

**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 upon Relator Robert O'Laughlin, M.D.'s Motion for Limited Reconsideration of this Court's Memorandum Opinion and Order granting in part and denying in part Defendants' Motion to Dismiss. (Doc. # 77). Defendants filed a Response in opposition (Doc. # 81) and Relator filed a Reply (Doc. # 83). Accordingly, the Motion has been fully briefed and is ripe for adjudication. For the reasons stated below, Relator's Motion for Limited Reconsideration is **denied**.

I. FACTUAL AND PROCEDURAL BACKGROUND

Dr. O'Laughlin initiated this *qui tam* action under the False Claims Act ("FCA"), 31 U.S.C. § 3729, *et seq.*, against Defendants based on their alleged fraudulent misrepresentations to Medicare, Medicaid, and other federal programs regarding radiation oncology and chemotherapy services they provided. (Doc. # 53 at 1-2). Relevant to Relator's Motion for Limited Reconsideration, Counts I and II of the Amended Complaint 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 supervised those services.* (See *id.* ¶¶ 72, 79).

The Court's October 20, 2020 Memorandum Opinion and Order granting in part and denying in part Defendants' Motion to Dismiss found, in relevant part, that Relator failed to state a claim in Counts I and II to the extent he alleged that Defendants falsely certified that a radiation oncologist (as opposed to another type of physician) supervised radiation oncology services. (See Doc. # 76 at 10-13). These claims were dismissed because Relator failed to identify a statute or regulation imposing a requirement that the supervising physician be a radiation oncologist. (*Id.* at 10-11). The Court first found that the Medicare Benefit Policy Manual does not contain such a requirement. (*Id.* at 11). As another basis for this requirement, Relator pointed to Medicare Regulation 42 C.F.R. § 410.26(a)(1), which governs "incident to" services. (*Id.* at 12). This provision covers "[s]ervices and supplies incident to a physician's professional services" and allows a supervising physician to bill Medicare for services performed by "auxiliary personnel" as long as the services are "an integral, though incidental, part of the service of a physician (or other practitioner)" and are performed under the "direct supervision of the physician." (*Id.*) (quoting 42 C.F.R. § 410.26(b)(2), (5)). The incident-to regulation defines "auxiliary personnel" to mean "any individual who is acting under the supervision of a physician (or other practitioner)" and who "meets any applicable requirements to provide incident to services, including licensure, imposed by the State in which the services are being furnished." (*Id.*) (quoting 42 C.F.R. § 410.26(a)(1)). In opposition to Defendants' Motion to Dismiss, Dr. O'Laughlin argued that this definition of auxiliary personnel incorporating Kentucky law is the source of the particularized supervision requirement, because

Kentucky law requires that a radiation oncologist supervise the provision of radiation oncology services. (See Doc. # 66 at 4, 9-14).

The parties dispute whether the “incident to” regulation, 42 C.F.R. § 410.26, applies to the services at issue. Rather than address the applicability of the regulation, the Court assumed that the provision applies and found that, even so, the definition of auxiliary personnel contained in the incident to regulation does not require that radiation oncology services be supervised by a radiation oncologist as opposed to another type of physician. (Doc. # 76 at 12-13). The Court specifically reasoned as follows:

Assuming that the radiation oncology services provided in this case were “incident-to” services covered by 42 C.F.R. § 410.26, **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.

(*Id.* at 12) (emphasis added). The Court also rejected Relator’s attempt to rely on, as the source of the alleged supervision requirement, a “Response” from CMS during the comment period for a Final Rule concerning the Medicare Hospital Outpatient Prospective Payment System as well as the regulation found at 42 C.F.R. § 414.2(5). (*Id.* at 12-13 n.7). Relator identified no other basis for a particularized supervision requirement. Relator now requests that the Court revisit this holding. (Doc. # 77 at 2-3). Based on the same reasoning, Relator also requests that the Court reconsider its dismissal of Relator’s claims based on Defendants’ provision of simulation services pertaining to Count VII of the Amended Complaint. (*Id.* at 6).

II. ANALYSIS

A. Standard of Review

The Court's Order granting in part and denying in part Defendants' Motion to Dismiss was not a final order. "District courts have authority both under common law and Rule 54(b) to reconsider interlocutory orders and to reopen any part of a case before entry of final judgment." *Rodriguez v. Tenn. Laborers Health & Welfare Fund*, 89 F. App'x 949, 959 (6th Cir. 2004) (citing *Mallory v. Eyrich*, 922 F.2d 1273, 1282 (6th Cir. 1991)). Federal Rule of Civil Procedure 54(b) provides that interlocutory orders "may be revised at any time before the entry of a judgment adjudicating all the claims" Traditionally, "courts will find justification for reconsidering interlocutory orders where there is (1) an intervening change of controlling law; (2) new evidence available; or (3) a need to correct a clear error or prevent manifest injustice." *Louisville/Jefferson Cnty. Metro. Gov't v. Hotels.com, L.P.*, 590 F.3d 381, 389 (6th Cir. 2009) (alteration omitted) (quoting *Rodriguez*, 89 F. App'x at 959). Although district courts have "significant discretion" to reconsider prior, interlocutory rulings, *Rodriguez*, 89 F. App'x at 959 n.6, "[m]otions for reconsideration are not intended to re-litigate issues previously considered by the Court or to present evidence that could have been raised earlier." *Ne. Ohio Coal. for the Homeless v. Brunner*, 652 F. Supp. 2d 871, 877 (S.D. Ohio 2009).

B. Clear error

Relator asserts in his Motion for Limited Reconsideration that the Court made a clear error of law by holding that the definition of auxiliary personnel contained in 42 C.F.R. § 410.26(a)(1) does not support his allegation that physicians supervising auxiliary personnel administering radiation oncology services must be radiation oncologists. (Doc.

77 at 2). The definition of auxiliary personnel requires that such personnel “meet[] 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). Dr. O’Laughlin simply reiterates his argument that this definition incorporating Kentucky law, which he says in turn requires supervision by a radiation oncologist, supports his claims in Counts I and II that Defendants violated the FCA by falsely certifying that certain radiation services were supervised by a radiation oncologist. (Doc. # 77 at 4). Relator’s repetition of this argument is neither an appropriate basis for reconsideration, see *Brunner*, 652 F. Supp. 2d at 877, nor persuasive. The Court’s previous reasoning stands: § 410.26(a)(1)’s mandate that *auxiliary personnel* meet state-imposed requirements, like licensure, cannot be read to impose a requirement that *supervising physicians* possess a particular specialty or credentials, i.e., that physicians supervising radiation services be radiation oncologists. The definition applies to auxiliary personnel, not supervising physicians. Moreover, the definition serves to explain the scope of “incident to” services; it does not appear to create a condition precedent for reimbursement. In short, Dr. O’Laughlin’s request that the Court re-examine this argument is an inappropriate basis for reconsideration and he has provided no new evidence or argumentation that counsels in favor of a different understanding of the implications of the auxiliary personnel definition.

In his reconsideration Motion, Relator proceeds to bolster his prior argument by citing to various other provisions within the “incident-to” regulation that he did not previously cite or rely upon in his original Response to Defendants’ Motion to Dismiss. For example, Relator cites 42 C.F.R. § 410.26(b)(7), which states that “[s]ervices and

supplies must be furnished in accordance with applicable State law.” (Doc. # 77 at 5). This provision appears to more broadly incorporate state-law requirements regarding the manner in which “incident to” services are to be provided. Yet, Relator provides no explanation for his failure to cite to this provision in his earlier briefing, which instead focused on the definition of auxiliary personnel contained in 42 C.F.R. § 410.26(a)(1) as well as several other sources that the Court examined and rejected. (See Doc. # 76 at 11, 12-13 n.7). Generally, arguments raised for the first time in a motion for reconsideration are considered forfeited. *Cf. Evanston Ins. Co. v. Cogswell Props., LLC*, 683 F.3d 684, 692 (6th Cir. 2012) (noting that arguments raised for first time in reconsideration motion are forfeited on appeal); see also *Memphis A. Phillip Randolph Inst. v. Hargett*, 485 F. Supp. 3d 1003, 1003 (M.D. Tenn. 2020) (“A motion for reconsideration should not provide the parties with an opportunity for a second bite at the apple.”). Thus, the Court declines to consider additional bases Relator sets forth for the first time upon reconsideration.

Regardless, Relator’s argument that Kentucky law requires radiation services provided by auxiliary personnel be supervised by a radiation oncologist is unsupported by Kentucky’s regulatory scheme and the language of incorporated practice guidelines. In making this argument based on Kentucky law, Relator relies entirely on his original briefing in opposition to Defendants’ Motion to Dismiss. Kentucky regulations do not in themselves set forth a specialized supervision requirement, but Relator argues that Kentucky regulations adopt by reference federal practice standards that establish such a requirement. (Doc. # 66 at 12-14).

As an initial matter, Relator refers to various Kentucky regulations in his original brief in response to Defendants' Motion to Dismiss, including 201 Ky. Admin. Reg. 46:040. (*Id.* at 12). However, the Court is unable to locate the excerpted language within that provision, which is not provided as an exhibit. In fact, Defendants point out the mistaken citation, (Doc. # 81 at 7 n.2), but Relator makes no attempt to clarify the provision he is attempting to rely upon. In any case, the most similar, relevant language appears to reside in 201 Ky. Admin. Reg. 46:035 and does not support Relator's argument that a radiation oncologist must be on hand to supervise auxiliary personnel. Title 201 Ky. Admin. Reg. 46:035 "establishes uniform standards for the licensure of individuals who perform medical imaging and radiation therapy for diagnostic and therapeutic purposes while under the supervision of a licensed practitioner of the healing arts." 201 Ky. Admin. Reg. 46:035 advisory notes. This regulation provides that:

A licensee shall perform according to practice standards of the discipline for which the licensee holds a credential, as established by the American Society of Radiologic Technologists (ASRT), the American College of Radiology (ACR), the American Association of Physicists in Medicine (AAPM), and the Society of Nuclear Medicine and Molecular Imaging (SNMMI) and incorporated by reference.

Id. § 3. Although §§ 3 and 4 of 201 Ky. Admin. Reg. 46:035 list numerous, specific practice standards incorporated into Kentucky law, the one Relator relies on—ASTRO Practice Parameter for Radiation Oncology—is not among them. (Doc. # 66 at 13). For this reason, Relator's reliance on that particular practice parameter is misguided. Even if the practice parameter cited by Relator were to apply, it does not clearly establish a particularized supervision requirement. The ACR-ASTRO Practice Parameter for Radiation Oncology states that:

A radiation oncologist should be available for direct care and quality review and should be on the premises whenever radiation treatments are being delivered. The radiation oncologist, facility and support staff should be available to initiate urgent treatment within a medically appropriate response time on a 24-hour basis or refer to a facility that is available to treat on a 24-hour basis. When unavailable, the radiation oncologist is responsible for arranging appropriate coverage.

(Doc. # 66-1 at 8). Relator's recitation of this section leaves out the following next sentence: "Exceptions may exist for rural practices regarding the availability requirements." (*Id.*). First, the language of this section is permissive, rather than mandatory—"should be on the premises whenever radiation treatments are being delivered." (*Id.*). Second, the exception for rural practices may very well apply in this case, as the Defendant Cancer Centers are located in the sparsely populated cities of Ashland and Prestonsburg, Kentucky. (Doc. # 53 at 2). Third, as Defendants point out, the ACR expressly states that its guidelines "are not intended, nor should they be used, to establish a legal standard of care." (Doc. # 81 at 7) (citing Doc. # 66-1 at 1). Relator's reliance on the ACR-ASTRO Practice Parameter for Radiation Oncology is therefore unpersuasive.

Another standard relator cites that does appear to be incorporated into the Kentucky regulations states that: "Radiation therapists assist the radiation oncologist in localizing the treatment area, participate in treatment planning and deliver high doses of ionizing radiation as prescribed by the radiation oncologist." (Doc. # 66 at 13) (citing ASRT Radiation Therapy Practice Standards); see *also* 201 Ky. Admin. Reg. 46:035 § 3(5) (incorporating The ASRT Practice Standards for Medical Imaging and Radiation Therapy – Radiation Therapy). Yet, this provision does not set forth a particularized supervision requirement and merely notes that the treatments should be *prescribed* by a

radiation oncologist. Because Relator has failed to direct the Court to a Kentucky regulation or incorporated practice standard setting forth a particularized supervision requirement, Relator's argument that Kentucky law mandates supervision by a radiation oncologist is a nonstarter.

Furthermore, given that the federal regulations only require physician supervision, Kentucky's adoption of more stringent practice guidelines is unlikely to create a material condition of payment for purposes of Medicare reimbursement. See *United States ex rel Hobbs v. Medquest Assocs., Inc.*, 711 F.3d 707, 714 (6th Cir. 2013) ("A false-certification theory only applies where the underlying regulation is a 'condition of payment,' meaning that the government would not have paid the claim had it known the provider was not in compliance."). In sum, Dr. O'Laughlin has not set forth an appropriate basis for reconsideration of his prior, rejected argument, and even upon a second look in light of the newly-cited regulations, the Court reaches the same conclusion. For the same reasons, the Court does not reach a different conclusion upon reconsideration with respect to Relator's dismissed claims based on Defendants' provision of simulation services.

III. Conclusion

Accordingly, for the reasons stated herein, **IT IS ORDERED** that Relator's Motion for Limited Reconsideration (Doc. # 77) is **denied**.

This 30th day of August, 2021.



Signed By:

David L. Bunning

Handwritten signature of David L. Bunning, consisting of the initials "DB" in a stylized, cursive font.

United States District Judge