UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA ex rel. JAMES F. ALLEN, Plaintiffs, v. ALERE HOME MONITORING, INC., ROCHE HEALTH SOLUTIONS, INC., ADVANCED CARDIO SERVICES, CARDIOLINK CORP., MDINR, LLC, PATIENT HOME MONITORING, INC., TAMBRA INVESTMENTS, INC., and U.S. HEALTHCARE SUPPLY, LLC, Defendants.	Civil Action No. 16-11372-PBS

MEMORANDUM AND ORDER

August 29, 2018

Saris, C.J.

INTRODUCTION

This False Claims Act ("FCA") case pertains to Medicare reimbursements for at-home blood-testing kits. The kits allow patients on blood-thinning medication to monitor their blood's clotting time at home rather than traveling to a hospital or clinic. The eight Defendants all supply these kits to patients and get reimbursed through Medicare. However, Defendants only provide kits to patients who test two to four times per month. According to Relator, this business practice of requiring two to

four monthly tests as a precondition to providing kits induces doctors to order medically unnecessary tests. Thus, Defendants run afoul of the FCA because they get reimbursed by Medicare for tests they know are not medically necessary.

After hearing and careful consideration, the motions to dismiss by Roche Health Solutions, Inc. ("Roche") (Dkt. No. 57), U.S. Healthcare Supply, LLC ("USHS") (Dkt. No. 87), Patient Home Monitoring, Inc. ("PHM") (Dkt. No. 91), and mdINR, LLC ("mdINR") (Dkt. No. 93) are **ALLOWED**. The motions by Alere Home Monitoring, Inc. ("Alere") (Dkt. No. 95), Cardiolink Corp. ("Cardiolink") (Dkt. No. 97), and Advanced Cardio Services ("ACS") (Dkt. No. 85) are **ALLOWED IN PART** and **DENIED IN PART**. The Court takes no action on the motion to dismiss filed by Tambra Investments, Inc. ("Tambra") (Dkt. No. 101), as the case against it has been stayed. Dkt. No. 136.

FACTUAL BACKGROUND

The following facts are drawn from the First Amended Complaint (Dkt. No. 17) ("FAC") and attached documents, with all reasonable inferences drawn in favor of Relator. Allegations focused on specific Defendants are discussed later.

I. Relator, Warfarin, and Blood Testing

Relator James Allen is a 70-year-old former Marine who lives in western New York. FAC ¶¶ 14, 32, 39. Since 2010, Allen has taken the blood-thinner warfarin to treat atrial

fibrillation and depressed left ventricle function. See FAC ¶¶ 33, 73. Because warfarin affects the blood's ability to clot, patients taking it must regularly monitor how long it takes for their blood to clot to ensure it remains within an acceptable range.[1] FAC ¶¶ 74-78. The correct range varies based on the condition being treated and each patient's reaction to specific doses of the drug. FAC ¶¶ 76-78. Therefore, testing is typically more frequent at the outset of a warfarin regimen. FAC ¶ 78. Once a proper dosage is determined and the patient stabilizes, testing can be less frequent, often once a month. FAC ¶¶ 78, 82.

Historically, blood testing for warfarin patients was done via blood draw at an outpatient clinic. FAC ¶ 85. In the 1980s, companies began to develop portable machines and accompanying supplies that allowed patients to do this testing at home. FAC ¶ 86. In 2002, the Centers for Medicare and Medicaid Services ("CMS") began allowing those companies to seek Medicare reimbursements for at-home testing, but only for very narrow categories of patients. FAC ¶ 87.

In 2008, after lobbying by a group that included Defendant Roche and a predecessor to Defendant Alere, CMS expanded its coverage for at-home testing. FAC ¶¶ 89-91. The new CMS

[1] The parties refer to this blood testing using technical terms -- prothrombin time ("PT") testing, or international normalized ratio ("INR") testing. See FAC ¶ 2. For ease of reference, this opinion uses the simpler term "blood testing."

determination permitted reimbursement for at-home testing for additional categories of patients and for up to one test per week. FAC ¶¶ 91, 93. In 2008, CMS paid a total of $5.5 million to all home-testing providers. FAC ¶ 8. In 2015, CMS paid over $116 million for at-home testing to the named Defendants, who received over 90 percent CMS's payments for such testing that year. FAC ¶ 7.

When Allen initially began his warfarin treatment in 2010, he tested at a Department of Veterans Affairs facility near his home in Buffalo, New York. FAC ¶ 34. In 2013, Allen transferred his care to Dr. Brian Riegel at Buffalo Cardiology & Pulmonary Associates ("BCPA"). FAC ¶ 35. BCPA has a clinic dedicated to blood testing for warfarin patients, and this is where Allen would go for his tests. See FAC ¶¶ 36, 39. The clinic uses an algorithm to determine the appropriate testing frequency for each patient. FAC ¶ 36. Once a patient has received two consecutive in-range results, the patient is considered stable, and the algorithm directs testing once every four weeks. FAC ¶ 38. Relator remained in this system until 2014. See FAC ¶ 39.

II. General Allegations

Relator makes several general allegations against all eight Defendants. He alleges that once a patient's blood-clotting time has stabilized, testing more often than monthly is rarely necessary. FAC ¶¶ 80-83. But Defendants allegedly coerce

patients and their doctors to agree to weekly testing (the maximum for which Medicare will reimburse) or to two tests per month without regard to whether those frequencies are medically necessary. FAC ¶¶ 109-16. They pressure doctors chiefly by removing less-frequent testing options from their pre-printed enrollment forms. FAC ¶¶ 118-21, 125-27. They also allegedly encourage the ordering of more tests than necessary through marketing material. FAC ¶¶ 128-29. For example, some marketing material references studies intended to lead patients and doctors to believe that more-frequent testing will lead to better health outcomes. FAC ¶¶ 130-31. Relator questions the validity and accuracy of these studies. FAC ¶¶ 130-41.

Allen also challenges the test-result reporting protocols of Alere, ACS, PHM, and mdINR. These companies' enrollment forms permit the prescribing physician to choose to receive reports (1) only monthly, or (2) only if the results are out-of-range. FAC ¶ 251. According to Allen, any Medicare reimbursement for a test whose result is not communicated to the prescribing physician violates Healthcare Common Procedure Coding System ("HCPCS") Billing Code G0249. FAC ¶¶ 252-53. Such reimbursements constitute payment for services not rendered. FAC ¶ 253.

III. Procedural History

Allen filed his complaint under seal in June 2016. Dkt. No. 1. He filed the FAC in June 2017. Dkt. No. 17. The FAC alleges five counts against all eight Defendants:

- Count I: presentment theory, 31 U.S.C. § 3729(a)(1)(A);
- Count II: false statements theory, 31 U.S.C. § 3729(a)(1)(B);
- Count III: reverse false claims theory, 31 U.S.C. § 3729(a)(1)(G);
- Count IV: payment under mistake of fact; and
- Count V: unjust enrichment.

The United States declined to intervene in November 2017, and the case was unsealed. Dkt. Nos. 21-22. Each of the eight Defendants have filed motions to dismiss. Dkt. Nos. 57, 85, 87, 91, 93, 95, 97, 101. Allen opposed the motions in a joint filing. Dkt. No. 127. Before the hearing on the motions, the Court stayed the case against Tambra, per the parties' request. Dkt. No. 136.

LEGAL STANDARDS

I. False Claims Act

Relator relies on three provisions of the FCA that target three distinct types of false claims. First, under the presentment theory, the FCA "penalizes those who present, or cause to be presented, 'false or fraudulent claim[s] for payment or approval' to the federal government." Hagerty ex rel. United

States v. Cyberonics, Inc., 844 F.3d 26, 31 (1st Cir. 2016) (alteration in original) (quoting 31 U.S.C. § 3729(a)(1)(A)). Under this theory, fraud "has two components: the defendant must submit or cause the submission of a claim for payment to the government, and the claim for payment must itself be false or fraudulent." Id. Second, under a false statements theory, the FCA punishes those who knowingly make or use "a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B). Third, under a reverse false claims theory, the FCA imposes liability on those who knowingly conceal or improperly avoid an obligation to pay or transmit money or property to the government. Id. § 3729(a)(1)(G).

Unlike other circuits, the First Circuit has "rejected rigid divisions between factual and legal falsity, and express and implied certification, noting that the text of the FCA does not make such distinctions." United States ex rel. Jones v. Brigham & Women's Hosp., 678 F.3d 72, 85 (1st Cir. 2012). Instead, this Circuit "take[s] a broad view of what may constitute a false or fraudulent statement." Id. The scope of the FCA, then, is circumscribed primarily by "'strict enforcement of [its] materiality and scienter requirements.'" Id. at 85-86 (quoting United States ex rel. Hutcheson v. Blackstone Med., Inc., 647 F.3d 377, 388 (1st Cir. 2011)).

"[T]he [FCA] defines 'material' to mean 'having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.'" Universal Health Servs., Inc. v. United States, 136 S. Ct. 1989, 1996 (2016) (quoting 31 U.S.C. § 3729(b)(4)). "The materiality standard is demanding." Id. at 2003. "A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment." Id. Nor is this element satisfied "where noncompliance is minor or insubstantial." Id.

> [P]roof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement. Conversely, if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.

Id. at 2003-04.

"The [FCA's] scienter requirement defines 'knowing' and 'knowingly' to mean that a person has 'actual knowledge of the information,' 'acts in deliberate ignorance of the truth or falsity of the information,' or 'acts in reckless disregard of the truth or falsity of the information.'" Id. at 1996 (quoting 31 U.S.C. § 3729(b)(1)(A)).

II. Medicare Rules and Regulations

By statute, Medicare only covers tests 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). By regulation, all diagnostic tests "must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem." 42 C.F.R. § 410.32(a). "Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary." Id.

Thus, in order to be eligible for Medicare coverage, the at-home testing program described above must be prescribed by a treating physician as provided in 42 C.F.R. § 410.32(a). See CMS, National Coverage Determination Manual, Chapter 1, Part 3, § 190.11 ("NCD § 190.11"). Four other criteria must also be met: (1) the patient must have been anticoagulated for at least three months prior to use of the home-testing device; (2) the patient must undergo a face-to-face educational program on anticoagulation management and must have demonstrated the correct use of the device prior to its use in the home; (3) the patient continues to correctly use the device; and (4) self-

testing with the device should not occur more frequently than once a week. Id.

Medicare reimbursements for at-home testing use at least three billing codes, including HCPCS Billing Codes G0248, G0249, and G0250. See CMS Manual System, Pub. 100-04, Transmittal 1562, July 25, 2008, Attachment: Business Requirements, at 2. The FAC focuses primarily on Billing Code G0249, which permits companies to bill Medicare for the "[p]rovision of test materials and equipment for home [blood coagulation] monitoring of [a] patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria." Id. It "includes [the] provision of materials for use in the home and reporting of test results to [a] physician; not occurring more frequently than once a week." Id.

III. Standard of Review

In analyzing whether a complaint has stated a claim sufficient to satisfy Rule 12(b)(6) of the Federal Rules of Civil Procedure, the Court must set aside any statements that are merely conclusory and examine the factual allegations to determine if there exists a plausible claim upon which relief may be granted. Foley v. Wells Fargo Bank, N.A., 772 F.3d 63, 75 (1st Cir. 2014). The Court must draw reasonable inferences in the pleader's favor. Id.

Because FCA claims sound in fraud, Rule 9(b) of the Federal Rules of Civil Procedure requires relators to allege their claims with particularity -- that is, with the "who, what, when, where, and how of the alleged fraud." Hagerty, 844 F.3d at 31 (quoting United States ex rel. Ge v. Takeda Pharm. Co., 737 F.3d 116, 123 (1st Cir. 2013)). That said, the First Circuit has "repeatedly emphasized that there is no checklist of mandatory requirements that each allegation in a complaint must meet to satisfy Rule 9(b)." Id. (internal quotation marks omitted).

DISCUSSION

To facilitate the analysis, the Court has sorted the Defendants into two groups. The first group includes Cardiolink, ACS, PHM, USHS, and mdINR. Relator seeks to find these Defendants liable primarily because they were willing to provide testing materials to him, even though he never enrolled in their programs. Accordingly, these are the "Willing Provider" Defendants. The second group includes Roche and Alere. Because these Defendants actually provided Relator with test materials, they are referred to as the "Test-Providing" Defendants.

I. The "Willing Provider" Defendants

A. Enrollment Forms Theory

The bulk of Relator's case against the "Willing Provider" Defendants rests on the premise that all of the Defendants' pre-printed enrollment forms are necessarily false because they all

provide for particular testing frequencies (e.g., two tests per month, or four tests per month). See Dkt. No. 127 at 13, 17-21, 25-27. In Relator's view, these limited frequency options induce doctors to increase the frequency with which patients test. See Dkt. No. 127 at 13. Thus, any claim for reimbursement based on one of the Defendants' enrollment forms (i.e., all of them) is necessarily false and violates the FCA. Dkt. No. 127 at 13, 25.

To survive a motion to dismiss, an FCA complaint typically must allege, at a minimum, an actual false claim. See, e.g., United States ex rel. Booker v. Pfizer, Inc., 847 F.3d 52, 57 (1st Cir. 2017) (describing evidence of an actual false claim as "the sine qua non" of an FCA violation); D'Agostino v. ev3, Inc., 845 F.3d 1, 10 (1st Cir. 2016) ("[T]he allegations must . . . establish that the fraudulent conduct actually caused the submission of false claims to the government for payment."). Moreover, the First Circuit has made clear that Rule 9(b) applies to FCA cases to give notice to defendants of a plaintiff's claim and prevent the filing of suits that simply hope to uncover relevant information during discovery. United States ex rel. Nargol v. DePuy Orthopaedics, Inc., 865 F.3d 29, 38 (1st Cir. 2017), cert. denied sub nom. Med. Device Bus. Servs., Inc. v. United States ex rel. Nargol, 138 S. Ct. 1551 (2018). Thus, mindful of Rule 9(b), a relator usually "alleg[es] with particularity examples of actual false claims submitted to

the government. By doing so, the relator conveys that if the facts alleged are true, the filing of a false claim is not merely a possibility, but rather, necessarily occurred." D'Agostino, 845 F.3d at 10 (citation omitted).

With the exception of Roche and Alere, discussed below, none of the "Willing Provider" Defendants is alleged to have submitted any claims to Medicare for testing that Allen performed. That defect alone causes serious Rule 9(b) problems for Relator's claims against these Defendants. See United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 232-33 (1st Cir. 2004) (listing examples of information "that may help a relator to state his or her claims with particularity"), abrogated on other grounds by Allison Engine Co. v. United States ex rel. Sanders, 553 U.S. 662 (2008).

Those problems are compounded in this case because Relator's theory hinges on a certification of medical necessity. In order to satisfy the scienter element under such a theory, Relator must sufficiently allege that each Defendant knew or recklessly disregarded the risk that an enrollment form was being used to order medically unnecessary tests. See Universal Health Servs., 136 S. Ct. at 1996. It is difficult to do that -- and Relator has failed to do so here -- without a single example of the company submitting a claim for a test despite known or obvious risks that the enrollment form was false with respect to

a particular patient's medical needs. See United States ex rel. Nowak v. Medtronic, Inc., 806 F. Supp. 2d 310, 354 (D. Mass. 2011) (rejecting complaint that failed to allege any claim for "medically unnecessary" use).

Some courts have held that bundled tests, ordered via a pre-printed form, can create FCA liability, provided the certifying entity is aware that one or more of the tests is medically unnecessary, or recklessly disregards such a risk. In United States ex rel. Groat v. Boston Heart Diagnostics Corp., a laboratory's pre-printed test-requisition form permitted doctors to order a panel of several tests by checking a single box. See 255 F. Supp. 3d 13, 18–20 (D.D.C. 2017), amended on reconsideration in part, 296 F. Supp. 3d 155 (D.D.C. 2017). This caused doctors to order panels of tests that were medically unnecessary. See id. Likewise, in United States v. Berkeley Heartlab, Inc., the defendants were accused of submitting false claims to Medicare by "encourag[ing] physicians to order tests that were medically unnecessary," including unnecessary genetic testing on patient blood samples. 225 F. Supp. 3d 487, 497 (D.S.C. 2016). The scheme was perpetrated, in part, by using requisition forms. See id. at 501. And in United States v. Family Medicine Centers of S.C., LLC, the Government alleged that the defendants used panels of diagnostic tests that included more tests than necessary for screening purposes. See

Civ. No. 3:14-382, 2016 WL 6601017, at *3 (D.S.C. Nov. 8, 2016). It also alleged that the laboratory implemented a standing order requiring staff to automatically perform certain tests whether or not ordered by a physician. See id.

Longstanding guidance from the Office of the Inspector General ("OIG") for the Department of Health and Human Services also supports Relator's view. The OIG has stated that "laboratories should construct the requisition form . . . to promote the conscious ordering of tests by physicians or other authorized individuals" and "to ensure that the physician . . . has made an independent medical necessity decision with regard to each test the laboratory will bill." Publication of OIG Compliance Program Guidance for Clinical Laboratories ("OIG Guidance"), 63 Fed. Reg. 45076-03, 45079 (Aug. 24, 1998).

Relator's premise that Defendants' enrollment forms resulted in Medicare reimbursements for some medically unnecessary tests is plausible in light of the allegation that testing is not generally medically necessary more than once monthly for a patient who has consistently recorded in-range results. However, all tests at issue here were approved by a treating physician, and, even according to the complaint, many were medically necessary. See FAC ¶¶ 77-78 (recognizing that blood testing must occur "frequently" at the outset of warfarin treatment); Dkt. No. 17-2 ¶ 13 (affidavit from Dr. Riegel noting

that clinic's algorithm required Relator to test weekly in 2013). Relator offers no categorical way of putting a Defendant on notice of which enrollment forms, if any, resulted in false claims because a physician signed off on more testing than needed. See United States ex rel. Kester v. Novartis Pharm. Corp., 23 F. Supp. 3d 242, 258 (S.D.N.Y. 2014) ("[T]he complaint must provide the defendant with enough details to be able to reasonably discern which of the claims it submitted are at issue" by "(1) providing sufficient identifying information about all the false claims, or (2) providing example false claims."). Without such details, Relator's FCA claims against the "Willing Provider" Defendants resemble the sort of hopeful fishing expedition that the First Circuit has rejected in FCA cases. See Nargol, 865 F.3d at 38.

One established exception to Rule 9(b)'s particularity requirement in an FCA case -- the one that Relator wants to apply here -- is the "more flexible standard" that governs where a defendant is alleged to have induced third parties to file false claims. See Nargol, 865 F.3d at 39; United States ex. rel. Kelly v. Novartis Pharm. Corp., 827 F.3d 5, 13 (1st Cir. 2016); United States ex rel. Duxbury v. Ortho Biotech Prods., L.P., 579 F.3d 13, 30 (1st Cir. 2009). The First Circuit has described these third-party inducement claims, which sometimes arise in

the context of off-label marketing of a prescription drug, as flowing from the following archetype:

> Drug was approved for Use X; Company successfully marketed it also for Use Y; lots of Drug has been prescribed in the United States; a significant number of U.S. patients are covered by government insurance; therefore it is rational to assume that some payments for off-label use of Drug have been made or reimbursed by the government.

Nargol, 865 F.3d at 39. That setup can trigger the "more flexible" Rule 9(b) standard, which is satisfied when the relator provides "'factual or statistical evidence to strengthen the inference of fraud beyond possibility without necessarily providing details as to each false claim' submitted." Kelly, 827 F.3d at 13 (quoting Duxbury, 579 F.3d at 29-30). The scheme alone is not sufficient to satisfy Rule 9(b); rather, the complaint "must pair the details of the scheme with 'reliable indicia that lead to a strong inference that claims were actually submitted.'" Nargol, 865 F.3d at 39 (quoting Duxbury, 579 F.3d at 29).

Here, it is unclear whether the relaxed standard should apply because Relator's complaint pertaining to the "Willing Provider" Defendants does not advance a traditional third-party inducement theory. Rather, each Defendant (not a third party) is responsible for the submission of the claim for reimbursement to the government. On the other hand, Relator alleges that these

claims were only made possible because the forms, by limiting doctors' options, induced them to order unnecessary tests.

But even if the "more flexible" standard did apply, Relator has not provided enough additional evidence to strengthen the inference of fraud beyond the level of possibility based on the enrollment forms alone. See Hagerty, 844 F.3d at 33 (quoting United States ex rel. Rost v. Pfizer, Inc., 507 F.3d 720, 733 (1st Cir. 2007). The physicians' intervening medical judgment is the main impediment to Relator's theory. That is, standing alone, the form does not permit one to distinguish between a claim that involved genuine medical judgment and a claim that was medically unnecessary. Thus, the forms, by themselves, may create a possibility of fraud by pressuring doctors into prescribing medically unnecessary tests to give their patients the convenience of at-home testing. But they do not give rise to a "strong inference" that false claims were actually submitted. See Nargol, 865 F.3d at 41 (quoting Duxbury, 579 F.3d at 29).

The Court addresses separately the claims against each Defendant below.

B. Defendant-Specific Allegations

1. Cardiolink

Allen contacted Cardiolink in November 2014. FAC ¶ 243. Cardiolink's enrollment form allows doctors to choose a testing frequency of "1 Test Per week" or "Other." FAC ¶ 245. A

Cardiolink representative told Allen that he was free to test once a month, but the company would bill Medicare for four tests per month regardless. FAC ¶ 244. The representative also told Allen the company uses an instructional DVD for at-home testers, rather than in-person instruction, which Allen claims is required under NCD § 190.11. FAC ¶ 247.

The Court concludes that the more flexible Rule 9(b) standard applies to Relator's claim regarding the instructional DVD, and that Relator has satisfied it. Cadriolink has not focused its briefing on this topic and addressed it only in passing at the hearing. See Dkt. Nos. 124, 134, 146 at 67-70. However, on its face, this allegation, if true, states a specific and plausible claim that Cardiolink uniformly fails to comply with NCD § 190.11, which requires home-testing patients to "undergo a face-to-face educational program on anticoagulation management" and "demonstrate[] the correct use of the [home-testing] device prior to its use in the home." Relator has also provided aggregate data demonstrating that Cardiolink submitted Medicare claims worth tens of thousands of dollars for at-home blood-testing materials between 2012 and 2015. See Dkt. No. 17-1.

Relator has not alleged a specific example of a Cardiolink claim for reimbursement. However, that is not necessary under this theory, which approximates the scheme discussed in Nargol.

There, it was alleged that more than half of the defendant's hip replacement implants did not comply with federal requirements and that doctors would have had no reason not to submit claims for reimbursement because the implants' defect was latent. Nargol, 865 F.3d at 41. Because these allegations "show[ed] that it [was] statistically certain that [the defendant] caused third parties to submit many false claims to the government," the First Circuit did not require additional particularity. Id. Here, although Relator's allegations based on Cardiolink's DVD training program do not comprise a typical third-party inducement theory, they would, if true, make it "statistically certain" that false claims were submitted. See id. That is, unlike the theory involving a medical necessity determination discussed above, seeking Medicare reimbursement despite a lack of compliance with the face-to-face training requirement would plausibly result in a false claim. These allegations satisfy the relaxed Rule 9(b) standard, as applied by the First Circuit in Nargol and the cases discussed therein.

These allegations also plausibly satisfy the materiality and scienter requirements, although Cardiolink has not challenged the former. Indeed, Cardiolink, in its papers, has not discussed or disputed the DVD allegation at all. See generally Dkt. Nos. 124, 134. Accordingly, the Court will allow this theory to move forward.

2. ACS

In December 2014, Allen contacted ACS. FAC ¶ 208. ACS's enrollment form states that "Medicare recommends weekly testing," and the company sent Allen materials that reinforce this point. FAC ¶¶ 212, 215-17. However, this is allegedly untrue. FAC ¶ 213. In subsequent communications, Allen asked the ACS representative whether Medicare would cover weekly tests even though his doctor told him he only needed monthly tests. FAC ¶ 221. The representative replied, "Yes, Medicare covers our services." FAC ¶ 222.

As with Cardiolink, the Court concludes that the flexible Rule 9(b) standard applies to Relator's theory regarding the statement on the ACS enrollment form, and that Relator has satisfied it. The form asserts that "Medicare recommends weekly testing." See FAC ¶ 212; Dkt. No. 17-5 at 31. Yet, Relator has plausibly alleged that Medicare makes no such recommendation. See FAC ¶ 213. This fits within the First Circuit's "broad view of what may constitute a false or fraudulent statement." See Jones, 678 F.3d at 85-86. And it is reasonable to infer that at least some doctors would rely on that statement in deciding whether to enroll a patient in ACS's service. See Nargol, 865 F.3d at 41 (discussing allegation that "the latency of the defect was such that doctors would have had no reason not to submit claims for reimbursement for noncompliant devices").

Relator has also plausibly alleged that while this form was in use, ACS billed Medicare for millions of dollars of blood-testing supplies. See FAC ¶¶ 208-09; Dkt. No. 17-1. Taken together, these allegations give rise to a "strong inference" that false claims were actually submitted. See Nargol, 865 F.3d at 41 (quoting Duxbury, 579 F.3d at 29). That is, Relator has plausibly alleged that ACS submitted Medicare claims based upon a form that makes a false statement, and that false statement plausibly induced doctors to sign patients up for weekly testing that they did not otherwise need. While ACS argues strenuously that its form did not override the independent medical judgment of any physicians, the company does not actually address the allegedly false statement about Medicare recommending weekly testing, other than to state that this form is no longer in use and that ACS is no longer in business. See generally Dkt. Nos. 86, 131, 145. Thus, Relator has plausibly stated a claim that ACS violated the FCA.

3. PHM

Allen contacted PHM in December 2014. FAC ¶ 198. After receiving a brochure from the company, he sent a letter informing PHM that he was a "stable" patient who typically tested once or twice per month. FAC ¶ 198. Allen asked whether the company would require him to get a new prescription for weekly testing. FAC ¶ 198. A company representative responded

that "since Medicare covers 80% of the cost they require our patients to test weekly as a preventative." FAC ¶ 199. The representative also wrote that "weekly testing is a must" for PHM's program. FAC ¶ 199. Allen pointed out that Medicare allows up to one test per week, but does not require a minimum testing frequency. FAC ¶ 201. The representative responded that Allen could not come on board as a monthly tester because PHM requires all of its patients to test weekly. FAC ¶ 202.

Through his own investigation of PHM, Allen discovered a 2010 PowerPoint presentation indicating that the company viewed at-home testing for warfarin patients as a growing market due to Medicare's expansion of coverage. FAC ¶ 203. The presentation also describes a marketing plan in which the company would explain to cardiologists that they could add $250,000 in revenue by adding 1,000 new home-testing patients. FAC ¶ 205.

Having rejected Relator's theory of falsity based on the enrollment forms alone, the Court concludes that Relator fails to plausibly state an FCA claim against PHM. With respect to the representative's assertion to Allen that Medicare "requires" its patients to test weekly, Relator has not alleged that this statement was made to his treating physician. And because there are no allegations that PHM submitted a claim for materials provided to Relator, the complaint does not plausibly allege

that this false statement caused the submission of a false claim.

The allegation regarding PHM's troubling marketing material also falls short of the mark. Absent a specific example showing that this promise of a new revenue stream actually induced a doctor to enroll a patient in weekly testing despite the lack of medical necessity, this theory fails under Rule 9(b). Thus, the FCA claims against PHM must be dismissed.

4. USHS

Allen inquired about USHS's at-home testing program in January 2015. FAC ¶ 189. He communicated that he had been testing once a month and asked whether USHS could "cover" that prescription. FAC ¶ 191. A company representative replied that USHS "typically" does not cover monthly testers due to the high up-front cost of the at-home meter. FAC ¶ 192. However, the representative told Allen that after a "few months" of weekly or biweekly testing, the company would "respect" a doctor's order for monthly testing. FAC ¶ 192.

In a subsequent exchange, USHS told Allen that the meter cost $700, so around five months of weekly testing would cover its cost. FAC ¶ 194. The representative also told Allen that "[i]f the [doctor] signs off on weekly testing and you test that way 4 weeks in a row and then your doctor sends in an order for monthly testing we won't dispute it[.] . . . [T]here are

loopholes and ways around things." FAC ¶ 194. Allen spoke with Dr. Riegel, and, a few days later, told the representative that his doctor said four tests per month were not medically necessary, so that was out of the question. FAC ¶ 196. The representative replied, "[U]nless you get a new [c]ardiologist who is willing to sign off on it[,] there is nothing we can do." FAC ¶ 197.

Again, these allegations do not satisfy Rule 9(b). Without any allegation that the alleged "loophole" offer actually caused the submission of a false claim, the complaint fails under Rule 9(b).

5. mdINR

Allen contacted mdINR in January 2015, asking whether Medicare would cover the company's services given Dr. Riegel's recommendation that Allen test once or twice a month. FAC ¶ 224. A company representative responded, "We are weekly only testing, so you and your doctor must agree to weekly testing to use our service." FAC ¶ 225. But a section of the company's website seems to contradict the weekly-only policy. FAC ¶¶ 228-29. It states that patients may test "at the frequency prescribed by [their] doctor." FAC ¶¶ 228-29.

Nothing in these allegations would lead to liability under the FCA independent of the theory that the Court rejected above. Accordingly, the claims against mdINR must be dismissed.

C. Summary

In sum, the motions to dismiss by PHM, USHS, and mdINR are **ALLOWED**. The motion by Cardiolink is **DENIED** with respect to the DVD training theory, but is otherwise **ALLOWED**. The motion by ACS is **DENIED** with respect to the theory described above; it is otherwise **ALLOWED**.

II. The "Test-Providing" Defendants

A. Roche

1. Facts Alleged

In 2014, Allen moved to Canandaigua, New York, nearly 100 miles from the BCPA clinic. FAC ¶ 39. Given the distance, Allen enrolled in an at-home testing program with Defendant Roche. FAC ¶¶ 39-41.

Allen performed his first Roche at-home test on March 2, 2014. FAC ¶ 41. Because he was using a new system, Allen tested himself again on March 13 and April 3. FAC ¶ 42. At that point, Allen had five consecutive in-range readings. FAC ¶ 42. When he informed the clinic of the April 3 result, the BCPA algorithm advised that his next test should occur on May 1, 2014; this was consistent with Dr. Riegel's prior guidance to Allen that stable patients should test once a month. FAC ¶ 43.

On April 28, 2014, Roche mailed Allen a letter stating that he had missed his test for the week of April 14, 2014. FAC ¶ 44. Allen called the company to ask about the letter. FAC ¶ 174. A

Roche representative told Allen about a "marketing report" that directed employees to inform home-testing customers that they would need to perform at least two tests per month in order to continue in Roche's program. FAC ¶ 174. However, Allen uncovered several Roche documents, including a 2012 newsletter and sections of its website, acknowledging that some warfarin patients only require one test per month. FAC ¶¶ 177-79.

In the course of his investigation, Allen also discovered that when he was enrolled in the Roche program by Dr. Riegel, in May 2013, Dr. Riegel signed a form selecting the "2-4 tests per month" option. FAC ¶¶ 40, 181. Allen complained to his doctor. FAC ¶ 182. In response, Dr. Riegel and a colleague countersigned a prescription clarifying that Allen only required one test per month so long as his results remained stable. FAC ¶¶ 182-83. The doctor attached this new prescription to a Roche enrollment form in July 2014; instead of selecting from the form's monthly test-frequency options of "4," "3," "2," and "2-4," the doctor checked a box for "Form attached" and attached the prescription. FAC ¶ 183-84. Shortly after, Roche changed its enrollment form to remove the "Form attached" option, leaving only the "4," "3," "2," and "2-4" options. FAC ¶¶ 184-85.

In August 2014, Roche informed Allen via letter that it was dropping him from the at-home testing program. FAC ¶ 186. The

letter relied on the opinions of Allen's doctors, who only recommended one test per month. FAC ¶ 186.

2. Analysis

The heart of Roche's argument for dismissal is that it kicked Relator out of its home-testing program as soon as Relator said he only needed to test once a month. Dkt. No. 58 at 2. Therefore, no false claims were submitted, and Relator has failed to plead his FCA theories with particularity as required under Rule 9(b). Dkt. No. 58 at 2-4. Relator counters that Roche's claim that it dismissed patients who required less-frequent testing is a factual issue that cannot be resolved at a motion to dismiss. Dkt. No. 127 at 22. He also incorporates the necessarily-false enrollment form argument described above. Dkt. No. 127 at 42.

Relator's allegations provide no basis from which the Court could infer that Roche knew or recklessly disregarded the risk that Relator did not need weekly testing. Roche first became aware of that possibility when Dr. Riegel made contact in July 2014. FAC ¶¶ 182-84. The very next month, Roche removed Relator from its program. FAC ¶ 186. This is exactly the opposite of what Allen would need to show to support his case against Roche. Rather than seek reimbursement for tests that the company knew or suspected to be medically unnecessary, the company suspended its service as soon as Dr. Riegel called into question the

medical necessity of more-frequent testing. Accordingly, the Court allows Roche's motion to dismiss the FCA claims.

B. Alere

1. Facts Alleged

Allen first inquired about Alere's at-home testing program through a letter dated January 7, 2015. FAC ¶ 142. The letter informed Alere that Allen's doctor was recommending one test per month so long as his levels remained stable. FAC ¶ 142. An Alere representative named Mary Wages responded via email two days later. FAC ¶ 143. Wages told Allen that Alere requires at least two tests per month. FAC ¶ 143. Allen responded by questioning this requirement in light of his stable readings. FAC ¶ 144. Wages repeated the two-tests-per-month minimum. FAC ¶ 145.

When Allen again questioned the requirement, Wages responded with an allegedly false or misleading statement: "All the studies indicate that patients who test more frequently have fewer adverse events." FAC ¶¶ 148-49. In all, Allen told Alere four times that his doctor believed testing more frequently than once a month would be unnecessary. FAC ¶ 153. Yet, Alere enrolled Allen in its home-testing program. FAC ¶ 156. Alere has submitted bills to CMS for Allen's tests at least every two weeks since March 11, 2015. FAC ¶ 156.

Dr. Riegel submitted a physician order form to Alere on January 30, 2015 -- before Allen began testing with Alere. FAC

¶¶ 159-60. The form approves Allen for two blood tests per month. FAC ¶¶ 159-60. Dr. Riegel now avers that more than one test per month was medically unnecessary for Allen, and that he only signed the Alere order form so Allen could have access to the company's at-home testing service. Dkt. No. 17-2, ¶ 22.

Through his investigation into Alere, Allen uncovered an earlier version of the physician order form, dated 2011. FAC ¶ 161. Unlike the form that Dr. Riegel signed, which was updated in 2013, the earlier version gave prescribing doctors a range of test-frequency options: "Weekly," "1-4 times/month," and "Other." FAC ¶¶ 159, 161. Allen claims Alere changed its forms solely to maximize the amount of testing that patients performed, regardless of whether the tests were medically necessary, so that it could increase its Medicare revenue stream. FAC ¶ 162. Allen also provides statistics suggesting that, from 2008 to 2015, the average number of monthly at-home tests billed to Medicare for Alere patients more than doubled, from around one per month to 2.36 per month.[2] FAC ¶¶ 171, 266.

Allen also takes aim at Alere's marketing practices. For example, he claims a 2014 Alere-sponsored study was intended to mislead doctors and patients into testing more frequently than

[2] The FAC details 2015 average test figures for all eight Defendants. They range from 1.74 tests per patient per month for Roche to 2.90 tests per patient per month for PHM. FAC ¶ 266.

independent medical literature would recommend. FAC ¶¶ 163-71. It did this, in part, by selecting a data set that skewed too heavily toward patients on warfarin for a mechanical heart valve, as opposed to other conditions, which may have affected the necessary testing frequency. See FAC ¶¶ 166-69.

2. Analysis

Relator advances two main theories against Alere: one based on the allegedly false certification of medical necessity, and one based on Medicare billing codes.

i. Medical Necessity Theory

Relator's theory based on a false certification of medical necessity is bolstered by specific information. Attached to the complaint are what appear to be three actual claims that Alere submitted for Medicare reimbursement based on blood tests for Allen.[3] See Dkt. Nos. 17-12, 17-13, 17-15. Relator contends that the majority of these tests (i.e., any tests beyond one per month) were medically unnecessary based on Relator's in-range test results. See Dkt. No. 17-14; Dkt. No. 127 at 43. These tests are coupled with allegations that Relator told Alere in writing that he only needed one test per month. FAC ¶¶ 142, 153. When reasonable inferences are drawn in Relator's favor, Alere

[3] Allen attached five additional Medicare reimbursement claims to his opposition brief that appear to show the same thing. See Dkt. No. 127-1. The Court cannot consider these documents without converting this into a motion for summary judgment. See Trans-Spec Truck Serv., Inc. v. Caterpillar Inc., 524 F.3d 315, 321 (1st Cir. 2008).

was on notice that there was a substantial risk that Dr. Riegel's certification was false.

As discussed above, some courts have held that bundled tests can create FCA liability when the certifying entity is aware that one or more of the tests are medically unnecessary, or recklessly disregards such a risk. See, e.g., Groat, 255 F. Supp. 3d at 18–20, 29-30. Applying those cases here, the Court concludes that when Alere removed the "Other" option from its enrollment form, FAC ¶¶ 159, 161, it left physicians with an unfortunate choice: order medically unnecessary tests, or deny patients the option of at-home testing. The modified form thus created a heightened risk that medically unnecessary tests would be ordered.

Relator has also plausibly and specifically alleged that, with respect to his own enrollment in the program, Alere ignored facts that would put a reasonable person on notice that more than one test per month was medically unnecessary for him. See Groat, 296 F. Supp. 3d at 165 (allegation that lab CEO was told "test panels included many unnecessary tests"); Berkeley Heartlab, 225 F. Supp. 3d at 497 (allegation that defendants "encouraged physicians to order tests that were medically unnecessary"); Family Med. Ctrs. of S.C., 2016 WL 6601017, at *3 (allegation that defendants "created" overly broad test panels and "stressed" to physicians to use them, "regardless of whether

all components of the panel were medically necessary"). That combination alleges a false claim with the requisite specificity and plausibility without resort to the "more flexible" standard discussed above.

Further, these allegations satisfy the FCA's scienter requirement. See 31 U.S.C. § 3729(b)(1) (defining "knowing" and "knowingly" as having "actual knowledge of the information," "act[ing] in deliberate ignorance of the truth or falsity of the information," or "act[ing] in reckless disregard of the truth or falsity of the information"). Relator has plausibly alleged scienter because Relator told Alere four times that he did not need testing more than one time per month and his test results were stable. FAC ¶ 153.

Alere argues that medical necessity is a determination for the physician, not the patient. See 42 C.F.R. 410.32(a). Thus, when determining how many blood tests Relator required, Alere argues it was entitled to trust Dr. Riegel's word on the enrollment form over Relator's earlier assertions. While Alere is generally entitled to rely on the independent judgment of a medical provider, see Groat, 296 F. Supp. 3d at 165, here Alere had a specific basis to second-guess Dr. Riegel's certification about Relator's medical needs: Relator's own communications describing a different medical need. FAC ¶ 153. When all

reasonable inferences are drawn in Relator's favor, the FAC plausibly alleges scienter.

Finally, Alere argues that the public disclosure bar precludes Relator's claim. "[T]he public disclosure bar forecloses a qui tam action 'if substantially the same allegations or transactions as alleged in the action . . . were publicly disclosed' in a list of enumerated sources." United States ex rel. Winkelman v. CVS Caremark Corp., 827 F.3d 201, 208 (1st Cir. 2016) (quoting 31 U.S.C. § 3730(e)(4)(A)). "[P]ublic disclosure occurs when the essential elements exposing the particular transaction as fraudulent find their way into the public domain." United States ex rel. Ondis v. City of Woonsocket, 587 F.3d 49, 54 (1st Cir. 2009).

Here, Alere's only argument in support of applying the public disclosure bar is that its enrollment form was publicly available on its website. See Dkt. No. 96 at 18-19. Alere cites no authority to support the proposition that, generally speaking, a form posted on a company's website fits within the statutory sources that may trigger the public disclosure bar. See 31 U.S.C. § 3730(e)(4)(A). Further, as just articulated, Relator's theory of falsity entails much more than just the form. It involves Relator's personal interactions with the company, as well as his own medical needs. Alere does not argue that these details were publicly disclosed prior to Relator's

complaint. As a result, the public disclosure bar does not apply here, and Alere's motion to dismiss must be denied.

ii. Billing Code Theory

Allen also contends that Alere, on at least two occasions (October 16, 2016, and December 2, 2016), billed Medicare for tests that were not performed. The complaint alleges that on these dates, Alere submitted claims after Allen only performed three tests, rather than the four called for by HCPCS Billing Code G0249. FAC ¶¶ 254-62. According to Relator, if this practice occurs regularly across Alere's entire patient population, it could result in fraudulent claims of up to $12 million per year. FAC ¶ 261.

Alere initially responded, in part, that the fourth tests may only appear to be missing because they may not have returned "numerical" results. Dkt. No. 132 at 9. The Court permitted limited discovery to develop this issue. See Dkt. No. 146 at 75-76. From the information uncovered, it appears that Allen performed tests on September 5, 2016, and October 16, 2016, that returned the result "Blood Sample Error" rather than the typical numerical value. Dkt. No. 149-1 at 2. He then performed another test on the same day that returned a numerical value. Dkt. No. 149-1 at 2. Each of the "Error" tests was part of a batch of four tests that Alere submitted to Medicare for reimbursement. Dkt. No. 149-1 at 2.

However, Relator disputes this characterization of what the limited discovery revealed, and he argues that, in any event, it was improper to bill for these "Error" test results. Because this issue required further factual development beyond the four corners of the complaint, the Court must take heed of the rule that "any consideration of documents not attached to the complaint, or not expressly incorporated therein, is forbidden, unless the proceeding is properly converted into one for summary judgment under Rule 56." Watterson v. Page, 987 F.2d 1, 3 (1st Cir. 1993). Of course, there is a "narrow" exception "for documents the authenticity of which are not disputed by the parties." Id. But here, Relator seems to dispute the authenticity of the Alere billing records, at least the summary version presented to the Court. See Dkt. No. 149 at 2.

On this theory, the details may matter, particularly with respect to whether Relator has satisfied the "demanding" materiality standard. See Universal Health Services, 136 S. Ct. at 2003-04. The Supreme Court described that standard as "look[ing] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation." Id. at 2002 (quoting 26 R. Lord, Williston on Contracts § 69:12 (4th ed. 2003)). That analysis is likely to turn on precisely what information Alere actually sent to the government regarding the

"Error" test results. Because the parties dispute that fact, the Court cannot dismiss the billing code theory at this stage.

C. Summary

For the reasons given, Roche's motion to dismiss is **ALLOWED**. Alere's motion to dismiss is **DENIED** with respect to the theories just discussed.

III. Test-Reporting Allegations

Relator makes one other FCA allegation against Alere, ACS, PHM, and mdINR. He argues that these companies gave physicians the option of receiving their patients' test results only if they were out of range and/or on a monthly summary basis. See FAC ¶¶ 207, 211, 227, 251. Relator contends that these test-reporting options conflict with HCPCS Billing Code G0249, and therefore result in the submission of false claims.

This theory fails for two reasons. First, Relator has not plausibly or specifically alleged any instance in which a physician actually selected one of these reporting options. Second, Billing Code G0249 requires only "reporting of test results to physician" -- without specifying a frequency. See Billing Code G0249. Given this ambiguity in what the billing code requires, Relator has not plausibly alleged materiality under the "demanding" standard of Universal Health Services. That is, he has not plausibly alleged that a physician's choice of when to receive test result data (only monthly or only when

the results fall out of range) actually did or likely would affect the government's decision to reimburse for the tests. See Universal Health Servs., 136 S. Ct. at 2003-04 (describing the types of evidence that could and could not support finding of materiality). Accordingly, Relator's claims based on this theory cannot survive a motion to dismiss.

IV. Common Law Counts

Collectively, Defendants assert that Allen's common law counts claiming payment under mistake of fact (Count IV) and unjust enrichment (Count V) must be dismissed for lack of standing. They point out that even if Allen's core FCA theories are true, he has suffered no harm by virtue of the government paying fraudulent Medicare claims. Allen's briefing does not counter this argument, which comports with the case law. See United States ex rel. Rockefeller v. Westinghouse Elec. Co., 274 F. Supp. 2d 10, 14 (D.D.C. 2003) ("A relator in a qui tam FCA action does not have standing to assert common law claims based upon injury sustained by the United States."), aff'd sub nom. Rockefeller ex rel. United States v. Washington TRU Sols. LLC, No. 03-7120, 2004 WL 180264 (D.C. Cir. Jan. 21, 2004); United States ex rel. Walsh v. Eastman Kodak Co., 98 F. Supp. 2d 141, 149 (D. Mass. 2000) (similar). Accordingly, the motions to dismiss with respect to the common law counts are **ALLOWED**.

ORDER

For the reasons given, the motions to dismiss by Roche (Dkt. No. 57), USHS (Dkt. No. 87), PHM (Dkt. No. 91), and mdINR (Dkt. No. 93) are **ALLOWED**. The motions by Alere (Dkt. No. 95), Cardiolink (Dkt. No. 97), and ACS (Dkt. No. 85) are **ALLOWED IN PART** and **DENIED IN PART** as stated above. The Court takes no action on the motion by Tambra (Dkt. No. 101) in light of the stay.

/s/ PATTI B. SARIS
Patti B. Saris
Chief United States District Judge