UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA *and* COMMONWEALTH OF MASSACHUSETTS, Relators, ex rel., LISA WOLLMAN, M.D., Relator, v. THE GENERAL HOSPITAL CORPORATION *et al.*, Defendants.	*	Civil Action No. 15-cv-11890-ADB

MEMORANDUM AND ORDER ON MOTION TO DISMISS

BURROUGHS, D.J.

Relator Lisa Wollman, M.D., a former anesthesiologist at Defendant Massachusetts General Hospital ("MGH"), brings this *qui tam* action under the False Claims Act, 31 U.S.C. § 3729 *et seq.* ("FCA") and the Massachusetts False Claims Act ("MFCA"), Mass. Gen. Laws ch. 12, § 5B *et seq.* against MGH, Massachusetts General Hospital's Physician Organization ("MGHPO"), and Partners Healthcare System ("Partners").[1] She alleges that Defendants fraudulently billed Medicare and Medicaid for "overlapping" surgeries in which a teaching physician concurrently performed two or three surgical procedures. Now pending before the Court is Defendants' motion to dismiss the Amended Complaint for failure to state a claim. [ECF No. 39]. For the reasons set forth below, the Amended Complaint is DISMISSED without

[1] At all times relevant to the Amended Complaint [ECF No. 31], MGHPO was a private corporation involved in billing for medical services and compensating staff members at MGH, and Partners was a nonprofit corporation that oversaw the medical residency programs at MGH. Am. Compl. ¶¶ 13−14.

prejudice. Relator is GRANTED leave to file a second amended complaint within 45 days of the entry of this Order.

I. BACKGROUND

The following facts are taken from the Amended Complaint [ECF No. 31], accepting the well-pleaded allegations as true and drawing all reasonable inferences in favor of Relator. United States ex rel. Booker v. Pfizer, Inc., 9 F. Supp. 3d 34, 41 (D. Mass. 2014) (quoting Watterson v. Page, 987 F.2d 1, 3 (1st Cir. 1993)).

Between 2010 and 2015, Relator was a treating anesthesiologist at MGH, a teaching hospital that provides medical services to, among others, Medicare and Medicaid beneficiaries. Am. Compl. ¶¶ 3–4, 27. MGH receives funds under Medicare Part A and other federal and state government programs to train residents (medical school graduates who are training in a medical specialty) and fellows (who have completed a residency program). Id. ¶¶ 12, 21−25. Such funding covers salaries for residents and fellows and other costs or expenses related to their training. Id. ¶¶ 24−26. Teaching hospitals like MGH are not typically reimbursed for the services provided by residents or fellows. Id. ¶¶ 31, 38. They may, however, seek payment under Medicare Part B and Medicaid for services provided by the teaching physicians who are charged with training the residents and fellows and supervising the services that they provide to patients. Id. ¶¶ 22, 26, 32−36.

A. Medicare and Medicaid Rules and Regulations

Relator's allegations rely upon the following rules and regulations of Medicare and Medicaid, as discussed further below: (1) billing and record keeping for overlapping surgeries; (2) billing for the administration of anesthesia; and (3) informed consent.

1. Overlapping Surgeries

To receive Medicare payments for services performed by a teaching physician, the services must either be (1) "personally furnished by a physician who is not a resident;" or (2) "furnished by a resident in the presence of a teaching physician," except as provided in, inter alia, 42 C.F.R. § 415.172. 42 C.F.R. § 415.170; Am. Compl. ¶ 39. Under section 415.172, if a resident participates in providing a service, MGH may be reimbursed "only if a teaching physician is present during the key portion of any service or procedure for which payment is sought." 42 C.F.R. § 415.172(a); Am. Compl. ¶ 40. "In the case of surgical, high-risk, or complex procedures," the teaching physician must be present during "all critical portions" of the procedure and "immediately available to furnish services during the entire service or procedure." 42 C.F.R. § 415.172(a)(1); Am. Compl. ¶ 41. When conducting overlapping surgeries, only once "all of the key portions of the initial procedure have been completed" may the teaching physician "begin to become involved in a second procedure." Centers for Medicare and Medicaid Services, Medical Claims Processing Manual: Chapter 12 – Phyisicans/Nonphyiscian Practitioners 160 (2017), available at https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c12.pdf ("CMS Manual"); see id. ("[T]he critical or key portions [of both procedures] may not take place at the same time."); Am. Compl. ¶ 42. "When a teaching physician is not present during non-critical or non-key portions of the procedure and is participating in another surgical procedure, [he or she] must arrange for another qualified surgeon to immediately assist the resident in the other case should the need arise." CMS Manual at 160; Am. Compl. ¶ 44. The teaching physician must also "personally document in the medical record that [he or she] was physically present during the critical or key portion(s)

of both procedures." CMS Manual at 160; Am. Compl. ¶ 49. No reimbursement is available for triple-booked surgeries. CMS Manual at 160; Am. Compl. ¶ 46.[2]

When submitting a claim for reimbursement, a teaching physician must state whether a resident participated in the service provided and must fully comply with the CMS Manual. CMS Manual at 165; Am. Compl. ¶ 48. MGH submits claims to Medicare using Form 1500 provided by the Centers for Medicare and Medicaid Services ("CMS"), which administers Medicare. Am. Compl. ¶¶ 27, 29−30, 38. By completing Form 1500, MGH certifies that the information on the form is true, accurate and complete; that sufficient information has been provided to allow the government to make an informed eligibility and payment decision; that the claim complies with all applicable Medicare rules and regulations for payment; and that the services provided were medically necessary. Id. ¶ 38.

2. Anesthesia

Medicare reimburses anesthesia practitioners for "anesthesia time," which is defined as "the period during which an anesthesia practitioner is present with the patient." CMS Manual at 121; Am. Compl. ¶ 57. Anesthesia time "starts when the anesthesia practitioner begins to prepare the patient for anesthesia services in the operating room or an equivalent area and ends when the

[2] The standard for seeking reimbursement for overlapping surgeries is substantially the same under the Massachusetts Medicaid program. Am. Compl. ¶ 52. The teaching physician "must be scrubbed and physically present during the key portion of the surgical procedure," and while the teaching physician is not physically present, "he or she must remain immediately available to return to the procedure, if necessary." 130 CMR 450.275(D)(4). With respect to overlapping surgeries, the teaching physician may become involved in a second procedure "[w]hen all of the key portions of the first procedure have been completed." Id. at 450.275(D)(4)(a). Because the teaching physician must be present "during the key portions of both operations," then the "key portions must not occur simultaneously." Id. When the teaching physician becomes involved in a second procedure, "he or she must arrange for another teaching physician to be immediately available to intervene as needed." Id. at 450.275(D)(4). The teaching physician's treatment notes must reflect "the key portions of both procedures . . . to demonstrate that he or she was immediately available to return to either procedure as needed." Id. at 450.275(D)(4)(a).

anesthesia practitioner is no longer furnishing anesthesia services to the patient, that is, when the patient may be placed safely under postoperative care." CMS Manual at 121; Am. Compl. ¶ 57. To the extent that Medicare generally excludes from coverage any claims for procedures that "are not reasonable and necessary for the diagnosis or treatment of illness or injury," 42 U.S.C. § 1395y(a)(1)(A), Relator asserts that unnecessarily prolonged administration of anesthesia may not be reasonable or necessary and therefore is not reimbursable. Am. Compl. ¶ 58.

3. Informed Consent

Medicare and Medicaid beneficiaries must give informed consent in order for the services provided to them to be reimbursed. Am. Compl. ¶¶ 60–63; see CMS, State Operations Manual: Appendix A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals 3 (2017), available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals /downloads/som107ap_a_hospitals.pdf (hospitals must be "in compliance with the Federal requirements set forth in the Medicare Conditions of Participation [] in order to receive Medicare/Medicaid payment"); 42 C.F.R. § 482.13(b)(1) (Condition of Participation includes patient's right "to participate in the development and implementation of his or her plan of care" and "right to make informed decisions regarding his or her care"); 42 C.F.R. § 482.51 (Condition of Participation includes "a properly executed informed consent form for the operation" being completed before surgery). CMS's guidelines further provide that a "well-designed consent process" might include a discussion of whether, besides the lead surgeon, other physicians (including residents or fellows) will perform important tasks related to the surgery. CMS, Revisions to the Hospital Interpretive Guidelines for Informed Consent 6 (Apr. 13, 2007), available at https://www.cms.gov/medicare/ provider-enrollment-and-certification/ surveycertificationgeninfo/downloads/scletter07-17.pdf.

B. Relator's Allegations

Relator contends that Defendants violated Medicare and Medicaid billing standards for overlapping surgeries, reasonable and necessary administration of anesthesia, and adequate informed consent. In support of her claims, she alleges that beginning in or around 2010, she was assigned to provide in-patient anesthesia services to surgical patients in MGH's department of orthopedic surgery. Am. Compl. ¶ 65. She witnessed the department's practice of scheduling overlapping surgeries that required the participation of residents and fellows outside of the presence of a teaching physician, but she never observed a double-booked surgeon designate another teaching physician to be immediately available while he or she was involved in an ongoing procedure. Id. ¶¶ 65−68, 79. Orthopedic surgeons at MGH regularly scheduled two surgeries concurrently in the morning and in the afternoon of the same day. Id. ¶ 66. Relator provides the date, surgeon (five in total), scheduled start time, location, duration, and surgery type for over twenty sets of overlapping surgeries that were performed between July 2011 and March 2013. Id. ¶ 74. In each of these overlapping surgeries, at least one of the patients involved was "65 years of age or older," meaning that "Medicare eligible patients were involved in the submissions of claims for these specific procedures." Id. ¶¶ 74−75. She describes certain surgeries in more detail, including instances in which a double-booked surgeon (1) did not scrub in until one and a half hours after the patient was put under anesthesia; (2) appeared in the operating room for only nine minutes and the patient was kept under anesthesia for an excessive period of time waiting for the surgeon to arrive; and (3) did not appear in the operating room at all for one of the overlapping surgeries. Id. ¶¶ 69, 70, 88. Surgeons conducting overlapping surgeries also allegedly falsified or failed to adequately annotate in the treatment records their presence or availability for the key or critical portions of concurrent procedures. Id. ¶¶ 69,

106–108, 114. To the extent that MGH's informed consent forms and practices provided inadequate information to patients prior to participating in overlapping surgeries, Relator asserts that every concurrent surgery performed at MGH violated a material requirement for reimbursement. Id. ¶¶ 60–62, 93–105, 114.[3]

Relator first raised concerns about MGH's concurrent surgery practices to MGH's senior leadership in May 2012, particularly with regard to a procedure in which the lead surgeon "never scrubbed into the case" and another instance in which that same surgeon was seeing patients in another building on MGH's campus while his overlapping surgery patients waited for his arrival, one of whom was under sedation. Id. ¶¶ 110–12.[4] The former chairman and chief executive officer of MGHPO told Relator that MGH had begun an internal investigation of MGH's overall concurrent surgery practices. Id. ¶¶ 111–12. The investigation concluded in the spring of 2012 but resulted in minimal changes to MGH's practices. Id. ¶ 115. When Relator raised similar concerns to her supervisors and MGH's Director of the Operating Rooms about the same surgeon's failure to appear in the operating room on another occasion, Relator was told that she

[3] In May 2013, MGH's consent form included the following statement: "My doctor will be there for the important parts of my procedure/surgery. My doctor will determine what other providers need to participate in my procedure/surgery and care." Am. Compl. ¶ 95. MGH's current consent form dated October 2014 reads:

> I understand that [MGH] is a teaching hospital. This means that resident doctors, doctors in a medical fellowship (fellows) and students in medical, nursing and related health care professions receive training here, and may take part in my procedure/surgery. A team of medical professionals will work together to perform my procedure/surgery. My doctor or an attending designee will be present for all the critical parts of the procedure/surgery, although other medical professionals may perform some aspects of the procedure as my doctor or the attending designee deems appropriate.

Id. ¶ 97.

[4] Dennis Burke, M.D., a former orthopedic surgeon at MGH, raised similar issues regarding MGH's concurrent surgery practices, improper record keeping, and inadequate informed consent forms, beginning in February 2011. Am. Compl. ¶¶ 109, 121−27.

may have violated the privacy rights of patients whose charts she reviewed to draw her conclusions and that she may be subject to disciplinary action. Id. ¶ 89. After reporting to her MGH supervisors that this particular surgeon tripled-booked concurrent surgeries on June 28, 2012, she was prohibited from working on cases with that surgeon. Id. ¶¶ 116–17.

II. PROCEDURAL HISTORY

Under the FCA and MFCA, either the Attorney General or a private party may initiate a lawsuit alleging fraud on the government. 31 U.S.C. § 3730(a)–(b); M.G.L. c. 12, § 5C(3)–(4). "A private enforcement action under the FCA is called a *qui tam* action, with the private party referred to as the 'relator.'" United States ex rel. Eisenstein v. City of New York, 556 U.S. 928, 932 (2009) (quoting Vermont Agency of Nat. Resources v. United States ex rel. Stevens, 529 U.S. 765, 769 (2000)). "*Qui tam* complaints are initially filed under seal, and relators must allow the government sixty days to intervene and assume primary responsibility for prosecuting the action." United States ex rel. Duxbury v. Ortho Biotech Prods., L.P., 719 F.3d 31, 33 (1st Cir. 2013) (citing 31 U.S.C. §§ 3730(b)(2)−(3), (c)). If the government declines to intervene, the relator "may pursue the action on its behalf." United States ex rel. Ondis v. City of Woonsocket, 587 F.3d 49, 53 (1st Cir. 2009) (citing 31 U.S.C. § 3730(b)(4)). Regardless of the government's intervention, "'[a] private relator is entitled to a portion of any proceeds from the suit.'" United States ex rel. Duxbury v. Ortho Biotech Prods., L.P., 579 F.3d 13, 16 (1st Cir. 2009) (quoting United States ex rel. Rost v. Pfizer, Inc., 507 F.3d 720, 727 (1st Cir. 2007), overruling in part recognized by United States ex rel. Wilson v. Bristol-Myers Squibb, Inc., 750 F.3d 111, 113–14 (1st Cir. 2014)).

On May 19, 2015, Relator filed the initial complaint in this action under seal. [ECF No. 1]. Pursuant to requests from the government for extensions of time to continue its investigation,

approximately one year and nine months from the filing of the complaint, both the United States and the Commonwealth of Massachusetts declined to intervene in this matter. [ECF Nos. 19, 20]. The initial complaint was ordered unsealed on April 12, 2017. [ECF Nos. 21, 23].

On June 7, 2017, Relator filed the Amended Complaint [ECF No. 31]. Counts I and V respectively allege violations of the FCA, 31 U.S.C. § 3729(a)(1), and the MFCA, M.G.L. c. 12 § 5B(a)(1), for knowingly causing false claims to be submitted to the government in violation of Medicare and Medicaid rules regarding overlapping surgeries, record keeping, informed consent, and unreasonable and unnecessary anesthesia. Am. Compl. ¶¶ 137–141, 155–159. Count II, FCA 31 U.S.C. § 3729(a)(1)(B), and Count VI, M.G.L. c. 12, § 5B(a)(2), allege that Defendants knowingly used false records or statements that caused false claims to be paid by the government. Am. Compl. ¶¶ 142–145, 160–164. Counts III and VII respectively allege violations of the FCA, 31 U.S.C. § 3729(a)(1)(C), and the MFCA, M.G.L. c. 12, § 5B(a)(3), for conspiracy to defraud the government. Am. Compl. ¶¶ 146–150, 165–169. Finally, Counts IV under FCA, 31 U.S.C. § 3729(a)(1)(G), and Count VIII under M.G.L. c. 12, § 5B(a)(9), assert that Defendants knowingly made false statements that were material to an obligation to pay money to the government. Am. Compl. ¶¶ 151–154, 170–173. Defendants now move to dismiss all counts for failure to meet the heightened pleading standard under Federal Rule of Civil Procedure 9(b) or for otherwise failing to state a claim. [ECF No. 39].

III. DISCUSSION

The FCA imposes liability on any person who, among other things, "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," or "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). A "claim" may include "direct requests to the

Government for payment," in addition to "reimbursement requests made to the recipients of federal funds under federal benefits programs." United States ex rel. Verrinder v. Wal-Mart Corp., No. 13-11147-PBS, 2016 WL 3460310, at *3 (D. Mass. June 21, 2016) (quoting Universal Health Servs., Inc. v. United States ex rel. Escobar, 136 S. Ct. 1989, 1996 (2016)). The FCA's "scienter requirement defines 'knowing' and 'knowingly' to mean that a person has 'actual knowledge of the information,' 'acts in deliberate ignorance of the truth or falsity of the information,' or 'acts in reckless disregard of the truth or falsity of the information.'" Escobar, 136 S. Ct. at 1996 (quoting 31 U.S.C. § 3729(b)(1)(A)). The FCA's materiality requirement defines "'material' to mean 'having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.'" Id. (quoting 31 U.S.C. § 3729(b)(4)).

Relator asserts that Defendants submitted claims to Medicare and Medicaid for double- or triple-booked surgeries, but that their concurrent surgery practices violated the conditions precedent for reimbursement. Defendants move to dismiss Relator's claims on the grounds that her allegations do not meet the particularity requirements of pleading fraud under Rule 9(b), and otherwise fail to satisfy the FCA's materiality or scienter requirements. As discussed below, even assuming, *arguendo*, that the Amended Complaint adequately pleaded materiality and scienter, it nonetheless fails to cross Rule 9(b)'s heightened threshold.

A. Rule 12(b)(6) Motion to Dismiss Standard

To evaluate a motion to dismiss for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6), the Court must "accept as true all well-pleaded facts alleged in the complaint and draw all reasonable inferences therefrom in the pleader's favor." A.G. ex rel. Maddox v. v. Elsevier, Inc., 732 F.3d 77, 80 (1st Cir. 2013) (quoting Santiago v. Puerto Rico, 655 F.3d 61, 72 (1st Cir. 2011)). The complaint must set forth "a short and plain statement of the claim showing

that the pleader is entitled to relief," and should "contain 'enough facts to state a claim to relief that is plausible on its face.'" Id. (quoting Fed. R. Civ. P. 8(a)(2) and Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). "To cross the plausibility threshold a claim does not need to be probable, but it must give rise to more than a mere possibility of liability." Grajales v. P.R. Ports Auth., 682 F.3d 40, 44–45 (1st Cir. 2012) (citing Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009)). "A determination of plausibility is 'a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.'" Id. at 44 (quoting Iqbal, 556 U.S. at 679). "[T]he complaint should be read as a whole, not parsed piece by piece to determine whether each allegation, in isolation, is plausible." Hernandez-Cuevas v. Taylor, 723 F.3d 91, 103 (1st Cir. 2013) (quoting Ocasio-Hernandez v. Fortuno-Burset, 640 F.3d 1, 14 (1st Cir. 2011)). "The plausibility standard invites a two-step pavane." Maddox, 732 F.3d at 80. First, the Court "must separate the complaint's factual allegations (which must be accepted as true) from its conclusory legal allegations (which need not be credited)." Id. (quoting Morales-Cruz v. Univ. of P.R., 676 F.3d 220, 224 (1st Cir. 2012)). Secondly, the Court "must determine whether the remaining factual content allows a 'reasonable inference that the defendant is liable for the misconduct alleged.'" Id. (quoting Morales-Cruz, 676 F.3d at 224).

B. Rule 9(b) Heightened Pleading Standard

Relator brings her FCA claims under 31 U.S.C. § 3729(a)(1) and therefore must plead them "with plausibility and particularity under Federal Rules of Civil Procedure 8 and 9(b)." Escobar, 136 S. Ct. at 2004 n.6; see United States ex rel. Gagne v. City of Worcester, 565 F.3d 40, 45 (1st Cir. 2009) ("[T]he heightened pleading requirements of Fed. R. Civ. P. 9(b) apply to claims brought under subsection (a)(1) of the FCA."). Applying Rule 9(b)'s heightened pleading standard to FCA claims serves to "give notice to defendants of the plaintiffs' claim, to protect

defendants whose reputation may be harmed by meritless claims of fraud, to discourage 'strike suits,' and to prevent the filing of suits that simply hope to uncover relevant information during discovery." United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 226 (1st Cir. 2004), abrogation on other grounds recognized in Gagne, 565 F.3d at 46 n.7 (quoting Doyle v. Hasbro, Inc., 103 F.3d 186, 194 (1st Cir. 1996)). Although the circuits "have varied . . . in their statements of exactly what Rule 9(b) requires in a *qui tam* action," including as to "whether, when, and to what extent a relator must state the particulars of specific examples of the type of false claims alleged," the First Circuit has established a generally applicable standard that is subject to at least one exception. United States ex rel. Nargol v. DePuy Orthopaedics, Inc., 865 F.3d 29, 38 (1st Cir. 2017), petition for cert. filed, 17-1108 (Feb. 7, 2018) (citing Foglia v. Renal Ventures Mgmt., LLC, 754 F.3d 153, 155−56 (3d Cir. 2014)).

1. General Standard

In Karvelas, the First Circuit established its "general position" on Rule 9(b)'s particularity requirement for *qui tam* actions. Nargol, 865 F.3d at 38. In every FCA case, "the defendant's presentation of false or fraudulent claims to the government is a central element." Karvelas, 360 F.3d at 232. Thus, "[a] health care provider's violation of government regulations or engagement in private fraudulent schemes does not impose liability under the FCA unless the provider submits false or fraudulent claims to the government for payment based on these wrongful activities." Id. "[W]rongful activities that result in the submission of fraudulent claims are included in the 'circumstances constituting fraud or mistake' that must be pled with particularity pursuant to Rule 9(b)," but those allegations alone are generally insufficient "unless they are linked to allegations, stated with particularity, of the actual false claims submitted to the government that constitute the essential element of an FCA *qui tam* action." Id.

The relator therefore "must provide details that identify particular false claims for payment that were submitted to the government." Karvelas, 360 F.3d at 232. "[M]erely alleging facts related to a defendant's alleged misconduct is not enough . . . . Rather, a [FCA complaint] must 'sufficiently establish that false claims were submitted for government payment' as a result of defendant's alleged misconduct.'" United States ex rel. Ge v. Takeda Pharm. Co. Ltd., 737 F.3d 116, 124 (1st Cir. 2013) (quoting Rost, 507 F.3d at 732−33); see United States ex rel. Booker v. Pfizer, Inc., 847 F.3d 52, 57 (1st Cir. 2017) ("That is, even when a relator can prove that a defendant engaged in 'fraudulent conduct affecting the government,' FCA liability attaches only if that conduct resulted in the filing of a false claim for payment from the government.'" (quoting Rost, 507 F.3d at 727)). "Because claims of fraud are involved, even at the pleading stage relators are required under Fed. R. Civ. P. 9(b) 'to set forth with particularity [at least] the who, what, when, where, and how of" an actual false claim alleged to have been filed because of the defendant's actions." Booker, 847 F.3d at 57−58 (quoting Lawton ex rel. United States v. Takeda Pharm. Co., 842 F.3d 125, 130 (1st Cir. 2016)). Allegations pled on "information and belief" are also subject to the particularity requirement, as well as the additional requirement that "the complaint set[] forth the facts on which the belief is founded." Karvelas, 360 F.3d at 227 (citation omitted); id. at 228 (reiterating that there is "no relaxation of the particularity requirement for 'information and belief' pleading"). Accordingly, a relator cannot "present general allegations in lieu of the details of actual false claims in the hope that such details will emerge through subsequent discovery." Id. at 231.

The Karvelas court further explained the level of specificity expected to meet the particularity requirement:

> [D]etails concerning the dates of the claims, the content of the forms or bills submitted, their identification numbers, the amount of money charged to the

> government, the particular goods or services for which the government was billed, the individuals involved in the billing, and the length of time between the alleged fraudulent practices and the submission of claims based on those practices are the types of information that may help a relator to state his or her claims with particularity.

Karvelas, 360 F.3d at 233. These details "do not constitute a checklist of mandatory requirements that must be satisfied by each allegation included in a complaint," but "some of this information for at least some of the claims must be [pled] in order to satisfy Rule 9(b)." Id. (quoting United States ex rel. Clausen v. Lab. Corp. of Am., Inc., 290 F.3d 1301, 1312 n.21 (11th Cir. 2002)). In sum, a relator generally meets the particularity threshold "by alleging with particularity examples of actual false claims submitted to the government." D'Agostino v. ev3, Inc., 845 F.3d 1, 10 (1st Cir. 2016). "By doing so, the relator conveys that if the facts alleged are true, the filing of a false claim is not merely a possibility, but rather, necessarily occurred." Id.

2. More Flexible Standard

"In applying this general rule [from Karvelas] over time, [the First Circuit] ha[s] nevertheless recognized at least one exception to the expectation that a relator should be able to allege the essential particulars of at least some actual false claims that were in fact submitted to the government for payment." Nargol, 865 F.3d at 39. In noting "a distinction between a *qui tam* action alleging that the defendant made false claims to the government, and a *qui tam* action in which the defendant induced third parties to file false claims with the government," Rost, 507 F.3d at 732, the First Circuit established a "more flexible" standard of particularity to apply to the latter category in which "the fraud alleged is in a different category than in Karvelas." Duxbury, 579 F.3d at 30; Rost, 507 F.3d at 732. Where the defendant allegedly induced third parties to file false claims with the government, "a relator [can] satisfy Rule 9(b) by providing 'factual or statistical evidence to strengthen the inference of fraud beyond possibility' without

necessarily providing details as to each false claim." Duxbury, 579 F.3d at 29 (quoting Rost, 507 F.3d at 733). "Such evidence must pair the details of the scheme with 'reliable indicia that lead to a strong inference that claims were actually submitted.'" Nargol, 865 F.3d at 39 (quoting Duxbury, 579 F.3d at 29). Relator contends that the Amended Complaint satisfies the particularity standard under Karvelas but alternatively suggests that the more flexible standard under Duxbury should otherwise apply here.

C. Analysis Under Karvelas

In Karvelas, the relator was a medical care provider (a respiratory therapist) who was formerly employed at the defendant hospital and claimed that the hospital submitted false claims to obtain Medicare and Medicaid payments. 360 F.3d at 223. The defendant allegedly failed to comply with the federal standards of patient care required for reimbursement by CMS (or its predecessor), but "falsely certified that they were in compliance with these standards and wrongfully billed Medicare and/or Medicaid, presumably on the basis of services that were being provided improperly or not at all." Id. (quotation marks omitted). In analyzing the complaint under Rule 9(b), the First Circuit described the deficiencies of the relator's allegations:

> [T]he complaint alleges that the defendants submitted false claims to the federal government, including cost reports that were falsely certified as complete, true, and correct. It states that the defendants wrongfully billed Medicare and Medicaid, and refers generally to false confirming orders and progress notes. However, the complaint never specifies the dates or content of any particular false or fraudulent claim allegedly submitted for reimbursement by Medicare or Medicaid. It provides no identification numbers or amounts charged in individual claims for specific tests, supplies, or services. It does not identify or describe the individuals involved in the improper billing or allege with particularity any certification of compliance with federal regulations in order to obtain payments.

Id. at 233.

As in Karvelas, Relator here is a medical care provider (an anesthesiologist) who was formerly employed at the Defendant hospital and alleges that Defendants submitted claims for

Medicare and Medicaid payments for surgeries that were improperly performed under CMS's standards for reimbursement. She provides notable detail with respect to the commonplace occurrence of overlapping surgeries at MGH, including the date, surgeon, start time, location, duration, and type of surgery for numerous procedures. Am. Compl. ¶ 74.[5] She also describes particular surgeries where the teaching physician either was not present at all or was present in the operating room for only a very brief period of time, plausibly suggesting that the overlapping surgery rules were violated in some instances. None of the factors enumerated in Karvelas are addressed, however, with respect to the actual submission of claims; no dates, identification numbers, amounts, services, individuals involved, or length of time are provided for a single claim on any overlapping surgery.[6] See Gagne, 565 F.3d at 47 (particularity standard not met where relators failed to "connect the only falsity or fraud for which they provide any detail . . . to an effort to get a false claim paid or approved by the government"); Verrinder, 2016 WL 3460310, at *6 (relator, a former pharmacist at Kmart, "provided some details about [the] allegation against Kmart, indicating where this practice occurred, how the fraud was perpetrated, and who participated," but failed to satisfy Rule 9(b) because he did "not identify one false claim submitted to Medicare or Medicaid as a result of this scheme"); United States ex rel. Driscoll v. Serono Inc., No. 00-11680-GAO, 2008 WL 728939, at *3 (D. Mass. Mar. 18, 2008) (Rule 9(b) not satisfied where the allegations "outline[d] a fraudulent scheme, but they fail[ed] to identify a single particular false claim submitted for payment by any of the pharmacy defendants to any

[5] Given that Relator describes the procedures discussed in paragraph 74 based on MGH's operating room schedules, she does not allege based on her knowledge that any of those procedures violated the overlapping surgery rules, except to the extent that she asserts generally that all overlapping surgeries conducted at MGH violated the informed consent rules.

[6] Relator identifies Form 1500 as the form that MGH generally uses to bill Medicare, but does not specify any particular instance in which Defendants submitted that form in relation to improperly conducted overlapping surgeries.

governmental agency at any time"). Thus, the Amended Complaint "suffers from precisely the same defect as did the complaint in Karvelas: it describes an allegedly illegal 'scheme,' but only refers to specific false claims in the most conclusory terms, rather than with the particularity as required by Rule 9(b), as interpreted by the First Circuit." Driscoll, 2008 WL 728939 at *3. Accordingly, if the First Circuit's general position from Karvelas governs the instant case, then Relator's complaint falls short of the particularity standard.

D. Applicability of Duxbury Exception

Relator alternatively asks the Court to apply the more flexible particularity standard from Duxbury. To strengthen the inference of fraud, she submits that (1) the government pays for a significant percentage of orthopedic surgeries; (2) Medicare was the primary payor for 63.3% of total knee replacements and 58.2% of total hip replacements in 2000, 54.7% of total knee replacements in 2009, and 52.8% of total hip replacements in 2009; and (3) MGH's orthopedic surgeons performed concurrent surgeries that involved patients who, because they were aged 65 or older, were likely to be covered by Medicare and/or Medicaid. Am. Compl. ¶¶ 8 & n.7, 69, 70, 72, 75. She further asks that the Court take judicial notice of the fact that more than 43 million people aged 65 or older were covered by Medicare in 2012, which allegedly results in nearly universal coverage for that age demographic. [ECF No. 52 at 22 n.25]. MGH also had a policy effective in 2012 that stated that MGH's policies complied with CMS's rules governing concurrent surgeries, implying that MGH bills the government for at least some concurrent surgeries. Am. Compl. ¶¶ 83−85. Relator attached to her opposition brief additional exhibits to show that Medicare paid MGH approximately $766 million for 33,702 inpatient and 752,283 outpatient claims for services provided to beneficiaries during 2010 and 2011, and approximately 2,218 Medicare in-patients underwent orthopedic surgery at MGH in 2016. [ECF No. 52 at 22].

Relator states that the First Circuit has not explicitly rejected the application of the more flexible standard to the circumstances of this case, but she also does not identify any instance in which the First Circuit has expanded the exception beyond cases involving third-party inducement (which is plainly not at issue here), and this Court is aware of none. More critically, she does not address the similarities between Karvelas and the instant case which makes distinguishing them all the more difficult. This case and Karvelas each involved a medical care provider who was formerly employed at the defendant hospital and claimed that the hospital submitted claims to obtain Medicare and Medicaid payments for services provided in violation of the applicable standards for reimbursement. In both cases, the relators provided significant detail concerning the allegedly fraudulent scheme or misconduct but lacked specificity with respect to the actual submission of claims to the government, which is "the *sine qua non* of a [FCA] violation." Karvelas, 360 F.3d at 225. Given the close comparison between the circumstances of Karvelas and this case, applying the more flexible standard would seemingly collapse the general rule within the exception.

Relator did not allege in the complaint but asserts in her briefing that because she lacks access to billing records and claim information, she should be excused from pleading certain allegations with particularity—an argument that was also raised in Karvelas. 360 F.3d at 228 ("[Relator] argues that even if Rule 9(b) applies to FCA claims, its requirements should be relaxed in his case because the information necessary to plead with particularity is within the possession and control of the defendants."). The First Circuit acknowledged that the particularity requirement has been relaxed in some circumstances where the requisite information is outside of the plaintiff's reach, but it nonetheless rejected the relator's argument that "it is inherently inconsistent with the goals of the [FCA] to require a *qui tam* relator to specify the time, dates,

places, and identities of the individuals involved in the fraud or the specific in the documents prepared and submitted by the defendant to obtain the funding at the time that the complaint is filed and prior to any additional discovery." Karvelas, 360 F.3d at 230 (internal quotation marks omitted).

In recognizing that the relator sought to stand on general allegations and take discovery to reinforce the cracks in the complaint, the court held that "allowing a relator to plead generally at the outset and amend the complaint at the 12(b)(6) stage after discovery would be at odds with the FCA's procedures for filing a *qui tam* action and its protections for the government (which is, of course, the real party in interest in a *qui tam* action)." Id. at 231. "[A]llowing a *qui tam* relator to amend his or her complaint after conducting further discovery would mean that 'the government will have been compelled to decide whether or not to intervene absent complete information about the relator's cause of action.'" Id. at 231 (quoting Boese, Civil False Claims and Qui Tam Actions § 4.04[C]). The First Circuit and other courts in this district have since emphasized that what discovery might show is not an adequate substitute for pleading with particularity. Rost, 507 F.3d at 733 (Rule 9(b) "discourages plaintiffs from filing allegations of fraud merely in the hopes of conducting embarrassing discovery and forcing settlement"); Verrinder, 2016 WL 3460310, at *3 (same). Although the Court understands that a lack of access to claim information presents a significant challenge to some relators, Relator has not provided an adequate basis for departing from the reasoning in Karvelas where the Court addressed substantially the same question on analogous facts. Accordingly, the more flexible standard applicable to third-party inducement cases does not apply here.[7] Therefore, the Amended

[7] The Amended Complaint might not suffice even under the more flexible standard. Relator alleges that some of the patients involved in overlapping surgeries were over 65 years old and therefore "Medicare eligible," and that based on the demographic and statistical data showing a high percentage of patients over the age of 65 are covered by Medicare, at least some of the

Complaint fails to meet the particularity standard of Rule 9(b).[8]

In sum, Karvelas dictates the outcome here. That case and its progeny underscore that the purpose of the FCA is to prevent fraud on the government. The *qui tam* mechanism is meant to arm the government with "a posse of ad hoc deputies to uncover and prosecute frauds against [it]." United Seniors Ass'n., Inc. v. Philip Morris USA, 500 F.3d 19, 24 (1st Cir. 2007) (quoting Karvelas, 360 F.3d at 224). The government, rather than the relator or even an affected individual, remains the real party in interest. Although it may seem unfair and perhaps even contrary to the public interest to require the relator to provide the requisite level of detail about fraudulent billing without the benefit of even minimal discovery, the FCA is fundamentally a tool to help the government recoup funds expended for false claims. To effect this purpose, relators must come forward at the outset with detailed information about fraudulent claims so

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overlapping surgeries conducted at MGH surely must have been billed to the government. Eligibility alone, however, does not necessarily show with particularity that claims were submitted. See Hagerty ex rel. United States v. Cyberonics, Inc., 844 F.3d 26, 29, 33 (1st Cir. 2016) (allegation that healthcare providers "had patients who were 'seriously disabled' and eligible for various healthcare programs, and that the [medical device] replacement surgeries conducted on those patients necessarily resulted in the submission of at least some false reimbursement claims" at most showed that fraud was possible, without "any allegation that the patients were actually covered by government programs"); D'Agostino v. ev3, Inc., 845 F.3d 1, 11 (1st Cir. 2016) (assumption that "physicians submitted claims for reimbursement merely because many of their patients in general were insured under government programs is faulty").

[8] Relator's claims under the MFCA are also subject to the particularity requirements of Rule 9(b). See Sheppard v. 265 Essex Street Operating Co., LLC, No. 16-11514-PBS, 2018 WL 1335359, at *3 (Mar. 14, 2018) ("A *qui tam* action on behalf of the Commonwealth of Massachusetts alleging violations of the MFCA must meet the special pleading requirements of Fed. R. Civ. P. 9(b)."); see also Lawton ex rel. United States v. Takeda Pharm. Co., 842 F.3d 125, 132 (1st Cir. 2016) ("Rule 9(b)'s heightened pleading standard generally applies to state law fraud claims brought in federal court."). Given that the MFCA is construed consistently with the FCA, Relator's state law claims cannot survive the motion to dismiss for the particularity deficiencies discussed above. See New York v. Amgen Inc., 652 F.3d 103, 109 (1st Cir. 2011) (noting the "substantive similarity" of the MFCA and FCA and construing the MCFA "consistently with the [FCA]"); Massachusetts v. Mylan Labs., 608 F. Supp. 2d 127, 140 (D. Mass. 2008) ("Massachusetts Courts will look for guidance in interpreting the MFCA to cases and treatises interpreting the FCA." (citing Scannell v. Att'y Gen., 872 N.E.2d 1136, 1138 (Mass. App. Ct. 2007))).

that the government can determine whether to intervene and take over the pursuit of the claims identified by the relator. In making this decision, the government has the resources and the authority to collect additional information that may not, as here, have been available to the relator. If the government declines to intervene, the relator may proceed on his or her own, but only if he or she has specific allegations of false billing as required under the statute. Karvelas makes clear that the relator's role is not to vindicate a particular interest or expose wrongdoing, unless there is a direct connection to fraudulent government billing. Karvelas, 360 F.3d at 234 ("[Relator] alleges serious violations by the defendants of federal standards governing the provision of patient care. However, alleged violations of federal regulations are insufficient to support a claim under the FCA."); cf. Booker, 847 F.3d at 60 ("[A]lthough [c]orrecting regulatory problems may be a laudable goal, those problems [are] not actionable under the FCA in the absence of actual fraudulent misconduct." (quoting Karvelas, 360 F.3d at 237)). Unless and until the First Circuit reexamines the principles of Karvelas, at least in instances where patient care is at issue, or where the relator is exceptionally limited in his or her access to billing information, the Court is bound by Karvelas and the Amended Complaint must be dismissed. See Webb ex rel. United States v. Miller Family Enterprise, No. 13-cv-169-DBH, 2014 WL 6611065, at *1 (D. Me. Nov. 20, 2014) (applying Karvelas and mentioning that "[i]f there is reason to alter that caselaw ([the court is] not suggesting there is), that is a matter for the Court of Appeals"). This does not mean that patient safety issues and hospital policies cannot be challenged, but under the current statutory scheme and First Circuit case law, a relator without evidence of specific false claims will not be able to proceed under the FCA without the participation and assistance of the government.

IV. LEAVE TO AMEND

"A party may amend its complaint more than once 'only with the opposing party's written consent or the court's leave.'" United States ex rel. Poteet v. Bahler Med., Inc., 619 F.3d 104, 116 (1st Cir. 2010) (quoting Fed. R. Civ. P. 15(a)(2)). "Rule 15(a) reflects a liberal amendment policy, . . . and provides that a court should freely give leave when justice so requires," providing the district court with "significant latitude in deciding whether to grant leave to amend." Gagne, 565 F.3d at 48 (quoting ACA Fin. Guar. Corp. v. Advest, Inc., 512 F.3d 46, 55 (1st Cir. 2008) (internal quotation marks omitted)). "Reasons for denying leave include undue delay in filing the motion, bad faith or dilatory motive, repeated failure to cure deficiencies, undue prejudice to the opposing party, and futility of amendment." Id. (citing Foman v. Davis, 371 U.S. 178, 182 (1962) and Rost, 507 F.3d at 733–34).

Relator has requested leave to file a second amended complaint. Although she faces an uphill battle, the Court cannot conclude at this time that her request for leave to amend is futile. See Verrinder, 2016 WL 3460310, at *6 (granting leave to amend where relator did not "identify one false claim submitted to Medicare or Medicaid"). In the interests of justice, Relator is granted leave to file a second amended complaint within 45 days of the entry of this Order.[9] Accordingly, the Amended Complaint is DISMISSED without prejudice. [ECF No. 39].

SO ORDERED.

March 30, 2018

/s/ Allison D. Burroughs
ALLISON D. BURROUGHS
U.S. DISTRICT JUDGE

[9] The Court reviewed Relator's requests for taking judicial notice of materials incorporated into her opposition briefing [ECF Nos. 48, 52], which were ultimately immaterial to the disposition of the Amended Complaint. Relator may, however, incorporate those materials into her second amended complaint.