IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

UNITED STATES OF AMERICA and the STATE OF TENNESSEE ex rel., KAREN J. HOBBS,	)	NO. 3:06-1169
	)	JUDGE HAYNES
Plaintiffs,	)	
v.	)	
MEDQUEST ASSOCIATES, INC., BIOIMAGING AT CHARLOTTE, INC.; BIOIMAGING OF COOLSPRINGS, INC., and BIOIMAGING AT HARDING, INC., now known as BIOIMAGING AT EDMONDSON,	)	
Defendants.	)	

MEMORANDUM

Plaintiff, Karen Hobbs, a former MedQuest employee filed this action as relator on behalf of the United States under the False Claims Act ("FCA") 31 U.S.C. §§ 3729 through 3733 against the Defendants: MedQuest Associates, Inc., ("MedQuest"), BioImaging at Charlotte, Inc., ("Charlotte Center"), BioImaging of Coolsprings, Inc. ("Coolsprings Center") and BioImaging at Harding, Inc. ("Harding Center"). On March 31, 2009, the Government notified the Court of its decision to intervene and filed its intervening complaint on May 22, 2009. (Docket Entry No. 49). In essence, the United States's claims are that the Defendants unlawfully conducted diagnostic tests at its independent testing facilities without the required and appropriate physician supervision and that the Defendants submitted false payment claims for diagnostic tests under another Medicare vendor's number. In addition to its FCA claims, the United States also asserts claims for unjust enrichment, payment by mistake and common law recoupment.

Before the Court is the Defendants' motion to dismiss (Docket Entry No. 61) contending, in sum, that the United States's claim for the Defendants' performing diagnostic imaging studies without direct supervision of a board certified radiologist or a physician pre-approved by the Medicare contractor fails to state a FCA claim. Defendants contend that the cited Medicare regulations on physician supervision of diagnostic tests require only that a physician serve as supervisor and the United States's reliance upon a Local Medical Review Policy ("LMRP") for its qualified physician supervision requirement lacks the force of law to support liability under the FCA.

Defendants also challenge the United States's claim that the Defendants "knowingly" delayed the change in the enrollment classification of its Charlotte Center from a "physician's office" to an independent diagnostic testing facility ("IDTF") because the Charlotte Center was classified as a physician's office. According to Defendants, the stock transfer between William S. Witt, Inc. and the Charlotte Center did not alter Dr. Witt's prior practice at the Charlotte Center nor constitute a "change of ownership" under Medicare regulations. In addition, Defendants cite the Centers of Medicare and Medicaid Services ("CMS") Medicare Program Integrity Manual that expressly allows billing for services back to the date that the Charlotte Center qualified as an IDTF.

In response, the United States assert that the challenged FCA claims rely upon Medicare regulations not the LMRP and that the Defendants' use of Dr. Witt's provider number for payments of testing performed at the Charlotte Center violated the FCA.

A. Analysis of the United States' Complaint

In its intervening complaint, the United States alleges that the Defendants submitted

claims for payment under Medicare codes for contrast studies that require direct supervision "by a radiologist or demonstrated proficient physician." The United States's specific allegations are as follows:

23. Medicare will pay for diagnostic tests only if the services is provided by a physician, a group practice of physicians, an approved supplier of portable x-ray services, a nurse practitioner, or an independent diagnostic testing facility ("IDTF"). 42 C.F.R. § 410.33(a)(1).

24. An IDTF is a facility that is separate and independent of a hospital or a physician's office, where patients go to obtain certain x-rays, scans, and other imaging and diagnostic tests that are ordered by the patients' physicians. For example, when a doctor orders that a patient obtain an x-ray, or a Computed Tomography scan (also known as a "CT" or "CAT scan"), or a magnetic resonance imaging scan (also known as a "MRI"), the patient can obtain that service from a hospital, a doctor's office that has the necessary equipment, of from an IDTF. An IDTF may be at a fixed location, a mobile unit, or an individual non-physician practitioner. 42 C.F.R. § 410.33(a)(1). IDTF rules may apply even when an IDTF furnishes the diagnostic tests in a physician's office. Id.

25. Medicare rules require that all diagnostic tests payable under the physician fee schedule must be furnished under the appropriate level of supervision by a physician, unless a specified exception applies. 42 C.F.R. § 410.33(b)(1). All diagnostic tests, such as those provided by an IDTF, must be furnished to the patient under a specified level of physician supervision. 42 C.F.R. § 410.33(b)(3). Medicare provides that some tests may be performed under the general supervision of a physician, while other tests require direct or personal supervision. 42 C.F.R. § 410.33(b)(3). "When direct or personal supervision is required, physician supervision at the specified level is required throughout the performance of the test." Id.

26. Medicare rules define "general supervision" as those diagnostic tests furnished under the physician's overall direction and control, but whose presence is not required during the performance of the procedure. 42 C.F.R. §410.32(b)(3)(I). For procedures that require "direct supervision," the physician must be present in the office suite and immediately available to furnish assistance and direction during the performance of the procedure. However, the physician is not required to be present in the actual room where the procedure is being performed. 42 C.F.R. § 410.32(b)(3)(ii).

27. The Medicare rules of direct physician supervision are not required for diagnostic services performed in hospitals or physician practices; but direct supervision is required for certain diagnostic services performed at an IDTF in order for the IDTF to bill and receive reimbursement from Medicare for services to Medicare beneficiaries. This because non-physicians may own or operate an IDTF, as opposed to a hospital staffed by physicians or a physician's practice. Medicare and Medicare carriers published criteria that an applicant is considered to be physician's office or a part of a hospital for the diagnostic test without being enrolled as an IDTF if:

- it is a physician practice that is owed, directly or indirectly, by one or more physicians or owned by a hospital;

- the provider primarily bills for physician services (seeing patients) and not for diagnostic tests; it furnished diagnostic tests primarily to patients whose medical conditions are being treated or managed on an ongoing basis by one or more physicians in the practice; and

- the diagnostic tests are performed and interpreted at the same location where the practice physicians also treat patients for their medical conditions.

28. Because many radiologist practices do not actually see patients but read and evaluate tests and render their professional medical opinion that is then forwarded to the patient's doctor, the criteria provided that for a radiologist practice to enroll with Medicare as a physician office rather than an IDTF, the office must:

- be owned by a radiologist, a hospital, or both;

- the owner radiologist and any employed or contracted radiologists regularly perform physician services (such as test interpretations) at the location where the diagnostic tests are performed;

- the entity's billing patterns reflect that it is not primarily a testing facility, and that it was organized to provide the professional services of a radiologist; and

- a substantial majority portion of the radiological interpretations are performed at the practice location where the diagnostic tests are performed.

29. However, if a substantial portion of the entity's business involves the performance of diagnostic tests, the physician or group may continue to be enrolled as a physician or group practice, but must also enroll as an IDTF.

(Docket Entry No. 49, Complaint at ¶¶ 23-25, 27-29) (emphasis added).

As to the direct supervision requirement, the United States's complaint cites Medicare regulation 42 C.F.R. § 410.33(a)(1), as requiring a qualified physician for certain contrast procedures, id. at ¶¶ 23 and 24, that regulation provides as follows:

> (a) General rule.
>
> (1) Effective for diagnostic procedures performed on or after March 15, 1999, carriers will pay for diagnostic procedures under the physician fee schedule only when performed by a physician, a group practice of physicians, an approved supplier of portable x-ray services, a nurse practitioner, or a clinical nurse specialist when he or she performs a test he or she is authorized by the State to perform, or an independent diagnostic testing facility (IDTF). An IDTF may be a fixed location, a mobile entity, or an individual nonphysician practitioner. It is independent of a physician's office or hospital; however, these rules apply when an IDTF furnishes diagnostic procedures in a physician's office.

42 C.F.R. § 410.33(a)(1)

In addition, the United States's complaint (Docket Entry No. 49, Complaint at ¶¶ 24-25) cites 42 C.F.R. § 410.33(b)(1) and (3) for its FCA claim, but the quoted language is from 42 C.F.R. § 410.32(b)(1) and (3). The latter regulations provide as follows:

> (b) Diagnostic x-ray and other diagnostic tests--
>
> (1) Basic rule. Except as indicated in paragraph (b)(2) of this section, all diagnostic x-ray and other diagnostic tests covered under section 1861(s)(3) of the Act and payable under the physician fee schedule must be furnished under the appropriate level of supervision by a physician as defined in section 1861(r) of the

Act. Services furnished without the required level of supervision are not reasonable and necessary (see § 411.15(k)(1) of this chapter).

* * *

(3) Levels of supervision. Except where otherwise indicated, all diagnostic x-ray and other diagnostic tests subject to this provision and payable under the physician fee schedule must be furnished under at least a general level of physician supervision as defined in paragraph (b)(3)(i) of this section. In addition, some of these tests also require either direct or personal supervision as defined in paragraphs (b)(3)(ii) or (b)(3)(iii) of this section, respectively. (However, diagnostic tests performed by a physician assistant (PA) that the PA is legally authorized to perform under State law require only a general level of physician supervision.) When direct or personal supervision is required, physician supervision at the specified level is required throughout the performance of the test.

(I) General supervision means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. Under general supervision, the training of the nonphysician personnel who actually perform the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the physician.

(ii) Direct supervision in the office setting means the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed.

(iii) Personal supervision means a physician must be in attendance in the room during the performance of the procedure.

Id.

In any event, the United States's complaint refers to Section 410.33(b)(1) that in turn refers to Section 410.33(b)(2). The United States also attached to its complaint the LRMP (Docket Entry No. 49-1) that cites "(C.F.R. § 410.33)" as the regulation for diagnostic tests by an "independent diagnostic testing facility" ("IDTF"). Section 410.33(b)(2) expressly addresses the

required supervision at an IDTF:

> (b) Supervising physician.
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> (2) **The supervising physician [of an IDTF] must evidence proficiency in the performance and interpretation of each type of diagnostic procedure performed by the IDTF.** The proficiency may be documented **by certification in specific medical specialties or subspecialties or by criteria established by the carrier for the service area in which the IDTF is located.** In the case of a procedure requiring the direct or personal supervision of a physician as set forth in § 410.32(b)(3)(ii) or (b)(3)(iii), **the IDTF's supervising physician must personally furnish this level of supervision whether the procedure is performed in the IDTF or, in the case of mobile services, at the remote location.** The IDTF must maintain documentation of sufficient physician resources during all hours of operations to assure that the required physician supervision is furnished. In the case of procedures requiring direct supervision, the supervising physician may oversee concurrent procedures.

42 C.F.R. § 410.33(b)(2) (emphasis added).

The LRMP that is cited by the Defendants also cites Section 410.33(b) on "Physician Supervision" that reads, in pertinent part, as follows:

> An IDTF is defined as a fixed location, a mobile entity, or an individual nonphysician practitioner. [An IDTF] is independent of a physician's hospital or office. The diagnostic tests in an IDTF must be performed by licensed, certified nonphysician personnel under appropriate physician supervision.
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> * * *
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> The supervising physician [of an IDTF] must evidence proficiency in the performance and interpretation of each type of diagnostic procedure performed by the IDTF.

(Docket Entry No. 49-1 at p. 1) (emphasis added).

The United States also attached to its complaint a MedQuest internal document entitled "Medicare Supervision Physician Information" distributed to all MedQuest Managers that reads,

in pertinent part:

> [Y]ou must ensure that your site(s) comply with the requirements. These requirements and compliance with them are critical . . .
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> * * *
>
> Please Note: The supervising physician/s that I have listed on your Medicare applications is the only physician/s you should use for contrast studies on Medicare patients. If you use other physicians not listed with Medicare, you are not in compliance.

Docket Entry No. 49-14, Exhibit N at pp. 1-2) (emphasis in the original).

According to the United States's complaint, Defendants knew of this requisite physician supervision as a condition of payment. (Docket Entry No. 49, Complaint at p. 2, Exhibits R and S). According to Exhibit R to the United States's complaint, the Defendants refunded money to Medicare because its Charlotte location had "insufficient documentation to substantiate the appropriate physician supervision for procedures involving the use of contrasts." (Docket Entry No. 49-18). The United States's allegations also refer to Defendants' internal documents acknowledging this requirement in the Defendants' training for a non radiologist physician and submission of the training material to the local Medicare carrier for its approval as a proficient supervising physician at its IDTF. Id. at ¶ 6, Exhibits O and P.

As to the Witt-Charlotte facility relationship, the United States alleges that in January 2004, MedQuest purchased Dr. Witt's practice and Dr. Witt transferred 100% of his stock in Williams S. Witt, Inc., to Bio-Imaging of Charlotte. In exchange, MedQuest paid Dr. Will $560,000 without him retaining any interest or control in the operating entity. (Docket Entry No. 49, Complaint at ¶ 42). After that transfer, Dr. Witt agreed to read film and provide supervision for all three MedQuest facilities in Nashville as an independent contractor. Id. at ¶ 46. In these

circumstances, the United States contends that the Charlotte facility was neither Dr. Witt's physician's practice nor office because Dr. Witt was neither located nor exclusively reading film at the Charlotte office. Id. at ¶¶ 46, 47. In addition, the Defendants allegedly violated the FCA by "knowingly" delaying the change in the enrollment classification of the Charlotte Center from a "physicians office" to an "IDTF." Id. at ¶¶ 51 through 64. According to the United States's complaint, in a state court action with Dr. Witt, the Defendants filed a counterclaim about Dr. Witt's performance:

> [P]articularly affected the Centers' ability to perform contrast studies that require injection of dye and that must be supervised by a radiologist for patients with governmental insurance. By law, a Medicare patient cannot receive a contrast study without a radiologist present.

(Docket Entry No. 49-20 at 5).

According to the United States's complaint, the Defendants also used Dr. Witt's physician provider number with Medicare for their claims for payment by Medicare for all diagnostic tests performed at the Charlotte facility. Id. at ¶¶ 39-50. After the submission of an enrollment form to Medicare in 2005, Defendants billed tests at Charlotte solely as an IDTF entity and ceased the use of Dr. Witt's Medicare provider number to bill as a physician's office for diagnostic services. Id. at ¶¶ 45, 72-73. In sum, the United States alleges that from January through June 2005, Defendants claims for Medicare payment as a physician's office were false because they knew they were not entitled to payment under Medicare regulations.

B. Conclusions of Law

For a Rule 12(b)(6) motion to dismiss, the Court must determine if the complaint's factual allegations "raise a right to relief above the speculative level." Bell Atlantic Corp. v.

Twombly, 550 U.S. 544, 555 (2007). "[T]he allegations of the complaint should be construed favorably to the pleader." Scheuer v Rhodes, 416 U.S. 232, 236 (1974) and the Court must "treat all of the well-pleaded allegations of the complaint as true." Miree v. Dekalb County, Ga., 433 U.S. 25, 27 n.2 (1977). Yet, a legally sufficient complaint, "requires more than bare essentials of legal conclusions." Columbia Natural Resources, Inc. v. Tatum, 58 F.3d 1101, 1109 (6th Cir. 1995) and the district court "need not accept as true legal conclusions or unwarranted factual inferences." Morgan v. Church's Fried Chicken, 829 F.2d 10, 12 (6th Cir. 1987). "In practice, 'a . . . complaint must contain either direct or inferential allegations respecting all the material elements to sustain a recovery under some viable legal theory.'" Lillard v. Shelby Bd. of Edu., 76 F.3d 716, 726 (6th Cir. 1996) (citations omitted).

In evaluating Plaintiffs' complaint, under Fed.R.Civ.P. 10(c), any matters attached to the pleadings are considered part of the complaint. See Weiner v. Klais and Co., Inc., 108 F.3d 86, 98 (6th Cir. 1997) (Sixth Circuit reiterated the general rule that: "[m]atters outside the pleadings are not to be considered by a court in ruling on a 12(b)(6) motion to dismiss," but recognized an exception for papers attached to or referred to a plaintiff's complaint)[1] (quoting Venture Assocs. Corp v. Zenith Data Sys. Corp, 987 F.2d 429, 431 (6th Cir. 1993); see also Neiman v. NLO, Inc., 108 F.3d 1546, 1555 (6th Cir. 1997).

"The purpose of the Federal Claims Act is 'to provide for restitution to the government

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[1]This principle does not extend to extrinsic evidence. Katt v. Titan Acquisitions, Ltd., 133 F. Supp. 2d 632, 637-38 (M.D. Tenn. 2000). The Court cannot presume the truth of the extrinsic information nor use such information in evaluating the pleadings. City of Monroe Employees Retirement System v. Bridgestone Corp., 399 F.3d 651, 665; see also Logan v. Denny's, Inc., 259 F.3d 558, 581 n. 5 (6th Cir. 2001) (court may not take judicial notice of disputed facts).

for money taken from it by fraud." United States ex rel. Marcus v. Hess, 317 U.S. 537, 551 (1943). For a claim under the FCA, the United States must allege sufficient facts that a Defendant knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval of payment. 31 U.S.C. § 3729(A)(1). The FCA defines a "claim" as "any request or demand, whether under a contract or otherwise, for money or property that is presented to an officer, employee or agent or is made to a contractor, grantee or other recipient if the money or property is spent or used on the Government's behalf or . . . will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded." 31 U.S.C. § 3729(b)(2)(a)(1)(ii)(II).

For a FCA claim, the complaint must allege facts that the Defendant's submissions were "false or fraudulent" and that Defendants did so "knowingly." United States ex rel Augustine v. Century Health Servs., Inc., 289 F.3d 409, 413 (6th Cir. 2002) or with reckless disregard of the Medicare laws, requirements for payment. United States ex rel A+ Homecare v. Medshares Mgmt. Group, Inc., 400 F.3d 428, 442-43 (6th Cir. 2005). Reckless disregard is sufficient for FCA liability because a specific intent to defraud is not required under the FCA. See United States v. Krizek, 111 F.3d 934, 941-42 (D.C. Cir. 1997) (finding reckless disregard in submission of Medicare claims sufficient for FCA violation).

A "legally false" claim under the FCA arises when a defendant "certif[ies] compliance with a statute or regulation as a condition to government payment, yet knowingly fail[s] to comply with such statute or regulation." United States ex rel. Conner v. Salina Regional Health Center, Inc., 543 F.3d 1211, 1217 (10th Cir. 2008) (quotation omitted). Accord United States ex

rel. Mikes v. Straus, 274 F.3d 687, 698 (2d Cir. 2001) and United States ex rel v. Jamieson Sci. & Eng'g, Inc., 214 F.2d 1327, 1376 (D.C. Cir. 2000)). In Medshares, the Sixth Circuit also adopted the implied certification theory, "which holds a defendant liable for violating the 'continuing duty to comply with the regulations on which payments is conditioned'" 400 F.3d at 454 n. 20; accord Augustine, 289 F.3d at 415 (a defendant "violates its continuing duty to comply with regulations on which payment is conditioned."). For the implied false certification, courts examine "the underlying statute or regulation to surmise if they make the certification a condition of payment." Conner, 543 F.3d at 1218.

The Sixth Circuit also requires a false claim to be "material" to the Government's decision to pay the claim, *i.e.*, the alleged act must be viewed for its "natural tendency" or "potential effect of the false statement when it is made." See A+ Homecare, 400 F.3d at 445; see also United States ex rel Flanders v. Baptist Mem'l Health Care Corp., 525 F. Supp. 2d 972, 977 (W.D. Tenn. 2007). The "materiality requirement holds that only a subset of admittedly false claims is subject to the False Claims Act liability." Flanders, 525 F. Supp. 2d at 979 (quoting United States ex rel Mikes v. Straus, 274 F.3d 687, 697 (2d Cir. 2001).

To be sure, not every statutory or regulatory violation states a FCA claim. Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 785 (4th Cir. 1999). Courts recognize a distinction between conditions of participation and conditions of payment that is critical to stating a FCA claim. In a word, federal statutes or regulations that are conditions of participation in the particular government program, cannot give rise to a FCA claim. See e.g., Landers, 525 F. Supp. 2d at 978. See also Conner, 543 F.3d at 1220 (refusing to find FCA liability for alleged violation of conditions of participation because they are enforced by the Government through

administrative mechanisms); United States ex rel. Mikes v. Straus, 274 F.3d 687, 692 (2d Cir. 2001); United States ex rel Gross v. AIDS Research Alliance-Chicago, 415 F.3d 60 1, 604 (7th Cir. 2005) (affirming dismissal and finding that "[a]n FCA claim premised upon an alleged false certification of compliance with statutory or regulatory requirements also requires that the certification of compliance be a condition of or prerequisite to government payment"); United States ex rel. Williard v. Humana Health Plan, 336 F.3d 375, 381-85 (5th Cir. 2003) (affirming dismissal of Medicare FCA claims because the alleged regulatory violations were not conditions of payment and "[i]n the healthcare context, liability does not arise from a healthcare provider's disregard of Government regulations or failure to maintain proper internal policies unless those acts allow the provider to knowingly ask the Government to pay amounts it does not owe.") (emphasis added); United States ex rel. Bane v. Breathe Easy Pulmonary Services, Inc., 597 F. Supp. 2d 1280, 1286 (M.D. Fla. 2009), (citing United States ex rel. Clausen v. Lab Corp. of America, 290 F.3d 1303 (11th Cir. 2002).

Here, the United States's theory is for an express false certification because Defendants certified that they would follow all requirements for these diagnostic tests by an IDTF to receive Medicare payments, but did not do so. Specifically, the United States asserts that the Defendants submitted false claims for payment of diagnostic tests with CPT codes that Defendants knew to be false given the express Medicare regulation requiring an appropriately qualified physician supervision as a condition of payment for IDTF's claim for diagnostic services with contrasts.

In their motion, the Defendants first contend that the Government's complaint in paragraphs 25-26 refers to "42 C.F.R. § 410.33(b), but the quoted language is actually in 42 C.F.R. § 410.32. In any event, Defendants argue that the United States's complaint does not

plead any alleged violations of 42 C.F.R. § 410.33(b)(2)." Defendants next contend that the cited parts of Section 410.33(b) do not require a board certified radiologist or carrier approved physician to supervise Contrast Studies as a condition of payment. Defendants argue that this omission is significant because to state a FCA claim, the Government must identify the regulation defining conditions of payments or compliance with regulation for its FCA violation, Conner, 543 F.3d at 1220 and cannot amend the allegations in its complaint by its brief.[2]

The Defendants also contend that the physician supervision is a condition of participation that is "enforced by administrative procedures and potential removal from the Medicare program." Conner, 543 F.3d at 1220 (citing Mikes, 274 F.3d at 687, 701-02). Defendants cite Sections 410.33(b)-(h) as further evidence of Section 410.33 as conditions of participation. Section 410.33(h) provides for revocation of the provider's billing privileges for an alleged failure to meet the (b)(l) supervising physician requirements. Similarly, Defendants also contend that Exhibit N relied upon by the Government was a memorandum drafted solely for "compliance" purposes and was not designed to require a board certified radiologists or carrier approved physicians was a condition of payment under the Medicare regulations. As to Exhibit O, Defendants assert that Dr. Tan marked those sections of the form under general supervision

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[2]For this contention, the Defendants cite Jocham v. Tuscola County, 239 F. Supp. 2d 714, 732 (E.D. Mich. 2003) ("The pleading contains no such allegation, and the plaintiffs may not amend their complaint through a response brief."); Chambliss v. Coca-Cola Bottling Corp., 274 F.Supp 401, 409 (E.D. Tenn. 1967) ("Although the original complaint has undergone considerable revision in this case, effort has been made to amend the amended complaint in the particulars mentioned in the cited brief. Even under liberal federal rules of pleading, the practice of amending by brief seems inappropriate"), aff'd on other grounds, 414 F.2d 256 (6th Cir. 1969), cert. denied, 397 U.S. 916, 90 S. Ct. 921 (1970); Car Carriers, Inc. v. Ford Motor Co., 745 F.2d 1101, 1107 (7th Cir. 1984) ("It is axiomatic that the complaint may not be amended by the briefs in opposition to a motion to dismiss.").

that would enable her to provide general supervision over the equipment, supplies and training of nonphysicians personnel performing diagnostic studies. Defendants argue the form reflects only Defendants' efforts to credential Dr. Tan with CIGNA to provide general supervision of an imaging center. Defendants further argue that Exhibit R shows that refunds were made due to insufficient documentation that a physician directly supervised the contrast coverage, and the refund letters do not refer to board certified radiologists or carrier approve physicians. Defendants contend that Exhibit T to the Government's complaint is a legal conclusion that cannot constitute an admission, citing Roger Miller Music, Inc. v. Sony/ATV Publ'g, LLC, 477 F.3d 383, 394 (6th Cir. 2007).

In paragraphs 24 and 25, the United States's complaint cites Section 410.33(b) that includes Section 410.33(b)(2).[3] For its analysis, the Court "must look at the regulations as a whole in determining the plain meaning of a term" in these regulations. Alaskan Trojan Partnership v. Gutierrez, 425 F.3d 620, 628 (9th Cir. 2005) (citing McCarthy v. Bronson, 500 U.S. 136, 139 (1991); see also Hadi Inc. v. United States, 1987 WL 35918 at *4 (6th Cir. March 24, 1987) (Merritt, J., concurring). Thus, the Court must consider all sections of Section 410.33 regardless of whether a subsection thereof is expressly cited in a particular paragraph in the United States's complaint.

As stated earlier, the Court must consider any attachment to the United States's complaint in evaluating the Defendants' motion to dismiss. (Docket Entry No. 49, Complaint at ¶ 25). Among the attachments to the United States's complaint is a document that refers to the

[3] In its complaint at ¶ 25, the United States quotes from § 410.32, but cites § 410.33. In any event, the United States does cite § 410.32 in ¶ 26 of its complaint.

Medicare regulations governing IDTFs and the specific reference is "(§ 410.33 for IDTFs)". (Docket Entry No. 49-1, at 1). In addition, to the other subsections quoted supra, 42 C.F.R. § 410.33(b)(2) also provides as follows for IDTF facilities:

> (b) Supervising physician.
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> * * *
>
> (2) The supervising physician must evidence proficiency in the performance and interpretation of each type of diagnostic procedure performed by the IDTF. The proficiency may be documented by certification in specific medical specialties or subspecialties or by criteria established by the carrier for the service area in which the IDTF is located. In the case of a procedure requiring the direct or personal supervision of a physician as set forth in § 410.32(b)(3)(ii) or (b)(3)(iii), the IDTF's supervising physician must personally furnish this level of supervision whether the procedure is performed in the IDTF or, in the case of mobile services, at the remote location. The IDTF must maintain documentation of sufficient physician resources during all hours of operations to assure that the required physician supervision is furnished. In the case of procedures requiring direct supervision, the supervising physician may oversee concurrent procedures.
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> * * *
>
> (d) Ordering of tests. All procedures performed by the IDTF must be specifically ordered in writing by the physician who is treating the beneficiary, that is, the physician who is furnishing a consultation or treating a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. (Nonphysician practitioners may order tests as set forth in § 410.32(a)(3).) The order must specify the diagnosis or other basis for the testing. The supervising physician for the IDTF may not order tests to be performed by the IDTF, unless the IDTF's supervising physician is in fact the beneficiary's treating physician. That is, the physician in question had a relationship with the beneficiary prior to the performance of the testing and is treating the beneficiary for a specific medical problem. The IDTF may not add any procedures based on internal protocols without a written order from the treating physician.

(emphasis added).

In the Court's view, with its express language, Section 410.33(b)(2) presents a condition for payment because for an IDTF's diagnostic testing with contrast to be paid, the presence of a

supervisory physician with " certification in specific medical specialties or subspecialties or by criteria established by the carrier for the service area in which the IDTF is located" is required. This conclusion is underscored by Sections 410.32(b)(1) and (3) that refer to physician supervision as necessary for "tests covered by section 1861(s)(3) [and 1861(r)] of the Act **and payable under the physician fee schedule**."[4] (emphasis added). Without such a qualified person, the entity cannot be compensated by the Medicare program, as Exhibit R to the United States's complaint illustrates. (Docket Entry No. 49-18). Moreover, under 42 C.F.R. § 410.33(h), "CMS will revoke a supplier's billing privileges if an IDTF is found not to meet the standards in paragraph (g) or (b)(1) of this section." These sections of Section 410.33, when read as a whole, establish that appropriate physician supervision is a condition of payment under the FCA. See United States ex rel. Barnes v. Breathe Easy Pulmonary Services Inc., 597 F. Supp. 2d 1280, 1287-89 (M.D. Fla. 2009) (FCA claim under Section 3729(a)(2) stated for the performance of tests at an IDTF without the written authorization of the patient's physician).

To be sure, the Defendants argue the requirement of supervising physicians is to ensure quality of care for diagnostic studies at an IDTF and "conditions of participation are quality of care standards directed toward an entity's continued ability to participate in the Medicare program rather than a prerequisite to a particular payment." Landers, 525 F. Supp. 2d at 978. Yet, the presence of a quality care purpose in Section 410.33(b)(2) is not determinative because Subsection 410.33(b)(1) (2) and (h) establish that the principal and dominant purpose of physician supervision of an IDTF is a condition of payment. Without such physician

[4] The statutory sections referenced in sections 410.32(b)(1) and (3) are codified at 42 U.S.C.A. § 1395x(s)(3) and § 1395x(r) and refer to coverage of diagnostic X-ray tests and defines the term "physician" under the Social Security Act, respectively.

supervision, the IDTF would not be paid under Medicare. To that extent, the United States's complaint states a viable FCA claim. If this physician supervision regulation were deemed to be a condition of participation, the United States's contention would also state a claim under the United States's unjust enrichment theory of liability.

As to Dr. Witt's role at the Charlotte office, the reading agreement entered into contemporaneously with the stock sale required Dr. Witt to provide physician services at the Charlotte Center "in a manner consistent with the past practices utilized by [him]" and required that Dr. Witt provide professional interpretative services as well as onsite coverage for Medicare-related contrast studies. (Docket Entry No. 49, Intervening Complaint at Exhibit H at ¶ 1). Defendants argue that Charlotte would have been classified as an IDTF effective with the date of the stock transfer and this classification would not have affected payment because both physicians' offices and IDTFs are paid under the same physician fee schedule. The United States responds that with the stock transfer, Medicare regulations required Dr. Witt to enroll as an IDTF. 42 C.F.R. § 410.33(a)(1) ("[T]hese rules apply when an IDTF furnishes diagnostic procedures in a physician's office."). Moreover, 42 C.F.R. § 410.33(a)(1) applies to an IDTF's billing of Medicare and provides as follows.

> (I) Effective date of billing privileges. The filing date of the Medicare enrollment application is the date that the Medicare contractor receives a signed provider enrollment application that it is able to process to approval. The effective date of billing privileges for a newly enrolled IDTF is the later of the following:
>
> (1) The filing date of the Medicare enrollment application that was subsequently approved by a Medicare fee-for-service contractor; or
>
> (2) The date the IDTF first started furnishing services at its new practice location.

Given Medquest's January 2004 acquisition of Dr. Witt's practice, Dr. Witt's apparent failure to

enroll as a IDTF and the Defendants' filing for its Medicare billing number in 2005, the Court concludes that the United States' complaint states a claim as to its allegations about the Defendants' relationship with Dr. Witt.

For the above stated reasons, the Court concludes that the Defendants' motion to dismiss (Docket Entry No. 61) should be denied.

An appropriate Order is filed herewith.

ENTERED this the 24th day of March, 2010.

WILLIAM J. HAYNES, JR.
United States District Judge