UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA, et al., ex rel. 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., initiated this qui tam 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. See Relator's Second Amended Complaint Pursuant to the Federal False Claims Act, 31 U.S.C. §§ 3729 et seq. and Pendent State False Claims Acts ("2d Am. Compl.") ¶ 1. On June 9, 2017, the Court granted in part and denied in part Boston Heart's motion to dismiss the relator's complaint. See United States ex rel. Groat v. Boston Heart Diagnostics Corp., 255 F. Supp. 3d 13, 17, 32–33 (D.D.C. 2017) (Walton, J.). Currently before the Court is Boston Heart Diagnostics Corporation's Motion for Reconsideration of the Court's Order on the Motion to Dismiss ("Def.'s Mot."). Upon careful consideration of the parties' submissions,[1] the Court concludes that it must grant in part and deny in part Boston Heart's motion for reconsideration.

[1] In addition to the filings already identified, the Court considered the following submissions in reaching its decision: (1) the Relator's Substitu[t]ed Oppos[i]tion to Defendant's Motion for Reconsideration ("Relator's

(continued . . .)

I. BACKGROUND

The Court discussed the factual background and statutory authority pertinent to this case in its Memorandum Opinion issued on June 9, 2017, see Groat, 255 F. Supp. 3d at 17–20, and will not reiterate those facts and authorities again here. In that opinion, the Court declined to dismiss the relator's presentment claim under § 3729(a)(1)(A) and false statements claim under § 3729(a)(1)(B), as well as her analog presentment and false statements claims under various state false claims act statutes, but dismissed her "reverse false claims" under § 3729(a)(1)(G) and the analog state statutes. See id. at 30–33. On June 23, 2017, Boston Heart filed its present motion, requesting that the Court reconsider its conclusion "that Boston Heart has an obligation to establish that the tests for which it seeks government reimbursement are medically necessary," id. at 25, which "underlies [the Court's] conclusions with respect to both falsity and knowledge as to [the r]elator's presentment . . . [and] false statements allegations," Def.'s Mot. at 9 (internal citations omitted).

II. STANDARD OF REVIEW

Under Federal Rule of Civil Procedure 54(b), any order or decision that does not constitute a final judgment "may be revised at any time before the entry of a judgment adjudicating all the claims and all the parties' rights and liabilities." Fed. R. Civ. P. 54(b). Although "district court[s] ha[ve] 'broad discretion to hear a motion for reconsideration brought under Rule 54(b),'" Univ. of Colo. Health at Mem'l Hosp. v. Burwell, 164 F. Supp. 3d 56, 62 (D.D.C. 2016) (quoting Isse v. Am. Univ., 544 F. Supp. 2d 25, 29 (D.D.C. 2008)), district courts

(. . . continued)
Opp'n"); (2) Boston Heart Diagnostics Corporation's Reply in Support of Its Motion for Reconsideration of the Court's Order on the Motion to Dismiss ("Def.'s Reply"); (3) the Brief of Amicus Curiae American Clinical Laboratory Association ("Amicus Br."); (4) the Relator's Response to Brief of Amicus Curiae American Clinical Laboratory Association ("Relator's Amicus Resp."); and (5) the Reply to Relator's Response to Brief of Amicus Curiae American Clinical Laboratory Association ("Amicus Reply").

grant motions for reconsideration of interlocutory orders only "as justice requires," Capitol Sprinkler Inspection, Inc. v. Guest Servs., Inc., 630 F.3d 217, 227 (D.C. Cir. 2011) (quoting Greene v. Union Mut. Life Ins. Co. of Am., 764 F.2d 19, 22–23 (1st Cir. 1985)).

In deciding whether "justice requires" reversal of a prior interlocutory order, courts assess circumstances such as "whether the court 'patently' misunderstood the parties, made a decision beyond the adversarial issues presented, made an error in failing to consider controlling decisions or data, or whether a controlling or significant change in the law has occurred." In Defense of Animals v. Nat'l Insts. of Health, 543 F. Supp. 2d 70, 75 (D.D.C. 2008) (quoting Singh v. George Wash. Univ., 383 F. Supp. 2d 99, 101 (D.D.C. 2005)); see also Davis v. Joseph J. Magnolia, Inc., 893 F. Supp. 2d 165, 168 (D.D.C. 2012) ("[A] motion for reconsideration is discretionary and should not be granted unless the movant presents either newly discovered evidence or errors of law or fact that need correction."). "The burden is on the moving party to show that reconsideration is appropriate and that harm or injustice would result if reconsideration were denied." United States ex rel. Westrick v. Second Chance Body Armor, Inc., 893 F. Supp. 2d 258, 268 (D.D.C. 2012) (citing Husayn v. Gates, 588 F. Supp. 2d 7, 10 (D.D.C. 2008)). And, motions for reconsideration are not vehicles for either reasserting arguments previously raised and rejected by the court or presenting arguments that should have been raised previously with the court. See Estate of Gaither ex rel. Gaither v. District of Columbia, 771 F. Supp. 2d 5, 10 & n.4 (D.D.C. 2011).

III. ANALYSIS

Boston Heart urges the Court to reconsider its conclusion "that Boston Heart has an obligation to establish that the tests for which it seeks government reimbursement are medically necessary," Groat, 255 F. Supp. 3d at 25, for three reasons, see Def.'s Mot. at 1–2. The Court

agrees that this conclusion warrants correction to clarify that a laboratory may rely on the ordering physician's determination of medical necessity in the laboratory's certification to HHS on the CMS–1500 form. Nonetheless, the Court concludes that despite its correction of the medical necessity ruling, its denial of Boston Heart's motion to dismiss the relator's federal and state presentment and false statements claims was proper.

A. The Court's Conclusion Regarding Laboratories' Obligations with Respect to Medical Necessity

1. HHS Compliance Program Guidance for Clinical Laboratories

First, Boston Heart argues that the Court's prior medical necessity conclusion "conflicts directly with the longstanding position of the Office of the Inspector General for the Department of Health and Human Services . . . that 'laboratories do not and cannot treat patients or make medical necessity determinations.'" Id. at 1 (quoting Publication of OIG Compliance Program Guidance for Clinical Laboratories ("OIG Guidance"), 63 Fed. Reg. 45,076, 45,079 (Aug. 24, 1998)); see also id. at 3–5 (discussing the OIG guidance). The relator argues in response that the OIG Guidance "firmly establishes a lab[oratory]'s duty to only submit claims for medically necessary tests and directly aligns with the CMS Form 1500 requirement for [a] 'physician or supplier' to certify" the medical necessity of each test ordered. Relator's Opp'n at 6. Although the Court agrees with the relator that a laboratory has a "legal duty to ensure that it is not submitting false or incorrect claims to Government . . . payors," OIG Guidance, 63 Fed. Reg. at 45,077, it concludes for the reasons set forth below that a laboratory cannot and is not required to determine medical necessity, but rather is permitted to rely on the ordering physician's determination that the laboratory tests billed to Medicare are medically necessary.

The OIG Guidance was issued "to refine and build on the original model guidance plan for clinical laboratories," which was published in 1997 as part of an effort "to engage the private

health care community in combating fraud and abuse." OIG Guidance, 63 Fed. Reg. at 45,076. This supplemental guidance was "intended to assist clinical laboratories in developing effective internal controls that promote adherence to applicable . . . law[s,] . . . [and to] advance the prevention of fraud, abuse, and waste in the clinical laboratory industry." Id. at 45,077. The OIG Guidance identifies for laboratories "specific areas of potential fraud," including, as relevant to this case, "marketing schemes, [ ] coding issues, . . . and improper claims submission." Id. at 45,078.

The OIG Guidance section devoted to "Medical Necessity" states, among other things, that

> [l]aboratory compliance programs, to be effective, should communicate to physicians that claims submitted for services will only be paid if the service is covered, reasonable, and necessary for the beneficiary, given his or her clinical condition. Laboratories should take all reasonable steps to ensure that [they are] not submitting claims for services that are not covered, reasonable and necessary. Upon request, a laboratory should be able to produce or obtain from the treating physician . . . the documentation to support the medical necessity of the service the laboratory has provided and billed to a Federal . . . health care program. We recognize that laboratories do not and cannot treat patients or make medical necessity determinations. However, there are steps that such facilities can take to assure compliance with the applicable statutes, regulations and the requirements of Federal . . . health plans.

Id. at 45,079 (footnote omitted).

The OIG Guidance recommends various processes a laboratory can implement to ensure that laboratories do not submit claims for unnecessary tests. For example, the OIG Guidance encourages a laboratory to

> construct [its] requisition form to capture the correct program information as required by Federal . . . health care programs and to promote the conscious ordering of tests by physicians . . . . The laboratory should construct the requisition form to ensure that the physician . . . has made an independent medical necessity decision with regard to each test the laboratory will bill. Laboratories should encourage physicians . . . to submit diagnosis information for all tests ordered, as

> documentation of the medical necessity of the service. The form should contain a statement indicating that Medicare generally does not cover routine screening tests.

Id. It also states that

> there are steps laboratories can take to determine whether physicians . . . are being encouraged to order medically unnecessary tests. More importantly, if the laboratory discovers that it has in some way contributed to the ordering of unnecessary tests, the OIG believes the laboratory has a duty to modify its practices, as well as notify the physician(s) . . . of its concerns and recommend corrective action.

Id. at 45,080. Finally, the OIG Guidance notes that

> [l]aboratories cannot alter the physician's order in any way either increasing or decreasing the number of services performed without the express consent of the ordering physician . . . . To ensure code accuracy, laboratories should require that individuals with technical expertise in laboratory testing review the appropriateness of the codes before the claims are submitted. Intentional or knowing upcoding (i.e., the selection of a code to maximize reimbursement when such code is not the most appropriate descriptor of the service) could violate the False Claims Act and/or other civil laws, and criminal law.

Id.

Upon review of the OIG Guidance, the Court concludes that it overstated a laboratory's "obligation to establish that the tests for which it seeks government reimbursement are medically necessary." Groat, 255 F. Supp. 3d at 25. Although it is true that when a laboratory "submits the CMS–1500 form, it certifies that the tests performed were medically necessary," id. (emphasis added), and that it has a role to play to ensure that it does not submit claims for medically unnecessary tests, see OIG Guidance, 63 Fed. Reg. at 45,077, the Court is now convinced that a laboratory cannot and is not required to determine medical necessity, but rather is permitted to rely on the ordering physician's determination that the laboratory tests billed to Medicare are medically necessary. The OIG Guidance makes clear that "laboratories do not and cannot treat patients or make medical necessity determinations," but "should be able to produce or obtain from the treating physician . . . the documentation to support the medical necessity of the service

the laboratory has provided." Id. at 45,079. Moreover, the OIG Guidance, in describing a laboratory's duties to ensure that it does not submit claims for medically unnecessary tests, does not include among those duties a laboratory's obligation to make an independent determination of the medical necessity of each test performed and billed. See id. at 45,079–080 (e.g., stating that laboratories should communicate with physicians, maintain documentation to support medical necessity, construct requisition forms to promote conscious ordering of tests by physicians, and review coding). In the Court's view, the OIG Guidance would have explicitly included that obligation among its recommended compliance processes if it had intended to impose such an obligation on laboratories, and to suggest otherwise would entirely contradict that explicit language of the OIG Guidance.[2]

2. HHS Regulation on Clinical Laboratory Recordkeeping

Second, Boston Heart argues that the federal regulation regarding laboratory recordkeeping "also underscore[s] that physicians, and not laboratories, establish the medical necessity of patient tests." Id. at 5; see also id. at 5–7 (discussing the regulation). The Court considered this regulation in its prior Memorandum Opinion and ultimately concluded that "Boston Heart's reliance on the Medicare regulation regarding documentation and recordkeeping requirements [wa]s unavailing because that provision does not address the entity's certification

[2] In its filings submitted in support of its motion to dismiss, Boston Heart had cited the OIG Guidance in support of its argument that laboratories are not required to independently verify the medical necessity of tests ordered by physicians, but only in its reply brief. See Boston Heart Diagnostics Corporation's Reply in Support of Its Motion to Dismiss Relator's Second Amended Complaint at 4 & n.5; see also Memorandum of Law in Support of Boston Heart Diagnostics Corporation's Motion to Dismiss Relator's Second Amended Complaint at iii–vii (not including the OIG Guidance in its Table of Authorities). Judges in this District have repeatedly held that arguments may not be raised for the first time in a party's reply. See, e.g., Akinsinde v. Not-For-Profit Hosp. Corp., 216 F. Supp. 3d 33, 41 (D.D.C. 2016) ("The court has no obligation to entertain arguments raised for the first time in a reply brief and declines to do so here."); Wright v. Metro. Life Ins. Co., 618 F. Supp. 2d 43, 47 n.5 (D.D.C. 2009) (Walton, J.) ("Courts 'highly disfavor[] parties creating new arguments at the reply stage that were not fully briefed during the litigation.'" (alteration in original) (quoting Pub. Citizen Health Research Grp. v. Nat'l Insts. of Health, 209 F. Supp. 2d 37, 43 (D.D.C. 2002))).

of medical necessity on the CMS–1500 form." Groat, 255 F. Supp. 3d at 26 (citing 42 C.F.R. § 410.32(d)(2)). The Court stated:

> 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, see [42 C.F.R.] § 410.32(d)(2)(i)–(ii), the CMS–1500 form requires the entity submitting the claim, be it a "physician or 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. See 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.

Id. However, the Court did not consider the regulation in the context of the negotiated rulemaking that produced it,[3] and which addressed the tension between Medicare's statutory medical necessity requirement, see 42 U.S.C. 1395y(a)(1)(A), and the "special circumstances related to laboratories," see Medicare Program; Negotiated Rulemaking: Coverage and Administrative Policies for Clinical Diagnostic Laboratory Services; Final Rule ("Laboratory Final Rule"), 66 Fed. Reg. 58,788, 58,801 (Nov. 23, 2001).[4]

[3] "Section 4554(b)(1) of the Balanced Budget Act of 1997 . . . mandate[d the] use of a negotiated rulemaking committee to develop national coverage and administrative policies for clinical diagnostic laboratory services payable under Medicare Part B . . . [in order] to promote program integrity and national uniformity and simplify administrative requirements . . . ." Medicare Program; Negotiated Rulemaking: Coverage and Administrative Policies for Clinical Diagnostic Laboratory Services; Proposed Rule, 65 Fed. Reg. 13,082, 13,083 (Mar. 10, 2000) (internal quotation marks omitted). Members of the committee included representatives of HHS, the American Association of Bioanalysts, the American Association for Clinical Chemistry, the American Association of Retired Persons, the American Clinical Laboratory Association, the American College of Physicians—American Society of Internal Medicine, the American Health Information Management Association, the American Hospital Association, the American Medical Association, the American Medical Group Association, the American Society for Clinical Laboratory Science, the American Society of Clinical Pathologists, the American Society for Microbiology, the Clinical Laboratory Management Association, the American Society for Clinical Laboratory Science, the College of American Pathologists, the Health Industry Manufacturers Association, the Medical Group Management Association, and the National Medical Association. Id. at 13,083–084.

[4] Again, in support of its motion to dismiss, Boston Heart cited the negotiated rulemaking only in its reply brief. See Boston Heart Diagnostics Corporation's Reply in Support of Its Motion to Dismiss Relator's Second Amended Complaint at 4 n.5, 5 n.9; see also Memorandum of Law in Support of Boston Heart Diagnostics Corporation's Motion to Dismiss Relator's Second Amended Complaint at iii–vii (not including the negotiated rulemaking in its Table of Authorities).

The regulation was promulgated to establish "uniform national coverage and administrative policies for clinical diagnostic laboratory services payable under Medicare Part B[,] . . . to promote Medicare program integrity and national uniformity[,] and simplify administrative requirements for clinical diagnostic laboratory services." Id. at 58,789. The negotiated rulemaking explained the division of responsibilities between the ordering physician and the laboratory with respect to documentation and recordkeeping requirements as follows:

> [T]he laboratory is responsible for maintaining information it receives from the ordering practitioner, and the practitioner[] is responsible for maintaining the information in the medical record. [HHS's] initial request for information is made to the entity submitting the claim. That entity should submit whatever documentation it has in support of the claim.
>
> If the documentation provided by the entity submitting the claim does not demonstrate that the service is reasonable and necessary, we will take the following action: (1) Provide the ordering physician information sufficient to identify the claim being reviewed; (2) request from the ordering physician those parts of a beneficiary's medical record that are relevant to the specific claim(s) being reviewed; and (3) if the ordering physician does not supply the documentation requested, inform the entity submitting the claim(s) that the documentation has not been supplied and deny the claim.
>
> Since the entity submitting the claim will be the entity to experience a payment denial if documentation does not support the medical necessity of the claim, we agreed laboratories should not be precluded from requesting additional diagnostic or other medical information from the ordering provider. In making requests for additional information, laboratories must focus their request for additional information on material relevant to medical necessity. In addition, documentation requests must take into account applicable laws and regulations related to patient confidentiality.

Id. at 58,800. HHS also noted that the regulation

> does not change the current provisions for liability on claims due to lack of information supporting medical necessity. Section 1862(a)(1)(A) of the [Social Security] Act provides that, notwithstanding any other provision of the Act, payment may not be made for services that are not reasonable and necessary for the diagnosis or treatment of illness or injury. Presently, all entities that bill the Medicare program are held liable when they bill for services and are not able to produce documentation of the medical necessity of the service. Although the [Negotiated Rulemaking] Committee discussed at length the special circumstances

> related to laboratories, which frequently do not have direct contact with the patient, the Committee recognized that the law does not provide the authority to exempt laboratories from the provision related to medical necessity.

Id. at 58,801 (emphasis added). Finally, HHS stated that it

> do[es] not agree [with some commenters] that the provision related to denial of claims for laboratory services when documentation is not provided is unfair. Rather, we believe it would be unfair to exempt laboratories from this provision while continuing to require it for other providers and suppliers. For example, durable medical equipment (DME) suppliers frequently do not have direct contact with beneficiaries but are dependent upon physician documentation of medical need in order to receive payment.

Id.

Upon review of HHS's explanations of the regulation, the Court concludes that HHS's view supports the Court's conclusion that, although laboratories, as the entity submitting a claim for payment, are required by statute to certify the medical necessity of the tests at issue, see id. ("[A]ll entities that bill the Medicare program are held liable when they bill for services and are not able to produce documentation of the medical necessity of the service."), neither the Medicare statute nor the regulation regarding laboratories require laboratories to independently determine the medical necessity of the tests billed. Rather, HHS recognized "the special circumstances related to laboratories [because they] frequently do not have direct contact with the patient," id., and, in the Court's view, issued the regulation regarding recordkeeping and documentation in an attempt to balance a laboratory's statutory requirement to certify medical necessity with the requirement that the ordering physician determine medical necessity, see id. (comparing laboratories to durable medical equipment suppliers, which "are dependent upon physician documentation of medical need in order to receive payment" (emphasis added)); see also 42 C.F.R. 410.32(a) (noting that "[t]ests not ordered by the physician who is treating the

beneficiary are not reasonable and necessary").[5] Therefore, although it is true that "[t]he 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," Groat, 255 F. Supp. 3d at 26 (emphasis added), upon review of HHS's explanation at the time it promulgated the regulation, the Court must clarify that even though the Medicare statute requires the laboratory to certify the medical necessity of any test for which it makes a claim for payment, the laboratory is not required to make an independent determination of medical necessity, but rather may rely on the ordering physician's determination.[6]

3. Cases Cited by the Court

Third, Boston Heart argues that the cases the Court cited in support of its conclusion regarding the medical necessity determination do not "support[] the proposition that a laboratory must independently establish the medical necessity of tests it performs on a physician's request." Def.'s Mot. at 9; see also id. at 7–9 (discussing cases). Upon further review of these cases, the Court agrees. In its Memorandum Opinion, the Court directly quoted a decision issued by the United States District Court for the Central District of California in support of its statement that "the regulatory scheme 'places the burden of establishing the medical necessity of diagnostic tests on the entity submitting the claim.'" Groat, 255 F. Supp. 3d at 26 (quoting Garcia v.

[5] This view is supported by HHS's decision to allow laboratories to request additional information relevant to medical necessity from the ordering physician. In other words, although a laboratory cannot make a medical necessity determination, it is permitted to ask the ordering physician for additional information supporting the medical necessity determination. See Laboratory Final Rule, 66 Fed. Reg. at 58,800 ("Since the entity submitting the claim will be the entity to experience a payment denial if documentation does not support the medical necessity of the claim, we agreed laboratories should not be precluded from requesting additional diagnostic or other medical information from the ordering provider.").

[6] The relator argues that Boston Heart fails to meet the standard for reconsideration under Rule 54(b). See Relator's Opp'n at 1–4. Because the Court concludes that it must clarify that a laboratory may rely on the ordering physician's determination of medical necessity in the laboratory's certification to HHS on the CMS–1500 form, see supra Part III.A, it also concludes that "justice requires" the Court to amend its prior memorandum opinion, see Capitol Sprinkler Inspection, 630 F.3d at 227.

Sebelius, No. CV 10-8820 PA (RZx), 2011 WL 5434426, at *7 (C.D. Cal. Nov. 8, 2011)). That case concerned a medical doctor's Administrative Procedure Act challenge of HHS's decision "to recoup what the Secretary determined were overpayments billed under [the doctor's] Medicare provider number." Garcia, 2011 WL 5434426, at *1. In Garcia, the entity submitting the claim was the physician himself, not a clinical laboratory, see id. at *3, and therefore, the Garcia court's statement regarding "the burden of establishing the medical necessity of diagnostic tests" did not address the issue of whether a laboratory must independently determine medical necessity or is permitted to rely on the ordering physician's determination in its certification to HHS.

This Court also cited to Nephropathology Associates, PLC v. Sebelius, No. 4:12CV00233JLH, 2013 WL 3285685, at *4 (E.D. Ark. June 27, 2013), for the proposition that "the burden remains on the entity submitting the claim to demonstrate that the services at issue were reasonable and necessary." Groat, 255 F. Supp. 3d at 26 (quoting Nephropathology Assocs., 2013 WL 3285685, at *4). In that case, a clinical laboratory appealed HHS's denial of payment for renal pathology services. See Nephropathology Assocs., 2013 WL 3285685, at *1. The Nephropathology court's statement that "the burden remains on the entity submitting the claim to demonstrate that the services at issue were reasonable and necessary" was in response to the laboratory's interpretation of 42 C.F.R. § 410.32(d) "to mean that [it] does not have to submit documentation of a physician's order unless and until [CMS] requests such documentation," id. at *4, and therefore, like Garcia, does not speak directly to the issue of whether a laboratory must independently determine medical necessity or is permitted to rely on the ordering physician's determination in its certification to HHS.

Finally, the Court also cited to four other federal circuit and district court cases for the proposition that (1) laboratories may challenge HHS's denial of payment to them for testing services rendered based upon the determination that such tests were not medically necessary, see Groat, 255 F. Supp. 3d at 26 (first citing KGV Easy Leasing Corp. v. Sebelius, No. 09-56393, 2011 WL 490990, at *1 (9th Cir. Feb. 14, 2011); then citing Strand Analytical Labs., LLC v. Burwell, No. 1:13-cv-00645-LJM-DKL, 2015 WL 4603258, at *1 (S.D. Ind. July 30, 2015)); and (2) laboratories may be sued under the False Claims Act "for allegedly submitting claims for medically unnecessary tests," Groat, 255 F. Supp. 3d at 26 (first citing United States ex rel. Merena v. SmithKline Beecham Corp., 205 F.3d 97, 98 (3d Cir. 2000); then citing United States ex rel. Lutz v. Berkeley Heartlab, Inc., 225 F. Supp. 3d 487, 495–97, 513–14 (D.S.C. 2016)). Again, the CMS–1500 form requires laboratories, as the entity submitting the claim for payment, to certify medical necessity, see Health Insurance Claim Form ("CMS–1500") at 2, available at https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf (last visited December 6, 2017), and laboratories are allowed to challenge payment denials, but they are not prohibited from relying on the ordering physician's determination of medical necessity. Moreover, as will be discussed in further detail below, see infra Part III.B, laboratories may be held liable under the False Claims Act. However, like Garcia and Nephropathology, none of these four cases specifically states whether a laboratory must independently determine medical necessity or is permitted to rely on the ordering physician's determination in its certification to HHS.

B. The Relator's Allegations Regarding Boston Heart's Falsity and Knowledge

In its Memorandum Opinion, the Court concluded that the relator's Second Amended Complaint sufficiently alleged that Boston Heart submitted claims that were expressly legally

false. See Groat, 255 F. Supp. 3d at 23 ("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."). The Court stated:

> 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. . . . Under [ ] an express . . . 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.

Id. (internal citations and quotation marks omitted). The Court also stated that "the knowledge element of a false claim or false statement action [ ] requires 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.'" Id. at 29 (quoting 31 U.S.C. § 3729(b)(1)(A)).

According to Boston Heart, if the Court agrees that laboratories are not obligated to independently determine a test's medical necessity, the relator has failed to sufficiently allege facts demonstrating the falsity and knowledge elements of her federal and state presentment and false statements claims, and these claims must be dismissed. See Def.'s Mot. at 9–10; see also Def.'s Reply at 5. The Court disagrees.

Boston Heart does not dispute the Court's summary of the relator's allegations regarding Boston Heart, namely

> that "Boston Heart encourages providers to order [ ] medically unnecessary tests" through marketing materials and test panels on pre-printed test requisition forms, 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, and their ability "to predict cardiac risk." 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."

Groat, 255 F. Supp. 3d at 19–20 (internal citations omitted).

Even though the Court now clarifies that Boston Heart is not required to independently determine the medical necessity of tests ordered by physicians, see supra Part III.A, accepting the relator's allegations as true, as it must, see Trudeau v. Fed. Trade Comm'n, 456 F.3d 178, 193 (D.C. Cir. 2006), her allegation that Boston Heart engaged in a scheme to encourage non-cardiology physicians to order medically unnecessary tests through a false marketing campaign and pre-printed test requisition forms would constitute a knowing violation of its "legal duty to ensure that it is not submitting false or incorrect claims to Government . . . payors," OIG Guidance, 63 Fed. Reg. at 45,077; see also id. at 45,079–080 (noting that laboratories should ensure that they do not submit claims for medically unnecessary tests by, inter alia, communicating with physicians regarding medical necessity, maintaining documentation of medical necessity, constructing requisition forms to promote conscious ordering of tests by physicians, and reviewing coding). Therefore, the Court remains convinced that the relator has sufficiently alleged facts that satisfy the falsity and knowledge elements of her federal and state presentment and false statements claims, and, once again, declines to dismiss these claims. See United States ex rel. Schaefer v. Family Med. Ctrs. of South Carolina, LLC, No. 3:14-382-MBS, 2016 WL 6601017, at *3–4 (D.S.C. Nov. 8, 2016) (denying a motion to dismiss the United States' complaint in which it "allege[d] that [the d]efendants created and utilized custom disease-oriented panels that included more diagnostic tests than typical for screening or routine testing," noting that "[t]he United States alleges that [the d]efendants stressed to the physicians . . . to utilize the laboratory panels designed by [the d]efendants, regardless of whether all components of the panel were medically necessary"); Berkeley Heartlab, 225 F. Supp. 3d at 499–500 (declining to dismiss the government's presentment claim against a laboratory because "[t]he complaint describes each of the four alleged schemes in

detail," including one scheme to encourage physicians to order medically unnecessary tests, and "specifies particular genetic testing that is medically unnecessary for the vast majority of the population, yet [was] still included in the panels [the d]efendants offered to physicians"); United States ex rel. Bane v. Breathe Easy Pulmonary Servs., Inc., No. 8:06-CV-40-T-24 MAP, 2007 WL 4885468, at *4, *7 (M.D. Fla. Nov. 30, 2007) (magistrate judge recommendation that district judge deny a laboratory's and an oxygen provider's motion to dismiss the relator's complaint alleging a scheme to bill Medicare for additional, unnecessary oxygen testing in violation of the False Claims Act), adopted in relevant part, 2008 WL 343158 (M.D. Fla. Feb. 5, 2008); United States ex rel. Downy v. Corning, Inc., 118 F. Supp. 2d 1160, 1172 (D.N.M. 2000) (denying defendant laboratories' motion to dismiss a complaint in which the relator alleged that the laboratories, "by using deceptive test order forms and by disseminating deceptive information concerning the necessity of performing both [of] the . . . tests [at issue], [the laboratories] induced physicians to order many medically unnecessary tests and then charged the costs of those tests to the government"), abrogated on other grounds by United States ex rel. Sikkenga v. Regence BlueCross BlueShield of Utah, 472 F.3d 702 (10th Cir. 2006); see also United States v. Neifert-White Co., 390 U.S. 228, 232–33 (1968) ("[The False Claims Act is] intended to reach all types of fraud, without qualification, that might result in financial loss to the Government. . . . [T]he Act is broadly phrased to reach any person who makes or causes to be made 'any claim upon or against' the United States . . . . [T]he Court has consistently refused to accept a rigid, restrictive reading [of the Act] . . . . This remedial statute reaches beyond 'claims' which might be legally enforced, to all fraudulent attempts to cause the Government to pay out sums of money.").

IV. CONCLUSION

In summary, although the Court is persuaded that it overstated the obligations of laboratories with respect to making medical necessity determinations, it still remains convinced that laboratories have a legal duty to ensure that they do not submit claims for medically unnecessary tests. In this case, the relator has sufficiently alleged that Boston Heart submitted false claims by engaging in a scheme that encouraged non-cardiology physicians to order medically unnecessary tests, and then billing the Government for those tests. See 2d Am. Compl.") ¶¶ 6, 19–22, 52, 94, 127, 132. Accordingly, for the foregoing reasons, the Court grants in part and denies in part Boston Heart's motion for reconsideration. Specifically, the Court amends its June 9, 2017 Memorandum Opinion, United States ex rel. Groat v. Boston Heart Diagnostics Corp., 255 F. Supp. 3d 13 (D.D.C. 2017) (Walton, J.), to clarify that a laboratory may rely on the ordering physician's determination of medical necessity, but denies Boston Heart's request to dismiss the remaining claims in this case.

SO ORDERED this 11th day of December, 2017.

REGGIE B. WALTON
United States District Judge