UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
NORTHERN DIVISION
AT ASHLAND

CIVIL ACTION NO. 16-148-DLB-EBA

UNITED STATES OF AMERICA
***ex rel.* ROBERT C. O'LAUGHLIN, M.D.** **PLAINTIFF**

v. **MEMORANDUM OPINION AND ORDER**

RADIATION THERAPY SERVICES, P.S.C., et al. **DEFENDANTS**

* * * * * * * * * * * * * * * *

This matter is before the Court on Defendants' Motion to Dismiss the Third Amended Complaint. (Doc. # 125). The Motion has been fully briefed and is now ripe for the Court's review. (Docs. # 131 and 135). Defendants' Motion to Stay Discovery (Doc. # 126) is also pending. For the reasons stated herein, Defendants' Motion to Dismiss is **granted in part and denied in part** and the Motion to Stay Discovery is **denied**.

I. FACTUAL AND PROCEDURAL BACKGROUND

This matter has a convoluted and lengthy procedural history. For the sake of brevity, the facts in this matter have been previously described, in detail, in this Court's October 20, 2020 Order ("2020 Order"). (Doc. # 76 at 1-5). By way of quick summary, Relator, Robert O'Laughlin, M.D. brings this *qui tam* action on behalf of the United States under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733, based on Defendants' allegedly fraudulent misrepresentations to Medicare, Medicaid, and other federal

programs regarding radiation oncology and chemotherapy services they provided. (Doc. # 124 at 1-2).

Relator O'Laughlin initiated this lawsuit on December 7, 2016. (Doc. # 1). Following a prior Joint Motion to Dismiss (Doc. # 50), Relator filed an Amended Complaint (Doc. # 53). Following this Court's Order addressing that motion to dismiss, Relator filed a Second Amended Complaint which also faced a second motion to dismiss. (Docs. # 91 and 95). After holding a hearing on the matter, the Court allowed Relator to file a Third Amended Complaint which rendered the second motion to dismiss moot. (Docs. # 123 and 124).

Defendants have now filed the instant Motion to Dismiss the Third Amended Complaint. (Doc. # 125). The Third Amended Complaint essentially alleges the same counts as its previous iterations. Counts I, III, V, and VII are related to four separate "false presentment" claims under 31 U.S.C. § 3729(a)(1)(A), which prohibits "knowingly present[ing], or caus[ing] to be presented, a false or fraudulent claim for payment or approval." (Doc. # 124 ¶¶ 47-68, 76-110, 118-163 and 171-189). Counts II, IV and VI allege false records claims under 31 U.S.C. § 3729(a)(1)(B), which prohibits "knowingly mak[ing], us[ing], or caus[ing] to be made or used, a false record or statement material to a false or fraudulent claim." (*Id.* ¶¶ 69-75, 111-117, and 164-170). Lastly, O'Laughlin alleges a conspiracy claim pursuant to 31 U.S.C. § 3729(a)(1)(C). (*Id.* ¶¶ 190-195).

II. ANALYSIS

A. Standard of Review

To survive a motion to dismiss, a complaint alleging FCA violations must comply with the heightened pleading standard of Federal Rule of Civil Procedure 9(b). *United*

States ex rel. Prather v. Brookdale Senior Living Cmtys., Inc., 838 F.3d 750, 760 (6th Cir. 2016). Under Rule 9(b), "a party must state with particularity the circumstances constituting fraud." At a minimum, a relator must allege the who, what, when, where, and how of the alleged fraud. *Sanderson v. HCA-The Healthcare Co.*, 447 F.3d 873, 877 (6th Cir. 2006). More specifically, courts have consistently noted that the particularity requirement under Rule 9(b) necessitates that the plaintiff sufficiently allege "(1) the time, place, and content of the alleged misrepresentation, (2) the fraudulent scheme, (3) the defendant's fraudulent intent, and (4) the resulting injury." *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 467 (6th Cir. 2011) (internal quotations and citations omitted). This aligns with the purpose of Rule 9(b) which "is to alert defendants as to the particulars of their alleged misconduct so that they may respond." *Id.* at 466 (citation omitted).

However, Rule 9(b) should not be read to "reintroduce formalities to pleading." *United States ex rel. Sheldon v. Kettering Health Network*, 816 F.3d 399, 408 (6th Cir. 2016) (internal quotations omitted). "Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." *Chesbrough*, 655 F.3d at 466 (quoting Fed. R. Civ. P. 9(b)). "In the *qui tam* context, 'the Court must construe the complaint in the light most favorable to the plaintiff, accept all factual allegations as true, and determine whether the complaint contains enough facts to state a claim to relief that is plausible on its face.'" *United States ex rel. Ibanez v. Bristol-Myers Squibb Co.*, 874 F.3d 905, 914 (6th Cir. 2017) (quoting *U.S. ex rel. SNAPP, Inc. v. Ford Motor Co.*, 532 F.3d 496, 502 (6th Cir. 2008)). Still, that does not obligate the Court to "accept claims that consist of no more than mere assertions and unsupported or unsupportable conclusions." *Sanderson*, 447 F.3d at 876 (citing *Kottmyer v. Maas*, 436 F.3d 684, 688 (6th Cir. 2006)).

B. Rule 9(b)

The Court notes that O'Laughlin has sufficiently pled what is required under Rule 9(b) as a matter of fact, that is "(1) the time, place, and content of the alleged misrepresentation, (2) the fraudulent scheme, (3) the defendant's fraudulent intent, and (4) the resulting injury." *Chesbrough*, 655 F.3d at 467. O'Laughlin provides very detailed factual allegations regarding the false presentment claims against Defendants in the form of tables outlining each patient's date of service, type of service, service billing code, the amount billed, the amount paid, and the date of payment. (Doc. # 124 ¶¶ 55, 58, 61, 86, 90, 94, 98, 102, 127, 135, 143, 151, 181, and 182). The false records claims piggyback off the false presentment claims as they essentially allege that Defendants knew these services were not provided in accordance with Medicare billing requirements and submitted them for reimbursement anyway.

O'Laughlin also generally alleges Defendants' scheme and intent of "scrubbing" insurance claims to guarantee they would pass review by insurance carriers. (*Id.* ¶ 40). Consequently, O'Laughlin alleges the resulting injury is the United States either paying out claims that it should not have or overpaying claims for services provided by employees other than qualified physicians. (*Id.* ¶ 66-68, 74-75, 109-110, 116-117, 149, 156, 162-163, 169-170, 188-189, and 194-195). These alleged facts are specific enough to alert Defendants to their so-called misconduct, even the specificity of the parties' briefing[1] leads this Court to believe that Defendants are sufficiently on notice of the specifics of the

[1] At this point, the parties have briefed the same or similar arguments three times. Defendants have not argued that the factual nature of the allegations is ambiguous, rather that the allegations do not constitute fraud. Therefore, Defendants do not have an issue with the factual particularity of the allegations, rather they take issue with the categorization of those actions as fraud.

allegations in the Third Amended Complaint. *Chesbrough*, 655 F.3d at 467, 470; *Ibanez*, 874 F.3d at 914 (noting that the allegations in the complaint should be viewed in the light most favorable to the plaintiff). Thus, the Court holds that O'Laughlin has satisfactorily pled the who, what, when, where, and how of the alleged fraud. *Sanderson*, 447 F.3d at 877. Yet, the parties focus their disagreement on whether Defendants' actions constituted fraud.

C. False Presentment and False Records Claims

The Medicare Program is administered by the Department of Health and Human Services through the Centers for Medicare and Medicaid Services ("CMS"). Medicare Part A covers hospital insurance for the elderly and disabled. Medicare Part B covers doctors' services and outpatient care. CMS reimburses Medicare claims through private insurance carriers who administer and pay claims as fiscal intermediaries. As discussed in the Court's 2020 Order, the FCA imposes liability on a person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." (Doc. # 76 at 6) (quoting 31 U.S.C. § 3729(a)(1)(A)). While the FCA provides the cause of action, relevant Medicare statutes and regulations define the requirements for submitted claims and form the basis of much of the dispute here as to the radiological and chemotherapy services provided by Defendants.[2]

As previously explained by the Court, a false certification theory is one possible way to allege a fraudulent claim under the FCA because "liability can attach if the claimant

[2] For example, Medicare Part B covers physician services, such as diagnosis, therapy, surgery, and consultations that are "reasonable and necessary." 42 U.S.C. §§ 1395x(q) and 1395y(a)(1)(A); 42 C.F.R. § 410.20(a); 42 C.F.R. § 410.35 (noting that radiation therapy services are covered under Medicare Part B).

violates its continuing duty to comply with the regulations on which payment is conditioned." *See Chesbrough*, 655 F.3d at 468; (Doc. # 76 at 6-7). To adequately allege a false certification claim, the Sixth Circuit has held that a relator must establish that defendants made a claim for payment that expressly stated that it complies with a particular statute, regulation, or contractual term that is a prerequisite for payment. *Sheldon*, 816 F.3d at 408 (internal quotation marks omitted).

Therefore, O'Laughlin must allege that compliance with the relevant regulation or law was a precondition of payment, in other words "that compliance with the standard was required to obtain payment." *Chesbrough*, 655 F.3d at 468. In analyzing a false certification theory, the Court "do[es] not look to the claimant's actual statements; rather, the analysis focuses on 'the underlying contracts, statutes, or regulations themselves to ascertain whether they make compliance a prerequisite to the government's payment.'" *U.S. ex rel. Hobbs v. MedQuest Assocs., Inc.*, 711 F.3d 707, 714 (6th Cir. 2013) (quoting *United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1218 (10th Cir. 2008)). Here, the parties dispute the relevant regulations, standards, and what constitutes a precondition of payment.

1. Counts I and II

Count I alleges that Defendants fraudulently billed for services provided by O'Laughlin during his employment with Defendants' treatment centers. (Doc. # 124 ¶¶ 49-50). Count II alleges false records claims related to the allegations in Count I. (*Id.* ¶¶ 69-70). Defendants argue that Counts I and II of the Third Amended Complaint should be dismissed because O'Laughlin provides no support for his allegation that the relevant services had to be performed by a "qualified radiation oncologist." (Doc. # 125 at 14).

Defendants further that O'Laughlin's allegation is essentially an attempt to revive his previously failed argument—that this Court rejected in its 2020 Order—that a radiation oncologist must be present to supervise radiation treatment. (*Id.*). Then, Defendants argue that O'Laughlin's allegation that a qualified radiation oncologist must review and approve guidance images prior to each daily treatment within 24 hours or prior to the next treatment delivery is also unsupported. (*Id.* at 15). To counter O'Laughlin's assertion, Defendants cite to an American Society of Radiation Oncology ("ASTRO") article that discusses the various roles and requirements of a radiology practice such as Defendants. (*Id.* at 16) (citing Doc. # 66-1).

In his Response, O'Laughlin answers that Defendants billed for both professional and technical components of services but that no qualified physician provided the professional component. (Doc. # 131 at 15). O'Laughlin seemingly posits that the professional component *must* be conducted by a radiologist or a radiation oncologist. (*Id.* at 15-17). As pointed out by Defendants, the Medicare Claims Processing Manual provides that claims must be paid for professional components of services furnished "by a physician to an individual patient in all settings under the fee schedule . . . *regardless of the specialty of the physician who performs the service*." (Doc. # 135 at 3); Medicare Claims Processing Manual, Ch. 13, § 20.1 (emphasis added). The Court agrees that O'Laughlin has failed to establish that the specific services had to be performed by a radiation oncologist instead of any physician. Moreover, Defendants are correct that this Court's 2020 Order rejected the idea that a radiation oncologist had to perform the relevant services instead of any physician, regardless of specialty. (Doc. # 76 at 10).

Second, O'Laughlin does not address Defendants' argument regarding ASTRO's guidance on review of images and provides no sources to the contrary. Indeed, ASTRO's guidance indicates that it is *recommended* that patient charts and images should be reviewed weekly, not that it is required prior to every treatment. (Doc. # 66-1 at 12). Since O'Laughlin's argument has been rejected previously by the Court and he has still failed to allege that the lack of a radiation oncologist's performance of services is a material precondition of payment, Counts I and II are hereby **dismissed**.

2. Counts III and IV

Count III alleges that Defendants submitted claims that certified physicians were present in the facilities where the services were rendered when they were actually not present. (Doc. # 124 ¶ 78). Count IV pleads a related false statement claim based upon the same allegations as Count III. (*Id.* ¶ 111). At the heart of these allegations is the claim that no physician provided the services described in the billing codes, no physician supervised the provision of the services, and no physician was on the premises at the time. (Doc. # 124 ¶¶ 79-80). Defendants retort that only two of the billing codes alleged represent a service with any professional component. (Docs. # 125 at 19-20 and 135 at 5-7). O'Laughlin simply responds, in four sentences, that the Third Amended Complaint corrects the deficiency the Court articulated in its 2020 Order by alleging that no physician performed the billed-for services nor was on the premises, as opposed to only the specific named physician on the insurance claim. (Doc. # 131 at 17).

Unfortunately for O'Laughlin, he fails to provide any relevant regulations or federal law that support his argument; instead, he simply alleges that "these false statements were material and pre-conditions of payment from the Medicare and Medicaid programs."

(*Id.*). O'Laughlin has been given several opportunities to amend his complaint, so the Court will not accept bare-bones assertions as adequate to state a claim. *Sanderson*, 447 F.3d at 876. Moreover, Defendants argue that the only two codes listed in these counts with professional components need not be performed on the premises since they require the interpretation of radiological procedures; O'Laughlin offers no response to these arguments. (Doc. # 125 at 20); *see Conrad v. U.S. Bank Nat'l Ass'n*, 391 F. Supp. 3d 780, 791-92 (S.D. Ohio 2019) (noting that because plaintiff did not respond in any way to defendants' argument that a claim should be dismissed, plaintiff concedes the point and waives opposition to dismissal). O'Laughlin has likewise waived his opposition to dismissal of these counts by failing to respond to Defendants' argument. Accordingly, Counts III and IV are **dismissed**.

3. Counts V and VI

Count V alleges that Medicare pays only 85% of the physician rate of a service performed by a physician's assistant or a nurse practitioner. (Doc. # 124 ¶ 119). O'Laughlin further alleges that Defendants billed for chemotherapy services as if they were provided by a physician, when in fact they were neither provided by nor directly or personally supervised by a physician. (*Id.* ¶ 121). Count VI pleads a related false statement claim based upon the same allegations as Count V. (*Id.* ¶ 164). Defendants argue that chemotherapy is reimbursable even when regularly performed and supervised by non-physicians (Doc. # 125 at 21-22); O'Laughlin agrees this is *per se* true but that the claims would be paid at 85% of the physician rate, instead of the full amount, unless the

services were provided "incident-to" the physician's services. (Doc. # 131 at 10-11).[3]

Defendants further argue that the relevant chemotherapy services are not "incident-to" professional services under 42 C.F.R. § 410.26(b), which allows for reimbursement of services incident to the service of a physician or other practitioner. (Doc. # 125 at 22-23).[4] Instead, Defendants assert that chemotherapy is a service performed by auxiliary personnel such as nurse practitioners and physician assistants. (Doc. # 135 at 11-12). Defendants cite to CMS's guidance in Medicare Carriers' Manual Transmittal 1776 under Headnote 15400(D):

> On days when a patient receives chemotherapy administration but the physician has no face-to-face contact with the patient, the physician may report and be paid for "incident to" services furnished by one of the physician's employees, in addition to the chemotherapy administration, if they are furnished under *direct personal supervision in the office by one of the physician's employees* and the medical records reflect the physician's active participation in and management of the course of treatment.

(*emphasis added*).

However, Defendants fail to adequately support either that the services are incident-to professional services or that they are exempt from the billing cap because they

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[3] Indeed, O'Laughlin's own source reinforces that "chemotherapy supervision in the freestanding setting, [] can be performed by either a physician or an [advanced practitioner]." Advisory Board, *What You Need to Know About Medicare's Physician Supervision Requirements*, March 29, 2018, https://www.advisory.com/blog/2018/03/what-you-need-to-know-about-medicares-physician-supervision-requirements. Nurse practitioners and physician assistants "are also known outside of the Medicare program by other names, such as advanced practice practitioners." Emily Jane Cook and Caroline Reignley, *CMS Proposes New Regulation to Clarify Physician and NPP "Split (or Shared)" Billing Policy*, JDSupra July 16, 2021, https://www.jdsupra.com/legalnews/cms-proposes-new-regulation-to-clarify-3157466/#:~:text=NPPs%20generally%20include%20nurse%20practitioners,advanced%20practice%20practitioners%20(APPs).

[4] Under 42 C.F.R. § 410.26, a practitioner "means a non-physician practitioner who is authorized by the Act to receive payment for services incident to his or her own services." Under 42 C.F.R. §§ 410.74(b) and 410.75(d), services furnished incident to the services of a nurse practitioner and physician's assistant are covered.

are performed by auxiliary personnel. The above quote discusses incident-to services billed by a physician. For services furnished by a non-physician that are "incident-to" a physician or other practitioner's services they "must be furnished under the appropriate level of supervision by a physician (or other practitioner.)" *See* 42 C.F.R. §§ 410.26 and 410.75(d). There are three levels of supervision: general, direct, and personal. 42 C.F.R. §§ 410.26(a)(2)-(3) and 42 C.F.R. § 410.32(b)(3). Therefore, if the chemotherapy services in question were incident-to *physician* services, a *physician* would have to at least be present on the premises, which O'Laughlin has alleged was not the case. *U.S. ex rel. Lockyer v. Hawaii Pac. Health*, 490 F. Supp. 2d 1062, 1073 (D. Haw. 2007), *aff'd in part sub nom. U.S. ex rel. Lockyer v. Hawaii Pac. Health Grp. Plan for Emps. of Hawaii Pac. Health*, 343 F. App'x 279 (9th Cir. 2009) ("Both parties seem to agree that under the incident to rules, services administered by a non-physician are only eligible for Medicare payment if there is a supervising physician in the same office suite where the services are furnished, and who is immediately available to provide assistance.").

But, Defendants are correct that nurse practitioners and physician assistants also qualify as "other practitioners" and can be the party supervising the incident-to services, as discussed above. While they can supervise the services, O'Laughlin is correct that the amount billed "may not exceed 85 percent of the physician fee schedule amount for the service." 42 C.F.R. §§ 414.56(c) and 405.520(a).

Additionally, Defendants' argument that "chemotherapy is a service performed by auxiliary personnel" and that physician supervision is not necessary may be true, but it does not refute the argument that those services would be capped at the amount they are reimbursed. (Doc. # 135 at 12). The Third Amended Complaint alleges that the

chemotherapy services were billed as if they were provided by physicians when they were actually provided by non-physicians (Doc. # 124 ¶ 121), and if that is true, the amount reimbursed would have been higher than what was allowed by the 85% reimbursement cap on physician assistant and nurse practitioner services. O'Laughlin specifically alleges amounts overpaid by insurance carriers for these insurance claims and that they would not have been paid at a certain physician rate had the insurance carriers known that non-physicians were providing the services. (*Id.* ¶¶ 132-133, 140-141, 148-149, 156). Therefore, considering the allegations in Count V and VI in the light most favorable to O'Laughlin as the non-moving party, he has adequately stated a claim for relief. *Ibanez*, 874 F.3d at 914. Accordingly, Defendants' Motion to Dismiss is **denied** as to Count V and VI and they may proceed with discovery on those Counts.

4. Count VII

Count VII alleges that Defendants submitted false claims related to simulation services, which is a clinical process used to establish radiation treatment locations and volume. (Doc. # 124 ¶¶ 171-174). O'Laughlin specifically alleges that Defendants failed to meet the documentation requirements for the relevant simulation billing codes submitted, such as the treating physician preparing a written record of the procedure as well as a copy of reviewed images with the physician's signature. (*Id.* ¶¶ 177-179).

Defendants counter that CMS policy contains no reference to these requirements as preconditions of payment and cite to a Medicare Administrative Contractor's ("MAC") guidance on the issue. (Doc. # 125 at 18). While the MAC website establishes that certain radiological services do require signed and dated documentation, the simulation codes referenced by O'Laughlin only require documentation of the medical necessity of

the treatment. Noridian Healthcare Solutions, *Radiation Oncology*, January 29, 2021, http://med.noridianmedicare.com/web/jfb/specialties/radiation-oncology#documentation.

O'Laughlin responds with citations to several sources but only one of which supports his argument that the documentation outlined in the Third Amended Complaint is necessary. (Doc. # 131 at 18-20).[5] O'Laughlin cites to a transmittal from a private healthcare organization, National Imaging Associates Inc. ("NIA"), titled "Coverage Indications, Limitations, and/or Medical Necessity." (Doc. # 131 at 19) (citing Doc. # 66-4 at 6). While O'Laughlin is correct that the transmittal states "[d]ocumentation of simulation requires a written record of the procedure and hard copy of a[n] x-ray film or electronic images and evidence of image review of physicians including signature or initials and data review," it is unclear from where NIA obtained this information, who requires this information, and if it is a precondition for payment of claims. There is no citation to any CMS policy or guidance that would make the alleged documentation requirements a material precondition of payment. Accordingly, Count VII is **dismissed**.

5. Count VIII

Count VIII alleges a conspiracy claim related to all the previous counts. (Doc. # 124 ¶¶ 190-195). Defendants argue that since all the counts in the Third Amended Complaint should be dismissed, this count should also be dismissed. (Doc. # 125 at 24). O'Laughlin responds that it logically follows that if any count survives, the conspiracy claim must also survive. (Doc. # 131 at 20-21).

[5] The other sources cited by O'Laughlin in his Response merely support the requirement that documentation of medical necessity is mandatory for claim reimbursement, a premise to which Defendants have agreed. (*See* Doc. # 131 at 18-20). However, O'Laughlin does not allege that any of the submitted claims lacked medical necessity nor that medical necessity was not documented.

O'Laughlin is correct that he has adequately alleged a conspiracy on the face of the Third Amended Complaint. For a conspiracy to exist in the FCA context, "a relator [must] plead facts showing that there was a plan or agreement 'to commit a violation of' one or more of the FCA subsections . . . they must show an agreement was made *in order* to violate the FCA." *Ibanez*, 874 F.3d at 917. Here, O'Laughlin specifically alleges that each Defendant engaged in the conspiracy to present false claims as to the only surviving counts: Count V (Doc. # 124 ¶ 120) and Count VI (*id.* ¶ 165). O'Laughlin alleges the specifics of the conspiracy as well: that the physicians prepared the service forms and that A One Biz converted the information into a viable claim through manipulating the information to pass review (*id.* ¶ 40). If these allegations are taken as true, then this would likely amount to conspiracy. Thus, the conspiracy claim survives as to Count V and VI. Defendants' Motion to Dismiss as to Count VIII is therefore **denied**.

III. CONCLUSION

For the reasons set forth herein, **IT IS ORDERED** that:

(1) Defendants' Motion to Dismiss Relator's Third Amended Complaint (Doc. # 125) is **GRANTED in part and DENIED in part** in that the only surviving claims are Counts V, VI, and VIII;

(2) Defendants' Motion to Stay Discovery (Doc. # 126) is **DENIED**; and

(3) The parties shall file a **proposed discovery plan** on the remaining Counts within **twenty (20) days** from the date of entry of this Order

This 23rd day of November, 2022.

Signed By:
David L. Bunning
United States District Judge

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