 1:15-cv-00121-GBL-JFA, ECF No. 9 (docket entry dated April 2, 2015).

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ECF No. 19. On August 19, 2016, the United States, along with the twenty-seven states and the District of Columbia on whose behalf the relator asserted false claims act violations, declined to intervene in this case, <u>see</u> Notice of Election to Decline Intervention and to Dismiss Claims Asserted on [] Behalf of Maryland (Aug. 19, 2016), ECF No. 28, and the Court dismissed the "claims brought by the relator on behalf of the State of Maryland" and ordered that the case be unsealed, Order at 1-2 (Aug. 24, 2016), ECF No. 29.<sup>5</sup>

On October 27, 2016, the relator filed her Second Amended Complaint. See 2d Am. Compl. at 1. Count I of the Second Amended Complaint alleges both a violation of 31 U.S.C. § 3729(a)(1)(A), the "false claims" provision of the False Claims Act, as well as a violation of 31 U.S.C. § 3729(a)(1)(B), the "false statements" provision. See 2d Am. Compl. ¶¶ 143–44. Count II alleges a violation of 31 U.S.C. § 3729(a)(1)(G), the "reverse false claims" provision of the False Claims Act. See 2d Am. Compl. ¶ 150. Counts III through XXXI allege violations of twenty-seven states' and the District of Columbia's false claims statutes. See id. ¶¶ 154–381. The defendant now moves to dismiss all of the relator's claims pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6).

### II. STANDARD OF REVIEW

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). Thus, to survive a motion to dismiss for "failure to state a claim upon which relief can be granted," Fed. R. Civ. P. 12(b)(6), the complaint "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that

<sup>&</sup>lt;sup>5</sup> The Court dismissed the claims on behalf of Maryland because that state's false claims statute only allows an action to proceed if the state intervenes. <u>See</u> Notice of Election to Decline Intervention and to Dismiss Claims Asserted on [] Behalf of Maryland at 1 (Aug. 19, 2016), ECF No. 28 (quoting Md. Code Ann., Health-Gen. § 2-604(a)(7) (2015)).

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is plausible on its face," Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). "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." Id. (citing Twombly, 550 U.S. at 556). Although the Court "must treat the complaint's factual allegations as true [and] must grant [the] plaintiff the benefit of all reasonable inferences from the facts alleged," Trudeau v. Fed. Trade Comm'n, 456 F.3d 178, 193 (D.C. Cir. 2006) (first alteration in original) (citation omitted), legal allegations devoid of factual support are not entitled to this assumption, see, e.g., Kowal v. MCI Commc'ns Corp., 16 F.3d 1271, 1276 (D.C. Cir. 1994). Moreover, a plaintiff must provide more than "a formulaic recitation of the elements of a cause of action." Hinson ex rel. N.H. v. Merritt Educ. Ctr., 521 F. Supp. 2d 22, 27 (D.D.C. 2007) (quoting Twombly, 550 U.S. at 555). "And, '[i]n determining whether a complaint states a claim, the court may consider the facts alleged in the complaint, documents attached thereto or incorporated therein, and matters of which it may take judicial notice." Farah v. Esquire Magazine, 736 F.3d 528, 534 (D.C. Cir. 2013) (alterations in original) (quoting Abhe & Svoboda, Inc. v. Chao, 508 F.3d 1052, 1059 (D.C. Cir. 2007)).

Fraud claims are also subject to the heightened pleading requirement of Rule 9(b), which provides that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b); <u>see also United States ex rel.</u> <u>Heath v. AT & T, Inc.</u>, 791 F.3d 112, 123 (D.C. Cir. 2015) (applying Rule 9(b) to claims filed pursuant to the False Claims Act). "The rule serves to 'discourage[] the initiation of suits brought solely for their nuisance value, and safeguards potential defendants from frivolous accusations of moral turpitude." <u>Heath</u>, 791 F.3d at 123 (alteration in original) (quoting <u>United</u> <u>States ex rel. Williams v. Martin-Baker Aircraft Co.</u>, 389 F.3d 1251, 1256 (D.C. Cir. 2004)).

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Further, "the complaint must be particular enough to 'guarantee all defendants sufficient information to allow for preparation of a response." <u>Id.</u> (quoting <u>Williams</u>, 389 F.3d at 1256). "Rule 9(b) is not an antithesis of Rule 8(a)'s 'short and plain statement' requirement, but rather a supplement to it." <u>Baker v. Gurfein</u>, 744 F. Supp. 2d 311, 315 (D.D.C. 2010) (Walton, J.) (citing <u>Williams</u>, 389 F.3d at 1256). Accordingly, in order to withstand a motion to dismiss for failure to plead a False Claims Act claim with the degree of particularity required by Rule 9(b), a "complaint must . . . provide a defendant with notice of the who, what, when, where, and how with respect to the circumstances of the fraud." <u>Stevens v. InPhonic, Inc.</u>, 662 F. Supp. 2d 105, 114 (D.D.C. 2009) (Walton, J.) (internal quotation marks and citations omitted)).

### III. ANALYSIS

### A. Count I

## 1. The Presentment Claim Allegation

"The False Claims Act imposes civil liability on any person who knowingly submits false claims to the government." <u>United States ex rel. Digital Healthcare, Inc. v. Affiliated Comput.</u> <u>Servs., Inc.</u>, 778 F. Supp. 2d 37, 44–45 (D.D.C. 2011) (Walton, J.) (citing 31 U.S.C. §§ 3729–3733). Section 3729(a)(1)(A) creates liability for "any person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). The elements for a "presentment claim" violation are "(1) the defendant submitted or caused to be submitted a claim to the government, (2) the claim was false, and (3) the defendant knew the claim was false." <u>United States ex rel. Morsell v. Symantec Corp.</u>, 130 F. Supp. 3d 106, 118 (D.D.C. 2015) (quoting <u>United States ex rel. Tran v. Comput. Scis. Corp.</u>, 53 F. Supp. 3d 104, 121–22 (D.D.C. 2014)).

### a. Whether Boston Heart Submitted Claims to the Government

Boston Heart argues that the relator failed to plead that Boston Heart submitted claims for government payment with the degree of particularity required by Rule 9(b) because "[s]he plead[ed] no information to identify any single claim that Boston Heart submitted to Medicare," Def.'s Mem. at 37, such as the specific individuals who submitted the allegedly false claims, <u>see id.</u>, or "the amount of reimbursement Boston Heart received from Medicare as a result of alleged false claims," <u>id.</u> at 38; <u>see also id.</u> at 26–27 (arguing that the relator failed to plead that Boston Heart submitted claims for payment). The relator argues in response that she is not "required to plead the facts or details of the fraudulent claims," such as the actual amount of false claims, nor the identity of any individual at Boston Heart with knowledge of the fraud, to satisfy Rule 9(b), Relator's Opp'n at 44, and that, in any event, she did plead "that Boston Heart submitted false claims to Medicare Advantage Plans and Managed Medicaid Plans, which are funded by Medicare and Medicaid dollars," <u>id.</u> at 36–37 (citing 2d Am. Compl. ¶ 136). The Court agrees with the relator that she has sufficiently pleaded the submission of claims to the government.

The District of Columbia Circuit has made clear that although Rule 9(b) requires the relator to "state with particularity the circumstances constituting <u>fraud</u>," <u>Heath</u>, 791 F.3d at 123 (emphasis added) (quoting Fed. R. Civ. P. 9(b)), she is not required "to plead representative samples of claims actually submitted to the government [because that] would require relators, before discovery, to prove more than the law requires to be established at trial," <u>id.</u> at 126; <u>see also id.</u> at 126–27 ("We decline to read Rule 9(b) as requiring more factual proof at the pleading stage than is required to win on the merits." (footnote omitted)). Nor is the relator required to identify specific individuals at Boston Heart allegedly responsible for the fraud, because she has alleged fraud at the corporate level. <u>See id.</u> at 125 (noting that "Heath <u>does</u> identify a specific

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actor—AT & T itself.... The complaint makes clear, in other words, that corporate levers were pulled; identifying precisely who pulled them is not an exorable requirement of Rule(9)(b) in all cases"); see also 2d Am. Compl. ¶¶ 6, 52, 94, 127, 132 (detailing Boston Heart's alleged scheme to induce general practitioners to order medically unnecessary tests through marketing materials and pre-printed test requisition forms).

What the relator pleads is that, based on her review of United data regarding Boston Heart laboratory tests in 2013, Boston Heart submitted over \$369,000 in claims to United <u>alone</u> for the genetic tests at issue on behalf of patients with the four relevant diagnoses insured under both Medicare and Medicaid, <u>see id.</u> ¶¶ 136–38, and that Boston Heart also submitted claims for the nongenetic tests at issue for similar patients, <u>see id.</u> ¶ 139. In other words, the relator "corroborated" her allegation that Boston Heart submitted claims to the government by providing a "concrete example" of a portion of the representative claims submitted to United for Medicare and Medicaid patients "that follow[] the [Second Amended C]omplaint's pattern." <u>See Heath</u>, 791 F.3d at 126 ("Heath's complaint passes th[e Rule 9(b)] test. He provides factual specificity concerning the type of fraud, how it was implemented, and the training materials used, all of which is then corroborated by the concrete example of the Detroit audit documenting the very type of overbilling that follows the complaint's pattern."). Accordingly, the relator sufficiently pleaded that Boston Heart submitted claims to the government for payment.<sup>6</sup>

<sup>&</sup>lt;sup>6</sup> Boston Heart also argues that the claims alleged in Counts I and II as to other federal health care programs besides Medicare should be dismissed because the relator "alleges no law or facts" regarding claims submitted for patients insured by those health care programs. Def.'s Mem. at 41. The Court agrees with the relator that because she has sufficiently "alleged that Boston Heart was in the business of conducting laboratory tests on patients with all types of health insurance and earned revenue by being paid by those health insurers for the tests in conducted," Relator's Opp'n at 43 n.25, the Court "must grant [the relator] the benefit of [the] reasonable inference," <u>Trudeau</u>, 456 F.3d at 193, that, "in addition to submitting claims for the tests at issue here directly to Medicare [and Medicaid plans], Boston Heart also submitted claims to TRICARE and the Veterans Administration," Relator's Opp'n at 43 n.25.

## b. Whether the Claims Were False

Under the False Claims Act, a claim may be either factually false, "in which a . . . claimant submits information that is untrue on its face," United States v. Kellogg Brown & Root Servs., Inc., 800 F. Supp. 2d 143, 154 (D.D.C. 2011), or legally false, in which the claim "rest[s] on a false representation of compliance with an applicable federal statute, federal regulation, or contractual term," id. (quoting United States v. Sci. Applications Int'l Corp., 626 F.3d 1257, 1266 (D.C. Cir. 2010) ("SAIC")). "A legally false claim, also known as a 'false certification,' can be either 'express' or 'implied.'" Id. (quoting SAIC, 626 F.3d at 1268). "An express false certification occurs when a claimant explicitly represents that he or she has complied with a contractual condition, but in fact has not complied." Id. An implied false certification, on the other hand, occurs when a claimant "makes no affirmative representation but fails to comply with a contractual or regulatory provision 'where certification was a prerequisite to the government action sought." Id. (quoting SAIC, 626 F.3d at 1266). Under either an express or implied false certification claim, the plaintiff must plead that the defendant "knowingly violated a requirement that the defendant knows is material to the Government's payment decision." Universal Health Servs., Inc. v. United States, \_\_ U.S. \_\_, \_\_, 136 S. Ct. 1989, 1996 (2016). The False Claims Act defines "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

Boston Heart argues that the relator failed to plausibly allege that the claims it submitted for payment were false for four reasons. The Court will consider each argument in turn.

# i. Boston Heart's Alleged Failure to Comply with Regulations or Submission of False Information

Boston Heart argues that because the relator does not plead "that any information on any claim submitted by Boston Heart was factually inaccurate," the relator has failed to plausibly allege falsity. Def.'s Mem. at 15. The Court is unpersuaded by this argument because, as discussed above, "legally false" claims are also viable under the False Claims Act. See, e.g., Kellogg Brown & Root Servs., 800 F. Supp. 2d at 154–55 (discussing the difference between factually false and legally false claims). The Second Amended Complaint makes clear that the relator is alleging that Boston Heart's claims were "legally false" because, according to the relator, Boston Heart certified that the tests it performed were medically necessary even though they were not medically necessary for certain populations. See 2d Am. Compl. ¶ 57–74. And, contrary to Boston Heart's assertion, see Def.'s Mem. at 15, the relator does allege that Boston Heart failed to comply with the Medicare rules restricting covered services to those that are medically necessary, see 2d Am. Compl. ¶¶ 32–43, 121–24; see also Gulfcoast Med. Supply, Inc. v. Sec'y, Dep't of Health & Human Servs., 468 F.3d 1347, 1349 (11th Cir. 2006) ("[Medicare] Part B coverage only extends to those medical services that are medically 'reasonable and necessary' for the beneficiary." (citing 42 U.S.C. § 1395y(a); 42 C.F.R. § 411.15(k)); United States ex rel. Riley v. St. Luke's Episcopal Hosp., 355 F.3d 370, 376 n.6 (5th Cir. 2004) ("That the services [billed are] medically necessary is a condition for payment under the [Medicare] regulations."). Accordingly, the relator does allege that Boston Heart failed to comply with Medical regulations despite its express certification to the contrary on the CMS-1500 form, see 2d Am. Compl. ¶¶ 33, 143, which, if true, would constitute an express false certification, see SAIC, 626 F.3d at 1266.

## ii. Boston Heart's Tests for Screening Purposes

Boston Heart argues that the relator did not plead that the claims it submitted were false because she "fails to allege any facts demonstrating that physicians ordered the Boston Heart [t]ests merely for screening purposes," Def.'s Mem. at 16, and fails to identify a single patient who did not warrant the specific tests ordered, <u>see id.</u> at 17. The relator argues in response that she alleged that the tests at issue are not medically necessary for patients with the four diagnostic codes, and thus were legally false. <u>See</u> Relator's Opp'n at 22.

The Court agrees with the relator that she has pleaded sufficient facts to support her claim that the tests were ordered for medically unnecessary screening purposes. The Second Amended Complaint states that, based upon the relator's examination of "the volume and type of genetic testing purportedly related to cardiac risk performed for thousands of patients by hundreds of laboratories that bill to United," 2d Am. Compl. ¶ 119, including Boston Heart, for the year 2013, see id. ¶ 120, "[t]he vast majority of the Boston Heart tests at issue here are being used for screening purposes (i.e. to discover whether the patient currently has heart disease) or to assess whether the patient has a risk of developing cardiac illness and potential cardiac complications in the future (cardiac risk)," id. ¶ 58. Further, the relator pleaded that "only one or some or all of the [four diagnostic codes] . . . are commonly seen in patients whose specimens have been submitted to the Boston Heart lab[oratory] for testing," id., but that, for patients without "other diagnostic codes, the [] tests [at issue] are worthless, of no therapeutic or predictive value whatsoever and known to be medically unnecessary," id. ¶ 59. The relator supported her allegations regarding lack of medical necessity by citing the Guideline, id. ¶¶ 61–64, the Medicare statute and regulations, id. ¶ 67, and local coverage determinations, id. ¶¶ 68–69, 74,

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77–78, 84, 90, 99–109, 111–17.<sup>7</sup> The relator also provided an example of a specific claim Boston Heart submitted to United, in which Boston Heart billed United for twenty-four tests performed for a patient identified as having high cholesterol, high blood pressure, and Type II diabetes. <u>See id.</u> ¶ 124. According to the relator, none of these tests "predict cardiac risk" or "provide any relevant medical information" for that patient. <u>Id.</u> Accordingly, the Court concludes that the relator has sufficiently pleaded facts demonstrating falsity because, based on her review of United's data regarding Boston Heart tests ordered for United insureds who have government health insurance, Boston Heart allegedly billed for tests that were used merely for screening purposes for patients with the four diagnostic codes, cited government and scientific authority to support those facts, and provided a specific example of Boston Heart tests ordered for a particular patient.

## iii. Whether Boston Heart Must Determine Medical Necessity

As stated above, the relator supported her allegations that the tests at issue are not medically necessary for patients with the four diagnostic codes by citing the Guideline. See 2d Am. Compl. ¶¶ 61–65. Boston Heart contends that because a doctor, and not a laboratory such as Boston Heart, determines the medical necessity of a particular test, it "is not in a position to

<sup>&</sup>lt;sup>7</sup> After Boston Heart filed its motion to dismiss, the relator filed her motion for judicial notice, requesting that the Court take judicial notice of various local coverage determinations, <u>see generally</u> Relator's Mot, which are available on CMS's website, <u>see Indexes</u>, Centers for Medicare & Medicaid Services, https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx (last visited June 2, 2017). Pursuant to Local Rule 7(m), the relator's counsel contacted Boston Heart's counsel, who indicated that Boston Heart opposed the relator's motion. <u>See id.</u> ¶ 12. Boston Heart, however, did not file an opposition to the relator's motion. Accordingly, the Court will grant the relator's motion as conceded, <u>see</u> Local Rule 7(b) (noting that if a memorandum in opposition to a motion is not filed within fourteen days, "the Court may treat the motion as conceded"), and take judicial notice of the local coverage determinations, <u>see Farah v. Esquire Magazine</u>, 736 F.3d 528, 534 (D.C. Cir. 2013) (stating that a court may consider "matters of which it may take judicial notice of information posted on official public websites of government agencies," <u>Pharm. Research & Mfrs. of Am. v. United States Dep't of Health & Human Servs.</u>, 43 F. Supp. 3d 28, 33 (D.D.C. 2014) (taking judicial notice of a page on the FDA's website); <u>see also United States ex rel.</u> Modglin v. DJO Global Inc., 114 F. Supp. 3d 993, 1001 n.34 (C.D. Cal. 2015) (taking judicial notice of a national coverage determination).

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apply [the Guideline] to any particular patient or test ordered, nor is it required to do so." Def.'s Mem. at 18. Consequently, Boston Heart contends, the Guideline is inapposite. See id. at 17. According to Boston Heart, "[w]hen a laboratory bills Medicare for testing ordered by a physician, it must only (1) maintain 'documentation [it] receives from the ordering physician'; and (2) ensure that 'the information that it submitted with the claim accurately reflects the information it received from the ordering physician." Id. at 9–10 (quoting 42 C.F.R. § 410.32(d)(2)(ii)(A)-(B)). Boston Heart contends that the CMS-1500 form "certification does not require that the billing laboratory make [the medical necessity] determination. Instead, under the Medicare Part B framework, the laboratory certifies that the services are medically necessary by relying on the clinical determination of the treating physician." Def.'s Reply at 21 n.26. The relator argues in response that Boston Heart "has an independent duty to ensure the medical necessity of the tests it performs," and that "[b]lind deference to the ordering physician is not allowed when the lab[oratory] itself is performing, and being paid by the Government for, the service." Relator's Opp'n at 26; see also id. at 10–12 (arguing that Boston Heart, as the entity submitting the claim for payment, "must certify the medical necessity of the services for which [it is] seeking reimbursement").

The Court agrees with the relator that Boston Heart has an obligation to establish that the tests for which it seeks government reimbursement are medically necessary because when it submits the CMS-1500 form, it certifies that the tests performed were medically necessary. <u>See</u> CMS-1500 at 2 (requiring the billing entity to certify that, among other things, "the services on this form were medically necessary"). Boston Heart's reliance on the Medicare regulation regarding documentation and recordkeeping requirements is unavailing because that provision does not address the entity's certification of medical necessity on the CMS-1500 form. <u>See</u> 42

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C.F.R. § 410.32(d)(2). Although Boston Heart is correct that the provision requires both the doctor ordering the service and the entity submitting the claim for payment to maintain documentation regarding medical necessity, <u>see id.</u> § 410.32(d)(2)(i)-(ii), the CMS-1500 form requires the entity submitting the claim, be it a "physician <u>or</u> supplier," to certify the medical necessity, CMS-1500 at 2 (emphasis added). The regulation simply does not state that only the ordering physician, and not the entity submitting the claim, has the obligation to certify the medical necessity of the tests at issue when submitting claims for payment. <u>See</u> 42 C.F.R. § 410.32(d)(2)-(3). In sum, the regulation, which concerns recordkeeping, has no bearing on the certification of medical necessity on the CMS-1500 form.

Moreover, the regulatory scheme "places the burden of establishing the medical necessity of diagnostic tests on the entity submitting the claim." <u>Garcia v. Sebelius</u>, No. CV 10-8820 PA (RZx), 2011 WL 5434426, at \*7 (C.D. Cal. Nov. 8, 2011) (citing 42 C.F.R. §§ 410.32(d)(2)(ii), (d)(3)); <u>see also Nephropathology Assocs. PLC v. Sebelius</u>, No. 4:12CV00233JLH, 2013 WL 3285685, at \*4 (E.D. Ark. June 27, 2013) ("According to the Secretary, the burden remains on the entity submitting the claim to demonstrate that the services at issue were reasonable and necessary . . . . The Secretary's interpretation is not unreasonable." (citing 42 U.S.C. § 13951(e); 42 C.F.R. § 424.5(a)(6)). Boston Heart's argument to the contrary is belied not only by court decisions reviewing Medicare coverage determinations for claims submitted by laboratories in which the government determined that the tests at issue were not medically necessary, and the <u>laboratories</u>, not the ordering physicians, argued to the contrary, <u>see, e.g., KGV Easy Leasing</u> <u>Corp. v. Sebelius</u>, No. 09-56393, 2011 WL 490990, at \*1 (9th Cir. Feb. 14, 2011) (affirming the Secretary's determination that the diagnostic testing services performed by KGV, and independent diagnostic testing facility, "were not reimbursable by Medicare because <u>KGV</u> failed

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to demonstrate that the tests were medically reasonable and necessary" (emphasis added)); Strand Analytical Labs., LLC v. Burwell, No. 1:13-cv-00645-LJM-DKL, 2015 WL 4603258, at \*1 (S.D. Ind. July 30, 2015) (affirming the Secretary's decision to deny Medicare coverage for the laboratory's DNA test after concluding that it was not medically necessary), appeal docketed, No. 15-3133 (7th Cir. Sept. 25, 2015), but also by other False Claims Act actions against laboratories for allegedly submitting claims for medically unnecessary tests, see, e.g., United States ex rel. Merena v. SmithKline Beecham Corp., 205 F.3d 97, 98 (3d Cir. 2000) (describing the laboratory's "scheme that allowed them to bill the federal government for unauthorized and unnecessary laboratory tests . . . [by] 'bundl[ing] a standard grouping of blood tests with some additional tests and . . . market[ing] this grouping to doctors by leading them to believe that the additional tests would not increase costs to Medicare and other government-sponsored health programs"); United States v. Berkeley Heartlab, Inc., F. Supp. 3d \_\_, \_\_, 2016 WL 7851459, at \*2–3, 18 (D.S.C. Mar. 28, 2016) (declining to dismiss the government's False Claims Act allegations against the laboratory for "encourag[ing] physicians to order tests that were medically unnecessary"); see also Press Release, Department of Justice Office of Public Affairs, Justice Department Recovers over \$4.7 Billion from False Claims Act Cases in Fiscal Year 2016 (Dec. 14, 2016), available at https://www.justice.gov/opa/pr/justice-department-recovers-over-47billion-false-claims-act-cases-fiscal-year-2016 (last visited May 9, 2017) (noting that "[0]f the \$4.7 billion recovered, \$2.5 billion came from the health care industry, including . . . laboratories" (emphasis added)). Accordingly, the Court concludes that the relator pleaded facts sufficient to support her claim that Boston Heart's certifications of medical necessity were

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legally false because it had an independent obligation to certify that the tests for which it requested government reimbursement were medically necessary.<sup>8</sup>

### iv. Whether Boston Heart's Tests Are Medically Necessary

Boston Heart further argues that the medical literature it cites in its opposition "regarding the efficacy of . . . testing renders wholly implausible any assertion that Boston Heart was submitting false claims," and that "[a] mere difference of clinical judgment does not suffice to allege either falsity or knowledge under the [False Claims Act]." Def.'s Mem. at 19. The relator argues in response that Boston Heart's arguments regarding the medical necessity of these tests raise "an evidentiary question [that] is plainly inappropriate [for resolution] at the motion to dismiss stage," Relator's Opp'n at 22; see also id. at 30 (stating that Boston Heart is "ask[ing] the Court to disregard [the r]elator's factual allegations and simply accept Boston Heart's assertion that its tests have medical utility. This is inappropriate at the pleading stage, where the purported evidence proffered by Boston Heart is irrelevant").

The Court declines Boston Heart's invitation to weigh the medical literature it cites that purportedly conflicts with the Guideline and other sources cited by the relator in her Second

<sup>&</sup>lt;sup>8</sup> Boston Heart also argues that the national coverage determinations "are irrelevant to [the relator's] claims and misleading" because (1) one "covers lipid tests that are not among the Boston Heart [t]ests challenged in this action," and (2) the other refers to a Warfarin response test that "Boston Heart does not offer or perform." Def.'s Mem. at 21. In the Court's view, the relator does challenge lipid testing, see 2d Am. Compl. ¶¶ 57, 98 (including non-genetic tests for lipid particles in its list of tests at issue), and the parties' disagreement as to whether or not Boston Heart offers the genetic test for Warfarin response, see Def.'s Mem. at 21, is inappropriate to resolve at the motion to dismiss stage, see Trudeau, 456 F.3d at 193 (noting that the Court "must treat the complaint's factual allegations as true [and] must grant [the] plaintiff the benefit of all reasonable inferences from the facts alleged" (first alteration in original) (citation omitted)). Boston Heart further argues that the local coverage determinations cited do not cover Massachusetts, where Boston Heart is located, id. at 22. The Relator argues in response that it "has alleged that [n]ational [c]overage [d]eterminations [] and [local coverage determinations] very specifically and directly state that Boston Heart's tests are not medically necessary," Relator's Opp'n at 28, and states that it cited to local coverage determinations outside of Massachusetts "because they contain a thorough examination and consideration of the state of the science when reaching a conclusion on when a test can be considered medically necessary," id. The Court agrees with the relator that she cited the local coverage determinations not to allege that they were binding on Boston Heart, but as further support for her contention that the specific tests for patients with the four diagnostic codes at issue are not medically necessary.

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Amended Complaint to determine the medical necessity of the challenged tests for the patients at issue, because to do so would require it to "resolv[e] questions of fact not before it upon a motion to dismiss." <u>Covad Commc'ns Co. v. Bell Atl. Corp.</u>, 398 F.3d 666, 676 (D.C. Cir. 2005). Although the Court agrees with Boston Heart that "the prevailing view of courts is that 'contradiction based on clinical judgment or opinion alone cannot constitute falsity under the [False Claims Act] as a matter of law," Def.'s Mem. at 19 (quoting <u>United States v. AseraCare Inc.</u>, 176 F. Supp. 3d 1282, 1286 (N.D. Ala. 2016), then citing <u>United States ex rel. Morton v. A</u> Plus Benefits, Inc., 139 F. App'x 980, 983 (10th Cir. 2005); <u>United States ex rel. Wall v. Vista</u> Hospice Care, Inc., No. 3:07-cv-00604-M, 2016 WL 3449833 at \*17 (N.D. Tex. 2016); <u>United States v. Prabhu</u>, 442 F. Supp. 2d 1008, 1033 (D. Nev. 2006); <u>United States ex rel. Harris v.</u> Bernad, 275 F. Supp. 2d 1, 6–7 (D.D.C. 2003)), the Court simply cannot determine, without weighing the evidence, whether the relator's allegations regarding medical necessity constitute a "contradiction based on clinical judgment or opinion alone," <u>AseraCare</u>, 176 F. Supp. 3d at 1286.

Indeed, many of the cases that Boston Heart cites in support of its position that the relator's allegations regarding medical necessity should be dismissed as a matter of law due to differences in clinical judgment are opinions issued at the summary judgment stage. <u>See Wall</u>, 2016 WL 3449833 at \*16–21 (granting the defendants' motion for summary judgment because the relator failed to demonstrate falsity); <u>AseraCare</u>, 176 F. Supp. 3d at 1284 (granting summary judgment in favor of the defendant after granting a new trial because the government "failed to point the court to any admissible evidence to prove falsity"); <u>Prabhu</u>, 442 F. Supp. 2d at 1032, 1036 (granting the defendant's motion for summary judgment because the government failed to "establish falsity as a matter of law"). And the cases Boston Heart relies on regarding

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differences in clinical judgment that were decided at the motion to dismiss stage are distinguishable. First, in Harris, another member of this Court "agree[d] that mere disagreements over scientific opinion, methodology, and judgments do not amount to claims under the [False Claims Act]," but that language amounted to dicta because the Court denied the defendants' motion to dismiss due to the fact that the government sufficiently alleged that the defendants "knowingly upcoded by fraudulently claiming [] levels of services on the [predecessor form of the CMS-1500] form that were higher than the [] levels of service they actually provided." 275 F. Supp. 2d at 6. In Morton, the Tenth Circuit affirmed the district court's dismissal of the relators' False Claims Act claims because the relators' claim that medical care provided to a premature infant was "therapeutic" rather than "custodial" was "inherently ambiguous." 139 F. App'x at 983–94. The Tenth Circuit, however, made clear that its holding was limited to the facts of that case, noting that it was "not prepared to conclude that in all instances, merely because the verification of a fact relies upon clinical medical judgments, ... the fact cannot form the basis of a [False Claims Act] claim." Id. (noting that "not all clinical diagnoses and characterizations of medical care are intrinsically ambiguous"). Here, the Court cannot determine that the relator's allegations regarding medical necessity necessarily involve a difference of clinical judgment because to do so would require the Court to weigh the evidence, which is inappropriate at this stage of the litigation. See United States v. Toyobo Co. Ltd., 811 F. Supp. 2d 37, 47–48 (D.D.C. 2011) ("Toyobo's argument raises questions of fact that are more appropriately resolved after discovery closes .... Thus, these factual issues will not be resolved at the motion to dismiss stage of the litigation, where the plaintiff's factual allegations are accepted as true."); but see United States ex rel. Polukoff v. St. Mark's Hosp., No. 2:16-cv-00304-JNP-EJF, 2017 WL 237615, at \*11 (D. Utah Jan. 19, 2017) (granting the defendant's

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motion to dismiss a False Claims Act suit alleging that a doctor billed the government for a medically unnecessary procedure because, upon application of <u>Morton</u>, the court found that the medical necessity standard for that procedure "is inherently ambiguous, [and thus] these representations cannot be objectively false"). Rather, treating the relator's factual assertions as true, as it must, the Court concludes that the relator has sufficiently alleged that Boston Heart's claims were false, based on her allegation that it sought payment for medically unnecessary services.

### c. Boston Heart's Knowledge

The False Claims Act defines the knowledge element of a false claim or false statement action as requiring a defendant to have "actual knowledge of the information" or to "act[] in deliberate ignorance . . . [or] reckless disregard of the truth or falsity of the information. 31 U.S.C. § 3729(b)(1)(A). Importantly, the statutory definition of "knowledge" does not require "proof of specific intent to defraud." Id. § 3729(b)(1)(B). Accordingly, "[b]ecause Rule 9(b) permits knowledge to be pled generally, there is no basis for dismissal for failure to plead knowledge with particularity." <u>United States v. Honeywell Int'l, Inc.</u>, 798 F. Supp. 2d 12, 22 (D.D.C. 2011).

Boston Heart argues that the relator "makes no plausible allegation that Boston Heart knowingly submitted false claims," Def.'s Mem. at 24, because, according to Boston Heart, "a laboratory has no obligation to question a physician's medical judgment regarding whether testing is necessary for any particular patient," <u>id.</u> at 26. The relator argues in response that Boston Heart <u>does</u> have "an independent duty to ensure the medical necessity of the tests it performs and to maintain documentation evidencing the medical necessity." Relator's Opp'n at 26. The Court concludes, for the reasons discussed above, see Part III.A.1.b.3, that Boston Heart

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has an independent obligation to certify that the tests for which it bills the government are medically necessary.

Boston Heart also argues that the relator "fail[ed] to identify a single person who had the requisite knowledge with respect to the allegations." Def.'s Mem. at 37. The relator contends in response that she specifically alleged that Boston Heart's CEO and its Vice President of Payor Innovation and Strategy were on notice that its tests were not medically necessary after the relator met with them on August 15, 2014, <u>see id.</u> at 35; <u>see also</u> 2d Am. Compl. ¶¶ 128–30 (alleging that the relator met with Jeff Craven and Susan Hertzberg "on behalf of Boston Heart"), and that "[a]t the very least, [the r]elator has sufficiently alleged that Boston Heart submitted claims for tests in deliberate ignorance or with reckless disregard that they were not medically necessary" given "clear industry guidelines," <u>id.</u> at 36.

The Court agrees with the relator's position that she has sufficiently pleaded that Boston Heart <u>knew</u> that its tests were medically unnecessary because she alleges that Boston Heart engaged in a "systematic and fraudulent scheme," 2d Am. Compl. ¶ 6, in which "General Practitioners and other non-cardiology physicians are [the] primary target" of Boston Heart's "false marketing statements as to the benefits of and scientific validation of its tests, recommendations, purported leadership in the cardiac testing field[,] and structure of its claim form," <u>id.</u> ¶ 127. Specifically, the relator alleges that "Boston Heart encourages providers to order these medically unnecessary tests through, <u>inter alia</u>, written marketing materials," <u>id.</u> ¶ 132, and pre-printed test panel forms that "increase the number of tests that the laboratory conducts" by "including a number of medically unnecessary tests," <u>id.</u> ¶ 52; <u>see also id.</u> ¶ 94 ("Boston Heart promotes each of these genetic tests individually and through test panels that group together only a few medically justified tests with many medically unnecessary tests,

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including cardiac genetic tests, in order to increase the number of these medically unnecessary and worthless tests . . . . "). Because Rule 9(b) allows knowledge to "be alleged generally," Fed. R. Civ. P. 9(b), and the District of Columbia Circuit has approved complaints alleging that a corporation <u>itself</u> made false statements, <u>see Heath</u>, 791 F.3d at 125, the Court is satisfied that the Second Amended Complaint sufficiently pleads that Boston Heart <u>itself</u> had a scheme to knowingly target doctors who were not cardiac specialists and encourage them to order specific tests that were medically unnecessary for patients with specific diagnoses. Accordingly, because the relator adequately pleaded all three elements of a presentment claim violation under 31 U.S.C. § 3729(a)(1)(A), the Court declines to dismiss this claim.

# 2. The False Statements Allegation

Section 3729(a)(1)(B) of the False Claims Act creates liability for "any person who . . . 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)(B). The purpose of the false statements provision is to "prevent those who make false records or statements . . . from escaping liability solely on the ground that they did not <u>themselves</u> prevent a claim for payment or approval." <u>Morsell</u>, 130 F. Supp. 3d at 122 (quoting <u>Totten v. Bombardier Corp.</u>, 380 F.3d 488, 501 (D.C. Cir. 2004)). To establish a "false statements" violation, the relator must show that "(1) the defendant made or used [or caused to be made or used] a 'record or statement;' (2) the record or statement was false; (3) the defendant knew it to be false; and (4) the record or statement was 'material' to a false or fraudulent claim" <u>Id.</u> (alterations in original) (footnote omitted) (quoting <u>United States ex rel. Hood v. Satory Global, Inc.</u>, 946 F. Supp. 2d 69, 85 (D.D.C. 2013).

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Boston Heart argues that Count I of the Second Amended Complaint, in which the relator alleges that Boston Heart made false statements in violation of 31 U.S.C. § 3729(a)(1)(B), should be dismissed because the relator did not allege that Boston Heart's certification that its laboratory tests were medically necessary, which it made on the CMS-1500 form, constitute false statements. Def.'s Reply at 21. Boston Heart further argues that if the Court does determine that the relator made this allegation in the Second Amended Complaint, Boston Heart's certification of medical necessity on the CMS-1500 was not a false statement for the same reasons that Boston Heart's claims were not legally false under § 3729(a)(1)(A). Def.'s Reply at 21. The relator argues in response that she did allege that Boston Heart made a false claim by certifying on the CMS-1500 form that its services were medically necessary, Relator's Opp'n at 39 (quoting 2d Am. Compl. ¶ 33), "[a]nd for all of the reasons stated above regarding falsity and scienter with respect to a presentment claim under 31 U.S.C. § 3729(a)(1)(A), [she] has properly ple[ade]d the elements of a 'false statements' claim," <u>id.</u> at 40.

The Court agrees with the relator that she alleged that Boston Heart made false statements when it certified that its tests were medically necessary on the CMS-1500 form. The Second Amended Complaint states that Boston Heart "billed government insurers for these medically unnecessary tests." 2d Am. Compl. ¶ 6; see also id. ¶¶ 19–22. The relator also alleged that, "in submitting reimbursement claims form CMS-1500 to obtain reimbursement from Medicare or other Federal health care programs, laboratories expressly certify that "that the services shown on [the] form were medically indicated and necessary for the health of the patient." Id. ¶ 33 (alterations in original). Finally, the relator repeatedly alleges that the laboratory tests at issue in this case are not medically necessary for patients with the four diagnostic codes. See, e.g., id. ¶¶ 5, 8, 46, 55, 57, 70, 73, 96. Reading these allegations together,

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and in light of the Court's prior determination that the relator has adequately pleaded that Boston Heart knew that its certifications regarding medical necessity were legally false, <u>see</u> Part III.A.1.b-c, the Court concludes that the relator sufficiently alleged that Boston Heart made false statements in conjunction with its claims for payment by certifying on CMS-1500 forms that its tests for the patients with the four diagnostic codes were medically necessary.<sup>9</sup> Further, the Court concludes that these allegedly false statements regarding medical necessity "hav[e] a natural tendency to influence" the government's payment, <u>see</u> 31 U.S.C. § 3729(b)(4), because the government will not pay for medically unnecessary services, <u>see Riley</u>, 355 F.3d at 376 n.6 (noting that medical necessity is a condition for payment of Medicare claims). Accordingly, because the relator adequately pleaded that Boston Heart made false statements, the Court declines to dismiss this component of Count I.

# **B.** Count II

Section 3729(a)(1)(G) of the False Claims Act, known as the "reverse false claims" provision, creates liability for "any person who . . . knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to . . . the Government." 31 U.S.C. § 3729(a)(1)(G). "[A] typical false claim action involves a defendant knowingly making a false statement in order to <u>avoid</u> having

<sup>&</sup>lt;sup>9</sup> Boston Heart also argues that the false statements violation alleged in Count I should be dismissed because it is not sufficiently pleaded with particularity as required by Rule 9(b). <u>See</u> Def.'s Mem. at 39 (arguing that the relator failed to identify when and where false statements were made, and who made them, and noting that its argument is made "[f]or many of the same reasons discussed above" regarding the false claims violation). Because the Court has already rejected Boston Heart's particularity argument with regard to the false claims violation, <u>see supra</u> Part. III.A.1.a, the Court concludes that the relator's false statements allegations are sufficiently particular under Rule 9(b), <u>see Hood</u>, 946 F. Supp. 2d at 85–86 (rejecting the defendant's particularity argument regarding the relator's false statements allegations because the Court had already rejected the "effectively identical" argument regarding the relator's false claims allegations).

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to pay the government when payment is otherwise due." <u>Pencheng Si v. Laogai Research</u> <u>Found.</u>, 71 F. Supp. 3d 73, 88 (D.D.C. 2014).

Boston Heart alleges that Count II should be dismissed because the relator has not "set forth any facts supporting this conclusory assertion" that it violated the reverse false claims provision. Def.'s Mem. at 32. The relator argues in response that "where there are sufficient allegations of violations of the [False Claims Act] and of submitted false claims under Rules 12(b)(6) and 9(b), the allegations of failure to report overpayments and to repay under 31 U.S.C. § 3729(a)(1)(G) should be sustained under those Rules as well." Relator's Opp'n at 40.

Two members of this Court have determined that

[a] reverse false claim may not rest, however, on the argument "that an obligation arose out of [the d]efendants' concealment of their allegedly fraudulent activity," because "by this logic, just about any traditional false statement or presentment action would give rise to a reverse false claim action; after all, presumably any false statement actionable under sections 3729(a)(1)(A) or 3729(a)(1)(B) could theoretically trigger an obligation to repay the fraudulently obtained money."

United States ex rel. Scollick v. Narula, 215 F. Supp. 3d 26, 41 (D.D.C. 2016) (quoting

<u>Pencheng Si</u>, 71 F. Supp. 3d at 97); <u>see also id.</u> ("Like the Court in <u>Pencheng Si</u>, this Court finds that the fraudulent actions alleged here do not trigger an obligation to repay the fraudulently obtained money.").

The Court agrees with its colleagues and therefore concludes that Count II must be dismissed because the Second Amended Complaint does not plead any monetary obligation owed by Boston Heart to the government independent of its "concealment of [its] allegedly fraudulent activity." <u>Id.</u> To the extent that the relator argues that Boston Heart had an obligation to repay any government funds gained as a result of its allegedly fraudulent activity, that argument "is the same as that which was rejected in <u>Pencheng Si</u> [and <u>Scollick</u>]." <u>Id.</u> at 42. Accordingly, the Court will dismiss Count II.

# C. Counts III Through XXXI

Boston Heart argues that because the relator "alleges no new facts in support of [the state false claims act c]ounts and because they suffer from the same deficiencies as the [federal False Claims Act counts], Counts III through XXXI should also be dismissed" for failing to meet the federal pleading standards outlined above. <u>See</u> Def.'s Mem. at 41. In addition, Boston Heart argues that Count XIV, brought on behalf of the State of Maryland, <u>see</u> 2d Am. Compl. ¶ 240–47, should be dismissed because the Court's August 24, 2016 Order dismissed with prejudice "claims brought by the relator on behalf of the State of Maryland." Def.'s Mem. at 42 (citing Order at 1 (Aug. 24, 2016), ECF No. 29. The relator argues in response that she "has stated her claims under the Federal [False Claims Act] and the various state false claims acts cited with the requisite particularity." Relator's Opp'n at 45.

Regarding Count XIV, the Court agrees with Boston Heart that the Court already dismissed any claim brought on behalf of Maryland. <u>See</u> Order at 1 (Aug. 24, 2016), ECF No. 29. As for the twenty-seven remaining state law claims, neither party has presented any argument specific to any of those particular statutes independent from the arguments concerning the federal claims. <u>See</u> Def.'s Mem. at 41; Relator's Opp'n at 45. Accordingly, the Court concludes that both parties agree that any count that is deficient under the federal statute is similarly deficient under the analog state statutes. As a result, because the Court has concluded that Count II, the federal "reverse false claims" allegation, must be dismissed, <u>see supra</u> at III.C, the Court will grant Boston Heart's motion to dismiss any state "reverse false claims" violations alleged in Counts III through XXXI.

# **IV. CONCLUSION**

For the foregoing reasons, the Court grants the relator's motion for judicial notice and grants in part and denies in part Boston Heart's motion to dismiss the Second Amended Complaint. Specifically, the Court grants the motion as to Count II, Count XIV, and any "reverse false claims" violations alleged in Counts III through XXXI, but denies the motion in all other respects.

**SO ORDERED** this 9th day of June, 2017.<sup>10</sup>

REGGIE B. WALTON United States District Judge

<sup>&</sup>lt;sup>10</sup> The Court will contemporaneously issue an Order consistent with this Memorandum Opinion.