394 F.Supp.3d 174
United States District
Court, D. Massachusetts.

UNITED STATES of America
and Commonwealth of
Massachusetts, Plaintiffs, ex rel.
Lisa Wollman, M.D., Relator,
v.
The GENERAL HOSPITAL
CORPORATION, et al., Defendants.

Civil Action No. 1:15-cv-11890-ADB
|
Signed 06/17/2019

Synopsis

Background: Relator, a former anesthesiologist at hospital, brought qui tam action against hospital, private corporation that was involved in billing for medical services and paying staff members at hospital, and nonprofit corporation that oversaw medical residency programs, alleging violation of the False Claims Act (FCA) and the Massachusetts False Claims Act (MFCA) in connection with violations of rules and regulations for Medicare and Medicaid reimbursement covering billing and record-keeping for overlapping and concurrent surgeries, billing for the administration of anesthesia, and informed consent. Defendants moved to dismiss for failure to state a claim.

Holdings: The District Court, Allison D. Burroughs, J., held that:

relator pled fraud with sufficient particularity to state a qui tam False Claims Act claim;

relator adequately pled that Medicare and Medicaid claims were false;

relator adequately alleged materiality; and

relator adequately pled scienter.

Motion denied.

Procedural Posture(s): Motion to Dismiss for Failure to State a Claim.

Attorneys and Law Firms

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MEMORANDUM AND ORDER ON DEFENDANTS' MOTION TO DISMISS

BURROUGHS, D.J.

Relator Lisa Wollman, M.D. ("Wollman"), a former anesthesiologist at Defendant Massachusetts General Hospital ("MGH"),

brings this *qui tam* action[1] under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729 *et seq.*, and the Massachusetts False Claims Act ("MFCA"), Mass. Gen. Laws ch. 12, § 5B, against MGH, Massachusetts General Physicians Organization ("MGPO"), and Partners Healthcare System ("Partners") (collectively "Defendants").[2]

Now pending before the Court is Defendants' motion to dismiss the Second ***179** Amended Complaint for failure to state a claim. [ECF No. 91]. For the reasons set forth below, the motion to dismiss [ECF No. 91] is DENIED.

I. BACKGROUND

The following facts are taken from the Second Amended Complaint. [ECF No. 89 ("SAC")]. The Court, as it must, accepts the well-pleaded allegations as true and draws all reasonable inferences in favor of Wollman. See Watterson v. Page, 987 F.2d 1, 3 (1st Cir. 1993) (citing Monahan v. Dorchester Counseling Ctr., Inc., 961 F.2d 987, 988 (1st Cir. 1992)). This procedural and factual summary largely restates the summary provided in the Court's memorandum and order on Defendants prior motion to dismiss. See generally United States ex rel. Wollman v. Gen. Hosp. Corp., No. 15-CV-11890-ADB, 2018 WL 1586027 (D. Mass. Mar. 30, 2018).

Between 2010 and 2015, Wollman was a treating anesthesiologist at MGH, a teaching hospital that provides medical services to, among others, Medicare and Medicaid beneficiaries. SAC ¶¶ 3, 10, 15, 30. 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. ¶¶ 25–28. Teaching hospitals like MGH are therefore not typically reimbursed under Medicare Part B for services that residents and fellows provide. Id. ¶¶ 31, 34. They may, however, seek payment under Medicare Part B and Medicaid for services provided by the teaching physicians charged with training the residents and fellows and who supervise services that residents and fellows provide. Id. ¶¶ 29, 35–36.

Wollman alleges that Defendants fraudulently billed Medicare and Medicaid for overlapping and concurrent surgeries in which a teaching physician performed two or three surgical procedures that required patients to be under anesthesia at the same time. Specifically, Wollman asserts that, in violation of applicable regulations promulgated by the Centers for Medicare and Medicaid Services ("CMS"), teaching surgeons in MGH's Orthopaedic Surgery Department routinely left patients who were undergoing surgery alone with residents and fellows in order to conduct concurrently scheduled surgeries, and that they did so without identifying another qualified teaching physician who would be immediately available in the event of an emergency and without keeping proper records. Id. ¶ 1. Wollman also asserts that this practice resulted in patients being under anesthesia for extended, medically unnecessary periods. Id. Additionally, Wollman claims that Defendants concealed the fact of concurrently scheduled surgeries from patients and failed to obtain patients' "informed consent" for the

inadequately supervised role that residents and fellows played. Id.

A. Procedural History

Under the FCA and the MFCA, the Attorney General or a private party may initiate a lawsuit alleging fraud on the government. 31 U.S.C. § 3730(a)–(b); Mass. Gen. Laws ch. 12, § 5C(1)–(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, 129 S.Ct. 2230, 173 L.Ed.2d 1255 (2009) (quoting Vt. Agency of Nat. Res. v. United States ex rel. Stevens, 529 U.S. 765, 769, 120 S.Ct. 1858, 146 L.Ed.2d 836 (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." ***180** 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), overruled in part as 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, Wollman filed the initial complaint in this action under seal. [ECF No. 1]. After several requests from the government for extensions of time to continue its investigation, on February 17, 2017, 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, Wollman filed her First Amended Complaint. [ECF No. 31]. Wollman's First Amended Complaint provided the surgery type, start time, and surgery duration for forty-six surgeries that occurred on sixteen different dates between July 2011 and March 2013. [ECF No. 31 ¶ 74]. Nearly all of the forty-six surgeries started at nearly the same time or substantially overlapped with one or two of the other listed surgeries. See id. Wollman also alleged that at least one of the patients who underwent each pair or trio of the concurrent or overlapping surgeries was eligible for Medicare. See id. ¶ 75. Although it asserted that claims for eligible patients had been submitted to Medicare and/or Medicaid, the First Amended Complaint lacked details establishing that the asserted claims had actually been submitted and paid. On March 30, 2018, following consideration of Defendants' motion to dismiss and Wollman's opposition, the Court dismissed the First Amended Complaint because although it "describe[d] an allegedly illegal 'scheme,' [it] only refer[ed] to specific false claims in the most conclusory terms." United States ex rel. Wollman, 2018 WL 1586027, at *6. In essence, Wollman's allegations had not identified the false claims for payment that had been submitted to the government, including the "who, what, when, where, and how" required by Federal Rule

of Civil Procedure 9(b). [ECF No. 65 at 13–16, 20–21]; see also United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 232 (1st Cir. 2004) ("pleadings invariably are inadequate 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"), abrogated on other grounds by Allison Engine Co., Inc. v. United States ex rel. Sanders, 553 U.S. 662, 128 S.Ct. 2123, 170 L.Ed.2d 1030 (2008).

On August 13, 2018, Wollman filed her Second Amended Complaint. [ECF No. 89]. The Second Amended Complaint is largely the same as the First Amended Complaint, except that Wollman has added specifics about several of the allegedly fraudulent claims that were submitted to the government for payment. See SAC ¶¶ 71, 73–78, 83. For eleven of the forty-six patients whose overlapping or concurrent surgeries are listed as examples to show that applicable regulations and rules were violated, Wollman now provides specifics for the claims that were submitted to Medicare or Medicaid, including services billed for, physician name, the billing provider, ***181** the amount billed, and the amount paid by the patient and government payor. Id. ¶ 83 nn.36–46, Exs. A, B. The specifics of these claims have been redacted and/or filed under seal to protect patient and provider privacy. Id.

Counts I and V allege violations of the FCA and MFCA, 31 U.S.C. § 3729(a)(1); Mass. Gen. Laws ch. 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. SAC ¶¶ 150–58, 168–71. Counts II and VI allege violations of the FCA and MFCA, 31 U.S.C. § 3729(a)(1)(B); Mass. Gen. Laws ch. 12, § 5B(a)(2), for knowing use of false records or statements that caused false claims to be paid by the government. SAC ¶¶ 155–58, 173–77. Counts III and VII allege violations of the FCA and MFCA, 31 U.S.C. § 3729(a)(1)(C); Mass. Gen. Laws ch. 12, § 5B(a)(3), for conspiracy to defraud the government. SAC ¶¶ 159–63, 178–82. Lastly, Counts IV and VIII allege violations of the FCA and MFCA, 31 U.S.C. § 3729(a)(1)(G); Mass. Gen. Laws ch. 12, § 5B(a)(9), for knowingly making false statements that were material to an obligation to pay money to the government. SAC ¶¶ 164–67, 183–86. Defendants move to dismiss all counts for failure to meet the heightened pleading standard required by Federal Rule of Civil Procedure 9(b) and for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6). [ECF No. 91].

B. Medicare and Medicaid Rules and Regulations

Wollman alleges violations of rules and regulations for Medicare and Medicaid reimbursement covering: (1) billing and record-keeping for overlapping and concurrent surgeries; (2) billing for the administration of anesthesia; and (3) informed consent.

1. Billing and Record-Keeping for Overlapping and Concurrent Surgeries

To receive Medicare payments for services performed by a teaching physician, the services must either be either (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 in certain specified situations. See 42 C.F.R. §§ 415.170, 415.172; SAC ¶ 42. 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); SAC ¶ 43. "In the case of surgical, high-risk, or other 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); SAC ¶ 44. 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." CMS, Medicare Claims Processing Manual: Chapter 12 – Phyisicans/Nonphyiscian Practitioners, 158–59 (2017) ("CMS Manual") ("[T]he critical or key portions [of overlapping surgeries] may not take place at the same time."), 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.").

"When a teaching physician is not present during non-critical or non-key portions of the procedure and is participating in ***182** another surgical procedure, [he or she] must arrange for another qualified surgeon to immediately assist the resident ... should the need arise." CMS Manual at 159; see SAC ¶ 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 159; SAC ¶ 52. No reimbursement is available for triple-booked surgeries. CMS Manual at 159 ("In the case of three concurrent surgical procedures, the role of the teaching surgeon ... in each of the cases is classified as a supervisory service to the hospital rather than a physician service to an individual patient and is not payable under the physician fee schedule."); SAC ¶ 49. [3]

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. MGH submits claims to Medicare using Form 1500 provided by the CMS, which administers Medicare. See SAC ¶¶ 30–33, 41. By completing a Form 1500, MGH certifies that the information on the form is true, accurate and complete, that the claim complies with all applicable Medicare rules and regulations for payment, and that the services provided were medically necessary. Id. ¶ 41. [4]

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 120; SAC ¶ 60. 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 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 120; SAC ¶ 60. As 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), unnecessarily prolonged administrations of anesthesia are not reimbursable.

3. Informed Consent

Hospitals are required to obtain Medicare and Medicaid beneficiaries' informed ***183** consent for the services provided to them in order to be reimbursed. SAC ¶¶ 63–65; see 42 C.F.R. § 482.13(b)(1)–(2) (stating that 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(b)(2) (stating that condition of participation includes "a properly executed informed consent form for the operation" being completed before surgery.); CMS, State Operations Manual: Appendix A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals, 3 (2017), https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf (requiring hospitals to be "in compliance with the Federal requirements set forth in the Medicare Conditions of Participation [ ] in order to receive Medicare/Medicaid payment."). CMS's guidelines further provide that a "well-designed informed 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), https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/downloads/scletter07-17.pdf.

C. Relator's Allegations

Wollman contends that Defendants violated the Medicare and Medicaid billing standards for overlapping and concurrent surgeries, reasonable and necessary administration of anesthesia, and adequate informed consent. 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 Orthopaedic Surgery. SAC ¶ 68. She witnessed the department's practice of scheduling overlapping and concurrent surgeries that required residents and fellows to conduct some or all of the surgery outside the presence of a teaching physician, but she never saw a double-booked surgeon designate another teaching physician to be immediately available while he or she was involved in another ongoing procedure. Id. ¶¶ 68–71, 88.

Orthopedic surgeons at MGH regularly scheduled two surgeries concurrently in the morning and in the afternoon of the same day. Id. ¶¶ 68–69. As examples, Wollman has provided the date, surgeon, scheduled start time, location, duration, and surgery type for overlapping surgeries that occurred on sixteen different dates between July 2011 and March 2013 and were performed by one of five named surgeons. Id. ¶ 83. In each of these overlapping surgeries, at least one of the patients involved was Medicare-eligible. Id. ¶ 84. The time periods during

which the patients were under anesthesia was unnecessarily extended by the concurrent and overlapping scheduling practices. See id. ¶¶ 73, 76, 78–79, 83, 95–96, 101.

Wollman has also provided information on the claims submitted to Medicare and Medicaid associated with procedures performed on eleven of the patients who received the overlapping surgeries, including the amount billed, amount paid, dates of the claims, the physicians listed, and the descriptions of the services billed for. Id. ¶¶ 75–78, 83 nn.36–46. Although the surgeons who performed concurrent surgeries were rendered unavailable whenever performing the other concurrently scheduled surgery and were therefore required to designate another qualified surgeon to assist should the need have arisen, qualified alternative surgeons were never designated. Id. ¶¶ 115–17, 123. Additionally, MGH surgeons generally did not record the ***184** number of physicians involved in cases, which procedures they deemed "key and critical," the time at which they entered and exited the surgery room, whether they were available to return if necessary, and whether another surgery was being conducted at the same time. See id. ¶ 115; cf. 42 C.F.R. § 415.172(b) ("[M]edical records must document the teaching physician was present at the time the service is furnished."). This overly limited record-keeping was itself a violation of applicable billing rules and helped conceal the arguably more serious and more dangerous violations of concurrent surgery billing rules meant to ensure the safety of patients by requiring that a qualified teaching physician be available to assist. See 42 C.F.R. § 415.172(b).

Wollman alleges that Defendants' "informed consent" forms and practices also provided inadequate information to patients scheduled for concurrent or overlapping surgeries. See SAC ¶¶ 63–65, 102–14, 123.[5] Most patients who were scheduled for such surgeries were not told that their attending physician would be attending to another patient while their surgery was ongoing, and Wollman claims that MGH concealed the fact of concurrent surgeries from patients by intentionally placing patients who were scheduled to be operated on by the same doctor at the same time in different rooms for their pre-operative phase. Id. ¶¶ 107–08.

Wollman first raised concerns about MGH's concurrent surgery practices with 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 surgery in which that same surgeon was seeing patients in another building on MGH's campus while his overlapping surgery patients, one of whom was sedated, waited for his arrival. Id. ¶¶ 119–21.[6] The former chairman and chief executive officer of MGPO told Wollman that MGH had begun an internal investigation of MGH's concurrent surgery practices. Id. ¶ 121. The investigation concluded in the spring of 2012 but resulted in minimal changes to MGH's practices. Id. ¶ 124. When Wollman 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, she was told that she had violated the privacy rights of patients and that MGH could take disciplinary action against her. Id. ¶ 98. After reporting to her MGH supervisors that the same surgeon tripled-

booked concurrent surgeries in June 2012, Wollman was prohibited from working on cases with that surgeon. Id. ¶¶ 125–26.

*185 II. 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)–(B). 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, —— U.S. ——, 136 S. Ct. 1989, 1996, 195 L.Ed.2d 348 (2016) ("Escobar II")). 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 II, 136 S. Ct. at 1996 (quoting 31 U.S.C. § 3729(b)(1)(A)). "[A] misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the False Claims Act." Id. at 2002. 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. at 1996 (quoting 31 U.S.C. § 3729(b)(4)).

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. 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. (first quoting Fed. R. Civ. P. 8(a)(2), then quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (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, 129 S.Ct. 1937, 173 L.Ed.2d 868 (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, 129 S.Ct. 1937). "[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 (citing Grajales, 682 F.3d at 45). 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 ***186** alleged.' " Id. (quoting Morales-Cruz, 676 F.3d at 224).

B. Rule 9(b) Heightened Pleading Standard

Wollman 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 II, 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." Karvelas, 360 F.3d at 226 (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 subject to limited exceptions. United States ex rel. Nargol v. DePuy Orthopaedics, Inc., 865 F.3d 29, 38 (1st Cir. 2017) (citing Foglia v. Renal Ventures Mgmt., LLC, 754 F.3d 153, 155–56 (3d Cir. 2014)), cert. denied sub nom. Med. Device Bus. Servs., Inc. v. U.S. ex rel. Nargol, —— U.S. ——, 138 S. Ct. 1551, 200 L.Ed.2d 770 (2018).

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 cases that allege a direct violation of the FCA, "the defendant's presentation of false or fraudulent claims to the government is a central element." Karvelas, 360 F.3d at 232; see also Guilfoile v. Shields, 913 F.3d 178, 188 (1st Cir. 2019) (distinguishing FCA retaliation claims from "direct" claims for violations of the FCA, and holding that pleading an FCA retaliation claim does not require adequately pleading the submission of a false claim or otherwise meeting the Rule 9(b) standards for pleading fraud).[7] 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." Karvelas, 360 F.3d at 232. "[W]rongful ***187** 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. (quoting Fed. R. Civ. P. 9(b)).

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The relator therefore "must provide details that identify particular false claims for payment that were submitted to the government." Id. "[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 the defendant's alleged misconduct.' " United States ex rel. Ge v. Takeda Pharm. Co., 737 F.3d 116, 124 (1st Cir. 2013) (emphasis in original) (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 226, 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.

***188 C. Analysis**

Defendants make four arguments as to why this case should be dismissed. First, they assert that Wollman has not pled fraud with the particularity required by Federal Rule of Civil Procedure 9(b). [ECF No. 92 at 6–10]. Second, Defendants argue that Wollman has not alleged violations of billing rules related to concurrent or overlapping surgeries, unnecessary anesthesia, or inadequate informed consent. Id. at 10–13, 17–19. Third, Defendants assert that even if their practices violated CMS rules, such violations were not material to payment. Id. at 5–6, 14–19. Fourth, Defendants claim that Wollman has not adequately plead scienter. Id. at 19–20. For the reasons explained below, the Court finds these arguments unavailing.

Wollman has pled fraud with sufficient particularity. As in Karvelas, 360 F.3d 220, Wollman 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. SAC ¶ 14. 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. E.g. id. ¶¶ 83, 97. As discussed further infra, Wollman has plausibly alleged that many of the surgeries that she provides detailed claim records for were conducted in violation of billing rules. Unlike Karvelas, where the relator provided "no identification numbers or amounts charged in individual claims for specific ... services," Karvelas, 360 F.3d at 233, Wollman has provided specific dates, identification numbers, amounts billed, services, individuals involved, and amounts paid for several claims that relate to improperly conducted overlapping and concurrent surgeries.[8] The examples of fraudulent claims in Wollman's Second Amended Complaint are sufficiently particular to satisfy Rule 9(b). See Gagne 565 F.3d at 45 (holding that Rule 9(b) may be satisfied "where, although some questions remain unanswered, the complaint as a whole is sufficiently particular to pass muster under the FCA"); Karvelas, 360 F.3d at 233 (requiring "some of this information for at least some of the claims must be [pled] in order to satisfy Rule 9(b)"); United States ex rel. Westmoreland v. Amgen, Inc., 738 F. Supp. 2d 267, 276 (D. Mass. 2010) ("pleading every instance of fraud would be extremely ungainly, if not impossible" (quoting United States ex rel. Franklin v. Parke-Davis, 147 F. Supp. 2d 39, 49 (D. Mass. 2001))).

Wollman has pled facts that, taken as true, show that the example claims at issue were false. See ***189** Guilfoile, 913 F.3d at 188. She has documented more than ten pairs or trios of surgeries that were carried out in violation of the rules governing concurrent or overlapping surgeries. See SAC ¶¶ 1,3 6, 7, 73–84, 118–25. Further, she asserts that the surgeons involved failed to designate a qualified teaching physician who would be able to assist when the primary surgeon was

absent and unavailable, that these practices resulted in unnecessarily prolonged anesthesia, that MGH used a relatively non-descript informed consent form and routinely took other affirmative steps to conceal the practice of concurrent and overlapping surgeries from patients that resulted in a lack of informed consent, and that surgeons falsified or failed to keep accurate records to conceal their practices. Id. ¶¶ 1, 3, 6–8, 73–83, 102–09, 115–38. Finally, Wollman's assertions imply that Defendants falsely certified compliance with the applicable regulations and billing rules when they submitted claims to Medicare and Medicaid. See id. ¶ 41. Taken as true, these allegations show that Defendants violated the billing rules discussed supra at Section I.A and submitted claims to Medicare and Medicaid that falsely asserted that the services provided complied with applicable regulations and rules. [9]

Wollman has also plausibly alleged that these violations of regulations and billing rules were, at least in conjunction with each other, material to the government's decision to pay Defendants' claims. The materiality analysis requires a "holistic approach" that considers three non-dispositive factors: (1) whether regulatory compliance was a condition of payment; (2) the centrality of the relevant requirements in the regulatory program; and (3) whether the government paid out on particular claims despite actual knowledge that the supposedly material requirements had been violated. See United States ex rel. Escobar v. Universal Health Servs., Inc., 842 F.3d 103, 110 (1st Cir. 2016) ("Escobar III"). Here, Defendants allegedly engaged in a scheme that allowed them to collect for services provided by residents and fellows outside the presence of a teaching physician, which violated a "condition[ ] for payment." 42 C.F.R. § 415.170; SAC ¶ 42. They also collected for concurrent and overlapping surgeries that violated CMS rules by deceiving the government and beneficiaries through noncompliant record-keeping, under-descriptive informed consent forms, and active concealment of concurrent surgeries. Although the billing requirements may not be among the most central to the Medicare and Medicaid programs overall, they are sufficiently central to the payment scheme for concurrent and overlapping surgeries to have received congressional attention ***190** and expressions of concern over noncompliance. See Staff of S. Comm. On Fin., 14th Cong., Concurrent and Overlapping Surgeries: Additional Measures Warranted (Dec. 6, 2016), https://www.finance.senate.gov/imo/media/doc/Concurrent% 20Surgeries% 20Report% 20FINAL% 20.pdf ("Senate Staff Report"). Additionally, accepting the allegations in the Second Amended Complaint and drawing reasonable inferences in Wollman's favor, Defendants' noncompliance with the billing rules cannot reasonably be described as "minor or insubstantial," and there is no evidence from which the Court can infer that the government was aware of the violations at issue. See Escobar II, 136 S. Ct. at 2003. [10] Wollman has adequately alleged materiality at this stage of the proceedings considering the billing requirements, their importance to the regulatory program, and the lack of clear evidence showing the non-materiality of the violations alleged. See United States ex rel. Scutellaro v. Capitol Supply, Inc., No. 10-cv-1094, 2017 WL 1422364, at *21 (D.D.C.

Apr. 19, 2017) (denying motion for summary judgment on materiality grounds despite "mixed signals" from government officials about the strength of company's compliance with disclosure requirements concerning the geographic origin of its products).

Wollman has also adequately pled scienter. "Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). The FCA prohibits "knowingly" presenting a false or fraudulent claim, or making, using, or causing a false record or statement to be made that is material to a false or fraudulent claim. 31 U.S.C. § 3729(a)(1)(A)–(B). "Knowingly" includes acting in deliberate ignorance of the truth or falsity of relevant information or reckless disregard of the truth or falsity of the information, and "require[s] no proof of specific intent to defraud." 31 U.S.C. § 3729(b)(1). To the extent that Wollman is required to plead scienter, she has adequately done so by identifying specific allegedly false claims and alleging a broader scheme to defraud Medicare and Medicaid that was supported by active concealment of concurrent surgeries from patients and intentionally restricted record-keeping practices designed to avoid government detection. SAC ¶¶ 3, 6–81 87–88. She has also described a reaction to internal allegations of non-compliance that, construed in the light most favorable to Wollman, suggests a deliberate indifference and reckless disregard for the trust or falsity of the alleged non-compliance with applicable regulations and rules. Id. ¶¶ 78–82, 118–34. Although Defendants correctly point out that certain of the regulatory requirements leave some determinations to the discretion of surgeons, such as what portions of surgeries are "key," e.g. 42 C.F.R. § 415.172(a) (requiring "teaching physician [to be] present during the *key portion* of any service or procedure for which payment is sought"); 130 Mass. Code Regs. 450.275 (requiring "medical record [to] clearly substantiate[ ] that the *key portions* of the services [were] personally provided by a teaching physician"), discovery ***191** is needed to determine whether Defendants' surgery scheduling, record-keeping, and informed consent practices were part of a good-faith effort to fully comply with a less than perfect regulatory regime or reflect a more sinister motive.

III. CONCLUSION

Accordingly, Defendants' motion to dismiss for failure to state a claim [ECF No. 91] is DENIED.

SO ORDERED.

All Citations

394 F.Supp.3d 174, Med & Med GD (CCH) P 306,533

Footnotes

1 " '*Qui tam*' is an abbreviation for '*qui tam pro domino rege quam pro seipso*,' which literally means "he who as much for the king as for himself. *Qui tam* provisions, which historically have allowed parties to initiate suit on the government's behalf and to share in the recovery as bounty, first gained popularity in thirteenth-century England as a supplement to ineffective law enforcement." United States ex rel. S. Prawer & Co. v. Fleet Bank of Me., 24 F.3d 320, 324 n.7 (1st Cir. 1994) (citations omitted).

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2 MGPO is a private corporation that was involved in billing for medical services and paying staff members at MGH, and Partners is a nonprofit corporation that oversaw the medical residency programs at MGH. [ECF No. 89 ("Second Amended Complaint" or "SAC") ¶¶ 16–17].

3 The standard for seeking reimbursement for overlapping surgeries is substantially the same under the Massachusetts Medicaid program. SAC ¶¶ 55–59. 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 Mass. Code Regs. 450.275(D)(4); SAC ¶ 56. 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." 130 Mass. Code Regs. 450.275(D)(4)(a); SAC ¶ 58. Because the teaching physician must be present during the key portions of both operations, the "key portions must not occur simultaneously." 130 Mass. Code Regs. 450.275(D)(4)(a). 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).

4 See CMS Form 1500 at 2, https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf ("I certify that ... this claim, whether submitted by me or on my behalf by my designated billing company, complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment....").

5 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." SAC ¶ 104. 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. ¶ 106.

6 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. SAC ¶¶ 118, 128–35.

7 The First Circuit has "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." United States ex rel. Nargol v. DePuy Orthopaedics, Inc., 865 F.3d 29, 39 (1st Cir. 2017). There is "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." United States ex rel. Duxbury v. Ortho Biotech Prods., L.P., 579 F.3d 13, 29 (citing United States ex rel. Rost v. Pfizer, Inc., 507 F.3d 720, 732 (1st Cir. 2007)). A "more flexible" standard of particularity applies to the latter category. Id. at 30 (citing United States ex rel. Gagne v. City of Worcester, 565 F.3d 40, 46 (1st Cir. 2009)); Rost, 507 F.3d at 731-32. 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).

8 Cf. United States ex rel. Gagne v. City of Worcester, 565 F.3d 40, 47 (1st Cir. 2009) (finding that particularity standard was 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"); United States ex rel. Verrinder v. Wal-Mart Corp., No. 13-cv-11147, 2016 WL 3460310, at *6 (D. Mass. June 21, 2016) (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-cv-11680, 2008 WL 728939, at *3 (D. Mass. Mar. 18, 2008) (finding 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 governmental agency at any time").

9 Defendants correctly assert that a physician is permitted to bill Medicare for an overlapping surgery where the physician (i) is "present for ... the critical or key portions of both surgeries (and those portions of the initial surgery must be complete before the physician becomes involved in the second surgery); (ii) document[s] in the medical record the teaching

physician's presence during these critical or key portions of both procedures; and (iii) when the teaching surgeon is not present, arrange[s] for a qualified surgeon to immediately assist should the need arise." [ECF No. 92 at 5 (citing 42 C.F.R. § 415.172(a))]. Wollman plausibly asserts that these rules, among others, were violated by documenting numerous simultaneously scheduled surgeries that included at least one surgery for which a government payor was billed, by alleging that surgeons never designated alternative qualified surgeons to be immediately available should a need arise, by stating that she witnessed surgeons engaged in surgery while another of their patients was undergoing surgery elsewhere, and by providing details about the claims that were submitted for reimbursement from and paid by the government that are consistent with her assertions.

10 Defendants argue that the violations of billing rules were not material because the government pays claims for overlapping surgeries that comply with the billing rules and because the December 2016 Senate Staff Report stated that CMS did not plan to change the rules for concurrent surgeries. [ECF No. 92 at 17]. The surgeries at issue here, however, allegedly did not comply with the current CMS billing rules. Further, the Senate Staff Report found CMS had "never undertaken a study to determine whether the surgical procedures Medicare paid for met CMS's billing requirements specific to overlapping surgeries performed in teaching hospitals," which suggests that CMS was not aware of the scope of billing violations at MGH or elsewhere. Senate Staff Report at 6.

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