

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO
Judge William J. Martínez**

Civil Action No. 12-cv-3029-WJM-CBS

MARTHA L. BAKER,

Plaintiff-Relator,

v.

BANNER HEALTH, and
BANNER MEDICAL GROUP COLORADO,

Defendants.

**ORDER GRANTING PLAINTIFF’S EARLY MOTION FOR PARTIAL
SUMMARY JUDGMENT**

Acting on her own behalf and on behalf of the United States, Plaintiff-Relator Martha L. Baker (“Baker”) brings this lawsuit against Banner Health and Banner Medical Group Colorado (together, “Banner”) for violation of the False Claims Act, 31 U.S.C. §§ 3729–3733. (ECF No. 38.) Before the Court is Baker’s Early Motion for Partial Summary Judgment. (ECF No. 51.) For the reasons stated below, the motion is granted.

I. LEGAL STANDARD

Summary judgment is warranted under Federal Rule of Civil Procedure 56 “if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a); *see also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248–50 (1986). A fact is “material” if, under the relevant substantive law, it is essential to proper disposition of the claim. *Wright v. Abbott Labs., Inc.*, 259 F.3d 1226, 1231–32 (10th Cir. 2001). An issue is “genuine” if

the evidence is such that it might lead a reasonable trier of fact to return a verdict for the nonmoving party. *Allen v. Muskogee*, 119 F.3d 837, 839 (10th Cir. 1997).

In analyzing a motion for summary judgment, a court must view the evidence and all reasonable inferences therefrom in the light most favorable to the nonmoving party. *Adler v. Wal-Mart Stores, Inc.*, 144 F.3d 664, 670 (10th Cir. 1998) (citing *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986)). In addition, the Court must resolve factual ambiguities against the moving party, thus favoring the right to a trial. *See Houston v. Nat'l Gen. Ins. Co.*, 817 F.2d 83, 85 (10th Cir. 1987).

II. FACTS

The relevant facts are minimal and undisputed. Banner operates certain medical facilities in Colorado, including North Colorado Medical Center, McKee Medical Center, and Sterling Regional MedCenter (collectively, the “Facilities”). (Movant’s Statement of Material Facts (“Plaintiff’s Facts”) (ECF No. 51 at 2–11) ¶ 1.) Among other things, the Facilities provide “external beam radiation therapy,” such as for treating cancer patients. (*Id.* ¶ 2.) Banner has submitted Medicare claims for external beam radiation therapy performed at the Facilities. (*Id.* ¶ 3.) In 2010, 2011, and 2012, Banner sometimes performed external beam radiation therapy at the Facilities without the physical presence of a medical practitioner authorized to prescribe such therapy. (*Id.* ¶¶ 24–25.)

III. ANALYSIS

A. Propriety of Early Summary Judgment

As discussed in more detail below, Baker’s theory of liability is that, to obtain

Medicare reimbursement, Medicare regulations (as applied in Colorado) require a physician with specialized training in radiation therapy to be physically present in any facility where external beam radiation therapy is taking place. (ECF No. 51 at 1.) Because Banner at times did not have such a physician present, but nonetheless billed Medicare for the procedure, Baker claims that Banner has submitted false claims, potentially compensable under the False Claims Act. (*Id.*)

The undersigned's practice standards normally limit parties to one motion for summary judgment "customarily filed at the conclusion of pretrial discovery. In addition, however, within 30 days after entry of the initial scheduling order, a party may also file one early motion for partial summary judgment . . . which presents a substantial and well-supported argument for significantly reducing the claims or issues in the case." WJM Revised Practice Standards III.E.2. Baker moves under this authority, arguing that "[a]n early ruling on [the proper interpretation of the relevant Medicare regulations] will significantly clarify and reduce the issues remaining in this case." (ECF No. 51 at 1–2.)

The Court is persuaded that early summary judgment is appropriate on this question. Baker's entire claim hangs on whether she correctly reads certain Medicare regulations and related Colorado regulations regarding radiation therapy. This appears to be a pure question of law, and is not speculative. Although Banner denies that a specially trained physician is required to be physically present in the facility where radiation therapy is ongoing, Banner admits that it performed radiation therapy at the Facilities without the physical presence of such a physician. (Response to Movant's Material Facts ("Defendants' Response") (ECF No. 52 at 4–6) ¶¶ 24–25.)

One thing the parties' competing statements of fact do not directly address is whether Banner *billed* Medicare for any of those particular instances of radiation therapy. Nonetheless, that accusation is implicit in Baker's entire claim, and Banner offers nothing to refute it. Rather, Banner offers additional facts regarding its specific consideration of whether it could provide Medicare-reimbursable radiation therapy in the absence of a specialized physician, and its conclusion that it could, so long as an advanced practice nurse supervised the procedure. (Additional Material Facts ("Defendants' Additional Facts") (ECF No. 52 at 6–11) ¶¶ 20–24.)

Given this, it appears that Banner indeed submitted Medicare claims for radiation therapy performed in the absence of the specialized physician that Baker claims must be present. If Baker is correct, it would significantly clarify Banner's potential liability. If Banner is correct, it would apparently eviscerate Baker's case. Accordingly, the Court will rule on the issue presented, even though presented early.

B. "Services That They May Personally Furnish in Accordance with State Law"

This case turns largely on the meaning of 42 C.F.R. § 410.27, which is lengthy but reads in relevant part as follows:

(a) Medicare Part B pays for therapeutic hospital or CAH^[1] services and supplies furnished incident to a physician's or nonphysician practitioner's service, which are defined as all services and supplies furnished to hospital or CAH outpatients that are not diagnostic services and that aid the physician or nonphysician practitioner in the treatment of the patient, including drugs and biologicals which are not usually self-administered, if—

¹ "CAH" means "critical access hospital" and generally refers to rural hospitals that meet certain criteria. See 42 C.F.R. § 400.202.

(1) They are furnished—

* * *

(iv) Under the direct supervision . . . of a physician or a nonphysician practitioner as specified in paragraph (g) of this section, subject to the following requirements:

(A) For services furnished in the hospital or CAH . . . “direct supervision” means that the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed;

* * *

(C) Nonphysician practitioners may provide the required supervision of services that they may personally furnish in accordance with State law . . . ;

* * *

(g) For purposes of this section, “nonphysician practitioner” means a clinical psychologist, licensed clinical social worker, physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse-midwife.

Baker’s argument focuses on the statement in subparagraph (a)(1)(iv)(C) that “direct supervision” can come through a nonphysician practitioner if the nonphysician practitioner “may personally furnish [the relevant service] in accordance with State law.” Baker argues that Colorado does not permit nonphysician practitioners to “furnish” radiation therapy services. Baker specifically points to regulations promulgated by the Colorado state board of health stating that “[n]o individual shall be exposed to the useful beam [*i.e.*, therapeutic radiation] except for medical therapy purposes pursuant to a written directive by an authorized user.” 6 Colo. Code Regs. § 1007-1:24.3.8.

“Authorized user” means “a physician who has a current active State of Colorado license” who has been certified by certain accrediting organizations in radiology, therapeutic radiology, radiation oncology, or similar disciplines. *Id.*, App’x 2K. Such a physician must also complete 700 hours of specified education and training, as well as three years of supervised clinical practice. *Id.*

Given these regulations, Baker argues that only a physician with the foregoing credentials may “personally furnish” radiation therapy “in accordance with State law.” 42 C.F.R. § 410.27(a)(1)(iv)(C). Baker’s interpretation is straightforward and appears correct on its face. Banner, however, offers several counterarguments, which the Court will address in turn.

Banner first emphasizes that § 410.27 permits nonphysician practitioners to provide the required “direct supervision.” (ECF No. 52 at 13–15.) Banner is correct, but this argument does not address § 410.27(a)(1)(iv)(C)’s requirement that the nonphysician practitioner be permitted under “State law” to “personally furnish” the service that he or she is supervising.

As to that, Banner claims that Colorado law actually does allow an advanced practice nurse to prescribe radiation therapy. (ECF No. 52 at 15–21.) Banner focuses on the term “practitioner of the healing arts,” which is a term of art in Colorado statutes and regulations relating to healthcare, and which Banner claims to encompass advanced practice nurses. (See *id.* at 17 & n.9.) Banner then highlights the following language from a Colorado statute authorizing the state board of health to regulate radiation-emitting machines: “The rules adopted pursuant to this [authorization] shall never be construed to limit the kind or amount of radiation that may be intentionally

applied to a person for diagnostic or therapeutic purposes by or under the direction of a duly licensed practitioner of the healing arts.” Colo. Rev. Stat. § 25-11-104(3). Banner takes this to mean that, by statute, a practitioner of the healing arts (including an advanced practice nurse) cannot be prohibited from furnishing radiation therapy.

Even assuming that “practitioner of the healing arts” includes advanced practice nurses, this argument has a number of flaws. To begin, the statute at issue appears to be directed at regulations regarding the safe use of radiation-emitting medical equipment. *See generally* Colo. Rev. Stat. §§ 25-11-101 through -113. It is not clear that this statute governs qualifications for prescribing radiation therapy. Perhaps it does, but Banner has pointed this Court to nothing establishing that the Colorado regulations on which Baker relies derive from this particular statute’s delegation of rulemaking authority.

Even if this statute provides the authority Banner claims, Banner’s argument implicitly reduces to an assertion that the Colorado regulations on which Baker relies conflict with a Colorado statute. The Eleventh Amendment prohibits this Court from delving into any such conflict. *See Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89, 106 (1984) (“ . . . it is difficult to think of a greater intrusion on state sovereignty than when a federal court instructs state officials on how to conform their conduct to state law. Such a result conflicts directly with the principles of federalism that underlie the Eleventh Amendment.”). Thus, the Court sees no relevance in the statutory directive that the state board’s rules “shall never be construed to limit the kind or amount of radiation that may be intentionally applied to a person for diagnostic or therapeutic purposes by or under the direction of a duly licensed practitioner of the

healing arts.” Colo. Rev. Stat. § 25-11-104(3).

Banner also appears to claim that Colorado law at least allows an advanced practice nurse to *supervise* radiation therapy sessions. (ECF No. 52 at 16.) The Court need not address that question, however, because it is not material to the current inquiry. Banner seems to be saying that “the required supervision of services that [nonphysician practitioners] may personally furnish in accordance with State law,” 42 C.F.R. § 410.27(a)(1)(iv)(C), refers to the “service” of supervising a radiation therapy session. But this effectively rewrites the regulation to address “the required supervision of supervision that nonphysician practitioners may personally furnish in accordance with State law,” which is nonsense. Thus, whether advanced practice nurses may supervise radiation therapy sessions does not inform whether they may “personally furnish” radiation therapy under § 410.27.

Banner finally falls back on the procedures surrounding radiation therapy. (ECF No. 52 at 19–20.) Banner points out that a radiation prescription is meticulously developed through cooperation between a radiation oncologist, a dosimetrist, a medical physicist, and a radiation therapist. (Defendants’ Additional Facts ¶¶ 4–13.) Moreover,

[o]nce the operator turns the machine on for a daily therapy session, it is not possible for anyone to revise the energy of the beam, the dose per fraction of treatment, or the treatment site. The only options are to deliver the therapy completely or to turn off the machine before the therapy session is complete.

(*Id.* ¶ 14.) And, if the radiation oncologist decides that the patient needs a different dose of radiation, the full process of creating a radiation prescription must be repeated.

(*Id.* ¶ 15.)

By raising these facts, Banner appears to be saying that it is unnecessary for radiation therapy sessions to be supervised by the type of physician that may personally furnish radiation services under Colorado law—because there is really nothing that such a physician could do during the session other than direct that the radiation machine be shut off prematurely. Banner further asserts that “treating a patient who is dehydrated and light-headed [during a therapy session], controlling pain, or helping with shortness of breath” are “well within the scope of practice of [an] advanced practice nurse.” (ECF No. 52 at 21.)

All of this may be true, but the Center for Medicare and Medicaid Services (“CMS”), which promulgated 42 C.F.R. § 410.27, has already rejected Banner’s basic premise. In the Federal Register commentary accompanying the finalization of § 410.27, CMS noted a comment from a concerned party

request[ing] that CMS consider the direct supervision requirement to be met for diagnostic or therapeutic radiation oncology services if a non-specialist practitioner who can handle an emergency provides the direct supervision and also has access by phone or other telemedicine link to a specialist who is able to change the plan of care should the need arise.

75 Fed. Reg. 71800, 72012 (Nov. 24, 2010). CMS responded:

We do not believe it is sufficient or consistent with our rules for direct supervision for the individual on site to be capable of only emergency management. The supervisory practitioner or nonphysician practitioner who is physically present should have the training and knowledge to clinically redirect the service or provide additional orders.

Id. Banner does not argue that CMS did not have authority to interpret its regulation in such a manner, or that its interpretation is unreasonable, or that the interpretation

deserves no deference. Accordingly, although Banner's explanation of the practical realities of radiation therapy raises an interesting question about why CMS requires supervision by a highly trained specialist, the fact remains that CMS specifically considered and rejected a lesser requirement.

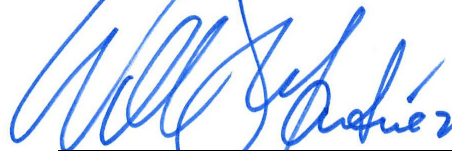
In sum, the Court concludes that Baker's interpretation of 42 C.F.R. § 410.27 is correct. Specifically, the portion of the regulation stating that "[n]onphysician practitioners may provide the required supervision of services that they may personally furnish in accordance with State law" does not currently apply in Colorado because Colorado law does not allow nonphysician practitioners to "personally furnish" radiation therapy services. The Court emphasizes, however, that this ruling does not resolve any question of intent under the False Claims Act. See, e.g., 31 U.S.C. § 3729(a) (requiring "knowing[]" presentation of false claims).

IV. CONCLUSION

For the reasons set forth above, Baker's Early Motion for Partial Summary Judgment (ECF No. 51) is GRANTED.

Dated this 28th day of May, 2015.

BY THE COURT:



William J. Martinez
United States District Judge