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' Joint Motion to Dismiss. (Doc. # 64). The Motion has been fully briefed, (Docs. # 66, 73, and 74),[1] and is now ripe for the Court's review. For the reasons stated herein, the Motion is **granted in part and denied in part**.

I. FACTUAL AND PROCEDURAL BACKGROUND

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, *et seq.*, based on Defendants' alleged fraudulent misrepresentations to Medicare, Medicaid, and other

[1] Relator's Motion for Leave to File a Sur-Reply (Doc. # 74) is **granted**, as it addresses an argument that Defendants raise for the first time in their reply brief. (*See* Doc. # 73 at 8) (arguing for the first time that "[r]adiation therapy services are not payable 'incident to' the professional services of a physician because they have their own benefit category at 42 U.S.C. § 1395(s)(4)"); *see also Vaughn v. Hawkins*, No. 5:14-cv-99, 2018 WL 2210873, at *2 (W.D. Ky. May 14, 2018) ("District courts are afforded broad discretion in deciding whether to permit a party to file a sur-reply, the classic reason being '[w]hen new submissions and/or arguments are included in a reply brief . . . .'" (quoting *Key v. Shelby Cnty.*, 551 F. App'x 262, 264 (6th Cir. 2014))).

The Court will also consider the "Errata" sheet Relator submitted pertaining to his response brief (Doc. # 67), as that filing does not make any substantive changes. Also considered as part of the record is Relator's Notice of Supplemental Authority (Doc. # 71), which directs the Court's attention to 42 C.F.R. § 414.2(5).

federal programs regarding radiation oncology and chemotherapy services they provided.[2] (Doc. # 53 at 1-2). Relator O'Laughlin's claims are based on his observations working as a radiation oncologist with Defendants from July 2012 through October 2015. (*Id.* at ¶ 4). The allegations, explained in further detail below, are alleged against (1) Radiation Therapy Services, P.S.C. d/b/a the Ashland Bellefonte Cancer Center ("Ashland BCC"), (2) Kirti Jain, M.D., d/b/a the Highlands Cancer Center ("Highlands CC"), (3) A One Biz Solutions, LLC, (4) Kirti Jain, M.D., and (5) Manish Jain. (*Id.* at ¶¶ 6-11, 14-16). The Amended Complaint also names Logan Oncology Care Associates, LLC d/b/a Logan Regional Cancer Center ("Logan CC") as a co-conspirator, but not as a defendant.[3] (*Id.* at ¶¶ 12-13).

During the relevant period, Dr. Kirti Jain served as the president of Ashland BCC and Highlands CC (collectively "Cancer Centers"). (*Id.* at ¶¶ 9, 11). Dr. Jain is a board-certified oncologist who practices medicine in the areas of blood and cancer care, as well as internal medicine. (*Id.* at ¶ 6). The Cancer Centers provide medical oncology, hematology, and radiation oncology services. (*Id.* at ¶¶ 8, 10). A One Biz Solutions, LLC provides medical billing services for the Cancer Centers, (*id.* at ¶ 14), and Defendant Manish Jain serves as a manager of A One Biz Solutions, LLC and Ashland BCC, (*id.* at

---

[2] "A 'relator' is simply an informer plaintiff, that is, a person with evidence of fraud on the government who is permitted to institute a damages suit in the government's name against those who perpetrated the fraud." *United States ex rel. Detrick v. Daniel F. Young, Inc.*, 909 F. Supp. 1010, 1012 n.2 (E.D. Va. 1995) (citing Black's Law Dictionary 1158 (5th ed. 1979)).

[3] On August 12, 2019, the United States elected to intervene as to Logan CC, (Doc. # 34), and on February 25, 2020, Relator and the United States voluntarily dismissed the claims against Logan CC pursuant to a settlement agreement, (*see* Doc. # 65). The United States has otherwise declined to intervene in this action. (Doc. # 34).

¶ 7). Dr. Jain was also a manager of A One Biz Solutions until 2009 or mid-2010. (*Id.* at ¶ 16).

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). The Amended Complaint sets forth 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. # 53 at ¶¶ 44-76 (Count I), 84-112 (Count III), 120-165 (Count V), and 173-194 (Count VII)).

More specifically, Count I alleges that from July 2012 until at least October 2015, Defendants presented false claims for reimbursement that certified either expressly or by implication that "Dr. O'Laughlin provided, or supervised, the radiation oncology services billed" when, in fact, Dr. O'Laughlin did not provide or supervise the services, which were also "not delegated to [a] physician qualified to perform the radiation oncology services." (*Id.* at ¶¶ 45-47, 72). Count I also alleges that Defendants falsely certified that a physician qualified to perform radiation oncology services "reviewed and approved guidance images produced prior to each daily treatment within 24 hours or prior to the next treatment delivery." (*Id.* at ¶ 72).

Count III alleges that Defendants submitted fraudulent claims insofar as the claims falsely certified either expressly or by implication that a "particular, Named Physician" (Dr. O'Laughlin or Dr. Jain) performed certain radiation services, when that "Named Physician" did not provide the services, did not supervise the services, and was not on the premises or otherwise available at the facility when the services were rendered. (*Id.* at ¶¶ 86-88, 108).

Count V asserts that Defendants presented claims that falsely certified expressly or by implication that certain chemotherapy services had been provided by or supervised by Dr. Jain, whereas the services were actually provided by either a physician's assistant or nurse practitioner without Dr. Jain's direct supervision. (*Id.* at ¶¶ 122-123, 161).

Finally, Count VII alleges that Defendants submitted fraudulent claims related to simulation procedures,[4] as the claims falsely represented by implication (1) that the treating physician prepared a record of the simulation procedure and signed or initialed the record of the procedure, (2) that Defendants maintained the required documentation of simulation procedures, and (3) that a radiation oncologist had performed the simulations. (*Id.* at ¶¶ 175-183).

In addition, Relator O'Laughlin brings three "false record" 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." (*See* Doc. # 53 at ¶¶ 78-83 (Count II), 113-119 (Counts IV), and 166-172 (Count VI)). Each of Dr. O'Laughlin's false record claims relates to the factual underpinnings of the first three "false presentment" claims described above, respectively. For example, in addition to alleging under Count I that Defendants presented claims that falsely represented Dr. O'Laughlin performed or supervised certain services, Count II further alleges that Defendants made false statements and created false records stating that Dr. O'Laughlin performed those services, which were material to the Government's decision to reimburse the Defendants. (*Id.* at ¶¶ 78-79).

[4] Simulations are "dry runs" for radiation treatments, which may entail "determining and establishing the radiation therapy treatment portals to a specific treatment volume" and "[o]rdering and interpreting special tests . . . to assist in the field settings." (Doc. # 53 at ¶ 177).

The Amended Complaint also sets forth a conspiracy claim pursuant to 31 U.S.C. § 3729(a)(1)(C). (*Id.* at ¶¶ 195-200) (Count VIII). That claim alleges that Defendants, along with co-conspirator Logan CC, "conspired and agreed together to defraud the Government by getting false or fraudulent claims approved or paid; and by making or using false statements and records material to false or fraudulent claims." (*Id.* at ¶ 196).

Pending before the Court is Defendants' Joint Motion to Dismiss Relator's Amended Complaint (Doc. # 64). Defendants seek to dismiss Relator's Amended Complaint in its entirety under Federal Rule of Civil Procedure 12(b)(6) on several grounds that are addressed below in turn.

II. ANALYSIS

A. Standard of Review

In order to survive a motion to dismiss, a complaint alleging FCA violations must comply with Federal Rule of Civil Procedure 9(b)'s heightened pleading standard. *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 "time, place, and content of the alleged misrepresentation on which [the injured party] relied." *United States ex rel. Bledsoe v. Cmty. Health Sys. Inc.*, 342 F.3d 634, 643 (6th Cir. 2003) (quoting *Coffey v. Foamex L.P.*, 2 F.3d 157, 161-62 (6th Cir. 1993)).

Rule 9(b) should not, however, 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). The "overarching" purpose of Rule 9(b) is to "ensure that [the] defendant possesses sufficient information to respond to an allegation of fraud."

Id. (quoting *United States ex rel. SNAPP, Inc. v. Ford Motor Co.*, 532 F.3d 496, 504 (6th Cir. 2008)). Moreover, "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 466 (6th Cir. 2011) (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 *SNAPP, Inc.*, 532 F.3d at 502).

B. False Presentment and False Record Claims

Defendants assert that Relator's false presentment and false record claims should be dismissed for failure to state a claim. (*See* Doc. # 64-1 at 14-24). Section 3729(a)(1)(A) of the FCA imposes liability on a person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." Section 3729(a)(1)(B) similarly imposes liability when a person "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." Several different legal theories can support a claim for liability under §§ 3729(a)(1)(A) and 3729(a)(1)(B). In the "paradigmatic case," a claim is false because it "involves an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided." *United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1266 (D.C. Cir. 2010) (quoting *Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001)); *see also United States ex rel. Hobbs v. Medquest Assocs.*, 711 F.3d 707, 714 (6th Cir. 2013). In addition, in certain situations, a defendant's failure to comply with a statute or regulation can make a claim "false" under the FCA. *Chesbrough*, 655

F.3d at 468. However, "[t]he [FCA] does not create liability merely for a health care provider's disregard of Government regulations . . . unless, as a result of such acts, the provider knowingly asks the Government to pay amounts it does not owe." *Prather*, 838 F.3d at 768 (quoting *Sanderson v. HCA—The Healthcare Co.*, 447 F.3d 873, 877 (6th Cir. 2006)).

Thus, under this so-called "false certification" theory, liability under the FCA is triggered when a claim certifies, either expressly or by implication, compliance with a particular regulation *that is a prerequisite for payment*. *Chesbrough*, 655 F.3d at 468; *see also Hobbs*, 711 F.3d at 714. Said another way, "a relator cannot merely allege that a defendant violated a standard—he or she must allege that compliance with the standard was required to obtain payment." *Chesbrough*, 655 F.3d at 468. When an FCA claim is proceeding on a false certification theory, "[c]ourts do 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." *Hobbs*, 711 F.3d at 714 (quoting *United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1218 (10th Cir. 2008)).

1. Radiation Oncologist Claims

Defendants argue that Relator's claims pertaining to radiation services should be dismissed insofar as Relator alleges Defendants falsely certified that a radiation oncologist either performed or supervised certain radiation oncology services. (Doc. # 64-1 at 13, 17-20). According to Defendants, there is no requirement that a physician perform these purely "technical" services. (*Id.* at 17-18). Defendants similarly argue that although a physician must *supervise* radiation services, there is no regulation or statute

requiring that such services be supervised by a radiation oncologist, in particular. (*Id.* at 19-20). While Defendants make these arguments broadly, they appear to specifically implicate Counts I and II, which allege that Defendants submitted false claims or documents certifying that Dr. O'Laughlin (a radiation oncologist) performed or supervised radiation oncology services, when in fact he did not; and that no other physician qualified to perform radiation oncology services provided or supervised those services. (*See* Doc. # 53 at ¶¶ 72, 79). These arguments also appear to attack Count VII, wherein Relator alleges, among other things, that Defendants falsely represented by implication that a radiation oncologist performed certain simulation services. (*Id.* at ¶ 183; *see also* Doc. # 64-1 at 8).

a. Performance by a radiation oncologist

The Court will first address Defendants' argument that because radiation services are purely technical, they need not be provided by a physician, let alone by a physician qualified to perform radiation oncology services. (Doc. # 64-1 at 17-18). In support of their argument, Defendants point to various provisions in the Medicare Benefit Policy Manual, which they say contemplate the performance of radiation therapy services by technical staff with only physician supervision required. Chapter 15, Section 90 of the Manual, entitled "X-Ray, Radium, and Radioactive Isotope Therapy" states that "[t]hese serves also include materials and services of technicians." Section 90 further provides in relevant part:

> X-ray, radium, and radioactive isotope therapy furnished in a nonprovider facility [like the Cancer Centers] require direct personal supervision of a physician. The physician need not be in the same room, but must be in the area and immediately available to provide assistance and direction throughout the time the procedure is being performed. **This level of physician involvement does not represent a physician's service and**

> **cannot be billed as a Part B service. The physician would have to furnish a reasonable and necessary professional service as defined in §§30 of this chapter, in order for the physician's activity to be covered.**

(emphasis added). Defendants also look to the Medicare Claims Processing Manual, Chapter 13, Section 70.3, which states that Medicare Administrative Contractors "pay for TC [technical component] services on a daily basis under CPT codes 77401-77416 for radiation treatment delivery." These sources taken together, Defendants argue, demonstrate that technical staff, rather than physicians, perform radiation services, albeit under the supervision of a physician. Thus, according to Defendants, Relator's claim that they violated the FCA by falsely certifying that Dr. O'Laughlin or another radiation oncologist *performed* certain radiation services fails as a matter of law because physician performance is not required.

Yet, the Amended Complaint identifies allegedly false claims for radiation oncology services that appear to correspond specifically to *physician services*, as opposed to services performed by technical staff. For example, Relator alleges that Defendants improperly billed for services falling outside the range labeled as "technical" by the Claims Processing Manual (codes 77401-77416). (*See, e.g.*, Doc. # 53 at 22-23). In his response brief, Dr. O'Laughlin explains that some of the billing codes for radiation oncology services identified in the Amended Complaint correspond to "Physician Level 2," as established by the Medicare Physician Fee Schedule. (*See* Doc. # 66 at 7) (identifying codes 77421TC, 77427, and G6013). The Medicare Fee Schedule allows for certain services to be split into a professional component and technical component, which can be billed separately. *See* Medicare Claims Processing Manual Ch. 23, § 50.6. "Physician Level 2" denotes a "professional component only code" meaning that it

"describe[s] the *physician* work portion of the selected diagnostic tests for which there is an associated code that describes the technical component of the diagnosis." *Id.* (emphasis added). Thus, Relator has adequately alleged that at least some of the radiation services at issue were not purely technical services, and rather, were required to have been performed by physicians.

Defendants' argument that radiation services, in general, are purely technical in nature is not responsive to Relator's specific allegations.[5] Furthermore, Defendants do not argue that, assuming some radiation services at issue require physician performance, that physician need not be a radiation oncologist. In other words, Defendants have not challenged Relator's assertion that certain services were required to have been performed by a physician who was *specifically qualified to perform radiation oncology* services, instead focusing on the issue of whether Medicare regulations require performance by a physician for radiation services at all. Accordingly, Relator's Amended Complaint survives to the extent it alleges Defendants falsely certified that certain radiation oncology services (denoting physician performance) were performed by Dr. O'Laughlin or another radiation oncologist.

b. Supervision by a radiation oncologist

Unlike his allegations related to the *provision* of radiation oncology services, Relator's allegation that Defendants falsely certified that certain radiation services were *supervised* by Dr. O'Laughlin or another radiation oncologist fails, because Relator has

---

[5] Defendants do not respond to Relator's argument that certain, specifically-identified billing codes correspond to services performed by physicians.

In addition, Defendants appear to acknowledge, for example, that certain weekly management services related to the provision of radiation therapy are "professional services" that are "wholly distinct from purely technical therapy sessions." (*See* Doc. # 64-1 at 18).

not identified a regulation or statute requiring that a radiation oncologist—as opposed to another type of physician—supervise the services. The Amended Complaint states that "[t]he administration of a specific type of radiation therapy requires a specific level of supervisory . . . care by a qualified physician, that is, by a Radiation Oncologist or other 'qualified radiation oncology physician.'" (Doc. # 53 at ¶ 32). However, no statute or regulation is cited for this proposition.

While Relator correctly asserts—and Defendants concede—that the Medicare Benefit Policy Manual requires "direct supervision" by a physician of radiation oncology services, (*see* Docs. # 64-1 at 19 and 66 at 6-7, 6 n.3), the Policy does not require that the supervising physician be a radiation oncologist in particular. According to the Medicare Benefit Policy Manual, Chapter 90, Section 15, "[x]-ray, radium, and radioactive isotope therapy furnished in a nonprovider facility [such as the Cancer Centers] require direct personal supervision *of a physician*." The Policy further provides that "[t]he physician need not be in the same room, but must be in the area and immediately available to provide assistance and direction throughout the time the procedure is being performed." *Id.* As the cited portions of the Policy do not speak to the need for the supervision of a radiation oncologist, the Policy cannot serve as the basis for Relator's assertion that Defendants violated a requirement that radiation services be supervised by a "qualified radiation oncology physician." *See United States v. Space Coast Med. Assocs. LLP*, 94 F. Supp. 3d 1250, 1261 (M.D. Fla. 2015) (holding that "[b]ecause Relators allege only an absence of a radiation oncologist present in the facility—not the absence of any physician—the Second Amended Complaint does not state a violation of the Medicare Benefit Policy Manual") (internal citation omitted).

Relator's reliance on Medicare Regulation 42 C.F.R. § 410.26(a)(1) is similarly misplaced. That regulation pertains to "[s]ervices and supplies *incident to* a physician's professional services" and permits a supervising physician to bill Medicare for services performed by "auxiliary personnel" so long as the services are "an integral, though incidental, part of the service of a physician" and are performed under the "direct supervision of the physician." 42 C.F.R. § 410.26(b). The "incident-to" regulation defines "auxiliary personnel" to mean "any individual who is acting under the supervision of a physician" who "meets any applicable requirements to provide incident to services, including licensure, *imposed by the State in which the services are being furnished*." 42 C.F.R. § 410.26(a)(1) (emphasis added). Relator argues this definition of auxiliary personnel in 42 C.F.R. § 410.26(a)(1) incorporates Kentucky law, which, in turn, requires that "a radiation oncologist supervise the provision of radiation oncology services." (*See* Doc. # 66 at 4, 9, 10-14). Assuming that the radiation oncology services provided in this case were "incident-to" services covered by 42 C.F.R. § 410.26,[6] the regulation's discussion of compliance with state-law standards clearly applies only to non-physician "auxiliary personnel," not to the supervising physicians. Thus, § 410.26 does not support Relator's assertion that federal regulations (incorporating Kentucky law) require that a "qualified radiation oncologist" *supervise* radiation oncology services. *See* (Doc. # 53 at ¶ 72).[7] Relator identifies no other legal basis for a specialized supervision requirement.

[6] The parties argue at length about whether § 410.26 even applies, i.e., whether the services at issue qualify as "incident-to" services under that Section. Because even if this Section were to apply, it does not establish qualifications/requirements for supervising physicians, the Court need not address that question.

[7] Relator further cites to a "Response" from CMS provided during the comment period on the 2011 Final Rule concerning the Medicare Hospital Outpatient Prospective Payment System,

Consequently, he has failed to state a claim for relief based on Defendants' alleged false certification that a radiation oncologist *supervised* certain radiation oncology services.[8]

c. Simulation services

Relator's false presentation claim regarding simulation services (Count VII) similarly fails to the extent Relator alleges that such services must be *performed* by a radiation oncologist, as Relator does not provide any legal basis for that contention. The Amended Complaint alleges that "[t]he Simulation claims were [ ] false and fraudulent, in that they represented by implication that a radiation oncologist had performed the simulations, whereas in truth and in fact no radiation oncologist had performed the simulations." (Doc. # 53 at ¶ 183). Defendants argue that simulation services need not be performed or even supervised by a radiation oncologist, and that such services only require the supervision of a physician (who is not necessarily a radiation oncologist). (Doc. # 64-1 at 8).

In response, Relator does not provide support for his contention that a physician or radiation oncologist must perform simulation services. In fact, Relator appears to

---

among other topics. (*See* Doc. # 66 at 9-10) (citing 75 Fed. Reg. 71799, 72912). However, it is not clear whether the information provided therein would apply to the Defendant Cancer Centers.

In addition, at various points, Relator cites to 42 C.F.R. § 410.20, which covers "physician's services" or services "furnished by" professionals, including doctors of medicine and osteopathy "who [are] legally authorized to practice by the State in which [they] perform[] . . . and who [are] acting within the scope of [their] license." (*See, e.g.*, Doc. # 66 at 4). Yet, Relator does not argue that this provision applies when the physician is merely supervising as opposed to personally administering medical services.

Finally, in his Notice of Supplemental Authority, Relator asserts that 42 C.F.R. § 414.2(5) provides an "alternative" and "independent" basis for his argument that "CMS properly and definitively requires the direct supervision of a physician for the provision of x-ray therapy." (Doc. # 71). Yet, the parties do not dispute that direct supervision by a physician is required.

[8] Defendants do not specifically challenge Relator's allegation in Count I that Defendants falsely certified "that a qualified physician reviewed and approved guidance images produced prior to each daily treatment within 24 hours or prior to the next treatment delivery." (Doc. # 53 at ¶ 72(e)). Thus, that claim may proceed to discovery.

concede that only supervision by a physician is required. In his response brief, Relator explains that the specific simulation services at issue were billed via codes 77280 and 77290 for simple and complex simulation procedures, respectively. (Doc. # 66 at 19-20; *see also* Doc. # 53 at ¶ 176). Dr. O'Laughlin further informs that the simulation services (billed using codes 77280 and 77290) correspond to "Physician Level 9," which, as Relator explains, means that either a physician can perform the services himself or a radiation therapist or technician can perform the services under the supervision of a physician. (*See* Doc. # 66 at 7-9). Thus, Relator acknowledges that these services were not required to be *performed* by a physician, and instead merely required physician supervision.[9] Accordingly, Defendants' Motion to Dismiss is granted to the extent the Amended Complaint alleges Defendants falsely certified that a radiation oncologist performed simulation services. (Doc. # 53 at ¶ 183).

Yet, Relator raises another basis for liability with regard to simulation services in the Amended Complaint. In addition to alleging that Defendants falsely certified that a radiation oncologist provided simulation services, Count VII also alleges that "[t]he simulation claims were false and fraudulent, in that they represented by implication that the required documentation had been prepared by the treating physician and was maintained by the Defendants, whereas in truth and in fact: (a) the treating physician did not prepare a written record of the simulation procedure, (b) the treating physician did not sign or initial a written record of the simulation procedure; and (c) the Defendants did not

[9] Relator also cites a Legal Coverage Determination ("LCD") finding that the personnel involved in administering simulations services must meet State regulations. (Doc. # 66 at 21) (citing *Novitas Sols., Inc.*, LCD L367711 (Dec. 1, 2016)). However, from that holding, it does not necessarily follow that technical personnel who meet State requirements must also be supervised by radiation oncologists.

possess or maintain the Required Documentation at any time." (Doc. # 53 at ¶ 181; *see also id.* at ¶ 190(a)-(c)).

In their reply brief, Defendants attack these documentation-related allegations for the first time, arguing that their alleged failure to properly document simulation procedures does not give rise to FCA liability. (Doc. # 73 at 17). Defendants more specifically argue that the failure to properly document the procedures does not amount to a "fraudulent claim." (*Id.*) (stating that "the fraudulent claim is the *sine qua non* of a False Claims Act violation") (quoting *U.S. ex rel. Sanderson*, 447 F.3d at 878). Yet, under the "false certification" theory of liability, failure to comply with a regulation can give rise to an FCA violation where compliance with that regulation is a precondition of payment. *Chesbrough*, 655 F.3d at 467. Defendants do not specifically argue that the documentation requirements at issue were not a precondition of payment. They also do not cite any regulations or caselaw demonstrating as much. Accordingly, Defendants have not shown that dismissal of these documentation-related claims regarding simulation services is warranted at this time.

2. Named Physician Claims

Defendants also seek dismissal of Relator's "named physician claims" (Counts III and IV), wherein Relator alleges that Defendants submitted false claims or records certifying that a *certain named physician* (either Dr. O'Laughlin or Dr. Jain) performed or supervised radiation services, when, in reality, *that named physician* did not perform or supervise those services. (*See* Docs. # 64-1 at 21-23 and 53 at ¶¶ 86, 87, 92, 100, 104, 115). These claims are distinct from Counts I, II, and VII, addressed above, wherein Relator alleges that Defendants falsely certified Dr. O'Laughlin performed or supervised

radiation or simulation services when in fact *no radiation oncologist* performed or supervised those services. By contrast, Counts III and IV merely allege that the particular physician listed on the claim form did not perform or supervise the service. Defendants argue that even assuming they listed the wrong physician (the physician who did not actually perform or supervise the service) on the form submitted to Medicare and other government programs for reimbursement, such a "clerical error" would not be material to payment of the claim. (Doc. # 64-1 at 21). The Court agrees.

Because Relator is relying on a false certification theory of liability under the FCA, he must allege that Defendants failed to comply with a regulatory or statutory requirement that *was a precondition of payment*, "meaning that the government would not have paid the claim had it known the provider was not in compliance." *Hobbs*, 711 F.3d at 714 (citing *Chesbrough*, 655 F.3d at 468). By way of illustration, the Sixth Circuit in *United States ex rel. Hobbs*, found that certain physician supervision requirements, while "conditions of participation," were not conditions of payment. 711 F.3d at 710, 717. The regulations at issue in *Hobbs* provided that for a diagnostic test to be "reasonable and necessary" (and thus, eligible for reimbursement) it "must be furnished under the appropriate level of supervision by a physician." *Id.* at 710 (citing 42 C.F.R. § 410.32(b)(1)). A separate section of the regulations also provided that for independent diagnostic facilities, like the defendant's in that case, certain approved "supervising physicians" must "personally furnish" the requisite level of supervision. *Id.* (quoting 42 C.F.R. § 410.33(b)(2)).

The defendant in *Hobbs* conceded that some procedures, although supervised by a physician, were not supervised by the "approved" "supervising physician," as required

by the regulations. *Id.* at 711. The court held, though, that "the natural reading of the relevant regulations supports only a conclusion that [the diagnostic test at issue] is not reasonable and necessary if it is not performed under direct supervision by a physician." *Id.* at 715. Thus, although the defendant was not "in complete regulatory compliance" because the services were not supervised by an approved physician, the defendants had nevertheless satisfied all of the conditions of payment for the diagnostic test because the tests were supervised by a physician. *Id.*

Here, the Amended Complaint alleges that Defendants' false statements concerning the named physicians were "material" because the government programs would "not have made payment on these claims without the Named Physician either providing, or personally or directly supervising these claims; and without being in or available at the facility where the services were provided." (*Id.* at ¶ 88). Yet, this statement amounts to a mere recitation of the materiality requirement—Relator must provide a legal or factual basis to support this otherwise conclusory allegation. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (noting that courts need not "accept as true a legal conclusion couched as a factual allegation") (quoting in parenthetical *Papasan v. Allain*, 478 U.S. 265, 286 (1986)).

Contrary to Relator's contention, 42 C.F.R. § 410.26(b), which governs "incident-to" services, does not support his argument that the actual, supervising physician must be named in order for the services at issue to be reimbursable. (*See* Doc. # 66 at 18). Section 410.26(b)(5) provides: "In general, services and supplies must be furnished under the direct supervision of the physician . . . . The physician [ ] supervising the auxiliary personnel need not be the same physician [ ] who is treating the patient more broadly.

However, only the supervising physician [ ] may bill Medicare for incident to services." According to Relator, the last sentence, stating that "only the supervising physician" can bill for incident-to services means that "billing to Medicare [must] be made in the name of the *actual* providing or supervising physician"—a material requirement. (Doc. # 66 at 18).

As an initial matter, Defendants argue that § 410.26(b)(5) is inapplicable to radiation oncology services. (Doc. # 73 at 8). But, even assuming § 410.26(b)(5) applies to the radiation services Relator identifies in Counts III and IV, the regulation's requirement that only the supervising physician bill Medicare is not a condition of payment. The last two sentences—"The physician [ ] supervising the auxiliary personnel need not be the same physician [ ] who is treating the patient more broadly. However, only the supervising physician [ ] may bill Medicare for incident to services"—taken together, most naturally were intended to clarify that only one physician may bill for a service. The regulation, for example, prohibits both the treating and supervising physician or both the supervising physician and auxiliary personnel from separately billing for a single incident-to service.

Thus, while Relator alleges that the particular physician named on certain claims did not actually supervise those services, whether the particular named physician, Dr. Jain or Dr. O'Laughlin, was actually the physician who supervised the service would not impact Medicare's obligation to pay for the services, so long as they *were directly supervised by a physician*. Because Relator does not allege that the identified services were not supervised by *any physician*, he has failed to allege a material violation of the FCA. *See United States ex rel. Rockey v. Ear Inst. of Chi., LLC*, 92 F. Supp. 3d 804, 822 (N.D. Ill. 2015) (finding materiality lacking where defendant listed the wrong provider

identification number because the error did not change Medicare's obligation to pay the claims).[10]

Perhaps realizing the deficiency in Counts III and IV, Relator, in his response brief, suggests that the Court should construe these Counts as alleging that *no physician* provided or supervised the services at issue. (*See* Doc. # 66 at 18). But the Amended Complaint could not be clearer that the claims and records at issue in Counts III and IV were allegedly false because the "particular physician" or "named physician" did not provide or supervise the services. (Doc. # 53 at ¶¶ 108, 115).

Moreover, based on the allegations in the Amended Complaint, it cannot be reasonably inferred that no other physician supervised the procedures in question in lieu of the named physician. At least two physicians worked at the Cancer Centers—Drs. O'Laughlin and Jain, (*id.* at ¶¶ 9, 11), and the Amended Complaint indicates that a third doctor, Anshu K. Jain, also worked at the Cancer Centers beginning in August 2014, (*id.* at ¶¶ 9(b), 11(b)). Even assuming there were only two possible physicians who could

---

[10] Relator cites *United States ex rel. Ortiz v. Mount Sinai Hosp.*, 256 F. Supp. 3d 433 (S.D.N.Y. 2017); however, in that case, the relator's FCA claim was based on the defendants' practice of billing under the name of a participating physician to cover up that fact that a non-participating physician had actually performed the services. *Id.* at 446. Here, by contrast, Relator has provided no allegations from which it can be inferred that listing one physician rather than another impacted reimbursement (other than the allegations in Counts I and II concerning whether the named physician was qualified to perform radiation oncology services, which is addressed separately).

Relator also cites *Nawaz v. Price*, No. 4:16-cv-387, 2017 U.S. Dist. LEXIS 99862 (E.D. Tex. June 28, 2017), to support his argument that billing under the name of a physician who did not actually supervise certain services constitutes a material violation. (Doc. # 66 at 18). However, that case involved the appeal of an administrative proceeding revoking two physicians' billing privileges. *Nawaz*, 2017 U.S. Dist. LEXIS 99862, at *3. It did not involve alleged violations of the FCA. As discussed in *Hobbs*, the FCA "is not a vehicle to police technical compliance with complex federal regulations." 711 F.3d at 717 (citing *United States ex rel. Williams v. Renal Care Grp., Inc.*, 966 F.3d 518, 532 (6th Cir. 2012)). Such technical violations may be enforced administratively through suspension, disqualification, or other remedy. *Id.*

have supervised the services, one being the Relator himself, it does not reasonably follow that if Dr. Jain did not supervise, then Dr. O'Laughlin did not either. Further, as Dr. O'Laughlin is the Relator, one might expect that he would be able to allege in good faith, even prior to discovery, that he did not perform services falsely attributed to Dr. Jain (although, it is possible he does not have a full record of his schedule spanning from July 2012 through October 2015). In addition, Relator has demonstrated with Counts I and II that he is capable of alleging that one particular physician (in that case, Dr. O'Laughlin) did not perform radiation oncology services *and that no other qualified physician* performed the services. (*See, e.g.*, *id.* at ¶ 47). *Cf. Metyk v. Key Corp.*, 560 F. App'x 540, 542-53 (6th Cir. 2014) (holding that reading complaint as a whole, the plaintiff failed to adequately allege particular theory of liability).

In short, Relator has not provided sufficient factual detail from which the Court could reasonably infer that by alleging *a certain physician* did not supervise services, *no physician* supervised those services. *Cf. Space Coast*, 94 F. Supp. 3d at 1261 (finding that because the relator did not allege "the absence of *any* physician—the Second Amended Complaint does not state a violation of the Medicare Benefits Policy Manual") (emphasis added); *see also Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009) ("[W]here the well-pleaded facts do not permit the court to infer more than a mere possibility of misconduct, the complaint has alleged—but it has not 'shown—that the pleader is entitled to relief.'") (alteration and internal quotation omitted) (quoting Fed. R. Civ. P. 8(a)(2)).

Further, Relator may not now effectively amend his Complaint through his brief in order to allege an entirely different theory of liability. *See United States ex rel. Roycroft v. GEO Grp. Inc.*, 722 F. App'x 404, 407 (6th Cir. 2018). He also cannot rely on additional

allegations in his brief to supplement or clarify the allegations in the Complaint. *See Johnson v. Metro. Gov't of Nashville & Davidson Cnty.*, 502 F. App'x 523, 541-42 (6th Cir. 2012) ("The Court may not . . . take into account additional facts asserted in a memorandum opposing the motion to dismiss, because such memoranda do not constitute pleadings under Rule 7(a)."") (quoting in a parenthetical Moore's Federal Practice § 12.34). Accordingly, accepting as true Relator's allegation that Defendants billed under the names of particular physicians who did not actually perform or supervise certain radiations services, and drawing all reasonable inferences in Relator's favor, Counts III and IV fail to allege that Defendants materially violated physician supervision requirements. Thus, Defendants' Motion to Dismiss is granted as to Counts III and IV of the Amended Complaint.

3. Chemotherapy Claims

Defendants similarly assert that Relator's claims regarding chemotherapy services should be dismissed for lack of materiality. (Doc. # 64-1 at 14-17). The Amended Complaint alleges that Defendants submitted false claims and created false records indicating that Dr. Jain provided or directly supervised certain chemotherapy services when, in reality, he did not. (Doc. # 53 at ¶¶ 120-172) (Counts V and VI). Relator alleges that, instead, a nurse practitioner or physician's assistant performed these chemotherapy services *without Dr. Jain's supervision*. (*Id.* at ¶¶ 161, 168). Relator further alleges that by certifying that Dr. Jain provided or directly supervised these services, Defendants overbilled the government, because the services of physician assistants and nurse practitioners are reimbursed no more than 85% of the amount payable to a physician. (*Id.* at ¶ 121).

Defendants seek dismissal of these claims because, as with Relator's "named physician claims," the Amended Complaint falls short of alleging that no physician supervised these chemotherapy services. (Doc. # 64-1 at 16). Thus, Defendants argue that even assuming Dr. Jain did not supervise the services, they could have properly been billed at the higher physician rate as "incident-to" services under 42 C.F.R. § 410.26, as long as some other physician supervised the services. (*Id.*).

The Court agrees that accepting Relator's allegations as true and drawing all reasonable inferences in his favor, he has failed to adequately allege a material violation with respect to the chemotherapy services. As with the "named physician" claims, Relator does not allege that *no* physician supervised the chemotherapy services, but rather, only that a particular physician—Dr. Jain—did not supervise those services. Yet, even without Dr. Jain's supervision, these claims would have been reimbursable at the physician level as incident-to services, as long as they were supervised by some other physician. As discussed in the previous section, while physician supervision is a precondition of payment for incident-to services, billing under a particular physician's name is not. Thus, Relator's allegation that *Dr. Jain* did not perform or supervise certain chemotherapy services does not allege a material FCA violation. Moreover, for the same reasons identified in the previous section, Relator has not provided factual allegations to support a reasonable inference that because Dr. Jain did not supervise the identified services, no physician supervised those services. Consequently, Relator has failed to sufficiently allege a material FCA violation concerning the provision of certain chemotherapy services, and Counts V and VI are dismissed for failure to state a claim.

C. Knowledge

Defendants argue, generally, that Relator has failed to adequately plead that Defendants submitted false claims for reimbursement with the requisite mental state of knowledge. (Doc. # 64-1 at 23-24). The false presentment and false records claims asserted in the Amended Complaint both require that the Defendants acted knowingly. *See* 31 U.S.C. § 3729(a)(1)(A) (prohibiting a person from "knowingly present[ing], or caus[ing] to be presented, a false or fraudulent claim for payment or approval"); *id.* § 3729(a)(1)(B) (prohibiting "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"). Under the FCA, "knowingly" is defined as actual knowledge, "deliberate ignorance of the truth or falsity of the information," or "reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A). "'No proof of specific intent to defraud is required' for an FCA claim." *United States ex rel. Wall v. Circle C. Const., L.L.C.*, 697 F.3d 345, 356 (6th Cir. 2012) (alteration omitted) (quoting 31 U.S.C. § 3729(b)(1)(B)). Moreover, at the motion-to-dismiss stage, knowledge need only be pled generally. *United States ex rel. Prather v. Brookdale Senior Living Cmty., Inc.*, 892 F.3d 822, 837 (6th Cir. 2018) (citing Fed. R. Civ. P. 9(b)). Nevertheless, a plaintiff must plead knowledge with sufficient detail to meet the plausibility standard of Rule 8. *Mourad v. Marathon Petroleum Co. LP*, 654 F. App'x 792, 798 (6th Cir. 2016); *see also Iqbal*, 556 U.S. at 686-87 (finding that Rule 9 does not permit a plaintiff "to evade the less rigid—though still operative—strictures of Rule 8").

Here, the Amended Complaint contains sufficient factual allegations to plausibly state that Defendants acted knowingly for purposes of the FCA. Based on the discussion above, the only false presentment and false record claims that may proceed at this time

are (1) Relator's claims under Counts I and II that Defendants submitted claims for reimbursement and records falsely certifying that certain radiation oncology services were performed by Dr. O'Laughlin or another radiation oncologist, and that Defendants falsely certified that a qualified physician reviewed or approved guidance images, *see supra* Part II.B.1.a-b, and (2) Relator's claims under Count VII that Defendants submitted claims falsely certifying that Defendants complied with documentation requirements for simulation services, *see supra* Part II.B.1.c.

Relator has adequately alleged knowledge with respect to these claims. The Amended Complaint alleges that when Defendant A One Biz processed information for claims, it "manipulated the information *for the purpose of* insuring that the claim would pass review . . . regardless of whether the information provided by the clinics to A One Biz was accurate, truthful, complete or misleading." (Doc. # 53 at ¶ 41(d)) (emphasis added). Additionally, Relator alleges that Defendants Dr. Jain and Manish Jain knew the information that served as the basis for claims was "inaccurate, untruthful, incomplete, and misleading because Kirti K. Jain operated, managed, and directed the administrative operation of [the Cancer Clinics]" and that Manish Jain "was fully aware of Dr. Kirti K. Jain's directives." (*Id.* at ¶ 41(e)). Accepted as true, these allegations provide a sufficient factual basis to support the Relator's conclusions that Defendants "knowingly and willfully presented and caused to be presented for payment or approval false and fraudulent claims to federally-funded federal health care programs," (*id.* at ¶¶ 45, 85, 174, 189), and "knowingly and willfully made and used, and caused to be made and used, false records and statements material to the above described false and fraudulent claims," (*id.* at ¶ 78).

D. Conspiracy Claim

Finally, Defendants argue that Relator's conspiracy claim should be dismissed because the claim fails as a matter of law under the "intracorporate conspiracy doctrine" which, according to Defendants, "bar[s] conspiracy claims where all the alleged conspirators are employees of the same corporate entity." (Doc. # 64-1 at 25-27) (citing *Jackson v. City of Cleveland*, 925 F.3d 793 (6th Cir. 2019)). This argument is not persuasive because, although there is overlap among the individual and corporate Defendants, that overlap is not complete.

Conspiracy may be alleged under the FCA pursuant to 31 U.S.C. § 3729(a)(1)(C), which provides that a person may be liable for conspiring to commit violations of the FCA as set forth in the other subparagraphs of the Section, including presenting false claims under § 3729(a)(1)(A) and making or using false records under § 3729(a)(1)(B). A civil conspiracy consists of "an agreement between two or more persons to injure another by unlawful action." *United States v. Murphy*, 937 F.2d 1032, 1039 (6th Cir. 1991) (quoting *Hooks v. Hooks*, 771 F.2d 935, 943-44 (6th Cir. 1985)). "Each conspirator need not have known all of the details of the illegal plan or all of the participants involved." *Id.* (quoting *Hooks*, 771 F.2d at 944). Rather, "[a]ll that must be shown is that there was a single plan, that the alleged coconspirator shared in the general conspiratorial objective, and that an overt act was committed in furtherance of the conspiracy that caused injury to the complainant." *Id.* (quoting *Hooks*, 771 F.2d at 944).

Pursuant to the intracorporate conspiracy doctrine, when "all of the defendants are members of the same collective entity, there are not two separate 'people' to form a conspiracy." *Jackson*, 925 F.3d at 817 (quoting *Johnson v. Hills & Dales Gen. Hosp.*, 40

F.3d 837, 839-40 (6th Cir. 1994)).[11] This also means that "members of the same legal entity cannot conspire *with one another* as long as their alleged acts were within the scope of their employment." *Id.* at 819 (quoting *Jackson v. City of Columbus*, 194 F.3d 737, 753 (6th Cir. 1999)). For example, in *Hull v. Cuyahoga Valley Joint Vocational School District Board of Education*, the Sixth Circuit held that the doctrine barred a conspiracy claim against a school superintendent, the executive director of the district, and a school administrator who were all employees or agents of the Board of Education. 926 F.2d 505, 510 (6th Cir. 1991).

Here, Defendants argue that the doctrine bars Relator's claim because the Amended Complaint alleges that Dr. Jain was the president of each of the Cancer Centers (Ashland BBC and Highlands CC), as well as a manager of A One Biz Solutions, LLC. (Doc. # 64-1 at 26-17) (citing Doc. # 53 at ¶¶ 9, 11, 16). Thus, Defendants argue that "the Amended Complaint essentially pleads that Dr. Jain conspired with himself through the Cancer Centers to defraud the Government." (*Id.* at 27). However, in Response, Relator points out that Dr. Jain was not a member of the named co-conspirator Logan CC, and that he was allegedly a member of A One Biz Solutions only up until mid-2010. (Doc. # 66) (citing Doc. # 53 at ¶ 16); (*see also* Doc. # 53 at ¶ 13). Thus, Dr. Jain could have conspired with Logan CC or A One Biz Solutions (after mid-2010) without running afoul of the intracorporate conspiracy doctrine. Relator also provides a chart summarizing the Defendants' (and Logan CC's) relationships, based on the allegations in the Complaint. (Doc. # 66 at 24). At this time, the Court need not detail how each of the

[11] Defendants acknowledge that the Sixth Circuit has not yet spoken on the issue of whether the intracorporate conspiracy doctrine applies to conspiracy claims brought under the FCA. (Doc. # 64-1 at 26). Thus, the Court assumes without deciding that the doctrine applies in this case.

parties could have conspired with each other; suffice it to say, Relator has adequately alleged that two or more people or entities conspired to violate the FCA that were not part of the same organization.[12]

E. Dismissal with Prejudice

Defendants request that the Court dismiss Relator's Amended Complaint with prejudice. (Doc. # 64-1 at 27-28). Defendants specifically assert that dismissal with prejudice is appropriate because Relator's "entire case is based upon a mischaracterization of the prerequisite conditions of payments for the services encompassed in this litigation." (*Id.* at 28). In response, Relator requests, generally, leave to amend should one or more counts be deemed deficient. (Doc. # 66 at 25).

The Court agrees that with respect to Counts I and II, Relator has demonstrated no basis in law for a requirement that certain radiation oncology services be *supervised* by a radiation oncologist. *See supra* Part II.B.1.b. Accordingly, Counts I and II will be dismissed with prejudice to the extent Relator alleges that Defendants falsely certified that certain radiation oncology services were supervised by a qualified radiation oncologist. (*See* Doc. # 53 at ¶¶ 47(b), 72(b)-(d), 79(c)). Relator has similarly failed to show a legal basis for his claim, alleged under Count VII, that Defendants falsely certified by implication that certain simulation services were *performed* by a radiation oncologist. *See supra* Part II.B.1.c. Thus, Count VII is dismissed with prejudice to the extent Relator alleges these simulation services required performance by a radiation oncologist. (*See* Doc. # 53 at ¶ 183).

[12] Defendants, in their reply, fail to respond to the conspiracy arguments raised in Relator's response, a fact that further counsels against dismissal of Relator's conspiracy claim.

At this time, Relator has not adequately pleaded that the radiation services and chemotherapy services identified in Counts III-VI were not *supervised* by a physician, alleging instead that a *particular* physician did not supervise the services. *See supra* Part II.B.2-3. Yet, the parties agree that radiation oncology services and incident-to services require some level of physician supervision. Moreover, in his response brief, Dr. O'Laughlin indicates that he intended to allege that *no physician* supervised the services. (*See* Doc. # 66 at 16, 18). Because it appears that with greater factual detail, Relator may be able to state a claim for relief, Counts III-VI will be dismissed without prejudice. *See Newberry v. Silverman*, 789 F.3d 636, 645-46 (6th Cir. 2015) (finding district court erred by denying plaintiff's fraud claim with prejudice where it appeared based on information in the record that "there [was] a reasonable probability that the complaint could have been saved by an amendment"). Thus, Relator may seek leave to amend in order to re-assert the claims in Counts III-VI, if he so chooses.

III. CONCLUSION

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

(1) Defendants' Motion to Dismiss Relator's Amended Complaint (Doc. # 64) is **GRANTED IN PART and DENIED IN PART**. Specifically:

(a) Relator's false presentment and false records claims alleged in Counts I and II are **dismissed with prejudice** to the extent they are based on Defendants' alleged false certification that certain radiation oncology services were supervised by a qualified radiation oncologist, (*see* Doc. # 53 at ¶¶ 47(b), 72(b)-(d), 79(c));

(b) Relator's false presentment and false records claims alleged in Counts I and II **may proceed** to discovery to the extent they are based on Defendants' alleged false certification that certain radiation oncology services were performed by Dr. O'Laughlin or another qualified radiation oncologist, (*see id.* at ¶¶ 47(a), (c), 72(a), (c)-(d), 79(a), (d)), and Defendants' alleged false certification that a qualified physician reviewed or approved guidance images, (*see id.* at ¶ 72(e));

(c) Relator's false presentment and false records claims alleged in Count III, Count IV, Count V, and Count VI are **dismissed without prejudice**;

(d) Relator's false presentment claim regarding simulation services alleged in Count VII is **dismissed with prejudice** to the extent it is based on Defendants' alleged false certification that certain simulation services were performed by a radiation oncologist, (*see id.* at ¶ 183), but **may otherwise proceed** to discovery; and

(e) Relator's conspiracy claim alleged in Count VIII **may proceed** to discovery.

(2) Any motion by Relator for leave to amend the Amended Complaint shall be filed **within fourteen (14) days** of the date of entry of this Order;

(3) If no motion for leave to amend is filed, Defendants **shall file** an Answer to the remaining viable claims in the Amended Complaint pursuant to Federal Rule of Civil Procedure 12(a)(4)(A) **not later than fourteen (14) days thereafter**; and

(4) The parties shall file a **Status Report within fourteen (14) days** indicating whether they would be amenable to mediation at this stage of the litigation.

This 20th day of October, 2020.

Signed By:
David L. Bunning
United States District Judge

J:\DATA\ORDERS\Ashland Civil\2016\16-148 MOO re MTD.docx