UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA ex rel. CHRIS RIEDEL, Plaintiff, v. BOSTON HEART DIAGNOSTICS CORPORATION, Defendant.	Civil Action No. 12-1423 (RBW)

MEMORANDUM OPINION

The plaintiff/relator, Chris Riedel, brings this qui tam action on behalf of the United States against the defendant, Boston Heart Diagnostics Corporation ("Boston Heart"), under the False Claims Act, 31 U.S.C. § 3729 (2012). See Relator's Second Amended Complaint for Money Damages and Civil Penalties for Violations of the False Claims Act ("2d Am. Compl.") ¶¶ 1, 108–21. Currently before the Court is Boston Heart Diagnostics Corporation's Motion to Dismiss Relator's Second Amended Complaint ("Def.'s Mot."), which seeks dismissal of the relator's claims pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6). See Def.'s Mot. at 1. 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 to dismiss.

[1] In addition to the filings already identified, the Court considered the following submissions in rendering its decision: (1) the Memorandum in Support of Boston Heart Diagnostics Corporation's Motion to Dismiss Relator's Second Amended Complaint ("Def.'s Mem."); (2) the Relator's Opposition 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").

I. BACKGROUND

A. Applicable Statutes

A brief overview of the Medicare program and the statutes at issue in this case will help elucidate the relator's allegations in his Second Amended Complaint.

1. The Medicare Program

Medicare is a federal health insurance program for the elderly and people with disabilities. See 42 U.S.C. § 1395c (2012). Medicare Part B, which provides outpatient coverage for, among other things, diagnostic laboratory tests, see 42 C.F.R. § 410.32 (2017), 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 ("Processing Manual") § 120.1 (2018).[2] "[E]ven 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." United States ex rel. Groat v. Boston Heart Diagnostics Corp., 296 F. Supp. 3d 155, 163 (D.D.C. 2017) (Walton, J.) (Groat II).

"The Secretary of the Department of Health and Human Services administers the Medicare program through the Centers for Medicare and Medicaid Services, which contracts

[2] The Court takes judicial notice of the Processing Manual because "judicial notice may be taken of public records and government documents available from reliable sources." Johnson v. Comm'n on Presidential Debates, 202 F. Supp. 3d 159, 167 (D.D.C. 2016).

with Medicare Administrative Contractors [('MACs')] to manage enrollment of health care providers and to process payments." Popkin v. Burwell, 172 F. Supp. 3d 161, 164 (D.D.C. 2016). This includes ensuring that claims for payment are "clean claims," meaning "claim[s] that ha[ve] no defect or impropriety." 42 U.S.C. § 1395h(c)(2)(A)–(B).

"When submitting claims for payment . . . , healthcare service providers . . . use standard billing forms[,] . . . [which] use numeric codes to describe the medical services for which the provider seeks payment." Ass'n of N.J. Chiropractors v. Aetna, Inc., No. 09-3761 (JAP), 2012 WL 1638166, at *1 (D.N.J. May 8, 2012). "Federal regulations, specifically 45 C.F.R. § 162.1002(a)(5), (b)(1), designate the American Medical Association's Current Procedural Terminology ('CPT') and the Centers for Medicare & Medicaid Services Common Procedure Coding System ('HCPCS') as the standard codes to be used for physician services and other health care services." Id. "HCPCS codes can define a single test or a panel (a group of tests that are commonly performed together)." Dep't of Health & Human Servs. Office of Inspector Gen., Questionable Billing for Medicare Part B Clinical Laboratory Services at 2 (2014). One "common Medicare fraud scheme[] involving clinical lab services . . . [is] unbundling tab tests." Id. "Unbundling is the practice of inappropriately reporting each component of a service or procedure instead of reporting the single comprehensive code." Id. at 2 n.12.

An entity seeking reimbursement for services provided to Medicare patients must submit a CMS-1500 form to the MAC. See United States ex rel. Hobbs v. MedQuest Assocs., Inc., 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."). 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, available at https://www.cms.gov/Medicare/

CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf (last visited Sept. 12, 2018).

2. The Anti-Kickback Statute

The Anti-Kickback Statute prohibits payments in exchange for referrals to federal healthcare programs, specifically prohibiting:

> knowingly and willfully offer[ing] or pay[ing] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person . . . to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program.

42 U.S.C. § 1320a-7b(b)(2)(A).

Unfortunately, the occurrence of kickbacks is reportedly common in the context of laboratory tests billed to Medicare. In 1994, the U.S. Department of Health and Human Services, Office of Inspector General ("OIG"), issued a Special Fraud Alert that addressed laboratory practices that violated the Anti-Kickback Statute, including, but not limited to, "routine waiver of Medicare Part B co-payments and deductibles." Publication of OIG Special Fraud Alerts, 59 Fed. Reg. 65,372, 65,373 (Dec. 19, 1994) ("1994 OIG Special Fraud Alert"). And the OIG has made clear that "disguising remuneration for Federal referrals through offers or payments of inflated amounts for non-Federal business or simply by offering or paying remuneration for non-Federal referrals to 'pull through' the Federal business" "may violate the [A]nti-[K]ickback [S]tatute." Dep't of Health & Human Servs. Office of Inspector Gen., Advisory Opinion No. 00-8: Spectrum Housing, d/b/a Housing Referrals of Maine at 5 (2000).

Consequently, in 2005, the OIG issued an Advisory Opinion stating:

> Where a laboratory pays a referring physician to perform blood draws, particularly where the amount paid is more than the laboratory receives in Medicare reimbursement, an inference arises that the compensation is paid as an inducement to the physician to refer patients to the laboratory . . . .

Dep't of Health & Human Servs. Office of Inspector Gen., Advisory Opinion No. 05-08 at 4 (2005) ("2005 OIG Advisory Opinion"). Thereafter, in 2014, the OIG issued a Special Fraud Alert regarding other laboratory payments to referring physicians, stating that it "ha[d] become aware of arrangements under which clinical laboratories are providing remuneration to physicians to collect, process, and package patients' specimens." Dep't of Health & Human Servs. Office of Inspector Gen., Special Fraud Alert: Laboratory Payments to Referring Physicians at 3 (2014) ("2014 OIG Special Fraud Alert"). The OIG noted that some of these arrangements may implicate the Anti-Kickback Statute, particularly if, inter alia, "[p]ayment exceeds fair market value for services actually rendered by the party receiving the payment," id. at 4, or the "[p]ayment is for services for which payment is also made by a third party, such as Medicare," id. at 5.

3. The Stark Law

The Stark Law prohibits physicians from referring patients to anyone with whom he or she has a financial relationship. Specifically, "if a physician (or an immediate family member of such physician) has a financial relationship with an entity . . . [,] the physician may not make a referral to the entity for the furnishing of designated health services." 42 U.S.C. § 1395nn(a)(1)(A). A financial relationship is defined as "an ownership or investment interest in the entity, or . . .a compensation arrangement . . . between the physician (or an immediate family member of such physician) and the entity." Id. § 1395nn(a)(2)(A)–(B).

4. The False Claims Act

"The False Claims Act imposes civil liability on any person who knowingly submits false claims to the government." United States ex rel. Dig. Healthcare, Inc. v. Affiliated Comput. Servs., Inc., 778 F. Supp. 2d 37, 44–45 (D.D.C. 2011) (Walton, J.) (citing 31 U.S.C. §§ 3729–

3733). Its purpose is "to reach all types of fraud, without qualification, that might result in financial loss to the Government," and "reaches beyond 'claims' which might be legally enforced, to all fraudulent attempts to cause the Government to pay out sums of money." United States v. Neifert-White Co., 390 U.S. 228, 232–33 (1968) (noting that "the Court has consistently refused to accept a rigid, restrictive reading [of the Act]"). "[V]iolations of [the Anti-Kickback] and Stark [statutes] can be pursued under the False Claims Act, since they would influence the government's decision of whether to reimburse Medicare Claims." United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am., Inc., 565 F. Supp. 2d 153, 159 (D.D.C. 2008) (Pogue II).

Three provisions of the False Claims Act are at issue in this case. 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). Section 3729(a)(1)(B) 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." Id. § 3729(a)(1)(B). And § 3729(a)(1)(G), 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." Id. § 3729(a)(1)(G).

B. Factual Background and Procedural History

The relator is a retired individual who previously "had a long career in the commercial reference laboratory business," 2d Am. Compl. ¶ 20, and was a member of the Board of Directors of Boston Heart "from 2007 until majority control of the Company was acquired by

Bain Capital Venture Fund in late 2010," id. ¶ 101. "Boston Heart is a medical laboratory that specializes in advanced lipid testing." Id. ¶ 22.

The relator filed his original Complaint under seal on August 28, 2012. See Relator's Complaint for Money Damages and Civil Penalties for Violations of the False Claims Act, 31 U.S.C. § 3730(b)(2) (Aug. 28, 2012), ECF No. 1. On August 19, 2016, the United States declined to intervene in this case, see Notice of Election to Decline Intervention (Aug. 19, 2016), ECF No. 24, and the Court therefore unsealed the case, see Order at 1 (Aug. 24, 2016), ECF No. 25. On February 18, 2016, the relator filed his First Amended Complaint. See Amended Complaint for Money Damages and Civil Penalties for Violations of the False Claims Act (Feb. 18, 2016), ECF No. 19. On September 20, 2017, the Court denied Boston Heart's motion to dismiss the relator's First Amended Complaint without prejudice and granted the relator's request for leave to file a Second Amended Complaint, see Order at 7 (Sept. 20, 2017), ECF No. 39, which he did on October 4, 2017, see 2d Am. Compl. at 1.

The Second Amended Complaint contains three causes of action: (1) a violation of the "false presentment" provision of the False Claims Act, see 2d Am. Compl. ¶¶ 108–12; see also 31 U.S.C. § 3729(a)(1)(A); (2) a violation of the "false statements" provision of the False Claims Act, see 2d Am. Compl. ¶¶ 113–17; see also 31 U.S.C. § 3729(a)(1)(B); and (3) a violation of the "reverse false claims" provision of the False Claims Act, see 2d Am. Compl. ¶¶ 118–21; see also 31 U.S.C. § 3729(a)(1)(G).

The relator asserts five theories of liability against Boston Heart that form the basis of his three causes of action: four alleged kickback schemes and one other purported violation of Medicare requirements. See id. ¶ 1 ("[Boston Heart] provides at least four forms of illegal kickbacks to doctors and clinics in order to induce those doctors and clinics to refer Medicare

business to them, and bills Medicare for redundant and unnecessary testing."). The four alleged illegal kickback schemes are: (1) "waiving co-payments or patient deductible payments from doctors' privately-insured patients," for physicians who "send all of their lipid-related business, including Medicare business," to Boston Heart, id. ¶ 2; (2) paying physicians inflated packaging fees, in excess of the actual cost of packaging and shipping specimens to Boston Heart, to induce physicians to refer their Medicare business to Boston Heart, see id. ¶ 4; (3) performing and billing the government for laboratory tests ordered by physicians who are Boston Heart shareholders in violation of the Stark Law, see id. ¶ 6; and (4) paying "outrageous consulting fees to referring physicians," id. ¶ 7. According to the relator:

> Each of these practices constitute[s] an illegal kickback scheme, no more legal than if [Boston Heart] handed doctors envelopes of cash in exchange for Medicare referrals. [Boston Heart] violated the False Claims Act by charging Medicare and other federally funded healthcare programs for lab tests that were referred to [ ] Boston Heart by providers because of kickbacks offered to those providers by [Boston Heart].

Id. ¶ 8. Boston Heart's other purported Medicare violation is performing and billing the government for medically unnecessary tests ordered through its own test panels. See id. ¶¶ 11–13. Each alleged theory of liability asserted in the Second Amended Complaint is now described in further detail below.

1. Waiving Co-Payments and Deductibles Theory of Liability

The relator alleges that from 2011 through 2016, id. ¶¶ 1, 98–99, 103, Boston Heart waived patients' co-payments and deductibles, in violation of the Anti-Kickback Statute, "as an incentive for physicians to refer business to Boston Heart," id. ¶ 39. According to the relator, private health insurance companies typically "require that a patient ordering a laboratory test make a co-payment of approximately 20% of allowable charges to the laboratory." Id. ¶ 40. And, "[p]rivate insurance companies also require their patients to make a deductible payment to

the laboratory until the patient has met his [or] her deductible amount for the year." Id. The relator alleges that "Boston Heart's most common panel of tests is the Complete One panel, which costs $614.29." Id. ¶ 42. Therefore, a 20% co-payment for the Complete One panel "would be approximately $122," if it were charged. Id. The relator alleges that Boston Heart's waiver of co-payments and deductibles were thus a "great benefit to the doctors, who [we]re able to attract and retain the business of patients by promising no co-payments or patient deductible amounts," and that "[k]nowing this, [Boston Heart] promise[d] physicians that it w[ould] waive the co[-]payment[s], as long as the physicians send all of their lipid-related business—including Medicare business—to [Boston Heart]." Id. ¶ 42; see also id. ¶¶ 43–44 (alleging the same waiver scheme and benefits for patients' deductibles). The relator further alleges that this scheme encouraged medically unnecessary tests because, "[b]y waiving patient deductible[s] and co-payments, the physician [wa]s no longer subject to any restraint on whether tests [we]re medically necessary because they [we]re free for patients," and "by removing the patient's financial stake in the transaction, [Boston Heart] ha[d] neutralized one of the market's inherent checks on frivolous treatment—individual monetary responsibility for the cost of care." Id. ¶ 46. According to the relator, Boston Heart "more than ma[d]e[] up" the amount of money it lost on the waived co-payments and deductibles "with the profits it earn[ed] on the Medicare referrals." Id. ¶ 45.

To support this allegation, the relator submitted with his Second Amended Complaint a copy of an Explanation of Benefits ("EOB") for a patient who received Boston Heart tests. See id., Exhibit ("Ex.") 3 (EOB (Jan. 25, 2017)). According to the relator, the EOB shows that $4,000 in costs were not covered by the patient's insurance, but that "the patient was never charged for the tests." Id. ¶ 43; see also id. ¶ 81 ("For the 2017 EOB . . . , the insurer declined all

charges, which amounted to over $4,000, but the patient never received an invoice for any amount.").

The relator alleges that Boston Heart continued its waiver practice until 2016, even though in 2014, the Department of Justice pursued enforcement actions against three different laboratories based on their "alleged failure to invoice patients for deductibles and co-payments." Id. ¶ 47 (alleging that the Department of Justice intervened in one false claims act action against one laboratory and settled with two others). According to the relator, in 2016, Boston Heart, "knowing the co-pay[ment] waivers violated the False Claims Act," id. ¶ 48, "tweaked its fraud," and instead of waiving co-payments and deductibles entirely, instead began "to charge patients a 'special fee' named a 'Know It Now [Fee],'" id. ¶ 3; see also id. ¶ 48 (alleging that Boston Heart replaced its co-payment and deductible waiver scheme "with a new form of inducement for patient invoices"); id., Ex. 2 (Know It Now Fee Schedule).

The relator alleges that the Know It Now Fee "[wa]s the amount . . . charged to patients in lieu of a standard calculation of their co-pay[ment] or deductible," and that this Fee "[wa]s a fraction of the co-payment requirement (usually in excess of $100) based on Boston Heart's charges to insurance companies." Id. ¶ 3 (alleging that the Fee is $2 or less for 75% of Boston Heart's tests, and is $7 or less for 95% of its tests); id. ¶ 49 (similar). According to the relator, the Know It Now Fee was "billed to patients as the total amount owed if [the patients] ha[d] not yet met their deductible for the year," and "where Boston Heart collect[ed] from an insurer for the services, and the only patient responsibility [wa]s for a co-payment, Boston Heart bill[ed] the 'Know [I]t Now' [Fee] to the patients, rather than the 20% co-payment." Id. ¶ 49. The relator alleges that "Boston Heart agree[d] with physicians up front that it w[ould] send 'two invoices' to the patients, but states that they 'd[id] not send patients to collections,'" id. ¶ 50, and therefore,

the Know It Now Fee was "effectively [a] waiver[] of patients' co-payments and deductibles," id. ¶ 51. Moreover, the relator alleges that "within months of Boston Heart beginning to invoice patients for deductibles and co-payments, even through use of its below cost, 'Know [I]t Now' [F]ees, Boston Heart lost 40% of its revenue." Id. ¶ 70. The relator also names over fifty individual physicians or medical practices who participated in the alleged waiver scheme until 2016. See id. ¶¶ 98–99.

2. Packaging Fees Theory of Liability

The relator alleges that Boston Heart, from 2011 through 2016, see id. ¶¶ 1, 69, 103, induced physicians to refer their Medicare business to Boston Heart by paying them packaging fees that are greater than the actual cost of packaging and shipping specimens to Boston Heart for testing, see id. ¶¶ 4, 53. The relator supports his allegation that these fees were inflated by comparing the standard Medicare draw fee of $3 with the amount Boston Heart allegedly paid to cover the physicians' costs associated with both drawing and shipping the specimens to Boston Heart. See id. ¶¶ 55, 57–58, 62. "Medicare allows the person who collects a specimen to bill Medicare for a nominal specimen collection fee in certain circumstances, including times when the person draws a blood sample," 2014 OIG Special Fraud Alert at 3, and the standard amount that the Centers for Medicare & Medicaid Services ("CMS") allows physicians or laboratories to charge in draw fees is $3, id. at 3 n.10; accord 2d Am. Compl. ¶ 55. CMS also reimburses "packaging fees," which are the costs of "processing and packaging specimens for transport to a clinical laboratory through a bundled payment." 2014 OIG Special Fraud Alert at 4.[3]

According to the relator, Boston Heart paid physicians between $15 and $25 to cover their costs associated with drawing specimens and packaging them for shipping to the laboratory.

[3] The Special Fraud Alert does not provide the standard amount CMS reimburses for packaging fees. See generally 2014 OIG Special Fraud Alert.

2d Am. Compl. ¶¶ 62, 64. The relator alleges that this payment constituted a kickback, and relies on the 2005 OIG Advisory Opinion prohibiting excessive draw fees in support of this assertion. See id. ¶¶ 54–55 (citing 2005 Advisory Opinion). In that Advisory Opinion, the OIG concluded that a laboratory paying a physician a draw fee of $6, plus blood-drawing supplies, would implicate the Anti-Kickback Statute. See 2005 Advisory Opinion at 4. The relator applies this conclusion to Boston Heart's alleged $15 to $25 packaging fee payments to physicians as support for his position that these payments also amounted to kickbacks. See 2d Am. Compl. ¶ 55 (alleging that "[t]he 'packaging' fees paid by [Boston Heart] to referring providers in this case are no different" than the scenario in the 2005 Advisory Opinion).

And, the relator alleges that "Boston Heart encourage[d] physicians to break up their testing needs among multiple colluding laboratories in order to receive draw fees from multiple sources rather than have one lab perform all the tests." Id. ¶ 59. The relator specifically identifies Health Diagnostic Laboratories, Singulex, Liposcience, and Atherotech as other colluding laboratories. Id. According to the relator, this scheme "facilitate[d] multiple 'packaging' fees per patient, rather than just one fee per patient, regardless of the number of labs to which the tests specimens [we]re sent." Id.; see also id. ¶ 61 (alleging that Boston Heart "promote[d] this practice by sponsoring seminars that discuss[ed] how profitable splitting up tests between laboratories c[ould] be for physicians.").

Further, the relator alleges that after the OIG issued its 2014 Special Fraud Alert warning that certain blood-specimen collection, processing, and packaging arrangements could implicate the Anti-Kickback Statute, see id. ¶ 63; see also 2014 OIG Special Fraud Alert at 2–5, "[i]n late 2014 and 2015," 2d Am. Compl. ¶ 62, Boston Heart began using third parties, "including, but not limited to LLmobileLab, Biotex, and VeniExpress," to funnel the fees to the physicians, id.

¶ 64; see also id. ¶ 63 ("After an OIG ruling in 2014 . . ., rather tha[n] stop the practice of incentivizing physician referrals through cash payments, Boston Heart simply changed its scheme to further conceal it by using third parties to make the payments to physician staff and families, rather than Boston Heart paying physicians directly."). In other words, the relator alleges that Boston Heart changed its packaging fee payment process in order to avoid detection by the government, see id. ¶¶ 63–66, and, as an example, states that a Boston Heart sales representative, Heidi Ann Mooney, told a California physician that "[the Department of Justice] said we can't pay you [the physician] directly, so we pay [a third party], they take some of the money and they pay you. It's all about perception," id. ¶ 66 (alterations in original); see also id. (alleging that a Biotex representative told the physician that "it didn't even matter if [the payee] was a relative as long as the last names were different" (alteration in original)). The relator alleges that Boston Heart ceased paying packaging fees after October 31, 2016, see id. ¶ 69, and also names over fifty individual physicians or medical practices who participated in the alleged packaging fees scheme, see id. ¶¶ 98–99.

3. Self-Referrals Theory of Liability

The relator alleges that, from 2011 through 2015, see id. ¶¶ 1, 99, two physicians who were Boston Heart shareholders referred their patients to Boston Heart for laboratory testing in violation of the Stark Law, id. ¶ 83, 99. To support this allegation, the relator relies on the CMS Voluntary Self-Referral Disclosure Protocol. See id. ¶ 85; see also Ctrs. for Medicare & Medicaid Servs., U.S. Dep't of Health & Human Servs., CMS Voluntary Self-Referral Disclosure Protocol (2010) ("CMS Protocol"). The CMS Protocol states that "conduct that raises liability risks under the physician self-referral law may also raise liability risks under . . . the federal [A]nti-[K]ickback [S]tatute," CMS Protocol at 1; see also 2d Am. Compl. ¶ 85, and

therefore, the relator claims, "each laboratory test Boston Heart billed to Medicare and performed on a patient referred by a physician with a financial stake in Boston Heart constitute[d] a violation of the [ ] False Claims Act," 2d Am. Compl. ¶ 85. The relator names two individual physicians who allegedly were Boston Heart shareholders and referred business to Boston Heart without disclosing their ownership interests to their patients. See id. ¶ 99.

4. Speaking and Consulting Fees Theory of Liability

The relator alleges that Boston Heart "paid outrageous consulting fees to referring physicians"; specifically, over $200,000 in 2012 and 2013 to a nurse practitioner and a physician who "were among the top referral sources to [Boston Heart]." Id. ¶ 7.[4] According to the relator, these

> fees were paid primarily for these physicians to solicit physician clients for Boston Heart by speaking at seminars where they explained to physicians how much money they could make by receiving packaging fees and splitting specimens between multiple labs, and how Boston Heart's large panels would have no impact on their patients.

Id. (emphasis removed).

5. Medically Unnecessary Testing Theory of Liability

Finally, the relator alleges that, "from at least 2009 to [2017]," id. ¶ 97, Boston Heart performed and billed for medically unnecessary tests by "encourag[ing] doctors to order their pre-selected panel tests," id. ¶ 87, and compares the industry-standard four-test lipid panel to Boston Heart's eight-test panel, id. ¶ 91; see also id., Ex. 1 (Boston Heart Test Panel). The relator relies on a MAC's Future Local Coverage Determination ("Determination") to support his allegation that these extra tests were medically unnecessary. See id. ¶ 86. That Determination

[4] The relator does not make clear whether he is alleging that the two individuals were paid $200,000 total or whether each was paid $200,000, nor does he provide a date or name the events associated with the payment(s). See 2d Am. Compl. ¶ 7.

states that "[cardiovascular] risk assessment panels, consisting of various combinations of biochemical, immunologic, hematologic, and molecular tests, is considered screening when performed on an asymptomatic patient, and, as such, are not a Medicare benefit." 2d Am. Compl., Ex. 4 (Future Local Coverage Determination (LCD): MoIDX: Biomarkers in Cardiovascular Risk Assessment (L36129) (Aug. 20, 2015)) at 2. The relator also relies on purported statements made by Dr. Paul Ziajka, a cardiologist, to support his allegation that Boston Heart's additional tests in its lipid panel were medical unnecessary. Id. ¶ 95.[5] And the relator alleges that Boston Heart's practice of billing for each test on its panel separately, or unbundling, allowed it to "charge Medicare over $100 per lipid panel, rather than the $18.97 allowed by Medicare." Id. ¶ 92.

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 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,

[5] The relator states Dr. Ziajka's qualifications include that he "has been an investigator in more than [fifty] clinical trials involving heart disease" and "has been published numerous times in peer-reviewed medical journals," 2d Am. Compl. ¶ 95, but does not directly quote Dr. Ziajka, cite to Dr. Ziajka's work or any sworn statement, or provide any further details regarding Dr. Ziajka, see id.

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 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); see also United States ex rel. Heath v. AT&T, Inc., 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.'" Heath, 791 F.3d at 123 (alteration in original) (quoting United States ex rel. Williams v. Martin-Baker Aircraft Co., 389 F.3d 1251, 1256 (D.C. Cir. 2004)). Further, "the complaint must be particular enough to 'guarantee all defendants sufficient information to allow for preparation of a response.'" Id. (quoting Williams, 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." Baker v. Gurfein, 744 F. Supp. 2d 311, 315 (D.D.C. 2010) (Walton, J.) (citing Williams, 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." Stevens v. InPhonic, Inc., 662 F. Supp. 2d 105, 114 (D.D.C. 2009) (Walton, J.) (internal citation and quotation marks omitted).

III. ANALYSIS

A. Count I: The False Presentment Claim Cause of Action

The elements of a false presentment claim cause of action 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." United States ex rel. Morsell v. Symantec Corp., 130 F. Supp. 3d 106, 118 (D.D.C. 2015) (quoting United States ex rel. Tran v. Comput. Scis. Corp., 53 F. Supp. 3d 104, 121–22 (D.D.C. 2014)); see also 31 U.S.C. § 3729(a)(1)(A).[6]

1. The Falsity Element of the Claim

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

[6] Because Boston Heart does not specifically challenge the submission element, see generally Def.'s Mem.; Def.'s Reply (challenging the relator's allegations regarding Boston Heart's participation in and knowledge of the purported schemes), the Court need not address it. In any event, upon review of the Second Amended Complaint, the Court finds that the relator adequately alleged that Boston Heart submitted claims to the government. See 2d Am. Compl. ¶ 23 (alleging that "more than 30% of the tests conducted by Boston Heart are for patients covered by Medicare"); id. ¶ 31 (alleging that "[e]ach claim for payment submitted by Boston Heart, from at least 2010 to [2016], to Medicare that was referred to [it] by a provider who [participated in the alleged kickback schemes] constitutes a false claim"); see also Druding v. Care Alternatives, Inc., 164 F. Supp. 3d 621, 630–31 (D.N.J. 2016) (concluding that the relator adequately alleged the submission element because, given his allegation that the defendant was "a certified Medicare provider," "[i]t [wa]s no great leap for the Court to infer that a Medicare provider would submit claims for reimbursement for any of the[] patients wh[o] had been [wrongfully] certified as terminally ill, and that these purportedly legally false medical records could have formed the basis of such a claim for reimbursement").

certification,' can be either 'express' or 'implied.'" Id. (quoting SAIC, 626 F.3d at 1266). "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).

As stated above, kickbacks and violations of the Stark Law are actionable under the False Claims Act. Under a theory of implied certification, "where the government pays funds to a party, and would not have paid those funds had it known of a violation of a law or regulation, the claim submitted for those funds contain[s] an implied certification of compliance with the law or regulation and [is] fraudulent." United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am., Inc., 238 F. Supp. 2d 258, 264 (D.D.C. 2002) (Pogue I); see Pogue II, 565 F. Supp. 2d at 159 ("Legion [of] other cases have held violations of [the Anti-Kickback Statute] and Stark can be pursued under the [False Claims Act], since they would influence the Government's decision of whether to reimburse Medicare claims."); see also United States ex rel. Barrett v. Columbia/HCA Healthcare Corp., 251 F. Supp. 2d 28, 33 (D.D.C. 2003) ("[C]ompliance with the Anti-Kickback [Statute] and Stark laws would affect the government's decision to pay."); United States ex rel. Ortega v. Columbia Healthcare, Inc., 240 F. Supp. 2d 8, 13 n.5 (D.D.C. 2003) ("Compliance with [the Anti-Kickback Statute and the Stark Law] is a condition for reimbursement under Medicare, and [the defendants] impliedly certified compliance with these law[s] in submitting claims to Medicare.").

Boston Heart argues that the relator fails to plausibly allege that its four alleged kickback schemes constitute kickbacks under the Anti-Kickback Statute, and therefore, the relator fails to

plausibly allege the falsity element of a false presentment claim. Def.'s Mem. at 9. Boston Heart additionally argues that the relator fails to plausibly allege that its practice of unbundling violates a Medicare provision or that Boston Heart charges for medically unnecessary tests, id. at 30, 33–34, and therefore, the relator does not plausibly allege the falsity element regarding Boston Heart's test panel billing practices, id. at 30. The Court will consider each challenge in turn.

a. Boston Heart's Alleged Kickback by Waiving Co-Payments and Deductibles

In response to the relator's allegation that Boston Heart's waiver of patients' co-payments and deductibles constitutes a kickback, Boston Heart first argues that the relator fails to allege that this practice provides any value to physicians, and thus cannot constitute a kickback. Def.'s Mem. at 24–25. The Court is unpersuaded by this argument because the relator does allege that the purported scheme benefits physicians. Specifically, the relator alleges:

> Waiving patients' insurance co-payments and deductibles is of significant benefit to physicians and their patients: physicians are not forced to explain expensive deductible and co-payment requirements to angry patients[,] and patients receive free laboratory testing. Physicians market free testing to their patients to make their offices more appealing, thereby improving the physicians' revenues.

2d Am. Compl. ¶ 37. In the Court's view, this allegation sufficiently alleges how Boston Heart's purported waiver practice provided value to physicians; namely, by saving their time not spent on explaining co-payment and deductible charges to patients and providing them an opportunity to market free laboratory testing.

Second, Boston Heart argues that the relator "fails to plausibly and with particularity allege inducement, an essential element of a kickback violation." Def.'s Mem. at 25; see also Def.'s Reply at 19–20 (contending that there was no connection between the purported reduction in costs and the inducement to physicians). Boston Heart relies heavily on Georgia ex rel.

Hunter Laboratories, LLC v. Quest Diagnostics Inc., No. 13-cv-01838 (SCJ), 2014 WL 12543888 (N.D. Ga. Mar. 14, 2014), for its position that "discounts do not establish an improper/illegal referral or Medicaid claim from such referral," Def.'s Mem. at 4. In Hunter Laboratories, the plaintiffs "allege[d that the defendants] operated [a] kickback scheme by improperly offering deeply discounted fees for laboratory services paid for by medical providers." 2014 WL 12543888, at *1. The district court granted the defendants' motion to dismiss, finding that the plaintiffs "fail[ed] to articulate any specific kickback at issue," particularly because they did not allege what the discounted rates were, and when and to whom they were offered. Id. at *4.

Boston Heart's reliance on Hunter Laboratories is misplaced. The district court in Hunter Laboratories did not state that discounts cannot constitute an unlawful referral as a matter of law; rather, it held that the plaintiffs "fail[ed] to provide sufficient particularity to satisfy the pleading standard of Rule 9(b)." Id. Moreover, the relator here does not allege that Boston Heart only provided discounts on co-payment and deductible payments, but rather alleges that Boston Heart waived these fees entirely. See 2d Am. Compl. ¶ 32 ("The first form of illegal remuneration is the waiver of private insurance co-payments and deductibles."). Therefore, Hunter Laboratories does not provide a basis for dismissal due to failure to allege inducement.

Third, Boston Heart argues that the 1994 OIG Special Fraud Alert, upon which the relator relies to support his allegation that waiving co-payments and deductibles constitute kickbacks, does not reference privately insured patients, and therefore is not applicable. See Def.'s Mem. at 25 ("[T]he 1994 Alert concerns Medicare beneficiaries and does not apply to waivers of amounts owed by privately insured patients."). The relator argues in response that "Boston Heart's reading of the 1994 OIG Fraud Alert is overly narrow and ignores the rationale underlying the

OIG's position," namely, that the payments at issue in that document "were improper not because it was a managed care patient or government funded payer, but instead because promising a physician [his or her] patients will not be charged a co-pay is a thing of value." Pl.'s Opp'n at 19–20 (emphasis removed).

The Court agrees with the relator. Although Boston Heart is correct that the 1994 OIG Special Fraud Alert references waiver of charges to managed care patients as an "example[] of lab services arrangements that may violate the [A]nti-[K]ickback [S]tatute," it notes that this example fits the category of "cases where the provision of free services results in a benefit to the provider," and thus, "the [A]nti-[K]ickback [S]tatute is implicated." 1994 OIG Special Fraud Alert, 59 Fed. Reg. at 65,377. In this case, the relator alleges that Boston Heart waives physicians' privately insured patients' co-payments and deductibles, "so long as the physicians send all of their lipid-related business—especially the highly profitable Medicare business—to [Boston Heart]." See 2d Am. Compl. ¶ 44 (emphasis removed); see also id. ¶ 42. In the Court's view, this allegation, if true, would also implicate the Anti-Kickback Statute because it would constitute the provision of free services, i.e., the waiver of co-payments and deductibles, that result in a benefit to the provider, i.e., by saving the physicians' time not spent on explaining co-payment and deductible charges to patients and providing them an opportunity to market free laboratory testing. And, the relator alleges that the objective of Boston Heart's waiver of co-payments and deductibles scheme is to gain additional Medicare business, which in turn results in federal funds being acquired by Boston Heart as a result of its fraudulent kickback scheme. See id. ¶ 45. Accordingly, Boston Heart's argument that the relator fails to plausibly allege inducement because the 1994 OIG Special Fraud Alert does not specifically reference privately insured patients fails. Therefore, the Court finds that the relator sufficiently alleges that Boston

Heart's waiver of patients' co-payments and deductibles constitutes a kickback, and therefore, sufficiently alleges the falsity element of a false presentment claim under the False Claims Act.

b. Boston Heart's Alleged Kickback Through Packaging Fees

Boston Heart argues that the relator fails to allege that the packaging fees Boston Heart paid physicians were above fair market value, and thus cannot constitute kickbacks. Def.'s Mem. at 13–14. According to Boston Heart, the relator incorrectly conflates draw fees and packaging fees. See id. at 15 ("The 2014 Special Fraud Alert explicitly distinguishes between Medicare's $3.00 'nominal specimen collection fee,' which has its own CPT code, and Medicare's 'reimburse[ment] [to] physicians for processing and packaging specimens for transport to a clinical laboratory,' . . . ." (brackets in original)). As stated previously, a "draw fee" is "a nominal specimen collection fee . . . [that can be assessed] when the person draws a blood sample through venipuncture (i.e., inserting into a vein a needle with syringe or vacuum tube to draw the specimen)," 2014 OIG Special Fraud Alert at 3, whereas a "packaging fee" refers to the costs of "processing and packaging specimens for transport to a clinical laboratory through a bundled payment," id. at 4. According to Boston Heart, the $3 fee set by Medicare that the relator references is the draw fee only, and the higher amount that Boston Heart pays physicians is actually the packaging fee. Def.'s Mem. at 14–15. Accordingly, Boston Heart argues that because the relator has failed to allege that Boston Heart has paid more than the fair market value for packaging, no kickback scheme has been plausibly alleged. Def.'s Mem. at 15–16. The Court disagrees.

The relator plainly alleges that "[t]he second form of illegal remuneration provided by [Boston Heart] to induce the referral of Medicare business is the payment to physicians of inflated 'packaging' fees." 2d Am. Compl. ¶ 53. Although it is true that the relator cites to the

2005 OIG Advisory Opinion regarding draw fees, see id. ¶ 54 (citing 2005 OIG Advisory Opinion at 4), the relator does not "conflate[]" the draw fees referenced in the Advisory Opinion with Boston Heart's packaging fees, as Boston Heart contends, see Def.'s Mem. at 15, but rather relies on the Advisory Opinion as prohibiting similar conduct, see 2d Am. Compl. ¶ 55 (alleging that Boston Heart's payment of packaging fees "to referring providers in this case are no different" than the illegal draw fees paid by a laboratory in the Advisory Opinion). Specifically, the relator alleges that "[a]s in the [draw] fees paid in the Advisory Opinion's scenario, the 'packaging' fee and other 'compensation provides an obvious financial benefit to the referring physician, and it may be inferred that this benefit would be in exchange for referrals to the lab.'" Id. (quoting 2005 OIG Advisory Opinion at 4); see also id. ¶ 60 (discussing the costs associated with drawing and packaging specimens). Accordingly, the Court finds that the relator sufficiently alleges that Boston Heart's payment of packaging fees constitutes a kickback, and therefore, sufficiently alleges the falsity element of a false presentment claim under the False Claims Act to avoid dismissal under Rule 12(b)(6).

c. Boston Heart's Alleged Kickback Through Speaking and Consulting Fees

Boston Heart argues that the relator fails to allege that the $200,000 paid to the physician and nurse practitioner for their consultation and speaking services was anything more than "a typical arms-length contract in which compensation is paid solely in exchange" for services and therefore, cannot constitute a kickback. Def.'s Mem. at 29 (quoting Cooper v. Pottstown Hosp. Co., 651 Fed. App'x 114, 116 (3d Cir. 2016)). The Court disagrees.

The relator alleges:

> The consulting fees were paid primarily for [the physician and nurse practitioner] to solicit physician clients for Boston Heart by speaking at seminars where they explained to physicians how much money they could make by receiving packaging

> fees and splitting specimens between multiple labs, and how Boston Heart's large panels would have no impact on their patients.

2d Am. Compl. ¶ 7 (emphasis removed). The relator, therefore, alleges both that the amount paid to the physician and nurse practitioner was not proportional to the purported service provided, see id. (labelling them "outrageous"), and that the fees were paid to the physician and nurse practitioner for their efforts to induce other physicians to refer patients' laboratory tests to Boston Heart, see id.

Regarding the amounts paid to the physician and nurse practitioner, whether these amounts were in fact not proportional to the services provided is a factual matter that is not appropriate for the Court to decide at this time. See Trudeau, 456 F.3d 178 at 193. As to Boston Heart's argument that the relator fails to allege that Boston Heart paid such fees to obtain referrals of Medicare patients, see Def.'s Mem. at 29, although it is true that the relator does not specifically mention Medicare patients in this portion of his Second Amended Complaint, he does allege that the two individuals paid by Boston Heart were explaining to other physicians the benefits of Boston Heart's packaging fees, see 2d Am. Compl. ¶ 7. As stated previously, the relator alleges that the packaging fees were part of the quid pro quo between Boston Heart and various physicians. See id. ¶¶ 4, 53, 98. Thus, taking the relator's allegations as true, as the Court must, the Court reasonably infers that the relator's reference to packaging fees incorporates his allegations elsewhere in the Second Amended Complaint regarding the alleged kickback scheme through inflated packaging fees. See id. ¶¶ 62–66. Accordingly, the Court finds that the relator sufficiently alleges that Boston Heart's purported payment of inflated speaking and consulting fees paid to a physician and nurse practitioner amounts to kickbacks, and therefore, sufficiently alleges the falsity element of a false presentment claim under the False Claims Act.

d. Boston Heart's Alleged Kickback in Violation of the Stark Law Through Stakeholder Physicians' Referrals

Boston Heart argues that the relator's allegations that it engaged in a kickback scheme through physician self-referrals "are no more than bald assertions." Def.'s Mem. at 34. The Court disagrees. The relator alleges that Boston Heart received referrals from physicians who were Boston Heart shareholders, 2d Am. Compl. ¶ 84, and provides the names of two specific physicians, id. ¶ 99. Taking the relator's allegations as true, this practice would violate the Stark Law because that statute prohibits a physician from referring patients to an entity in which the physician has an ownership interest, see 42 U.S.C. § 1395nn(a)(1)(A)–(B), and accordingly, can constitute a False Claims Act violation, see Pogue II, 565 F. Supp. 2d at 159 (holding that a violation of the Stark Law is actionable under the False Claims Act). Accordingly, the Court finds that the relator has properly alleged a violation of the Stark Law, and therefore, sufficiently alleges the falsity element of a false presentment claim under the False Claims Act.[7]

e. Boston Heart's Alleged Medically Unnecessary Testing

Boston Heart argues that the relator fails to plausibly allege that unbundling constitutes a false claim because unbundling is expressly allowed by Medicare. Def.'s Mem. at 30. Although Boston Heart is correct that CMS permits laboratories to unbundle lipid panel tests, see Processing Manual § 90.2 (Note) ("If a laboratory chooses, it can bill each of the component tests of . . . panels individually, but payment will be based upon [the Medicare] rules."), the Court is not persuaded that unbundling, on its own, forms the basis of the relator's theory of liability. Rather, as explained above, the relator alleges that Boston Heart "encourage[d] doctors

[7] As support for Boston Heart's argument that the relator's allegations do not amount to a violation of the Stark Law, Boston Heart states that it repaid the government for prior Stark Law violations. Def.'s Mem. at 34. This fact, even if true, is immaterial, because it does not mean that Boston Heart is not liable for any additional Stark Law violations, such as the ones that the relator alleges here.

to order [its] pre-selected panel tests," 2d Am. Compl. ¶ 87, which purportedly contain four additional tests that are medically unnecessary, id. ¶¶ 91, 95, and by billing for each test on its panel separately, Boston Heart "charge[s] Medicare over $100 per lipid panel, rather than the $18.97 allowed by Medicare," id. ¶ 92. And, although the relator specifically acknowledges that CMS allows parties to unbundle lipid panels, he alleges that Boston Heart

> is not protected by the fact that CMS allows parties to bill component parts of panels individually so long as they accept the lower panel reimbursement amount because Boston Heart's bloated lipid panel has no unique CPT code or lowered reimbursement amount. Thus, b[y] adding redundant tests, Boston Heart is able to bill for substantially more than it would receive if it properly tested and billed.

Id. ¶ 94. Therefore, the basis of the claim is not unbundling in isolation, but rather allegedly including medically unnecessary tests in its test panels and billing Medicare for those additional tests. See id. ¶¶ 91–94. Accordingly, Boston Heart's argument fails.

Boston Heart additionally argues that the relator fails to adequately allege that it billed for medically unnecessary tests because he "[failed] to identify any Medicare or other requirement mandating the composition of tests on a lipid panel," and "there is not a single factual allegation supporting the conclusory assertion that Boston Heart cannot also include the 'four additional tests' on its own lipid panel, as long as it bills for them correctly." Def.'s Mem. at 33. The Court again disagrees.

The relator's primary allegation is not that Boston Heart violated a specific lipid panel standard, but rather that Boston Heart encouraged and billed Medicare for medically unnecessary tests. And, "improper inducements such as providing kickbacks or promoting medically unnecessary testing" is a violation of the False Claims Act. United States ex. rel Lutz v. Berkeley Heartlab, Inc., 225 F. Supp. 3d 487, 501, 497 (D.S.C. 2016) (declining to dismiss the government's False Claims Act allegations against a laboratory for "encourag[ing] physicians to

order tests that were medically unnecessary"); see also Groat II, 296 F. Supp. 3d at 166 (holding that "laboratories have a legal duty to ensure that they do not submit claims for medically unnecessary tests" and that promoting medically unnecessary tests is a violation of the False Claims Act). Therefore, because the relator alleges that Boston Heart's additional tests on their lipid panels are medically unnecessary because they contain Apo B and LDL-P tests, 2d Am. Compl. ¶¶ 86, 95, and it is not the Court's role to make medical necessity determinations at this stage of the litigation, see United States ex rel. Groat v. Boston Heart Diagnostics Corp., 255 F. Supp. 3d 13, 27–29 (D.D.C. 2017) (Walton, J.) (Groat I) (declining to make medically necessity determinations at the motion to dismiss stage), the relator does allege a violation of a Medicare requirement, i.e., that the tests Boston Heart billed were not medically necessary. Therefore, the Court finds that the relator plausibly alleges falsity under this theory of liability.

In summary, the Court finds that the relator adequately alleges the falsity element of his presentment claim with respect to each of his five theories of liability because in each instance, he alleges that Boston Heart submitted legally false claims. See Groat I, 255 F. Supp. 3d at 23 (holding that the relator sufficiently pleaded the falsity element by "alleg[ing] that Boston Heart failed to comply with the Medicare rules restricting covered services to those that are medically necessary"); Ortega, 240 F. Supp. 2d at 13 n.5 ("Compliance with [the Anti-Kickback Statute and the Stark Law] is a condition for reimbursement under Medicare, and [the defendants] impliedly certified compliance with these law[s] in submitting claims to Medicare.").

2. The Knowledge Element of the Claim

The knowledge element of a false presentment cause of action requires a defendant to have "actual knowledge of the information" related to the false claim or to "act[] in deliberate ignorance . . . [or] reckless disregard of the truth or falsity of the information" related to the false

claim. 31 U.S.C. § 3729(b)(1)(A). However, the statutory definition of "knowledge" does not require "proof of specific intent to defraud." Id. § 3729(b)(1)(B). Moreover, "[b]ecause Rule 9(b) permits knowledge to be pled generally, there is no basis for dismissal for failure to plead knowledge with particularity." United States v. Honeywell Int'l, Inc., 798 F. Supp. 2d 12, 22 (D.D.C. 2011).

With respect to the five foregoing theories of liability, the relator relies on his experience as a former member of Boston Heart's Board of Directors to allege that Boston Heart's false claims were made knowingly and willfully. According to the relator, he was a member of Boston Heart's Board of Directors "from 2007 until majority control of [Boston Heart] was acquired by Bain Capital Venture Fund in late 2010," and he "resigned from the [B]oard around the fourth quarter of 2010," 2d Am. Compl. ¶ 101, although "he remained a shareholder," id. ¶ 104. He alleges that during his time on the Board of Directors, "competitors' policies of paying packaging and handling . . . fees to physicians and never billing patients was discussed at several board meetings. During those meetings, [the relator] and others voiced concerns about the propriety and legality of the conduct, and it was ultimately decided that Boston Heart would not employ [those policies]." Id. ¶ 102; see also id. ¶ 101 ("Prior to his resignation, [the relator] advised Boston Heart against engaging in the practices described in the [Second Amended Complaint] on several occasions."). However, according to the relator, after Bain Capital Venture Fund acquired Boston Heart, "Boston Heart instituted the payment of packaging fees to physicians and of never billing patients for co[-payments] or deductibles." Id. ¶ 103. The relator alleges that he sent three letters to Boston Heart's Board of Directors from September to November of 2011, warning it of the potential liability issues related to its practices regarding

self-referrals, packaging fees, and waiving of co-payments and deductibles, but received no response. Id. ¶¶ 105–06.

Boston Heart argues that the letters that the relator alleges to have sent it "were merely [the relator's] recitation of what violations he believes Boston Heart was committing," and "do not in any way reflect that Boston Heart actually engaged in such conduct or that it did so with the requisite intent." Def.'s Mem. at 3. The relator argues in response that Boston Heart must have known "that [its] conduct was unlawful, knew [it] was acting with a bad purpose, or knew [it] was acting with evil intent without justifiable excuse." Relator's Opp'n at 14–15 (quoting United States ex rel. Lutz v. Berkeley Heartlab, Inc., No. 9:14-230 (RMG), 2017 WL 4803911, at *3 (D.S.C. Oct. 23, 2017), appeal docketed, No. 18-1813 (4th Cir. July 18, 2018)).

The Court agrees with Boston Heart's argument that the letters the relator alleges he sent to it demonstrate that the relator thought that Boston Heart was engaged in illegal conduct (and perhaps that Boston Heart was aware of the relator's opinion), but not that Boston Heart knew or should have known that it was indeed engaging in such conduct. In the Court's view, this is not sufficient to show that Boston Heart itself thought that its conduct was illegal. Accordingly, the Court does not find that the relator's letters to Boston Heart are sufficient to satisfy the knowledge element.[8] Compare with Honeywell Int'l, 798 F. Supp. 2d at 23–24 (concluding that the government adequately alleged the defendant's knowledge by pleading that it "intentionally obscured its . . . data" and its "bad faith in selectively disclosing those findings").

[8] Boston Heart also argues that the relator "fails to plausibly allege that Boston Heart acted knowingly" because he fails to make allegations "regarding Boston Heart's receipt of and internal response to his letter." Def.'s Mem. at 21. Although it is true that the relator does not allege receipt of his letters, given the Court's conclusion that the content of the letters, even if received, does not satisfy the knowledge requirement on the part of Boston Heart, the Court need not decide the issue of whether alleging that letters were sent, without alleging their receipt, sufficiently alleges Boston Heart's knowledge.

The relator, however, makes other factual allegations regarding Boston Heart's knowledge with respect to the specific theories of liability, which the Court will consider in turn.

a. Boston Heart's Knowledge that Its Waivers of Co-payments and Deductibles Were Unlawful

Regarding the co-payment and deductible waivers, the relator relies on Boston Heart's conduct following the Department of Justice's action taken against Berkeley Heart Laboratories for waiving co-payments and deductibles to demonstrate Boston Heart's knowledge. See 2d Am. Compl. ¶¶ 47–48. First, the relator alleges:

> In 2014, the Department of Justice intervened in a false claims act complaint against Berkeley Heart Laboratories, alleging the failure to invoice patients for deductibles and co-payments to be illegal inducements under the Anti-Kickback laws—strong evidence the government considered the practice to be illegal. The same year, the Department of Justice settled with two other Boston Heart competitors for $49 million based on their alleged failure to invoice patients for deductibles and co-payments. Despite this, Boston Heart continued.

Id. ¶ 47. The relator further alleges:

> Eventually, knowing the co-pay waivers violated the False Claims Act, in 2016 Boston Heart ceased the 100% waivers of co-pays and deductibles and replaced them with a new form of inducement for patient invoices. As described to a southern California physician by Boston Heart sales person Mooney, "insurance companies in some states require that we must bill patients, so we came up with a fee schedule. It is not a co-pay or a deductible, but rather a special fee."

Id. ¶ 48. In other words, the relator alleges that once Boston Heart realized that the Department of Justice might discover its waiver scheme, it adopted its "Know It Now Fee." Id. ¶¶ 48–50. The relator contends that this fee is so low that it is "effectively [a waiver] of patients' co-payments and deductibles," id. ¶ 51, and accordingly, Boston Heart "continue[d] to offer inducements to physicians despite knowing that waiving co-pay[ment]s or deductibles is illegal," id. ¶ 50 (emphasis added). Thus, the relator alleges that Boston Heart evidenced its knowledge that its practice of waiving co-payments and deductibles was illegal when it "came up with a fee

schedule" to replace its waiver practice. Id. ¶ 48. Taking the relator's allegations as true, the Court finds that the relator sufficiently alleges the knowledge element with respect to his waiver theory by alleging that Boston Heart implemented its "Know It Now Fee" in order to avoid detection of its waiver practice by the Department of Justice. See Honeywell Int'l, 798 F. Supp. 2d at 23 (concluding that the relators adequately alleged knowledge by noting that the relator "intentionally obscured" its data to avoid the negative consequences of its disclosure); see also United States v. Newman, No. 16-1169 (CKK), 2017 WL 3575848, at *8 (D.D.C. Aug. 17, 2017) ("The Court will not dismiss this case at the outset merely because the allegations in the complaint are rebutted by assertions about [the d]efendant's state of mind in her briefing on her motion to dismiss.").

b. Boston Heart's Knowledge that Its Payment of Packaging Fees Was Unlawful

Regarding the relator's allegation that Boston Heart had knowledge that its inflated packaging fees paid to physicians would induce the physicians to increase their referral of Medicare business to Boston Heart, the relator relies on Boston Heart's actions following the OIG's 2014 Special Fraud Alert that laboratories' payment of packaging fees, among other services, to referring physicians "could constitute illegal remuneration under the [A]nti-[K]ickback [S]tatute." 2014 OIG Special Fraud Alert at 1. According to the relator, after the Special Fraud Alert was issued, "rather than stop the practice of incentivizing physician referrals through cash payments, Boston Heart simply changed its scheme to further conceal it by using third parties to make the payments to physician staff and families, rather than Boston Heart paying physicians directly." 2d Am. Compl. ¶ 63. Furthermore, the relator alleges that a Boston Heart representative told a physician: "[the Department of Justice] said we can't pay you [the physician] directly, so we pay [a third party], they take some of the money and they pay you. It's

all about perception." Id. ¶ 66 (emphasis and brackets in original). Finally, the relator alleges that Boston Heart's CEO and two members of its Board of Directors "were involved in the decision to institute the payment of packaging fees to physicians." Id. ¶ 103.

Boston Heart argues that "it is not sufficient to allege that a low-level employee or agent's knowledge can be imputed to the company as a whole," Def.'s Mem. at 7 (citing SAIC, 626 F.3d at 1275), and that the relator "failed to describe the source of [his knowledge of its employees' alleged statements]," id. at 10 n.7. Boston Heart further argues that the relator must allege that Boston Heart "had knowledge that it was submitting false claims and that it took specific actions to do so." Id. at 7 (emphasis added). However, the relator does allege that Boston Heart took specific actions to submit false claims, alleging that Boston Heart began funneling excess packaging fees through specific third parties in order to avoid discovery because it knew that what it was doing was illegal. See 2d. Am. Compl. ¶ 63; see also id. ¶ 66 (alleging that Boston Heart funneled this money through Biotex, LLmobileLab, and VeniExpress). Putting aside the statements allegedly made by the Boston Heart representative, taking the relator's allegations as true, as it must, the Court finds that the relator sufficiently alleges Boston Heart's knowledge of this purported scheme by alleging that Boston Heart's CEO and two members of its Board of Directors "were involved in the decision to institute the payment of packaging fees to physicians," id. ¶ 103, that Boston Heart "promote[d] this practice by sponsoring seminars that discuss[ed] how profitable splitting up tests between laboratories can be for physicians," id. ¶ 61, and that Boston Heart changed its practice of directly paying referring physicians for their packaging fees following the 2014 OIG Special Fraud Alert to instead paying those payments through third parties to avoid government detection, see id. ¶¶ 63–66. Like the alleged waiver scheme, the Court concludes that the relator sufficiently

alleges Boston Heart's knowledge, given that the relator contends that Boston Heart altered its practice to hide its scheme in response to government action. See Lutz, 225 F. Supp. 3d at 500 (concluding that the relator sufficiently alleged the defendants' knowledge by alleging that they "knew of the illegality of the [processing and handling] fees and tried to disguise them"). The Court therefore finds that the relator has sufficiently pleaded Boston Heart's alleged knowledge of this scheme.

c. Boston Heart's Knowledge of Physicians' Self-Referrals

The relator does not discuss Boston Heart's knowledge regarding self-referrals by physicians who were Boston Heart shareholders, and he never specifically alleges that Boston Heart knew that it received referrals from such physicians apart from the letters that the relator sent Boston Heart following his resignation. See 2d. Am. Compl. ¶¶ 83–85, 99, 105. Therefore, the Court does not find that the relator sufficiently alleges Boston Heart's knowledge of this purported scheme as required under 31 U.S.C. § 3729(b)(1)(A). Accordingly, the relator cannot proceed on this theory of liability.

d. Boston Heart's Knowledge that Its Payment of Speaking and Consulting Fees Was Unlawful

Boston Heart argues that the relator's complaint is "devoid of any indicia of [Boston Heart's] intent to operate a kickback scheme" through the payment of speaking and consulting fees to a physician and nurse practitioner. Def.'s Mem. at 29 (quoting Cooper, 651 Fed. at 116). However, as discussed before, the relator alleges that Boston Heart paid "outrageous" speaking and consulting fees to the physician and nurse practitioner with the specific purpose of expanding its packaging fee kickback scheme. See 2d. Am. Compl. ¶ 7 ("The consulting fees were paid primarily for [the physician and nurse practitioner] to solicit physician clients for Boston Heart by speaking at seminars where they explained to physicians how much money they

could make by receiving packaging fees and splitting specimens between multiple labs . . . .") (emphasis omitted)). Taking the relator's allegations as true, and because the Court has already found that the relator sufficiently alleges Boston Heart's knowledge of the packaging fee scheme, the Court finds that the relator sufficiently alleges Boston Heart's knowledge of this alleged scheme by pleading that the fees it paid to the physician and nurse practitioner were above market value with the specific purpose of perpetuating its scheme to defraud the government.

e. Boston Heart's Knowledge that It Was Performing Medically Unnecessary Testing

The relator alleges that Boston Heart included medically unnecessary tests in its panels. 2d. Am. Compl. ¶ 95. In Groat II, this Court held "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," 296 F. Supp. 3d at 163, the relator in that case sufficiently "allege[d] 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," id. at 165. In this case, the relator alleges that Boston Heart employees encouraged physicians to use its test panels, which included more tests than the industry standard, and that the additional tests were not medically necessary. See 2d. Am. Compl. ¶¶ 11–13. However, the relator never specifically alleges that Boston Heart knew that these additional tests were medically unnecessary tests, nor can the Court reasonably infer Boston Heart's knowledge on the basis of any alleged scheme, like the one in Groat, where the relator specifically alleged that "'General Practitioners and other non-cardiology physicians [we]re Boston Heart's primary target' for its allegedly false marketing statements regarding the

medical necessity of its tests." Groat I, 255 F. Supp. 3d at 19. Rather, the relator in this case merely alleges, with respect to this theory, that "[Boston Heart] knew that Federal law prohibited code stacking and the manipulation of Medicare reimbursement." 2d. Am. Compl. ¶ 96.[9] Therefore, the Court finds that the relator has not sufficiently alleged that Boston Heart knew that the additional tests on its test panels were medically unnecessary, and therefore, the relator cannot proceed on this theory of liability.

For the foregoing reasons, the Court is satisfied that the relator properly alleges Boston Heart's knowledge for his false presentment theories of liability regarding (1) the waiver of co-payments and deductibles, (2) the payment of packaging fees, and (3) the payment of speaking and consulting fees. The Court dismisses the self-referral and medically unnecessary testing theories of liability because the relator has not adequately alleged Boston Heart's knowledge with respect to these theories as required under 31 U.S.C. § 3729(b)(1)(A).[10]

3. Whether the Relator's Allegations Satisfy Rule 9(b)

Federal Rule of Civil Procedure 9(b) requires that a plaintiff allege the "who," "what," "when," and "where" with respect to the circumstances of an alleged fraud. See Heath, 791 F.3d at 124; Stevens, 662 F. Supp. 2d at 114. Boston Heart argues that the relator's Second Amended Complaint does not satisfy this heightened pleading requirement because for all three theories of liability that have otherwise survived the motion to dismiss, he does not allege "who at Boston

[9] The Court recognizes that the relator also alleges, in discussing the packaging fees scheme, that "Boston Heart actively encourage[d] physicians to order additional tests—whether medically necessary or not—in order to increase the number of 'packaging' fees physicians receive[d]." 2d Am. Compl. ¶ 61. In the Court's view, this allegation does not constitute an allegation that Boston Heart knew that its additional tests on its lipid panel were medically unnecessary; rather, it constitutes an allegation that Boston Heart knew that ordering additional tests would mean increased packaging fees for the physician, and that in the relator's view, such tests were often not medically necessary.

[10] These two theories of liability are dismissed with respect to both the relator's false presentment and false statements causes of action because the knowledge element is a required component of both claims. See 31 U.S.C. § 3729(a)(1)(A)–(B), (b)(1).

Heart made the [kickback] agreements with physicians (or sent the agreements that physicians 'received'); when [ ] such [kickback] agreements occur[red]; where and how [ ] such [kickback] agreements come to be; and . . . the terms of the agreement[s]." Def.'s Mem. at 26.

The Court finds that the relator does sufficiently allege the "who" requirement of Rule 9(b), i.e., which Boston Heart employees were part of the scheme, having identified the following individuals as knowing participants of all three purported schemes: (1) Boston Heart's President and CEO, Susan Hertzberg; (2) the Chairman of Boston Heart's Board of Directors, Peter Parker (3) Boston Heart's Chief Business Officer, Alice Limkaking; (4) Boston's Heart's General Counsel, Frank Yunes; and (5) Boston Heart's Director, Jeff Crison. 2d. Am. Compl. ¶ 107. Because these specific, high-level employees have been identified as having allegedly participated in the schemes, the Court finds that the "who" element is satisfied.[11] See United States ex rel. Scott v. Pac. Architects & Eng'rs (PAE), Inc. d/b/a PAE Gov't Servs., Inc., 270 F. Supp. 3d 146, 154 (D.D.C. 2017) (concluding that the who element was satisfied because the complaint named "some of the employees involved").

The Court similarly finds that the relator satisfies the "when" requirement of Rule 9(b). Although the relator alleges the timeframe of Boston Heart's scheme generally, stating that the

[11] Boston Heart concedes that even if the relator had not identified specific individuals, under Heath, "individual employees at a corporation need not always be named, especially where fraud is alleged to be a specific corporate policy." Def.'s Mem. at 26 n.17 (citing Heath, 791 F.3d at 125). Boston Heart seeks to distinguish Heath from the circumstances here by arguing that the relator "alleges something different than a Boston Heart policy; [rather, the relator] alleges that Boston Heart and certain physicians came to an understanding regarding waiver of co-payments and deductibles and medical referrals." Id. However, the Court does not see a difference between the facts in Heath and the facts here. In Heath, the relator "allege[d] that [the defendant] orchestrated and implemented through its subsidiaries a corporate-wide scheme to have false claims submitted to [a government] Fund by depriving schools and libraries in the [Fund's Internet and telephone] program of the lowest corresponding price for services." Heath, 791 F.3d at 117. The Court finds that in this case, like in Heath, the relator has alleged that there was "a corporate-wide scheme to have false claims submitted to [the government]," id., because the relator alleges that the scheme was perpetrated by some of Boston Heart's highest-level officers and employees, see 2d Am. Compl. ¶ 107. Calling what happened in Heath a "policy," while arguing that what the relator alleges here is not a policy, makes the two actions distinguishable in name only. That is so because in both cases, the relators allege "a corporate-wide scheme to have false claims submitted to [the government]." Heath, 791 F.3d at 117; see also 2d Am. Compl. ¶ 107.

fraud has been occurring "since 2011," 2d. Am. Compl. ¶ 1, and that the scheme was tweaked in 2016, id. ¶ 3, that is sufficient under Heath, where the relator identified only the years when the scheme was perpetrated, see 791 F.3d at 124 ("In short, Rule 9(b)'s requirements of particularity as to . . . when (1997 to 2009) [has] been satisfied."); see also United States ex rel. Head v. Kane Co., 798 F. Supp. 2d 186, 203 (D.D.C. 2011) ("Where a 'scheme spans several years,' 'Rule 9(b) does not require plaintiffs to allege every fact pertaining to every instance of fraud . . . .'" (alteration in original) (quoting Williams, 389 F.3d at 1259)). Therefore, the timeline that the relator alleges is sufficient to satisfy Rule 9(b).

The Court also finds that the relator has satisfied the "where" requirements of Rule 9(b). In Heath, the Circuit found that Rule 9(b) was satisfied by the relator alleging that the scheme took place "through nineteen subsidiaries and their interactions with [program] schools and libraries across the Country." Heath, 791 F.3d at 124. The relator here alleges that the scheme was perpetrated with the participation of over fifty physicians through their interactions with their patients, their fellow physicians, and Boston Heart. See 2d. Am. Compl. ¶ 98 (naming over fifty physicians involved in the alleged scheme and providing their practices' addresses). Therefore, the relator alleges the conduits and locations through which the scheme allegedly occurred, see 2d. Am. Compl. ¶ 98, which sufficiently pleads the "where" requirement of Rule 9(b), see Heath, 791 F.3d at 124; see also Scott, 270 F. Supp. 3d at 154 (noting that the "what and where" elements were satisfied by alleging "the contracts and location effected").

The "what" requirement varies for each surviving theory of liability. In Heath, the "what" requirement of Rule 9(b) was satisfied by the relator providing a "detailed identification of a centralized and institutionalized failure to comply with the lowest-corresponding-price

requirement, which resulted in massive overbilling of a governmental program." 791 F.3d at 124. Specifically, the relator in Heath alleged that

> AT&T orchestrated and implemented through its subsidiaries a corporate-wide scheme to have false claims submitted to the [government] Fund by depriving schools and libraries in the [Internet and telephone] program of the lowest corresponding price for services. Schools and libraries, unaware of those overcharges, then passed those inflated costs on to the federal government for reimbursement through the [government] Fund.
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> * * *
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> . . . AT&T chose not to train its employees in the lowest-corresponding-price requirement . . . [and] as a result of AT&T's knowing or reckless decision not to train its employees, AT&T's sales representatives nationwide overbilled [participating] schools and libraries—that, in turn, passed those inflated costs onto the [government] Fund—for more than a decade.

Id. at 117–18. For all three surviving theories of liability, the relator here contends that Boston Heart "has perpetrated a multi-million dollar fraud on U.S. taxpayers through a Medicare kickback scheme." 2d. Am. Compl. ¶ 1. This, along with the relator's identification of five of the highest-level Boston Heart officials allegedly involved in the scheme, id. ¶ 107, and of over fifty named physicians who allegedly participated in the scheme, id. ¶ 98, conveys that this scheme was both "centralized" and "institutionalized," see Heath, 791 F.3d at 124, thus satisfying part of the Heath requirement, see id. (holding that the "what" requirement was satisfied by the relator's "detailed identification of a central and institutionalized failure to comply with the [government price] requirement").

The Court must now additionally consider whether the relator provides a "detailed identification" of the scheme, see id., underlying each surviving theory of liability in order to determine whether the "what" requirement of Rule 9(b) is satisfied.

a. Whether the Relator Satisfies the "What" Requirement of Rule 9(b) Regarding the Waiver of Co-payments and Deductibles Theory of Liability

Boston Heart argues that the relator fails to "plausibly allege a nexus or link between Boston Heart's alleged waiver of co-payments and deductibles and physician referrals of Medicare-covered testing to Boston Heart." Def.'s Mem. at 27. Boston Heart also argues that the relator's allegations regarding waiver of co-payments and deductibles are "vague[] and conclusory" because he fails to allege the "terms of the agreement[]." Id. at 26. The Court disagrees.

The relator alleges that Boston Heart "promise[d] physicians that it w[ould] waive deductibles, so long as the physicians sen[t] all of their lipid-related business—especially the highly profitable Medicare business—to [Boston Heart]'s laboratory." 2d Am. Compl. ¶ 44. In the Court's view, this sufficiently provides both the link between Boston Heart and the physicians' referral of Medicare business, as well as the terms of the agreement, because the relator specifically alleges that Boston Heart agreed to waive co-payments and deductibles in exchange for physicians referring Medicare patients to Boston Heart—the link is a quid pro quo with the terms of agreement being that Boston Heart would only waive co-payment and deductibles if it received referrals of Medicare patients.

The relator also provides a "detailed identification" of the purported waiver of co-payments and deductibles scheme. See Heath, 791 F.3d at 124. The relator alleges that Boston Heart waives co-payments and deductibles for physicians' privately insured patients in return for their referral of their Medicare business, 2d Am. Compl. ¶ 45, with Boston Heart profiting from the Medicare referrals, id., and the physicians benefitting from the increased private patient flow resulting from their advertising the waiver of co-payments and deductibles, id. ¶ 37.

Furthermore, the relator alleges that when Boston Heart learned that its waiver scheme might be detected, it switched to a Know It Now Fee system instead of waiving co-payments and deductibles, id. ¶¶ 47–49, attaching a copy of the Know It Now Fee schedule, id., Ex. 2, showing that the new fees, mostly ranging between $1 and $5, were significantly lower than what Boston Heart could have charged through co-payments and deductibles, and thus, Boston Heart continued to induce physicians to send it their Medicare business, id. ¶ 51.

In Heath, the Circuit found that when the relator provided "factual specificity concerning the type of fraud [and] how it was implemented," as well as a document allowing the court to "corroborate[] by . . . concrete example" the alleged fraud, this was enough to satisfy Rule 9(b), 791 F.3d at 126. The same is true here: the relator provides a detailed account of the alleged scheme, including how it was implemented, as well as the attached Know It Now Fee schedule, which shows the fees that Boston Heart charged instead of co-payments and deductibles. Therefore, the relator has provided corroboration of the specific details of the scheme through the submission of the Know It Now Fee schedule. Accordingly, the Court finds that the relator has satisfied Rule 9(b) regarding the waiver of co-payments and deductibles. See Kellogg Brown & Root Servs., 800 F. Supp. 2d at 153–54 ("While the [plaintiff] conceivably could have provided additional details—such as individual claim numbers or the specific submissions that are allegedly false—the same could be said of virtually every complaint, particularly those based on multiple claims . . . . What matters here is that the complaint fulfills Rule 9(b)'s underlying purpose of providing [the defendant] with 'sufficient notice of the claims against [it] to prepare a defense.'" (third alteration in original) (quoting Ortega, 240 F. Supp. 2d at 18)).

b. Whether the Relator Satisfies the "What" Requirement of Rule 9(b) Regarding Boston Heart's Payment of Packaging Fees

Boston Heart makes several arguments regarding why the relator has not satisfied Rule 9(b)'s "what" requirement for the packaging fees scheme theory of liability. Boston Heart argues that the relator "does not identify the amount of [packaging] fees Boston Heart paid with respect to any claim submitted to the government." Def.'s Mem. at 16. The relator argues in response that he did provide the amount of the packaging fees, see Relator's Opp'n at 16, because he alleged that Boston Heart paid LlmobileLab, Biotex, and VeniExpress $15, 2d Am. Compl. ¶ 64, and sometimes up to $25, per blood draw, id. ¶ 62. The Court therefore agrees with the relator that he provided the amount of the packaging fees that Boston Heart allegedly paid to physicians.

Boston Heart next argues that the relator "does not identify the fair market value for the [packaging] services associated with such fees." Def.'s Mem. at 16. The relator alleges that the standard draw fee allowed by Medicare is $3, 2d. Am. Compl. ¶ 55, and cites to an OIG Advisory Opinion stating that a $6 draw fee is illegal, see id. ¶ 54 (citing 2005 OIG Advisory Opinion). Although the relator does not cite or provide what constitutes a standard packaging fee, see id. ¶¶ 54–55, this is presumably because CMS has not established one, see generally 2014 OIG Special Fraud Alert, but the Special Fraud Alert, in its discussion of packaging fees, states that "arrangements providing free or below-market goods or services to actual or potential referral sources are suspect and may violate the [A]nti-[K]ickback [S]tatute, depending on the circumstances," id. at 2; see also id. at 4 (providing various factors to consider "[w]hen determining the fair market value of a physician's services"). And, OIG noted:

> Whether an actual violation of the [Anti-Kickback S]tatute occurs depends on the intent of the parties—the [A]nti-[K]ickback [S]tatute prohibits the knowing and willful payment of such amounts if even one purpose of the payment is to induce

> or reward referrals of Federal health care program business. This is true regardless of whether the payment is fair market value for services rendered.

Id. at 4 (emphasis added). Here, the relator has alleged that Boston Heart's intent in covering physicians' packaging fees was to "induce[] physicians to order tests from [Boston Heart]," 2d Am. Compl. ¶ 62. Because the OIG has made clear that the Anti-Kickback Statute may be violated even if the payment in question is of an amount equivalent to fair market value, so long as the parties intend to induce referrals of federal health care business, the Court does not find that the relator's failure to provide a fair market value for packaging fees is grounds for dismissal under Rule 9(b).

Boston Heart next argues that the relator "does not identify any specific payment to any specific physician." Def.'s Mem. at 16. The relator responds that he "identified dozens of physicians who received packaging fees and zero balance billing and who made referrals to Boston Heart." Relator's Opp'n at 16; see 2d Am. Compl. ¶ 98 (providing a list of several specific physicians who purportedly received packaging fees or waivers of co-payments and deductibles). Because the relator provides the names and locations of over fifty physicians who allegedly referred Medicare business to Boston Heart after allegedly receiving inflated packaging fees, 2d Am. Compl. ¶ 98, the Court is not persuaded by Boston Heart's argument.[12]

Finally, Boston Heart argues that the relator fails to satisfy Rule 9(b) in regards to the alleged packaging fees scheme because in Heath, the Circuit relied on "the concrete example of

[12] Boston Heart also argues that the relator "does not provide any evidence establishing a nexus between the alleged [packaging] fee agreement with physicians and the referral of Medicare business to Boston Heart." Def.'s Mem. at 17. As an initial matter, the relator need not provide evidence to satisfy Rule 9(b); rather, he must state allegations with sufficient particularity. See Fed. R. Civ. P. 9(b). And the Court finds that the relator sufficiently alleges a nexus between Boston Heart's allegedly inflated packaging fees and Medicare referrals. Specifically, the relator alleges that Boston Heart pays physicians packaging fees that "far exceed fair market value . . . designed to induce the referral of Medicare business to [Boston Heart]." 2d. Am. Compl. ¶ 4; see also id. ¶ 53 ("The second form of illegal remuneration provided by [Boston Heart] to induce the referral of Medicare business is the payment to physicians of inflated 'packaging' fees.").

[an] audit documenting the [scheme]" provided by the relator as the basis for finding that Rule 9(b) had been satisfied. See Def.'s Mem. at 17 (quoting Heath, 791 F.3d at 126). The Court is unpersuaded by this argument. Although a concrete example can be helpful in analyzing the pleading of claims under Rule 9(b), other members of this Court have found that "plaintiffs are not required to 'affix actual claims for payment to the complaint.'" Head, 798 F. Supp. 2d at 203 (quoting Pogue I, 238 F. Supp. 2d at 269); see also Kellogg Brown & Root Servs., 800 F. Supp. 2d at 153–54. This Court agrees with its colleagues that requiring a concrete example of the alleged fraud would "require claimants to essential provide detailed proof of their allegations," which is not required "on a 9(b) motion to dismiss." Head, 798 F. Supp. 2d at 202–03 (footnote omitted). Therefore, this argument fails as well.

c. Whether the Relator Satisfies the "What" Requirement of Rule 9(b) Regarding Boston Heart's Payment of Speaking and Consulting Fees

Boston Heart argues that the relator's characterization of Boston Heart's speaking and consulting fees paid to a nurse practitioner and a physician as "outrageous," 2d. Am. Compl. ¶ 7, is "conclusory," Def.'s Mem. at 29. The Court agrees. The relator alleges that the speaking and consulting fees paid by Boston Heart were $200,000, and that the payment of this amount was "outrageous." 2d. Am. Compl. ¶ 7. Although the Court must treat this allegation as true under Rule 12(b)(6), and finds that the relator plausibly alleges that a kickback occurred, see supra at 23–24, Rule 9(b) requires "a party [to] state with particularity the circumstances constituting fraud or mistake," Fed. R. Civ. P. 9(b). Without providing any further detail regarding why payment of the $200,000 qualifies as an "outrageous" speaking and consulting fee for a physician or nurse practitioner, the Court cannot find that the relator alleges a fraud with sufficient particularity. Although the relator does allege in the introduction of his Second

Amended Complaint that Boston Heart paid such speaking and consulting fees to the physician and nurse practitioner to "explain[] to [other] physicians how much money they could make by receiving packaging fees," 2d. Am. Compl. ¶ 7, and also alleges that packaging fees are part of Boston Heart's kickback scheme, id. ¶ 4, he never specifically alleges that the physician and nurse practitioner were promoting inflated packaging fees, nor does he provide any further detail regarding the scheme or even mention the scheme again, see generally id. With nothing more than an attenuated connection between Boston Heart's payment of speaking and consulting fees and the alleged inflation of packaging fees, the Court concludes that the relator fails to allege a speaking and consulting fee fraud with sufficient particularity under Rule 9(b). Accordingly, the Court holds that the "what" requirement of Rule 9(b) has not been satisfied, and therefore dismisses the theory of liability based on the payment of speaking and consulting fees to the physician and nurse practitioner.

In conclusion, as to the relator's false presentment cause of action, the Court finds that two theories of liability survive Boston Heart's motion to dismiss: (1) the waiver of patient co-payments and deductibles theory, and (2) the payment of inflated packaging fees to physicians theory. The Court dismisses the three following theories of liability: (1) the physician self-referral theory, (2) the medically unnecessary testing theory, and (3) the payment of excessive speaking and consulting fees theory.

B. Count II: The False Statements Claim Cause of Action

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 themselves present a claim for payment or approval." Morsell, 130 F. Supp. 3d at 122 (quoting Totten v. Bombardier Corp., 380 F.3d 488, 501 (D.C. Cir. 2004)). "[T]he elements for a count brought under [§] 3729(a)(1)(B) are practically identical to the requirements for a count brought under [§] 3729(a)(1)(A)." Penchang Si v. Laogai Research Found., 71 F. Supp. 3d 73, 87 (D.D.C. 2014). Thus, to establish a "false statements" violation, a 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." Morsell, 130 F. Supp. 3d at 122 (alterations in original) (quoting United States ex rel. Hood v. Satory Global, Inc., 946 F. Supp. 2d 69, 85 (D.D.C. 2013)).

The relator "incorporate[s] by reference and reallege[s] all of the allegations contained in [the False Presentment section] of [his Second Amended] Complaint," 2d Am. Compl. ¶ 113, to allege that "[Boston Heart] knowingly . . . made, used, or caused to be made or used false records or statements material to false or fraudulent claims," id. ¶ 114. Boston Heart argues that the relator's false statements claim must be dismissed because the relator "fails to make a single allegation concerning a false statement or record," and "appears to have tacked on a [§] 3729(a)(1)(B) claim based on the same set of facts as [the r]elator's [§] 3729(a)(1)(A) false presentment claim." Def.'s Mem. at 35. The Court disagrees.

The Court is unpersuaded by Boston Heart's argument that the relator's false statements claim must be dismissed because the relator has not alleged an "independent reason" for liability under the false statements cause of action. See Def.'s Mem. at 35. Other members of this Court have allowed a relator to proceed with both a false presentment cause of action and a false statements cause of action based on the same factual allegations. See, e.g., Scott, 270 F. Supp.

3d at 154 (concluding that the relators presented viable presentment and false statements causes of action under the same set of facts). It is immaterial that the relator alleges a false statements claim based on the same set of facts as his false presentment claim because "the elements for a count brought under [§] 3729(a)(1)(B) are practically identical to the requirements for a count brought under [§] 3729(a)(1)(A)." Penchang, 71 F. Supp. 3d at 87. Furthermore, parties are entitled to plead claims in the alternative. See Fed. R. Civ. P. 8(d)(2); see also 5 Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 1282 (3d ed. 2005) ("Federal Rule 8(d)(2) affords a party considerable flexibility in framing a pleading by expressly permitting claims for relief or defenses to be set forth in an alternative or hypothetical manner." (footnote omitted). Because the Court has already found that the relator has sufficiently alleged that Boston Heart made statements that were legally false in its claims for Medicare payments, see supra at 27, the Court finds that the relator also plausibly alleges a false statements cause of action for Boston Heart's (1) waiver of patient co-payments and deductibles, and (2) the payment of inflated packaging fees to physicians.

C. Count III: The Reverse False Claims Cause of Action

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).

> Whereas a traditional false claim action involves a false or fraudulent statement made to the government to support a claim for money from the government, a typical reverse false claim action involves a defendant knowingly making a false statement in order to avoid having to pay the government when payment is otherwise due.

Pencheng Si, 71 F. Supp. 3d at 88 (citing United States v. Caremark, Inc., 634 F.3d 808, 814–15 (5th Cir. 2011)).

Boston Heart argues that the relator's reverse false claims act claim must be dismissed because the relator's allegation simply realleges the relator's false statements and false presentment causes of action. Def.'s Mem. at 35. The Court agrees.

> This Court, as well as three other 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."

Groat I, 255 F. Supp. 3d at 32 (citing United States ex rel. Scollick v. Narula, 215 F. Supp. 3d 26, 41 (D.D.C. 2016)) (quoting Pencheng Si, 71 F. Supp. 3d at 97); see also Scollick, 215 F. Supp. 3d at 41 ("Like the Court in Pencheng Si, this Court finds that the fraudulent actions alleged here do not trigger an obligation to repay the fraudulently obtained money."); see also Scott, 270 F. Supp. 3d at 155 (same). Because the relator "does not plead any monetary obligation owed by Boston Heart to the government independent of its concealing of [its] allegedly fraudulent activity," Groat I, 255 F. Supp. 3d at 32 (quoting Scollick, 215 F. Supp. 3d at 40), the Court must dismiss the relator's reverse false claims cause of action.

IV. CONCLUSION

For the foregoing reasons, the Court grants in part and denies in part Boston Heart's motion to dismiss the Second Amended Complaint. Specifically, the Court grants the motion and dismisses the following theories of liability under both the false presentment and false statements causes of action (Counts I and II): (1) the payment of speaking and consulting fees theory, (2) the physician self-referral theory, and (3) the medically unnecessary testing theory. The theories of

liability regarding (1) the waiver of patient co-payments and deductibles and (2) the payment of inflated packaging fees to physicians survive under both Counts I and II. Finally, the Court grants Boston Heart's motion to dismiss the reverse false claims cause of action (Count III).

SO ORDERED this 12th day of September, 2018.[13]

REGGIE B. WALTON
United States District Judge

[13] The Court will contemporaneously issue an Order consistent with this Memorandum Opinion.