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,	)	
	)	3:06-01169
	)	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.	)	

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I. Procedural History

Plaintiff, Karen Hobbs, a former employee of MedQuest Associates, Inc. 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 Relator's and United States's common claims are first that the Defendants unlawfully conducted diagnostic tests of Medicare beneficiaries at its Nashville area testing centers without the required and appropriate physician supervision and that MedQuest caused false claims to be submitted and paid by Medicare for such testing in violation of 31 U.S.C.§ 3729(a)(1). At its Charlotte center, the Relator and the United States also assert that MedQuest caused false claims to be submitted and paid by Medicare by using another Medicare vendor's billing number in violation of 31 U.S.C.§ 3729(a)(1). The Relator also asserts a FCA claim for retaliatory discharge after she complained about Defendants' testing practices. In addition to its FCA claims, the United States asserts common law claims for unjust enrichment, payment by mistake and recoupment.

In earlier proceedings, the Court denied the Defendants' motion to dismiss (Docket Entry No. 95) concluding that Medicare regulations on physician supervision of diagnostic tests are a condition of payment and that under the factual allegations and relevant Medicare regulations, the United States and the Relator stated claims for violations of the FCA. (Docket Entry No. 94, Memorandum at 15-19).

Before the Court are the United States's motion for summary judgment (Docket Entry No. 127); the Defendants' motion for summary judgment on Relator's claims (Docket Entry No. 128); Defendants' motion to dismiss Relator's amended complaint (Docket Entry No. 148); and the Defendants' motion for summary judgment on the United States's claims. (Docket Entry No. 149).

In its motion for summary judgment, the United States contends, in essence, that the undisputed facts establish that the Defendants submitted claims for payment to Medicare for diagnostic tests of Medicare beneficiaries conducted at its Nashville area facilities without the required physician supervision and by physicians who were not approved by Medicare's designated carrier. The United States also contends that the undisputed facts are that from January, 2004 to July 1, 2005, MedQuest used a physician's Medicare billing number for its Medicare billings for tests of Medicare beneficiaries at its Charlotte facility.

In their motions for summary judgment and motion to dismiss and in their response to the United States's motion, the Defendants argue first that the Relator's retaliation claim lacks factual bases and is time barred. As to the United States's claims, Defendants contend, in sum: (1) that the FCA claims fail as a matter of law, for lack of proof of a violation of a federal statute or regulation; (2) that the cited Medicare regulations do not require a board certified radiologist as a supervising physician at its Nashville area centers; (3) that any physician can supervise the diagnostic tests at issue; (4) that other Medicare carriers permit any physician to supervise these diagnostic tests; (5) that Medicare regulations and expert testimony support the allowance of any physician, as defined by the Medicare Act, to supervise these tests; and (6) that for the times at issue, the Charlotte center was a physician's office rendering appropriate the billings with Dr.

Witt's Medicare number. For these reasons, Defendants assert the Government and Relator cannot prove any FCA violation.

In their responses, the United States contends that its FCA claims are supported by undisputed facts that establish violations of controlling Medicare regulations. The Relator asserts that the Defendants' motion to dismiss that is supported by evidentiary materials, is a motion for summary judgment. Relator argues that material factual disputes exist on the merits of Relator's retaliation claim under the FCA as well as the nature of her employment relationship with MedQuest to bar summary judgment on Defendants' statute of limitations defense. In a supplemental submission, Relator argues additional precedent supports the timeliness of her FCA retaliation claim.

II. Defendants' Motion to Dismiss and for Summary Judgment On Relator's Retaliation Claim

MedQuest hired Relator in December, 2002 as a lead technologist and later, promoted her to chief technologist. MedQuest's November, 2002 offer of employment included a "Termination" provision that "MedQuest is an *at will* employer, which means that either you or MedQuest may terminate the employment agreement at any time with or without notice or cause." (Docket Entry No. 148-3 at 2) (emphasis added). According to this offer, Relator's "signature on this letter indicates [Relator's] acknowledgment and acceptance of these as the full and complete terms of our employment offer." Id. Relator signed the November, 2002 offer letter on November 27, 2002. Id. at 3.

MedQuest also provided Relator its employee handbook that has an "Acknowledgment and Disclaimer of Employment Contract," to be signed by its employees. This disclaimer also

provides that "either the employee or the Company[1] may terminate the employment relationship *at will, with or without cause or advance notice, at any time*." (Docket Entry No. 148-4 at 1) (emphasis added). This disclaimer also reads in relevant part, that MedQuest's employee handbook does not create "an employment contract, a right of employment, or any other type of contract" and that "the Company . . . reserves the right to change, revise, add, or delete policies and guidelines without notice when such action is deemed necessary by the Company." Id.

As relevant to these motions, during the course of her employment, Relator was informed and informed her supervisors as well as MedQuest's higher management that MedQuest's Nashville area centers were conducting diagnostic tests using contrast without trained physicians approved by Medicare and in some instances by the centers' staff members who are not physicians. (Docket Entry No. 166-1, Hobbs affidavit). Although Relator received some favorable assessments of her work, (Docket Entry No. 166-11), there were complaints about Relator's work. (Docket Entry No.130-20). On October 26, 2004, after an action plan deadline (Docket Entry No. 130-3), Ruth Giorgtio, Relator's supervisor, terminated Relator for "Poor job performance conduct." (Docket Entry No. 148-5).

A defendant can file a motion to dismiss based upon statute of limitation defense. Jones v. Brock, 549 U.S. 199, 215 (2007) ("If the allegations . . . show that relief is barred by the applicable *statute of limitations*, the complaint is subject to dismissal for *failure to state a claim*.") (emphasis added). Yet, the Court agrees with Relator that given the supporting evidentiary materials that are considered by the Court, Defendants' motion to dismiss is converted into a motion for summary judgment. Fed. R. Civ. P. 12(d).

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[1] The term "Company" is defined as "MedQuest Associates and *affiliated Imaging Centers.*" See Employee Acknowledgment (emphasis added).

When this action was filed, the FCA lacked a limitations period for retaliation claims and the Court would "borrow" the applicable state statute of limitations for a retaliatory discharge claim. See Graham County Soil & Water Conservation Dist. v. United States ex rel. Wilson, 545 U.S. 409, 417-18 (2005). Tennessee law has two statutes of limitation for retaliatory discharge claims based upon the nature of the plaintiff's employment. See Gunter v. Laboratory Corp. of America, 121 S.W.3d 636, 642 (Tenn. 2003). In selecting among these statutes of limitations, the issue is whether Plaintiff's injury was to his property or person. Id. at 641. For injury to one's property, the three-year statute of limitations applies, but for personal injury, the one-year statute of limitations governs. Id.

Claims of employees who are terminable at will are deemed personal injury claims. Weber v. Moses, 938 S.W. 2d 387, 393 (Tenn. 1996). If the employment relationship is contractual, then the injury is characterized as a property right. See Gunter 121 S.W.3d at 642. In either instance, the limitation period for a retaliatory discharge commences on the date of a plaintiff's termination. Weber, 938 S.W.2d at 391-92 ("[A] discriminatory termination ceases and is complete, when the plaintiff is given unequivocal notice of the employer's termination decision.").

Here, the documentary evidence of MedQuest's November 2002 Offer Letter and employee handbook establishes that Plaintiff was an employee at will. MedQuest's handbook stated that "neither this handbook nor any provision of this handbook creates an employment contract, a right of employment, or any other type of contract." Under Whittaker v. Care-More, Inc., 621 S.W.2D 395, 397 (Tenn. Ct. App. 1981), an employee handbook must contain "guarantees or binding commitments" for an employment contract. Thus, Plaintiff's retaliation claim is governed by a one year statute of limitation.

Here, MedQuest terminated Relator on October 26, 2004, but Relator did not file this action until 2006. The facts involving her termination were known at the time of her termination. Plaintiff contends that material factual disputes exist, but the Court is unable to discern the factual bases for any such dispute. Accordingly, the Court concludes that Relator's retaliation claim under the FCA is time-barred.

Relator's supplemental filing contends that her retaliation claim is governed by FCA's new three years statute of limitation for retaliation claims in the "Dodd-Frank Wall Street Reform Act and Consumer Protection Act", Pub. L 111-203, 124 Stat. 1376 (2010), amending 31 U.S.C. § 3730(h)(3). By its express provisions, that Act has an effective date of July 22, 2010. Id. Congress's statement of the effective date of an Act is not dispositive. Immigration and Naturalization Serv. v. St. Cyr., 533 U.S. 289, 318 (2001). Graham County's holding on the "borrowing" of state statutes of limitation was clearly established in 2005. Statutes of limitation represent a public policy favoring the filing of timely claims. Burnett v. New York Cent. R. Co., 380 U.S. 424, 429 (1965). To apply the FCA's new three years limitations would have the effect of reviving an otherwise time-barred claim for non-continuing conduct that occurred in 2004. Thus, the Court concludes that FCA's new three years limitation period should not be applied here.

III. United States's and Defendants' Motions for Summary Judgment

A. Findings of Fact[2]

[2] Upon a motion for summary judgment, the factual contentions are viewed in the light most favorable to the party opposing the motion for summary judgment. Duchon v. Cajon Co., 791 F.2d 43, 46 (6th Cir. 1986). As discussed infra, upon the filing of a motion for summary judgment, the opposing party must come forth with sufficient evidence to withstand a motion for directed verdict, Anderson v. Liberty Lobby, 477 U.S. 242, 247-52 (1986), particularly where there has been an opportunity for discovery. Celotex Corp. v. Catrett, 477 U.S. 317, 326 (1986).

1. MedQuest

MedQuest is the leading diagnostic testing firm in the United States that operates more than ninety "Independent Diagnostic Testing Facilities" ("IDTFs") throughout the United States in thirteen states. MedQuest establishes the procedures for each of its IDTF's operations; hires their managers and radiologists; enrolls and provides credentialing for their staffs for Medicare and commercial insurers. For each facility, MedQuest leases or purchases the building, provides payroll services, purchases or rents diagnostic equipment, obtains insurance, and provides compliance and training for its testing centers' employees. MedQuest's centers' managers lack money to purchase large equipment, or pay physicians for services both of which MedQuest pays. (Docket Entry No. 140-5, Schaefer Deposition at 19-23, 50-54).[3] None of the MedQuest Nashville area centers has a separate bank fund. (Docket Entry No. 132, Just Declaration at 2 and Docket Entry No. 140-9, Dunphy Deposition at 8). MedQuest bills the Medicare program for diagnostic testing of Medicare beneficiaries at its IDTFs.

MedQuest's Nashville area IDTFs are the Defendants: BioImaging of Cool Springs, Inc., BioImaging at Harding, Inc., now Edmondson and BioImaging at Charlotte, Inc. For the damages period at issue, January 2004 through 2006, MedQuest's Harding and CoolSprings centers were enrolled and operated as IDTFs with CIGNA, Medicare's carrier for Tennessee. (Docket Entry Nos. 150-13 and 150-14). The Harding center's Medicare provider number was 3790454 and subsequently 3790906. (Docket Entry No. 138, Haines Declaration). The

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The Court concludes that under the applicable law, there are not any material factual disputes. Thus, this section constitutes finding of facts under Fed. R. Civ. P. 56(e).

[3] For uniformity of reference, unless otherwise stated, the evidentiary references are to the pagination in the Court's electronic case filing system.

CoolSprings center's Medicare provider number was 3790904 and subsequently 3790907. Id. From January 2004 until July 1, 2005, MedQuest used another provider's Medicare billing number for payment of its claims for testing of Medicare beneficiaries at its Charlotte center. Id. at 3.

MedQuest's Charlotte center arises out of its past relationship with Dr. William Witt, a board certified radiologist and former chief radiologist at a Veterans' Administration ("VA") hospital. In November 1998, Nashville Diagnostic Imaging ("NDI"), a management company affiliated with MedQuest, entered into an agreement with Dr. Witt "to provide management and related services to Dr. Witt at the site of his outpatient physician practice." (Docket Entry No. 150-15, 1998 Management Agreement at 1). Under this agreement, Dr. Witt would "continue to practice radiological medicine and practice as a physician practicing outpatient radiological medicine at 1800 Charlotte Avenue, Nashville, Tennessee" Id. After 1998, Dr. Witt converted his outpatient diagnostic center into a professional corporation, William S. Witt, M.D., P.C., and thereafter to a general business corporation, William S. Witt, Inc. (Docket Entry No. 150-16, Stock Purchase Agreement at 1).

On January 14, 2004, Dr. Witt sold all of his shares in William S. Witt, Inc. to BioImaging at Charlotte, Inc. for five hundred sixty thousand dollars ($560,000.00). MedQuest paid the $560,000.00 for this purchase that included MedQuest's ownership of Dr. Witt's Certificate of Need issued by State health care officials for the diagnostic testing center at that location. (Docket Entry No. 140-6, Schaefer Deposition at 4, 12-13). After the stock sale, according to Dr. Witt, "my physician practice no longer existed at the 1800 Charlotte center." (Docket Entry No. 133, Witt declaration at 2).

Dr. Witt, however, agreed to provide physician services "in a manner consistent with the past practices and procedures utilized by [Dr. Witt] while engaged by the Corporation." (Docket Entry No. 150-19, Reading Agreement). Under this latter agreement, Dr. Witt would set diagnostic/radiological standards and maintain professional and clinical standards. Id. at ¶ 1(c)-(d). Dr. Witt leased his building to the Charlotte Center. (Docket Entry No. 150-18, Lease Agreement at 1-2). The lease agreement was between "William S. Witt, M.D., maintaining a principal office and place of business" at his home address, as "Landlord," and BioImaging at Charlotte, Inc., with its principal office and place of business at 1800 Charlotte Avenue, Nashville, Tennessee ("Tenant"). Id. John K. Luke, president of BioImaging at Charlotte, Inc., signed the lease. Id. at 20, 21. As discussed in more detail infra, MedQuest controlled the business and employee operations at the Charlotte center. MedQuest used Dr. Witt's Medicare provider number to bill Medicare for all diagnostic testing of Medicare patients at its Charlotte facility until July 1, 2005. (Docket Entry No. 140-1, Blank Deposition at 25).

As to MedQuest's key officers for the issues here, Dan Schaefer is MedQuest's chief operating officer for the diagnostic centers; is listed as the authorized official on all three defendant BioImaging centers' Medicare applications that he also signed; and is responsible for Medicare billings. (Docket Entry No. 140-5, Schaefer Deposition 38-40, 43 and Docket Entry No. 140-6, 15-16, 45-56, 61-70). Wayne Blank was MedQuest's chief compliance officer for Medicare. (Docket Entry No. 140-1, Blank deposition). Marcy Burke, now Marcy Burke Delozier, was a MedQuest employee in its credentialing department and worked at its corporate headquarters. (Docket Entry No. 137, Delozier declaration at 1). Sally Bradley was Delozier's supervisor in 2002 and reported to Schaefer, but Bradley left MedQuest in 2005. (Docket Entry No. 131, Bradley Declaration at 1). Kim Hounshell was a diagnostic testing center manager and

marketer at a MedQuest diagnostic testing centers until February 2005, when she became assistant director of credentialing at MedQuest's corporate headquarters. (Docket Entry No. 144, Hounshell Deposition at 3, 5). Hounshell had training on Medicare CMS 855, the IDTF application form for Medicare participation as well as instructions on enrollment of IDTFs and physician practices for IDTFs in the Medicare program. Id. at 13-16. Chris Wicker was director of financial services. (Docket Entry No. 141-3, Dozier Deposition at 2). Christina Dozier worked in the billing department before her transfer to its credentialing department where she worked from April 2005 until October, 2007 with Hounshell as her supervisor. Id. at 2-3.

2. The Medicare Enrollment Process

Medicare has a multi-layered administrative management structure. The Secretary of the Department of Health and Human Services ("DHHS") is responsible for the administration of the Medicare program and is authorized to issue regulations and rules.[4] The Center for Medicare and Medicaid Services ("CMS"), an agency within DHHS, actually administers the Medicare and Medicaid programs. CMS acts for the Secretary and sets policies, issues manuals and forms, conducts research and establishes procedures for Medicare enrollment by health care providers as entities or individual providers.[5] CMS also employs private insurance companies as carriers to implement Medicare regulations and policies, as well as to monitor and to pay billings of health care providers enrolled in Medicare.[6]

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[4] 42 U.S.C. § § 1395x(v)(1)(A) and 1395hh (a)(1).

[5] See 42 U.S.C. §§ 1302 and 1395hh and 42 C.F.R. §§ 413.20 through 413.24 and 413.180(b).

[6] 42 C.F.R. §§ 413.20 through 413.24 and 413.180(b).

Medicare established the IDTF as a health care provider category in July 1998, (Docket Entry No. 140-2 at 14) and as discussed infra, the Secretary issued an extensive regulation for IDTFs. CMS form 855 is the application form with instructions for enrollment of facility as an IDTF. CMS form 855 requires, inter alia, the names of the physicians who will provide the supervision for the IDTF's testing. (Docket Entry Nos. 150-13at 22, 24-25 and 150-14 at 20, 23). This CMS form 855 has a section entitled "Authorized Official Signature" that Daniel J. Schaefer, MedQuest's chief operating officer signed. In this statement, Schaefer agreed that: "If I become aware that any information in this application is not true, correct or complete, I agree to notify the Medicare program contractor of this fact immediately." Id. at 13,19. CMS had to be informed if a physician is being added, deleted or changed with the effective date, and the name of the supervising physician and related information, including his/her Medicare number. (Docket Entry No. 137, Burke Declaration at 2, 6).

As to supervising physicians, CMS form 855 informs applicants: "Note: Personal/Direct: If this Supervising Physician performs Personal or Direct Supervision, he/she must be currently enrolled in Medicare with the Medicare carrier to which this application is being submitted." (Docket Entry No. 141-5 at 19) (emphasis added). An attachment to CMS 855 for IDTFs also instructs that "[T]his section is to be completed with information about all supervising physicians. If there is more than one supervising physician, copy and complete this section for each." Id. On the supervising physician page, the applicant for Medicare enrollment as an IDTF must state whether the level of supervision to be provided by the supervising physician will be general, direct, or personal supervision. Id. In addition, Medicare's IDTF application requires for Medicare enrollment that each physician must attest that he or she is "proficient" with the

tests to be supervised and must specifically exclude any tests that the physician will not supervise at the facility. Id. at 24-25.

The CMS Medicare enrollment form for an IDTF facility also requires a listing of the specific Current Procedural Terminology codes ("CPT") that the IDTF will provide; the names and credentials of the technologists performing the diagnostic tests for those CPT codes; the name and Medicare provider number of all physician(s) who would be providing the interpretations of the diagnostic tests; and the name and Medicare number of the physician(s) who supervise the diagnostic tests to be billed. (Docket Entry No. 150-14 at 21-25).

CMS publishes manuals, policies and procedures for an IDTF compliance with the Medicare program. The CMS Manual on supervising physicians at IDTFs reads, in relevant part, as follows:

> 4.19.5- Supervising Physicians
>
> (Rev. 277; Issued: 12-19-08; Effective/Implementation Date: 01-20-09)
>
> **A. General Principles**
>
> **Under 42 CFR §410.33(b)(1), an IDTF must have one or more supervising physicians who are responsible for:**
>
> **The direct and ongoing oversight of the quality of the testing performed**;
>
> The proper operation and calibration of equipment used to perform tests; and
>
> The qualifications of non-physician IDTF personnel who use the equipment.
>
> Of course, not every supervising physician has to be responsible for all of these functions. For instance, one supervising physician can be responsible for the operation and calibration of equipment, while other supervising physicians can be responsible for test supervision and the qualifications of non-physician personnel. **The basic requirement, however, is that all the supervisory physician functions must be properly met at each location, regardless of the number of physicians involved. This is particularly applicable to mobile IDTF units that are allowed to use different supervisory physicians at different locations.**

They may have a different physician supervise the test at each location. The physicians used need only meet the proficiency standards for the tests they are supervising.

Under 42 CFR §410.33(b)(l), each supervising physician must be limited to providing supervision to no more than three IDTF sites. This applies to both fixed sites and mobile units where three concurrent operations are capable of performing tests.

B. Information about the Supervising Physicians

The carrier shall check and document that each supervisory physician: (1) is licensed to practice in the State(s) where the diagnostic tests he or she supervises will be performed, (2) is Medicare enrolled, and (3) is not currently excluded or debarred. The physician(s) need not necessarily be Medicare enrolled in the State where the IDTF is enrolled.

In addition:

The carrier shall verify the licensure for the State where the IDTF is being enrolled for each supervisory physician enrolled with another carrier, based upon the physician's license submission and discussions with the carrier where they are enrolled.

Each physician of the group who actually performs an IDTF supervisory function must be listed.

If a supervising physician has been recently added or changed, the updated information must be reported via a CMS-855B change request. The new physician must have met all the supervising physician requirements at the time any tests were performed.

If the carrier knows that a listed supervisory physician has been listed with several other IDTFs, the carrier shall check with the physician to determine whether the physician is still acting as supervisory physician for the previously enrolled IDTFs.

C. General, Direct, and Personal Supervision

Under 42 CFR §410.33(b)(2), if a procedure requires the direct or personal supervision of a physician as set forth in 42 CFR §410.32(b)(3), the carrier shall ensure that the IDTF's supervisory physician furnishes this level of supervision.

> The carrier's enrollment staff shall be familiar with the definitions of personal, direct and general supervision set forth at 42 CFR §410.32(b)(3), and shall ensure that the applicant has checked the highest required level of supervision for the tests being performed.
>
> Each box that begins with -Assumes responsibility, II must be checked. However, as indicated previously, the boxes can be checked through the use of more than one physician.

(Docket Entry No. 150-11 at 5-7) (emphasis added).

In its Medicare "Program Integrity Manual ("PIM"), CMS requires the supervising physician to acknowledge that he or she is aware of the responsibilities on that capacity. (Docket Entry No. 141-6 at 7). CMS's PIM also requires its Medicare carrier to document that each supervisory physician: "(1) is licensed to practice in the State(s) where the diagnostic tests he or she supervises will be performed, (2) **is Medicare enrolled**, and (3) is not currently excluded or debarred." (Docket Entry No. 141-6 at 6) (emphasis added). In addition, for the Medicare program "[i]f a supervisory physician has been recently added or changed, the update information is required to be reported via Form *CMS*-855 Change of Information form within 90 days of the change." Id.[7] (italics in the original).

CMS's PIM also contains instructions on the supervising physician page that includes an "Attestation" by which the supervising physician described the CPT codes that he or she will supervise or exclude specific codes that the supervising physician will not supervise. (Docket Entry No. 150-14 at 24; Docket Entry No. 150-13 at 23). Defendants knew Medicare's requirements for physician supervision of diagnostic tests with contrast and provided the

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[7] MedQuest was experienced with providing Medicare with notice of changes of its technologists and physicians who were providing diagnostic services at the centers at each BioImaging centers. (Docket Entry No. 140-9, Dunphy Deposition at 21; Docket Entry No. 144, Hounshell Deposition at 28-32; Docket Entry No. 150-9, Delozier Deposition at 3; and Docket Entry No. 137, Burke declaration at 2, 6, and 7).

Medicare carrier with the lists of CPT codes of the diagnostic testing services to be provided at its BioImaging centers in the Nashville area. (Docket Entry No. 137, Delozier Declaration at 2-3).

CIGNA is Medicare's carrier for Tennessee and decides requirements for health care providers at IDTFs. (Docket Entry No. 150-6 at 7). In 2000, CIGNA published a "Local Medical Review Policy" ("LMRP") for Tennessee Medicare providers, including IDTFs. (Docket Entry No. 139-32). This Medicare Bulletin dated November/December 2000, (Docket Entry No. 139 at 32-39), includes a section entitled "Independent Diagnostic Testing Facility (IDTF)," with an effective date of December 15, 2000. Id. at 32. This Medicare Bulletin parallels CMS's Manual quoted supra at 13-15, and describes the credential requirements for IDTFs, where diagnostic tests are performed by non-physicians, citing 42 C.F.R. §410.33. Id.

> Medicare will cover diagnostic tests performed by an IDTF when the medical necessity set forth in the individual Local Medical Review Policies are met and when furnished in accordance with the criteria listed below:
>
> Supervising physician
>
> **An IDTF must have one or more supervising physicians who are responsible for the direct and ongoing oversight of the quality of the testing performed, the proper operation and calibration of the equipment used to perform tests, and the qualification of non-physician personnel who use the equipment. This level of supervision is the requirement for general supervision.**
>
> **The supervising physician must evidence proficiency in the performance and interpretation of each type of diagnostic procedure performed by the IDTF. In the case of a procedure requiring the direct or personal supervision of a physician, the IDTF's supervising physician must furnish this level of supervision whether the procedure is performed in the IDTF or, in the case of mobile services, at the remote location.**

Id. at 32 (emphasis added)

Under the heading "Documentation Requirements," CIGNA's bulletin also requires an IDTF to maintain documentation "to demonstrate sufficient physician attendance during all hours of operation to assure that the required physician supervision is furnished. In cases of procedures requiring direct supervision, the supervising physician may oversee concurrent procedures. When direct or personal supervision is required, the record must clearly state this requirement was fulfilled." (Docket Entry No. 139 at 34).

Appendix I to CIGNA's LMRP bulletin also lists CPT codes, id., at 37-39 and the corresponding level of physician supervision during the performance of the diagnostic test, as well as the physician qualifications for the supervising physician for that test. The "MD Qualification" represents the medical specialties that would be accepted as possessing the skill and competency necessary to supervise adequately the respective tests. Id. at 36. Physicians who were not board certified in the specified specialty in a State, had to present proof of additional continuing medical education or participation in a certification programs specific to the skills involved in the tests at issue. Id.

During the relevant time, CPT codes with the corresponding level of physician supervision were published in a Medicare bulletin or CMS's or CIGNA's website with the corresponding level of physician supervision and qualifications of the supervising physician and administering technician for each CPT code, id. at 37-39 that CMS approves. (Docket Entry No. 141-1, Winter deposition at 4-5, 14, 24-25). The CPT codes include one for the diagnostic tests requiring Level 2 supervision or direct supervision, as reflected in the physician fee schedule and CIGNA's publications. (Docket Entry No. 138, Haines Declaration at 2-3 and Docket Entry No. 137, Delozier Declaration at 2-5).

CIGNA consults with CMS and other Medicare carriers' medical directors and medical specialty boards on the appropriate qualification requirements for supervising physicians at IDTFs. One such collaboration was CIGNA's 2006 working group on supervising physicians at IDTFs that found, in pertinent part:

> **[T]he proficiency or expertise in the performance and interpretation of the procedure being performed by the physician must be documented. This role of the Supervising Physician in an IDTF clearly precludes any physician who does not have the specialized training required for the specific procedure from "supervising" the testing without documentation of additional training in this exclusive area of proficiency. A statement of 'considerable experience . . . related to imaging . . .' does not suffice as evidence of proficiency in the performance of such testing.**
>
> In order to assist providers in meeting these requirements and determining the required board certifications for supervising physicians, **the national carrier workgroup with the assistance of carrier medical directors and medical specialty boards, assigned a listing of physician qualifications to each diagnostic CPT code.**

(Docket Entry No. 150-5 at 3) (emphasis added).

As to the rationale of the importance of the supervisory physician's qualifications for an IDTF, this working group study found that:

> **An IDTF by virtue of its 'independent status' does not have the availability of numerous medical specialists to consult with each other in decision making as would be the case in a hospital or large medical clinic, and the physicians who refer their patients to an IDTF are relying on the expertise of the supervising/interpreting physician at that IDTF to assist them in making a medical diagnosis that will be used in treating the patient. To this end, it is expected that the highest level of expertise be available, therefore alternatives to board certification in the specialty required is not a viable option for physicians or technologists.** This would also exclude "Residents" or those physicians who are "Board eligible" until such time as they attain certification status. **The rampant proliferation of IDTFs nation wide has only served to increase the need for more stringent criteria to assure our beneficiaries of the best possible diagnostic services, not the most numerous.**

Id. at 4. (emphasis added). See also Docket Entry No. 169-3 at 2.

Defendants note that a CIGNA representative requested guidance from CMS on whether a board certified radiologist is actually required for contrast coverage, but did not get a response. (Docket Entry No. 150-6, Guerrero Deposition at 10-12). There are not any published CMS criteria for the proficiency requirements for direct or personal physician supervision at an IDTF. (Docket Entry No. 150-2, Bossenmeyer Deposition at 3).

Defendants knew Medicare required direct physician supervision of diagnostic tests with contrast and provided CIGNA with the lists of CPT codes of the diagnostic testing services BioImaging centers. (Docket Entry No. 137, Delozier declaration at 3; Docket Entry No. 144, Hounshell Deposition at 12, 46 and 47). Christina Dozier, a former MedQuest credentialing specialist and a MedQuest contact with CIGNA, understood that the supervising physician on MedQuest's CMS 855 form had to provide the services to bill Medicare for the service, unless the physician coverage was locum tenens[8] coverage. "If it's not a locum tenens, then Medicare needs to know about the doctor before we can bill for it." (Docket Entry No. 141-3, Dozier Deposition at 6-7).

3. MedQuest's Medicare Applications for the Nashville Area IDTFs

During the IDTF application process, CIGNA informed MedQuest that "a physician of an IDTF must be proficient in the performance and interpretation of each type of diagnostic p[er]formed by the IDTF and provide documentation evidencing proficiency." (Docket Entry No. 141-2 at 2, 34). On May 10, 2002 and June 6, 2005, MedQuest submitted to CIGNA the CMS 855 change of information forms for its BioImaging IDTFs at Cool Springs and Harding.

[8] As discussed infra, "locum tenens" refers to a physician who substitutes for the IDTF's listed supervising physician who is temporarily unavailable, as for example, on vacation, but Medicare must be informed and that substitute physician must also be approved by Medicare.

(Docket Entry Nos. 150-13 at 1, 13 and 150-14 at 1, 13, 19). As to supervising physicians, MedQuest's 2002 CMS 855 change of information form for supervising physicians listed two supervising physicians for its Cool Springs IDTF, Dr. Witt and Dr. Robert A. Cooney. (Docket Entry No. 150-14 at 24-25). CIGNA approved both doctors, but MedQuest withdrew Dr. Cooney as a supervising physician on November 15, 2002. (Docket Entry No. 137 at 6).

Effective April 27, 2003, MedQuest submitted a CMS 855 change of information form listing Dr. Jean Tan, an internist, as a supervising physician at its Cool Springs IDTFs. (Docket Entry No. 140-7 at 1- 5). Dr. Tan marked those sections of the form under general, personal and direct supervision that would enable her to provide general supervision over the equipment, supplies and training of non-physicians personnel performing diagnostic studies. Id. CIGNA approved Dr. Tan as a supervising physician, but only after proof of her additional training for diagnostic testing. (Docket Entry No. 131 at 2-4, Bradley Declaration, and Docket Entry No. 151-6, Dunphy deposition at 4).

On July 18, 2005, CIGNA denied MedQuest's request for approval of Dr. Thomas Henry, as a supervising physician at MedQuest's Cool Springs facility because he was "not board certified in Radiology" as required by 42 C.F.R. § 410.33. (Docket Entry No. 140-2 at 2, 34). CIGNA informed MedQuest of the appeal process for its denial. Id. CIGNA denied other MedQuest's informal telephonic requests for approval of physicians as supervising physicians who were not board certified radiologist or a physician trained for IDTF testing. (Docket Entry No. 169-2 at 3).

Effective July 1, 2005, Defendant BioImaging at Charlotte enrolled with CIGNA as an IDTF with the Medicare program. (Docket Entry No. 151-20). After its earlier purchase of William S. Witt, Inc. in January 2004, MedQuest billed the Medicare program for diagnostic

testing of Medicare beneficiaries at the Charlotte facility, but used Dr. Witt's Medicare provider number from January 15, 2004 through June 30, 2005. (Docket Entry No. 146, Haines Deposition at 2, 14; Docket Entry No. 138, Haines Declaration at 3; and Docket Entry No. 64, Defendant's Answer at 45). Before January 2004, Dr. Witt was enrolled with Medicare as a physician practice for diagnostic services at 1800 Charlotte. (Docket Entry No. 140-1, Blank deposition at 59). The Medicare number for billing for an IDTF refers to a facility rather than to an individual. (Docket Entry No. 144, Hounshell Deposition at 43). Medicare billing numbers can be researched from public records. (Docket Entry No. 140-2, Blank deposition at 5-6).

MedQuest's enrollment of its Charlotte facility as an IDTF arose after Aetna, a private insurer, was processing Medicare claims and raised issues about MedQuest's billing for testing at its Charlotte facility, using a Medicare billing number that belonged to Dr. Witt. (Docket Entry No. 139 at 17, 18). When Dozier first attempted to change the tax identification number with CIGNA, CIGNA instructed Dozier that Medicare required a CMS 855 enrollment change form for this change. (Docket Entry No. 141-3, Delozier deposition at 14-20). An executive report from Choice Point, a computer research firm employed by CIGNA, identified all persons or entities previously associated with the Charlotte Center provider number and identified the prior providers as William Witt, M.D. and William Witt, Inc. (Docket Entry No. 151-3). CIGNA's files did not reflect its awareness of MedQuest's classification of the center as a physician's practice. MedQuest did not inform Medicare of its purchase until July 1, 2005. (Docket Entry No. 140-1 at 47).

As to why the Charlotte center did not apply as an IDTF in 2004, Wayne Blank, MedQuest's chief compliance officer explained that "they just messed up and didn't get it enrolled until they decided to do the tax ID, and that's when they saw it was still enrolled as

William Witt." (Docket Entry No. 140-2 at 2). Blank described the Charlotte center as operating as an IDTF as of January, 2004, id. at 2, but did not consider "a lot of difference" between a physician practice and an IDTF. Id. As quoted earlier supra at 9, as of January, 2004, Dr. Witt considered his prior physician practice ended with MedQuest's stock purchase of his corporation.

MedQuest submitted a new enrollment application for its Charlotte facility and filed the Choice Point report with its new application. (Docket Entry No. 140-1, Blank deposition at 47 and Docket Entry No. 140-2 at 1). MedQuest also consolidated all of the Nashville area BioImaging Centers under one tax identification number. Chris Wicker, MedQuest's director of accounts receivables, changed the tax identification number for the BioImaging Centers effective July 1, 2005, and consolidated all BioImaging centers with a single tax identification number.

4. MedQuest's Nashville Area IDTFs' Performance

MedQuest operated the BioImaging IDTFs', including the Charlotte Center and provided administrative services to all BioImaging Centers, including information technology. At MedQuest's Nashville area IDTFs, the standard procedure was for a physician to supervise contrast studies regardless of payor, and the IDTF staff selected physicians for contrast studies. (Docket Entry No. 151-5, Baggett's Deposition at 6 and Docket Entry No. 151-6 Dunphy's Deposition, at 4). MedQuest's IDTFs retained radiologists to read diagnostic images off-site so as to allow on-site radiologists more time to provide contrast coverage. (Docket Entry No. 151-6 at 8). Yet, the standard practice did not require a radiologist who was already on-site at one of MedQuest's Nashville area IDTFs to perform a diagnostic procedure and/or to read or interpret a diagnostic image or to sign the physician log. (Docket Entry No. 151-6, Dunphy Deposition at 5). In 2003, a MedQuest memorandum instructed its IDTF centers' staffs that only physicians

on MedQuest's Medicare applications should be used for contrast studies of Medicare patients. (Docket Entry No. 137, Delozier declaration at 12-14).

For its Nashville area IDTFs, MedQuest had Medicare's approval of Dr. Witt as a supervising physician beginning in 2002 and Dr. Tan in 2003. Problems arose in ensuring the availability of Dr. Witt who was responsible for all three MedQuest centers in the Nashville area, for contrast injection coverage. (Docket Entry No. 169-1 at 4 and Docket Entry No. 139 at 4). Dr. Witt failed to give MedQuest's Nashville area IDTFs' staffs notice of when he would take a day off or would leave early or arrive late. (Docket Entry No. 140-6 at 42 and Docket Entry No. 141-10 at 10-12). Dr. Witt was also unavailable during "after hours," (Docket Entry No. 141-7, Baggett deposition at 7) as MedQuest Nashville area IDTFs remained open until 8:00 or 9:00 p.m. (Docket Entry No. 166-1, Hobbs Affidavit at 4).[9] In 2003, Dr. Witt was seriously injured in an accident and was unable to provide diagnostic coverage services for a time, but provided reading services from his residence. (Docket Entry No. 140-5, Schaefer deposition at 65-67). When Dr. Witt returned to work, by separate agreement, Dr. Witt agreed to provide supervision at MedQuest's three Nashville area IDTFs. (Docket Entry No.163, Roberts's declaration at 3).

When Drs. Witt and Tan were unavailable to provide the physician supervision of contrast tests billed to Medicare, MedQuest's Nashville IDTFs' staffs would contact several physicians to provide contrast coverage at MedQuest's Nashville area IDTFs. (Docket Entry No, 132, Just declaration at 2). MedQuest's corporate compliance officer and regulatory counsel, Wayne Blank, conceded that Medicare required such supervision to be covered by a physician on

[9] This citation is to the actual page number of the Hobbs' affidavit.

its IDTF's CMS 855 form, unless there was locum tenens[10] coverage. (Docket Entry No. 140-1, Blank Deposition at 41-42).

At some point, MedQuest's Nashville area IDTF managers and employees began to list contrast alerts on the daily calendar to inform staff of the time and location of scheduled contrast studies so as to ensure a supervising physician for that procedure. (Docket Entry No. 151-6 Dunphy Deposition at 6). The schedulers, the technologists, and the local IDTF staff had access to the IDTF's daily calendar, including contrast alerts. Id. at 6-7. These contrast alerts were to avoid scheduling conflicts in arranging for physician supervision of contrast studies at the different centers. Id. Technologists who were unable to schedule a supervising physician for a contrast procedure would reschedule the patient for the contrast procedure rather than inject the patient with contrast material. Id. at 9-10.

MedQuest's Nashville area IDTFs maintained a list of physicians for staff to contact and that list was posted at its individual IDTF. (Docket Entry No. 150 at 21-22 and Baggett Transcript at 44:9-23). To document these physicians' supervision of contrast studies where a radiologist was unavailable, MedQuest's Nashville IDTF's staff utilized sign-in logs for these physicians, but some physicians did not sign the log sheets for their contrast coverage. (Docket Entry No. 151-5, Baggett deposition at 2-7 and Docket Entry No. 151-6, Dunphy deposition at 6). All of these BioImaging Centers used this same supervising physician logbook form to record physician supervision of diagnostic tests administered. This log also recorded the

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[10] As noted earlier, locum tenens means a physician who is temporarily covering for another physician and is identified on a claim submitted to Medicare by attaching a modifier to the claim which identifies it to the Medicare program. Defendants knew that claims submitted to Medicare as locum tenens claims should have included the locum tenens claims modifier that requires notice to Medicare of the substitute physician for Medicare's approval. (Docket Entry No. 140-5, Schaefer Deposition at 62; Docket Entry No. 171-7, Blank Deposition at 3).

patient's name, the names or initials of the physician who injected the contrast and provided coverage of the contrast injection and the date of the contrast tests. (Docket Entry No. 151-5, Baggett deposition at 3-4). This log did not require a radiologist to sign and does not reflect whether the signing physician was approved by Medicare. (Docket Entry No. 151-6, Dunphy deposition at 4, 5).

The undisputed facts are that the physicians on these logs were not approved by Medicare for these tests. (Docket Entry No. 141-9, Defendants' Response to the United States Requests for Admissions at ¶¶ 4-24). These physicians who provided direct supervision of diagnostic tests of Medicare patients using contrast at these MedQuest centers, were not disclosed to CIGNA and CIGNA had not evaluated these physicians' "proficiency" to supervise these tests as Medicare providers. (Docket Entry No. 138, Haines Declaration at 1-6, 37-38; Docket Entry No. 146, Haines Deposition at 13-14, 19). Yet, MedQuest billed and Medicare paid for these non-Medicare approved physicians' supervision of the tests at its Nashville area IDTFs. Id.

At times, IDTF managers and technicians began to inject patients for contrast studies without a physician present because they felt pressured to do so. (Docket Entry No. 141-8, Hobbs deposition at 17, 18; Docket Entry No. 141-7, Baggett deposition at 9, 10, 15). Baggett reported her injections without a physician to her supervisors Hobbs, Just and Dunphy. (Docket Entry No. 141-7 at 10). MedQuest's managers' responses to technician injections were to provide names of more physicians. Id. at 11-12. Defendants' employees at these Nashville area centers refer to obtaining physician coverage of diagnostic tests involving contrast as "difficult to schedule." (Docket Entry No. 166-1, Hobbs Affidavit at ¶ 9). According to Dunphy, appropriate physician supervision of contrast coverage at all their Nashville area centers was "always a

concern."[11] (Docket Entry No. 140-9 at 3). Dunphy described securing a qualified supervising physician as "difficult" and "definitely not an easy task to get contrast coverage." Id. at 17. Hobbs complained to her MedQuest supervisors about technicians injecting patients without supervision. (Docket Entry No. 166-1, Hobbs Affidavit at ¶ 18). MedQuest's Nashville area IDTFs staff employees did so because they were pressured to generate billings. Id. at ¶ 10.

According to Hobbs, MedQuest's Nashville area physicians credentialed by Medicare could not cover all three MedQuest IDTFs as supervising physicians. (Docket Entry No. 166-1, Hobbs Affidavit at ¶¶ 5,7, 9). Sally Bradley, MedQuest's director of credentialing attributed these coverage issues to CIGNA. "The problem lies in the Local Medical Review Policies for Medicare of Tennessee. They require that virtually all tests at an IDTF be supervised by a radiologist, which is much more stringent than other states." (Docket Entry No. 131, Bradley declaration at 5).

On January 28, 2003, Marcy Burke Delozier, an employee in MedQuest's corporate credentialing department, issued a Memorandum to "All Center Managers" and all "Regional Managers" regarding Medicare requirements for physician supervision of diagnostic tests and copied MedQuest's management. (Docket Entry No. 137 at 3, 12-18). Delozier, a compliance

[11] The Government notes that in 2003, MedQuest returned monies to CIGNA as an "overpayment" of a total of $43,987 by Medicare for paid claims for diagnostic testing at the BioImaging of Cool Springs and BioImaging at Charlotte from 1999-2002 for which MedQuest "had insufficient documentation to substantiate the appropriate physician supervision for procedures involving the use of contrast." (Docket Entry No. 163, Roberts Declaration at 4,5, and 6). Jim Roberts MedQuest's regional manager received instructions from Charles Self, MedQuest's director of corporate compliance, to return these funds to the Medicare program. (Docket Entry No. 140-6 at 39-41, Schaefer Deposition). Daniel Schaefer, MedQuest's chief operating officer was aware of those deficiencies. Id. The United States seeks recovery here from January 15, 2004 to September 12, 2006.

officer, described "extensive" discussions with Schaefer and other MedQuest management about the lack of supervising physicians at MedQuest's Nashville area IDTFs.

> One of the issues that I discussed extensively with Dan Schaefer and others while I worked at MQA [MedQuest] was about physician supervision at the centers. I spoke at length about physician supervision with various center managers as well as with MQA managers, including Mr. Schaefer and Mr. Villa. It was my understanding that supervising physicians had to be proficient with respect to the particular tests they were supervising in order for the test to be billed to Medicare. Level 2 required direct supervision, and Level 3 required personal supervision. This requirement was discussed at MQA with management, including Mr. Schaefer. The CMS 855 forms also contained a physician attestation about the type of supervision the physician is going to provide.
>
> It was also clear to me that if a physician was not listed on the CMS 855 forms provided to Medicare, or was not shown to be proficient for the tests the physician was supervising, the physician could not provide the supervision of tests given to Medicare patients for billing to Medicare.
>
> I felt that when I raised concerns about Medicare requirements to Mr. Schaefer and other members of MQA management, the requirements were not taken seriously. I also was concerned that others at MQA were giving center managers information that conflicted with the Medicare requirements that I understood. Many of the centers wanted to use non-radiologists for physician supervision. Therefore, in January 2003, I sent out a memorandum to all center managers and regional managers clearly stating the Medicare requirements for physician supervision. Copies of my memorandum, with its attachments, that I distributed to all of the centers and to MQA management are attached to this declaration.
>
> I explained in the memorandum the physician supervision that was required for the three levels of supervision, and reminded everyone that only those physicians credentialed on the center's Medicare applications could be used for services provided to Medicare patients. I tried to stress that following the memorandum's instructions was very important and had to be followed or the centers would not be in compliance with Medicare rules and regulations. I also attached and provided to the center managers an example of the Medicare CMS 855 physician attestation that had to be completed by the physicians, and the template of a physician supervision log sheet for each center to document the physician supervision.

(Docket Entry No. 137 at 3).

Burke's January 2003 Memorandum, entitled "Medicare Supervising Physician Information," included among other things the following:

> Attached you will find several pages of very important information to be followed for compliance with Medicare. Probably most important is the section on Supervising Physicians, their responsibilities and the Levels of Supervision they provide to Medicare patients.
>
> You will also find information on the following: Supervision Physician Log, Physician Orders, Emergency Phone Numbers, Technologist's Certification, Site Visits and Return Site Visits.
>
> I have attached copies of the following documents: Medicare Supervising Physician Attestation, Supervising Physician Log and Supervising Physician/Emergency Phone Numbers form.
>
> You must ensure that your site(s) comply with the requirements. These requirements and compliance with them are critical. Feel free to call me if you need additional information.
>
> * * *
>
> The supervising physicians have to meet only the proficiency standards for the tests they are supervising. If they are supervising all tests they have to meet the proficiency standards for all tests. See attached copy of Medicare's Supervising Physician Attestation that each supervising physician must sign.
>
> **Please Note: The supervising physician/s that I have listed on your Medicare application is the only physician/s you should use for contrast enhanced studies on Medicare patients. If you use other physicians not listed with Medicare, you are not in compliance.**

Id. at 12, 13 (emphasis in the original). Burke's memorandum attached copies of the CMS 855 IDTF Attachment 2 Supervising Physician form with the physician attestation, and a copy of a Supervising Physician Logbook page. Id. at 16-18.

On November 7, 2005, MedQuest expressed its concerns to CMS about CIGNA's requirement of a board certified radiologist as a supervising physician at its IDTFs. Citing 42 C.F.R. § 410.33(b)(2) as the governing regulation for an IDTF, Wayne Blank and Kimberly Hounshell of MedQuest wrote:

Background

Independent Diagnostic Testing Facilities ("IDTF") is a relatively new category of provider. Effective July 1, 1998, Medicare provided for the implementation of this new provider designation of IDTF at 42 C.F.R. § 410.33. The IDTFs replaced the previous provider category of Independent Physiological Laboratory ("IPL"). The IDTF designation is described as fixed location, mobile entities and individual non-physician practitioners.

* * *

Clearly the regulations **do not** require that the supervising physician be a Board Certified Radiologist. Other physicians may have training or continuing medical education which provides them with proficiency to supervise the operation of the imaging equipment as well as, respond to any patient medical issues which may arise during the imaging procedure. The greatest concern with regard to patient safety in the imaging area concerns problems which may arise from a patient's adverse allergic reaction to the administration of the contrast agent utilized for certain imaging procedures. The response to such a reaction would be handled by a qualified physician through administration of appropriate drugs required to control such allergic reaction.

The IDTF Model

By their very nature IDTFs are independent from diagnostic imaging services offered by facilities owned by hospitals or physicians. The cost structure is designed to provide quality imaging services at a cost far below that of an institutional setting. Furthermore, in many instances IDTF providers offer early morning, evening or weekend hours as a means of providing greater access and flexibility to patients which would not necessarily be available in a hospital or physician office setting. With staffing shortages in the field of radiology, for those hours outside of the core work hours of 8:00a.m. to 5:00p.m. it is difficult for IDTF providers (or other imaging providers) to find radiologists to staff a facility. Given that they will not be the one required to read or interpret images taken at these times, non-radiologist physicians (with appropriate proficiency) are more than capable of supervising the imaging operations and providing for the safety of the patients.

* * *

Recommended Solutions

We would request that CMS instruct the carriers to re-evaluate the interpretation of supervising physician requirements and offer the following recommendation. We believe the following supervision levels provide the quality levels sought and

> while allowing IDTFs the flexibility to operate and provide needed diagnostic imaging assess to Medicare patients.

(Docket Entry No. 140-2 at 16-17, 20). From 2003 to 2007, CIGNA's requirement of a radiologist or a physician appropriately trained in diagnostic testing to be performed at an IDTF was not modified, amended or changed. (Docket Entry No. 176, Statement of Undisputed Facts at ¶¶ 79-80). As stated earlier, CIGNA approved Dr. Tan, an internist with additional training, as a supervising physician at MedQuest Nashville area IDTFs. (Docket Entry No. 131, Bradley declaration at 2).

Finally, Defendants contend that Medicare did not suffer any adverse financial impact from MedQuest's Charlotte's facility's lack of an IDTF status prior to July 1, 2005 and cite the Medicare policy that authorizes back-billing of testing at Witt's Charlotte facility prior to its pre-IDTF approval. The CMS Manual authorizes back-billing for successor entities, but such authorization is not automatic. Medicare requires its carriers to certify that any successor facility met all requirements of an IDTF during the back-billing period. Moreover, the successor entity had to notify the Medicare carrier of the change of ownership and apply as an IDTF.

A. Backbilling

> Like any other non-certified supplier, an IDTF applicant may back bill from the date it met all the IDTF requirements - assuming it can furnish reasonable evidence that it indeed met the applicable standards on that date. For example, suppose an applicant was granted an IDTF number on July 1, 2005, but met all of the necessary requirements - properly calibrated equipment, qualified technicians, qualified supervisory physicians, etc. - as of May 1, 2005. **The applicant can back bill for IDTF services performed on or after May 1, 2005. Evidence that the carrier shall consider in determining whether such standards were met include payroll records, personnel records, contracts, equipment purchase records, etc. The carrier, when necessary, shall request such confirming documents from the applicant or, as an alternative, may review such documents as part of the site visit. The carrier shall also document the file with the method used for determining when the applicant is entitled to bill**

> **for services. Note that the applicable personnel and equipment do not have to be the same as those of July 1, 2005.**
>
> **An applicant that has purchased the assets of an existing IDTF is not automatically allowed to continue billing. It must apply as a new IDTF and may back bill once enrolled.** Obviously, use of the same personnel and equipment as the previously enrolled IDTF can facilitate the determination that the new IDTF can bill as of the date of the sale.

(Docket Entry No. 150-11 at 1). Defendants do not offer any proof that CIGNA made such inquiries or certified its Charlotte center for its operation during the back-billing period.

5. Expert Proof on Medicare Administrative Practice Approving Supervising Physicians

Dr. Gary Oakes, CIGNA's associate medical director, testified that a radiologist is the most proficient specialty to determine the modality, *i.e.*, the type of diagnostic procedure and most appropriate treatment for a patient presenting a clinical condition during such testing. (Docket Entry No. 150-1, Oakes deposition at 2, 6, 9). Dr. Oakes admitted that the referring physician decides the type of test and when the test is ordered and that any state licensed physician can provide treatment in the event of a contrast reaction, id. at 11-12, but insisted some specialized training for physician supervision of diagnostic testing at an IDTF is necessary.

> Q. Okay. So is it fair to say that unless a physician can provide either board certification in a specialty attached to the CPT listings or some society that's equivalent to a board certification you will not approve?
>
> A. Correct.
>
> Q. Has that always been the case?
>
> A. Since I've been here.
>
> Q. And if I understand your testimony, the reason for this is you believe that board certification provides the competency criteria that you're looking for?
>
> A. It -- yes.

MR. MATHERNE: I think you said competency and proficiency, if there's a difference.

Q. (By Ms. Plowman) Is there a difference?

A. They meet the standards of the board which would normally envelope the particular procedure. **But, yes, we expect proficiency and competency, and we depend upon the board to determine what is appropriate for that particular specialty.**

Q. Let's take, for example, a radiology code, let's say MRI.

A. Sure.

Q. **When you're looking for competency and proficiency in the procedure, what are you looking for?**

A. **Somebody that knows the mechanics of the MRI; the indications; and as important, if not more so, the contraindications; and which particular test is the best test given the clinical scenario.**

Q. And when you say indications and contraindications, what are you referring to?

A. Well, just what I said, what are the medical indications for an MRI versus another imaging test. And the contraindications, is there anything such as a metal implant that would prohibit you doing this.

Q. For instance, if you have a pacemaker, you can't perform an MRI?

A. That's correct.

Q. Or at least it's contraindicated to perform the MRI?

A. Right.

Q. That's what you're talking about, those kind of things?

A. Or if you have any other implant that's –

Q. But some sort of metal implant that would be contraindicated to perform an MRI?

A. Or some other reason not to be able to do it.

Q. Okay. All right. But it's indications or contraindications for the particular test that's being performed?

A. Correct. And then to handle any complications of that test. So we know with contrast that a certain amount of people will have a reaction to it, and they have to be able to respond and correctly address that reaction.

Q. And what -- what would a physician do to address the complications of a reaction?

A. Depends on the reaction.

Q. Say they develop a rash.

A. Again, it depends upon the contrast material and the particular patient. I can't give you a specific guideline per se.

Q. Okay. What -- you don't -- as you sit here today, you don't know how a physician would address a reaction to contrast?

MR. MATHERNE: Asked and answered.

Q. (By Ms. Plowman) You can answer.

A. Okay. I know how I would address it.

Q. And how would you address it?

A. I would address it in the way that's set down, by starting IVs; giving fluids; giving an antihistamine; if necessary, epinephrin; protecting the airway; and calling for the radiologist to assist me.

Q. **Okay. The steps that you've just referred to, can any physician institute those steps?**

A. **Any physician that's licensed in the state of Tennessee to take those steps. But to clarify, they may not know the contraindications and indications for a particular test.**

(Docket Entry No. 150-1, Oakes deposition at 9-12) (emphasis added).

The evidence establishes that CIGNA sets the supervising physician requirements, not CMS. CIGNA, however, consulted on these requirements with medical specialty groups. Id. at

6. Defendants note that despite repeated requests, the task force did not secure guidelines from CMS on physician supervision requirements[12] (Docket Entry No. 150-6, Guerrero deposition at 10), but CMS reviews all LCDs promulgated by a carrier. (Docket Entry No. 150-1, Oakes deposition at 7). CIGNA has approved non-radiologists with appropriate training to serve as supervising physicians, as CIGNA did with Dr. Tan for MedQuest. (Docket Entry No. 131, Brandley declaration at 2; Docket Entry No. 151-2, Hounshell deposition at 2; and Docket Entry No. 151-10 at 1).

Other Medicare carriers, First Coast Service Options, Inc., and Palmetto also have requirements for supervising physicians at IDTFs. First Coast April 2005 Medicare Guidelines for IDTFs provides as follows:

> Supervising Physician(s)
>
> An IDTF must have one or more supervising physicians who are responsible for the direct and ongoing oversight of the quality of the testing performed, the proper operation, maintenance, and calibration of the equipment used to perform tests, and the qualification of nonphysician personnel who use the equipment. This level of supervision is the requirement for general supervision.
>
> **The supervising physician must evidence proficiency in the performance and interpretation of each type of diagnostic procedure performed by the IDTF**. In the case of a procedure requiring the direct or personal supervision of a physician, 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.

(Docket Entry No. 151-18 at 5) (emphasis added).

Palmetto also requires that physicians providing direct supervising exhibit an appropriate level of supervision.

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[12] Defendants refer to CMS's silence as a declaration, but given the Medicare regulations on IDTFs cited infra, 42 C.F.R. § 410.33(b)(2), the Secretary designated the Medicare carrier to decide the IDTF providers' proficiency.

> Diagnostic Radiology-Many diagnostic test are radiological procedures that require the professional services of a radiologist. . . .
>
> * * *
>
> All General supervising Physicians must be proficient in the services being performed by the IDTF. . .
>
> **Direct Supervising Physicians**
>
> - Must hold a valid, current state license and be Medicare enrolled in the state where services are being performed.
> - **The Direct Supervising Physician must show proficiency in the services he/she is supervising.**
> - Direct Supervision-testing requires that the physician must be present in the office and immediately available to furnish assistance and direction throughout the performance of the testing. Physician does not have to be present in the room while the procedure is being performed.

(Docket Entry No. 150-8 at 3, 9). Several Medicare carriers have approved non-radiologists to serve as supervising physicians at IDTFs for contrast procedures, including First Coast and Palmetto, among others. (Docket Entry No. 151-1, Dozier Transcript at 5-6; Docket Entry No. 151-2, Hounshell deposition at 2-4, 8; and Docket Entry No. 140-1 at 35-36).

According to Dr. David Levin, a radiologist and defense expert who is in charge of the radiology department at the Jefferson Medical College and Thomas Jefferson University Hospital, there are two distinct phases to computerized tomography ("CT") and Magnetic Resonance Imaging ("MRI"). "The first phase is the performance of the scan, which is typically carried out by a qualified technologist," and "i[f] the scan requires the use of contrast, a physician needs to be present because of the possibility of a contrast reaction," (Docket Entry No. 150-3 at 1). The "second phase is the interpretation of the scan, which ideally is done by a trained radiologist, but which in some facilities is done by physicians from other specialties." Id. In Dr. Levin's opinion, where contrast is utilized for diagnostic testing, any physician with any

clinical medical experience is qualified and proficient to respond to an allergic reaction. Id. Dr. Levin asserts that the purpose of a physician's direct supervision of the contrast study is solely to provide medical care if the patient has an adverse or allergic reaction to the contrast medium.[13]

Alan Gillespie, another defense expert and former senior technical advisor in CMS's division of providers and supplier enrollment opined that "there is no CMS requirement that a supervisory physician has to be a radiologist" based upon his review of CMC's PIM, 855 form and manuals. (Docket Entry No. 150-7 at 2).

Defendants also cite CMS's response published at 64 Fed. Reg. 59380, 59415 (Nov. 2, 1999) commenting on the issues of physician supervision, including at IDTFs about the qualifications of nurse practitioners and clinical nurse specialists to perform radiology procedures without physician supervision. In this publication, CMS stated, in relevant part, that

> since we have not imposed requirements regarding specific training requirements for physician specialties to be able to perform and bill for these diagnostic tests, **we believe that it is inappropriate to apply these requirements to practitioners whom the Congress has specifically recognized as having the ability to furnish services that would be physician services if furnished by a physician, subject to the provisions of State law**.

(Docket Entry No. 151-12 at 2) (emphasis added).[14]

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[13] Dr. Levin also explains that the regulation is drafted as a "may" rather than a "must" from which Dr. Levin opines that a patient's adverse reaction is "the only proficiency that must be demonstrated is in the performance of the contrast injection." Id. at 1 (emphasis in the original). The Court cannot accept Dr. Levin's opinion about a Medicare regulation. See Berry v. City of Detroit, 25 F.3d 1342, 1353-54 (6th Cir. 1994).

[14] In reviewing the Defendants' exhibits, the Court could not find the Defendants' second quotation from the Federal Register in their supporting memorandum (Docket Entry No. 150 at 36), but because the Secretary designated the Medicare carrier, not CMS, to decide the qualifications of IDTF providers in 42 C.F.R. § 410.33(b)(2), this inability is not material.

Finally, Gillespie, a former Medicare management analyst, insurance specialist and senior technical advisor in the CMS division of providers and supplier enrollment, also opined that because the legal name of Witt, Inc. and its tax identification number did not change, there was not any necessity for MedQuest to enroll its Charlotte center as an IDTF. (Docket Entry No. 150-7 at 1). Gillespie explains that if, after receiving the new enrollment application, CIGNA had any questions about the Charlotte Center's classification as of January 2004, CIGNA should have raised the issue then. Id. at 2.

6. Damages Proof

In sum, both parties presented proof on damages that conforms to their respective theories of the case.

The United States identified supervising physician logs of MedQuest's Nashville area IDTFs for Medicare claims for diagnostic testing with contrast without an approved Medicare physician that Medicare paid. (Docket Entry No. 138, Haines declaration at 2-3). That analysis revealed Medicare paid 474 claims for such testing without approved physicians at MedQuest's Nashville area IDTFs from January 15, 2004 through September 12, 2006, for a total of $343,758.22. Id. at 3. From January 15, 2004 to June 30, 2005, after MedQuest purchased Dr. Witt's practice and used Dr. Witt's Medicare billing number for Medicare payments, the United States identified 995 claims with Dr. Witt's Medicare billing number for which Medicare paid $493,185.46 to MedQuest. Id.

Charles Overstreet, Defendants' damages witness, examined MedQuest's Medicare claims for which there was lack of documentation of a physician's signature for diagnostic testing with contrast. (Docket Entry No. 151-16 at 4). With various assumptions and averages,

Overstreet's analysis revealed that from January 1, 2003 through April 18, 2007, Medicare overpaid MedQuest $15,070 for such contrast studies. Id. at 4-5.

B. Conclusions of Law

"The very reason of the summary judgment procedure is to pierce the pleadings and to assess the proof in order to see whether there is a genuine need for trial." Advisory Committee Notes on Rule 56, Federal Civil Judicial Procedure and Rules (West Ed. 1989). Moreover, "district courts are widely acknowledged to possess the power to enter summary judgment sua sponte, so long as the opposing party was on notice that she had to come forward with all of her evidence." Celotex Corp. v. Catrett, 477 U.S. 317, 326 (1986). Accord, Routman v. Automatic Data Processing, Inc., 873 F.2d 970, 971 (6th Cir. 1989).

In Anderson v. Liberty Lobby, Inc., 477 U.S. 242 (1986), the United States Supreme Court explained the nature of a motion for summary judgment:

> Rule 56(c) of the Federal Rules of Civil Procedure provides that summary judgment `shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.' By its very terms, this standard provides that the mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no genuine issue of material fact.
>
> As to materiality, the substantive law will identify which facts are material. Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment. Factual disputes that are irrelevant or unnecessary will not be counted.

477 U.S. at 247-48 (emphasis in the original and added in part). Earlier the Supreme Court defined a material fact for Rule 56 purposes as "[w]here the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no `genuine issue for trial.'"

Matsushita Electrical Industrial Co. v. Zenith Radio Corp., 475 U.S. 574, 587, 106 S. Ct. 1348, 1356, 89 L.Ed.2d 538 (1986) (citations omitted).

A motion for summary judgment is to be considered after adequate time for discovery. Celotex Corp. v. Catrett, 477 U.S. 317, 326 (1986). Where there has been a reasonable opportunity for discovery, the party opposing the motion must make an affirmative showing of the need for additional discovery after the filing of a motion for summary judgment. Emmons v. McLaughlin, 874 F.2d 351, 355-57 (6th Cir. 1989). But see Routman v. Automatic Data Processing, Inc., 873 F.2d 970, 971 (6th Cir. 1989).

There is a certain framework in considering a summary judgment motion as to the required showing of the respective parties as described by the Court in Celotex

> Of course, a party seeking summary judgment always bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any," which it believes demonstrate the absence of a genuine issue of material fact. . . . [W]e find no express or implied requirement in Rule 56 that the moving party support its motion with affidavits or other similar materials negating the opponent's claim.

Celotex, 477 U.S. at 323 (emphasis deleted).

As the Court of Appeals explained, "[t]he moving party bears the burden of satisfying Rule 56(c) standards." Martin v. Kelley, 803 F.2d 236, 239, n. 4 (6th Cir. 1986). The moving party's burden is to show "clearly and convincingly" the absence of any genuine issues of material fact. Sims v. Memphis Processors, Inc., 926 F.2d 524, 526 (6th Cir. 1991)(quoting Kochins v. Linden-Alimak, Inc., 799 F.2d 1128, 1133 (6th Cir. 1986)). "So long as the movant has met its initial burden of `demonstrating the absence of a genuine issue of material fact,' the nonmoving party then `must set forth specific facts showing that there is a genuine issue for

trial.'" Emmons v. McLaughlin, 874 F.2d 351, 353 (6th Cir. 1989) (quoting Celotex and Rule 56(e)).

Once the moving party meets its initial burden, the Court of Appeals warned that "[t]he respondent must adduce more than a scintilla of evidence to overcome the motion [and]. . . must `present affirmative evidence in order to defeat a properly supported motion for summary judgment.'" Street v. J.C. Bradford & Co., 886 F.2d 1472, 1479 (6th Cir. 1989)(quoting Liberty Lobby). Moreover, the Court of Appeals explained that

> The respondent must `do more than simply show that there is some metaphysical doubt as to the material facts.' Further, `[w]here the record taken as a whole could not lead a rational trier of fact to find' for the respondent, the motion should be granted. The trial court has at least some discretion to determine whether the respondent's claim is `implausible.'

Street, 886 F.2d at 1480 (cites omitted). See also Hutt v. Gibson Fiber Glass Products, No. 89-5731 (6th Cir. filed September 19, 1990) ("A court deciding a motion for summary judgment must determine `whether the evidence presents a sufficient disagreement to require a submission to the jury or whether it is so one-sided that one party must prevail as a matter of law." (quoting Liberty Lobby).

If both parties make their respective showings, the Court then determines if the material factual dispute is genuine, applying the governing law.

> More important for present purposes, summary judgment will not lie if the dispute about a material fact is `genuine' that is, if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.
>
> * * *
>
> Progressing to the specific issue in this case, we are convinced that the inquiry involved in a ruling on a motion for summary judgment or for a directed verdict necessarily implicates the substantive evidentiary standard of proof that would apply at the trial on the merits. If the defendant in a run-of-the-mill civil case moves for summary judgment or for a directed verdict based on the lack of proof of a material fact, the judge must ask himself not whether he thinks the evidence

> unmistakably favors one side or the other but whether a fair-minded jury could return a verdict for the plaintiff on the evidence presented. The mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient; there must be evidence on which the jury could reasonably find for the plaintiff. The judge's inquiry, therefore, unavoidably asks whether reasonable jurors could find by a preponderance of the evidence that the plaintiff is entitled to a verdict -- `whether there is [evidence] upon which a jury can properly proceed to find a verdict for the party producing it, upon whom the onus of proof is imposed.'

Liberty Lobby, 477 U.S. at 248, 252 (citation omitted and emphasis added).

It is likewise true that

> [I]n ruling on a motion for summary judgment, the court must construe the evidence in its most favorable light in favor of the party opposing the motion and against the movant. Further, the papers supporting the movant are closely scrutinized, whereas the opponents are indulgently treated. It has been stated that: `The purpose of the hearing on the motion for such a judgment is not to resolve factual issues. It is to determine whether there is any genuine issue of material fact in dispute. . . .'

Bohn Aluminum & Brass Corp. v. Storm King Corp., 303 F.2d 425, 427 (6th Cir. 1962) (citation omitted). As the Court of Appeals stated, "[a]ll facts and inferences to be drawn therefrom must be read in a light most favorable to the party opposing the motion." Duchon v. Cajon Company, 791 F.2d. 43, 46 (6th Cir. 1986) app. 840 F.2d 16 (6th Cir. 1988) (unpublished opinion) (citation omitted).

The Court of Appeals further explained the District Court's role in evaluating the proof on a summary judgment motion

> A district court is not required to speculate on which portion of the record the nonmoving party relies, nor is it obligated to wade through and search the entire record for some specific facts that might support the nonmoving party's claim. Rule 56 contemplates a limited marshalling of evidence by the nonmoving party sufficient to establishing a genuine issue of material fact for trial. This marshalling of evidence, however, does not require the nonmoving party to "designate" facts by citing specific page numbers. Designate means simply "to point out the location of." Webster's Third New InterNational Dictionary (1986).

> Of course, the designated portions of the record must be presented with enough specificity that the district court can readily identify the facts upon which the nonmoving party relies; but that need for specificity must be balanced against a party's need to be fairly apprised of how much specificity the district court requires. This notice can be adequately accomplished through a local court rule or a pretrial order.

InterRoyal Corp. v. Sponseller, 889 F.2d 108, 111 (6th Cir. 1989) cert. denied 110 S.Ct. 1839, 108 L.Ed.2d 967 (1990). Here, the parties have given some references to the proof upon which they rely. Local Rule 8(b)(7)(A) and (C) require a showing of undisputed and disputed facts.

In Street, the Court of Appeals discussed the trilogy of leading Supreme Court decisions, and other authorities on summary judgment and synthesized ten rules in the "new era" on summary judgment motions

1. Complex cases are not necessarily inappropriate for summary judgment.

2. Cases involving state of mind issues are not necessarily inappropriate for summary judgment.

3. The movant must meet the initial burden of showing `the absence of a genuine issue of material fact' as to an essential element of the non-movant's case.

4. This burden may be met by pointing out to the court that the respondent, having had sufficient opportunity for discovery, has no evidence to support an essential element of his or her case.

5. A court should apply a federal directed verdict standard in ruling on a motion for summary judgment. The inquiry on a summary judgment motion or a directed verdict motion is the same: `whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that the party must prevail as a matter of law.'

6. As on federal directed verdict motions, the `scintilla rule' applies, i.e., the respondent must adduce more than a scintilla of evidence to overcome the motion.

7. The substantive law governing the case will determine what issues of fact are material, and any heightened burden of proof required by the substantive law for an element of the respondent's case, such as proof by clear and convincing evidence, must be satisfied by the respondent.

> 8. The respondent cannot rely on the hope that the trier of fact will disbelieve the movant's denial of a disputed fact, but must `present affirmative evidence in order to defeat a properly supported motion for summary judgment.'
>
> 9. The trial court no longer has the duty to search the entire record to establish that it is bereft of a genuine issue of material fact.
>
> 10. The trial court has more discretion than in the `old era' in evaluating the respondent's evidence. The respondent must `do more than simply show that there is some metaphysical doubt as to the material facts.' Further, `[w]here the record taken as a whole could not lead a rational trier of fact to find' for the respondent, the motion should be granted. The trial court has at least some discretion to determine whether the respondent's claim is `implausible.

Street, 886 F.2d at 1479-80.

The Court has distilled from these collective holdings four issues that are to be addressed upon a motion for summary judgment: (1) has the moving party "clearly and convincingly" established the absence of material facts?; (2) if so, does the plaintiff present sufficient facts to establish all the elements of the asserted claim or defense?; (3) if factual support is presented by the nonmoving party, are those facts sufficiently plausible to support a jury verdict or judgment under the applicable law?; and (4) are there any genuine factual issues with respect to those material facts under the governing law?

The Sixth Circuit has affirmed an award of summary judgment on FCA claims. United States ex rel Compton v. Midwest Spec., Inc., 142 F.3d 296 (6th Cir. 1998). This Court has also awarded summary judgment on FCA claims. United States ex rel Wall v. Circle Construction, LLC, 700 F. Supp. 2d 926, 930 n.2, 939-40 (M.D. Tenn. 2010). See also United States v. Macomb Contracting Co., 763 F. Supp. 272, 274 (M.D. Tenn. 1990) (Higgins, J. affirming a report and recommendation). Although the filing of cross-motions for summary judgment do not preclude a material factual dispute, cross-motions for summary judgment may be probative of

the absence of any factual disputes. See United v. States v. Oakley, 744 F.2d 1553, 1555-56 (11th Cir. 1984).

The United States's FCA theory is two-fold. The first is a legally false claim theory in that Medicare regulations and Medicare's designated carrier require a supervising physician for contrast testing at an IDTF to be a board certified radiologist or a physician with appropriate training and approved by CIGNA. The United States's proof establishes the Defendants' knowledge of this Medicare requirement through Defendants' internal documents and managers' testimony. The Government argues that its proof also establishes that MedQuest submitted claims to Medicare that were paid for contrast testing at its Nashville area IDTFs who utilized physicians for contrast studies who were neither radiologists nor physicians approved by Medicare in violation of Medicare's regulations and policies. The United States contends that these undisputed facts establish that the Defendants "knowingly" violated or recklessly disregarded Medicare's requirements for payment of claims for such testing, both of which establish violations of the FCA.

The United States' second theory is that MedQuest knowingly delayed the change of its Charlotte Center to an "IDTF" from a "physician's office" and intentionally used Dr. Witt's Medicare provider number for Medicare payment for diagnostic tests of Medicare tests at MedQuest's Charlotte facility. The United States contends that from January 2004 through June 2005, MedQuest's claims for Medicare payment as a physician's office were false because MedQuest knew that as an IDTF, MedQuest's Charlotte center was not entitled to payment as a physician's office under Medicare regulations.

In sum, the Defendants' proof and argument is that neither Medicare regulations nor sound medical practice require a radiologist as a supervising physician because the only medical

problem would be a patient's adverse reaction to a contrast injection for which any physician is able to address. Absent a controlling statute or regulation, the Defendants contend that any failure to satisfy a requirement of CMS and/or CIGNA, its Medicare carrier, cannot establish a FCA violation. Moreover, Defendants cite a conflict among Medicare carriers on the requirement of a radiologist for direct supervision of an IDTF's testing that also precludes any FCA liability. Defendants also assert that Medicare's backbilling policy would pay for any billing, prior to Medicare's approval of the Charlotte facility as an IDTF. Defendants note that CIGNA did not take any action after notice of MedQuest's Charlotte Center's billings with Dr. Witt's Medicare billing number.

As a threshold issue, the Court considers the Defendants' contention that a violation of a statute or regulation is necessary for a FCA violation. Under this contention, Defendants argue that their statements or omissions on CMS's enrollment forms or responses or omissions to CIGNA's directives cannot establish FCA liability.

1. The Necessity of a Statute or Regulation

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)(emphasis added). The Supreme Court stated that the FCA "should not be given a narrow reading" and "reaches . . . all fraudulent attempts to cause the Government to pay out sums of money." United States v. Neifert-White Co., 390 U.S. 228, 233 (1968). The legislative history of the FCA reflects that: "[A] false claim may take many forms, the most

common being a claim for goods or services not provided, or provided in violation of contract terms, specification, statute, or regulation." S. Rep. No. 99-345, at 9, reprinted in 1986 U.S.C.C.A.N. 5266, 5274 (emphasis added).

As the United States notes, the First Circuit has expressly held that a violation of a statute or regulation is not a prerequisite for a FCA claim. United States ex rel. Hutcheson v. Blackstone Med. Inc., No. 10-1505, 2011 WL. 2150191 at **2, 7 (1st Cir. June 1, 2011)("[W]e reject the argument that, in the absence of an express legal representation or factual misstatement, a claim can only be false or fraudulent if it fails to comply with a precondition of payment expressly stated in a statute or regulation.") Yet, as Defendants respond, the Third Circuit declined such an expansive view of the FCA and limited FAC theories of liability to express or imply false certification for violation of "regulations" that "was a condition of payment." Wilkins v, United Health Group, Inc., No. 10-2747, 2011 WL 2573380 at *8 (3rd Cir. June 30, 2011).

Court have found FCA liability for false statements on Medicare enrollment applications, United States ex rel. Tyson v. Amerigroup Illinois, Inc., 488 F. Supp. 2d 719, 727-28 (N.D.Ill. 2007) ("[T]he enrollment forms are claims because they were 'submitted in order to receive payment,' even if payment was not immediate… Defendants argue that because the enrollment forms do not explicitly demand any particular amount of capitation-based payments, there was insufficient evidence of falsity. As this Court stated in the summary judgment decision, 'a claim does not need to be an actual invoice'.") (quoting U.S. ex rel. Schwedt v. Planning Research Corp., 59 F.3d 196, 199 (D.C. Cir. 1995)). See also United States v. The Health Alliance of Greater Cincinnati, No. 1:03-cv-0067, 2008 WL 5282139 (S.D. Ohio Dec. 18, 2008) ("Ohio Heart similarly claims the government has not identified any claim upon which an FCA cause of

action may be based. However, the Complaint plainly alleges that Ohio Heart submitted CMS-1500 forms to Medicare, and corresponding Medicaid or Tricare forms, even though it knew it was out of compliance with regulations and laws…")(emphasis added).

In sum, "FCA actions may be predicated upon a variety of underlying allegations." United State, ex rel. Villafane v. Solinger, 543 F. Supp. 2d 678, 682 (W.D. Ky. 2008). A FCA claim can be based upon false statements about compliance with a contract. United States v. United Technologies Corp., 626 F.3d 313, 319-20 (6th Cir. 2010) ("[The parties] do not dispute that the false statements were material to the government's decision to enter into a contract with Pratt. … [A]n invoice, which itself does not contain a falsity, may supply the premise for a false claim if submitted in connection with a fraudulently obtained contract."); Mikes v. Straus, 274 F.3d 687, 698 (2d. Cir. 2001) ("An expressly false claim is, as the term suggests, a claim that falsely certifies compliance with a particular statute, regulation **or contractual term, where compliance is a prerequisite to payment**.") (emphasis added).

False statements on costs reports are also actionable under the FCA. United States ex rel Augustine v. Century Health Services Inc., 136 F. Supp. 2d 876, 878 (M.D. Tenn. 2000). See also United States v. Rogan , 459 F. Supp. 2d 692, 717 (N.D. Ill. 2006). ("Medicaid claims submitted to the state are also 'claims' to the federal government under the FCA.").

Lack of documentation for cost claims can also state a FCA violation. United States ex rel. Davis v. District of Columbia, 591 F. Supp. 2d 30, 38 (D.D.C. 2008)) ("Plaintiff alleges that the cost claim is false because defendants lacked adequate supporting documentation… As plaintiff describes in his Personal Disclosure Statement, he had several meetings with defendants that confirmed the facts forming the basis of this suit. For these reasons, plaintiff has pleaded with sufficient particularity.")

To be sure, not every statutory or regulatory violation is actionable under the FCA. Harrison v. Westinghouse Savannah River Co. 176 F.3d 776, 785 (4th Cir. 1999). "'[V]iolations of laws, rules, or regulations alone do not create a cause of action under the FCA' ... [F]alse certifications of compliance create liability under the FCA when certification is a prerequisite to obtaining a government benefit." United States ex rel.Thompson v. Columbia/HCA, 125 F.3d 899, 902 (5th Cir. 1997). Technical violations of administrative regulations are not actionable under the FCA "unless the violator knowingly lies to the Government about them". United States ex rel. Swafford v. Borgess Medical Ctr. , 98 F. Supp. 2d 822, 828 (W.D. Mich. 2000) aff'd, 24 Fed. Appx. 491 (6th Cir. 2001) (internal quotation marks omitted).

In the Court's view, these precedents demonstrate that violation of an express statute or rule is not necessary for a FCA violation. Here, Schaefer's statements on MedQuest's completed CMS application that Medicare approved, resulted, in effect, in a contract with Medicare under which MedQuest certified or agreed that testing at its IDTF including contrast studies at an IDTF would be provided in conformity with the Secretary's regulations requiring testing at its IDTFs by an approved supervising physician. In addition, the Secretary's regulations, CMS's manuals and application instructions as well as CIGNA's directives, constitute specifications for such testing at an IDTF.

For their contention on this issue, Defendants cite United Sates ex rel. Conner v. Salina Regional Health Center, Inc., 543 F.3d 1211, 1217 (10th Cir. 2008) where the Tenth Circuit referred to the "express false certification theory" involving the anti-kickback statute that was defined as where "a government payee 'falsely certifies compliance with a particular statute, regulation **or contractual term** where compliance is a prerequisite to payment'." (emphasis added and citation omitted). Thus, by its own language, Conner does not limit FCA liability to

violation of a statute or regulation. Here, MedQuest's completed CMS 855 application included a certification and in effect, an agreement that the physicians listed in its enrollment form would provide the direct supervision for applicable testing, such as tests using contrast materials at MedQuest's Nashville area IDTFs. MedQuest's completed CMS's 855 form also certified that MedQuest would provide notice to CIGNA of any changes of these physicians. The requirement of a physician approved by Medicare for these tests was also a specification and by language of the regulation, a condition for Medicare's payment of tests by an IDTF. Thus, the Court's conclusion here is consistent with Conner.

Thus, assuming the lack of a governing statute or regulation, the Court concludes that proof of Defendants' false and material statements and omissions in MedQuest's enrollment applications, its claims for payment or its omissions in its reporting responsibilities necessary to secure a payment of Medicare funds, would violate the FCA. Moreover, as discussed infra, the facts here demonstrate that the Defendants violated express Medicare regulations applicable to IDTFs.

2. The Governing Medicare Regulations and Rules

Congress established Medicare in the Department of Health and Human Services with its Secretary as a governing official with authority to promulgate regulations. 42 U.S.C. §1302(a), §§ 1395x(v)(1)(A) and 1395hh. See Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 506-07 (1994). CMS administers these programs under the Secretary's supervision. Banner Health v. Sebelius, 715 F. Supp. 2d 142, 145 (D.D.C. 2010). The Secretary created the CMS under the Secretary's regulations, 42 C.F.R. § 401.101 et seq. If a regulation under the Act applies, a CMS manual is not controlling and cannot supersede a Secretary's regulation that is controlling. See GCI HealthCare Centers Inc. v. Thompson, 209 F. Supp. 2d 63, 73 (D.D.C 2002) ("The

Secretary has the authority to balance competing concerns of the Medicare Act"). In such instances of an overriding regulation, the CMS Manual can be instructive or persuasive, but not controlling. Id. at 70-71[15].

As to the legal authority of CMS and CIGNA, 42 U.S.C. § 1395u(a) provides that "[t]he administration [of the Medicare Act] ... shall be conducted through contracts with medicare administrative contractors under section 1395kk-1." Forty-two U.S.C. § 1395kk–1(a)(1), provides that "[t]he Secretary may enter into contracts with any eligible entity to serve as a medicare administrative contractor with respect to the performance of any or all of the functions described in" 42 U.S.C. § 1395kk-1(a)(4). The term "medicare administrative contractor" includes any "agency, organization, or other person with a contract under this section," whether private or public. 42 U.S.C. § 1395kk–1(a)(3)(A). The "functions" described in Section 1395kk-1(a)(4)(A),(G) include "Determining ... the amount of the payments required pursuant to this subchapter to be made to providers of services, suppliers and individuals" and "[**p]erforming such other functions ... as are necessary to carry out the purposes of this subchapter.**" (emphasis added). As discussed below, the Medicare Act requires its health care providers to possess demonstrated proficiency in the services to be provided. 42 U.S.C.§ 1395ddd(c)(1).

Medicare carriers are considered "indispensable components of the governmental program and are in a unique position to combat the drain on public resources caused by fraudulent claims." Pani v. Empire Blue Cross Blue Shield**,** 152 F.3d 67, 73 (2d Cir. 1998) (citing United States v. Erika, Inc., 456 U.S. 201, 203, 208 n. 11 (1982) (discussing efficiency of

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[15] As to CMS's statements in the Federal Register, those statements can only be considered if consistent with the Secretary's regulation. CMS officials cannot alter the Secretary's clear regulation that is wholly consistent with, the Medicare statute, requiring some objective measure of proficiency acceptable to a Medicare carrier.

private insurance companies paying Medicare claims given the volume of such claims)). See Group Health Inc. v. Blue Cross Assn., 739 F. Supp. 921, 933 (S.D.N.Y. 1990) ("HHS and the Secretary rely heavily on the participation of fiscal intermediaries, who possess accounting and health care expertise, in order to efficiently administer the [Medicare] program.").

Under Medicare regulations, the Secretary delegated to CIGNA as a Medicare carrier authority to decide issues in administering the Medicare Act: "Intermediaries and carriers act on behalf of CMS in carrying out certain administrative responsibilities that the law imposes." 42 C.F.R. § 421.5(b). Specifically, 42 C.F.R.§ 410.33(b)(2) provides for an IDTF that: "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."** (emphasis added).

The appropriateness of the Secretary's delegation to the Medicare carriers has been recognized. Pani, 152 F.3d at 73 (" 'The complexities and magnitude of governmental activity have become so great that there must of necessity be a delegation and redelegation of authority as to many functions, and we cannot say that these functions become less important simply because they are exercised by officers of lower rank in the executive hierarchy' or by private contractors.") (quoting Burr v. Matteo, 300 U.S. 564, 572-73 (1959)). See also The Ocean Conservancy v. Evans, 260 F.Supp.2d 1162, 1183 (M.D. Fla. 2003) (delegation by a federal agency to a private party permissible where the federal agency "retained sufficient final reviewing authority over the findings of the independent scientific panel" so as not to violate federal law); Nat'l Park & Conservation Ass'n v. Stanton, 54 F. Supp. 2d 7, 19 (D.D.C. 1999).

As to whether Defendants actually violated a Medicare statute or rule, the Defendants argue that for its Medicare payments, IDTFs are governed by 42 C.F.R. § 410.32 that does not require a board certified radiologist and expressly allows any "physician" as defined by 42 U.S.C. § 1395x(r)(1) of the Medicare Act to provide coverage of its testing, including testing with contrast. Defendants contend that Section 410.33 that is cited by the United States, refers only to physicians at IDTFs that perform general supervision and note that Section 410.33 refers back to Section 410.32.

To analyze these regulations, 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 *4-5 (6th Cir. March 24, 1987) (Merritt, J., concurring). This rule is parallel to the "fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." Davis v. Michigan Dept. of Treasury, 489 U.S. 803, 809 (1989). Thus, the Court must consider all parts of Sections 410.32 and 410.33. Moreover, the Court must give deference to an agency's interpretation of its rules. Chevron, U.S.A. Inc., v. Natural Res. Defense Council Inc., 467 U.S. 844, 846 (1984).

The legal authority for Sections 410.32 and 410.33 is 42 U.S.C. § 1395ddd that is entitled "Medicare Integrity Program." This statute requires health care providers in the Medicare program to possess the "demonstrated capability to carry out [their contractual] activities." 42 U.S.C.§1395 ddd(c)(1). That statute also provides that the Medicare providers must also "meet such other requirements as the Secretary may impose." 42 U.S.C. § 1395ddd(c)(5).

42 C.F.R. § 410.32 is entitled "Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions" and contains the following pertinent provisions:

(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. (emphasis added).

Section 410.33 is entitled "Independent diagnostic testing facility" that is dedicated solely to IDTFs and reads in its entirety[16] 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.**
>
> (2) Exceptions. The following diagnostic tests that are payable under the physician fee schedule and furnished by a nonhospital testing entity are not required to be furnished in accordance with the criteria set forth in paragraphs (b) through (e) and (g) and (h) of this section.
>
> (i) Diagnostic mammography procedures, which are regulated by the Food and Drug Administration.
>
> (ii) Diagnostic tests personally furnished by a qualified audiologist as defined in section 1861(ll)(3) of the Act.
>
> (iii) Diagnostic psychological testing services personally furnished by a clinical psychologist or a qualified independent psychologist as defined in program instructions.
>
> (iv) Diagnostic tests (as established through program instructions) personally performed by a physical therapist who is certified by the American Board of Physical Therapy Specialties as a qualified electrophysiologic clinical specialist and permitted to provide the service under State law.
>
> **(b) Supervising physician.**

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[16] The Court regrets the length of this quotation, but this regulation's length and detail reflect its application to all IDTFs, as many of its provision are inapplicable to other diagnostic testing.

(1) Each supervising physician must be limited to providing general supervision to no more than three IDTF sites. This applies to both fixed sites and mobile units where three concurrent operations are capable of performing tests.

(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.

(c) Nonphysician personnel. Any nonphysician personnel used by the IDTF to perform tests must demonstrate the basic qualifications to perform the tests in question and have training and proficiency as evidenced by licensure or certification by the appropriate State health or education department. In the absence of a State licensing board, the technician must be certified by an appropriate national credentialing body. The IDTF must maintain documentation available for review that these requirements are met.

(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.

(e) Multi–State entities.

(1) **An IDTF that operates across State boundaries must--**

(i) Maintain documentation that its supervising physicians and technicians are licensed and certified in each of the States in which it operates; and

(ii) Operate in compliance with all applicable Federal, State, and local licensure and regulatory requirements with regard to the health and safety of patients.

(2) The point of the actual delivery of service means the place of service on the claim form. When the IDTF performs or administers an entire diagnostic test at the beneficiary's location, the beneficiary's location is the place of service. When one or more aspects of the diagnostic testing are performed at the IDTF, the IDTF is the place of service.

(f) Applicability of State law. An IDTF must comply with the applicable laws of any State in which it operates.

(g) Application certification standards. The IDTF must certify in its enrollment application that it meets the following standards and related requirements:

(1) Operates its business in compliance with all applicable Federal and State licensure and regulatory requirements for the health and safety of patients.

(2) Provides complete and accurate information on its enrollment application. Changes in ownership, changes of location, changes in general supervision, and adverse legal actions must be reported to the Medicare fee-for-service contractor on the Medicare enrollment application within 30 calendar days of the change. All other changes to the enrollment application must be reported within 90 days.

(3) Maintain a physical facility on an appropriate site. For the purposes of this standard, a post office box, commercial mailbox, hotel, or motel is not considered an appropriate site.

(i) The physical facility, including mobile units, must contain space for equipment appropriate to the services designated on the enrollment application, facilities for hand washing, adequate patient privacy accommodations, and the storage of both business records and current medical records within the office setting of the IDTF, or IDTF home office, not within the actual mobile unit.

(ii) IDTF suppliers that provide services remotely and do not see beneficiaries at their practice location are exempt from providing hand washing and adequate patient privacy accommodations.

(4) Has all applicable diagnostic testing equipment available at the physical site excluding portable diagnostic testing equipment. The IDTF must--

(i) Maintain a catalog of portable diagnostic equipment, including diagnostic testing equipment serial numbers at the physical site;

(ii) Make portable diagnostic testing equipment available for inspection within 2 business days of a CMS inspection request.

(iii) Maintain a current inventory of the diagnostic testing equipment, including serial and registration numbers and provide this information to the designated fee-for-service contractor upon request, and notify the contractor of any changes in equipment within 90 days.

(5) Maintain a primary business phone under the name of the designated business. The IDTF must have its--

(i) Primary business phone located at the designated site of the business or within the home office of the mobile IDTF units.

(ii) Telephone or toll free telephone numbers available in a local directory and through directory assistance.

(6) Have a comprehensive liability insurance policy of at least $300,000 per location that covers both the place of business and all customers and employees of the IDTF. The policy must be carried by a nonrelative-owned company. Failure to maintain required insurance at all times will result in revocation of the IDTF's billing privileges retroactive to the date the insurance lapsed. IDTF suppliers are responsible for providing the contact information for the issuing insurance agent and the underwriter. In addition, the IDTF must--

(i) Ensure that the insurance policy must remain in force at all times and provide coverage of at least $300,000 per incident; and

(ii) Notify the CMS designated contractor in writing of any policy changes or cancellations.

(7) Agree not to directly solicit patients, which include, but is not limited to, a prohibition on telephone, computer, or in-person contacts. The IDTF must accept only those patients referred for diagnostic testing by an attending 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).

(8) Answer, document, and maintain documentation of a beneficiary's written clinical complaint at the physical site of the IDTF (For mobile IDTFs, this documentation would be stored at their home office.) This includes, but is not limited to, the following:

(i) The name, address, telephone number, and health insurance claim number of the beneficiary.

(ii) The date the complaint was received; the name of the person receiving the complaint; and a summary of actions taken to resolve the complaint.

(iii) If an investigation was not conducted, the name of the person making the decision and the reason for the decision.

(9) Openly post these standards for review by patients and the public.

(10) Disclose to the government any person having ownership, financial, or control interest or any other legal interest in the supplier at the time of enrollment or within 30 days of a change.

(11) Have its testing equipment calibrated and maintained per equipment instructions and in compliance with applicable manufacturers suggested maintenance and calibration standards.

(12) Have technical staff on duty with the appropriate credentials to perform tests. The IDTF must be able to produce the applicable Federal or State licenses or certifications of the individuals performing these services.

(13) Have proper medical record storage and be able to retrieve medical records upon request from CMS or its fee-for-service contractor within 2 business days.

(14) Permit CMS, including its agents, or its designated fee-for-service contractors, to conduct unannounced, on-site inspections to confirm the IDTF's compliance with these standards. The IDTF must--

(i) Be accessible during regular business hours to CMS and beneficiaries; and

(ii) Maintain a visible sign posting its normal business hours.

(15) With the exception of hospital-based and mobile IDTFs, a fixed-base IDTF is prohibited from the following:

(i) Sharing a practice location with another Medicare-enrolled individual or organization;

(ii) Leasing or subleasing its operations or its practice location to another Medicare-enrolled individual or organization; or

(iii) Sharing diagnostic testing equipment used in the initial diagnostic test with another Medicare-enrolled individual or organization.

(16) Enrolls for any diagnostic testing services that it furnishes to a Medicare beneficiary, regardless of whether the service is furnished in a mobile or fixed base location.

(17) Bills for all mobile diagnostic services that are furnished to a Medicare beneficiary, unless the mobile diagnostic service is part of a service provided under arrangement as described in section 1861(w)(1) of the Act.

(h) Failure to meet standards. If an IDTF fails to meet one or more of the standards in paragraph (g) of this section at the time of enrollment, its enrollment will be denied. CMS will revoke a supplier's billing privileges if and IDTF is found not to meet the standards in paragraph (g) or (b)(1) of this section.

(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.

(emphasis added).

The CMS Manual on supervising physicians at IDTFs cites Section 410.33 as the governing source. This CMS manual reads, in relevant part, that Medicare carriers are to determine the qualifications of an IDTF's supervising physician and requires the IDTF to inform CMS of any changes in supervising physicians by an amended CMS form 855:

4.19.5- Supervising Physicians

(Rev. 277; Issued: 12-19-08; Effective/Implementation Date: 01-20-09)

A. General Principles

Under 42 CFR §410.33(b)(1), an IDTF must have one or more supervising physicians who are responsible for:

The direct and ongoing oversight of the quality of the testing performed;

* * *

Of course, not every supervising physician has to be responsible for all of these functions. For instance, **one supervising physician can be responsible for the operation and calibration of equipment, while other supervising physicians can be responsible for test supervision** and the qualifications of non-physician personnel. **The basic requirement, however, is that all the supervisory physician functions must be properly met at each location, regardless of the number of physicians involved.** This is particularly applicable to mobile IDTF units that are allowed to use different supervisory physicians at different locations. **They may have a different physician supervise the test at each location. The physicians used need only meet the proficiency standards for the tests they are supervising.**

Under 42 CFR §410.33(b)(l), each supervising physician must be limited to providing supervision to no more than three IDTF sites. This applies to both fixed sites and mobile units where three concurrent operations· are capable of performing tests.

B. Information about the Supervising Physicians

The carrier shall check and document that each supervisory physician: (1) is licensed to practice in the State(s) where the diagnostic tests he or she supervises will be performed, (2) is Medicare enrolled, and (3) is not currently excluded or debarred. The physician(s) need not necessarily be Medicare enrolled in the State where the IDTF is enrolled.

In addition:

The carrier shall verify the licensure for the State where the IDTF is being enrolled for each supervisory physician enrolled with another carrier, based upon the physician's license submission and discussions with the carrier where they are enrolled.

Each physician of the group who actually performs an IDTF supervisory function must be listed.

If a supervising physician has been recently added or changed, the updated information must be reported via a CMS-855B change request. The new

physician must have met all the supervising physician requirements at the time any tests were performed.

If the carrier knows that a listed supervisory physician has been listed with several other IDTFs, the carrier shall check with the physician to determine whether the physician is still acting as supervisory physician for the previously enrolled IDTFs.

C. General, Direct, and Personal Supervision

Under 42 CFR §410.33(b)(2), if a procedure requires the direct or personal supervision of a physician as set forth in 42 CFR §410.32(b)(3), the carrier shall ensure that the IDTF's supervisory physician furnishes this level of supervision.

The carrier's enrollment staff shall be familiar with the definitions of personal, direct and general supervision set forth at 42 CFR §410.32(b)(3), and shall ensure that the applicant has checked the highest required level of supervision for the tests being performed.

Each box that begins with -Assumes responsibility, II must be checked. However, as indicated previously, the boxes can be checked through the use of more than one physician.

(Docket Entry No. 150-11 at 5-7) (emphasis added).

Section 410.33's detailed provisions for an IDTF's operation reflect its governance of IDTFs. The IDTF was first recognized as an approved Medicare provider in 1998 and a separate section to detail its operations and staffing is a reasonable interpretation of these two sections.. Section 410.33 has an express provisions for Multistate IDTFs, such as MedQuest, on express subjects at isuue here:

(e) Multi–State entities.

(1) An IDTF that operates across State boundaries must--

(ii) Operate in compliance with all applicable Federal, State, and local licensure and regulatory requirements with regard to the health and safety of patients.

* * *

> (g) Application certification standards. The IDTF must certify in its enrollment application that it meets the following standards and related requirements:
>
> (1) Operates its business in compliance with all applicable Federal and State licensure and regulatory requirements for the health and safety of patients.
>
> **(2) Provides complete and accurate information on its enrollment application. Changes in ownership, changes of location, changes in general supervision, and adverse legal actions must be reported to the Medicare fee-for-service contractor on the Medicare enrollment application within 30 calendar days of the change.** All other changes to the enrollment application must be reported within 90 days.

42 C.F.R. §§410.33(e)(1)(ii) and (g)(1) and (2). Moreover, as quoted supra, at 17, the CIGNA study groups composed of Medicare carriers' medical directors and medical specialty boards set forth the reasons for distinguishing the supervising physicians at an IDTF from a hospital or clinic

As the governing regulation, Subsection 410.33(b)(2) expressly requires a supervising physician to "**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."** 42 C.F.R. § 410.33(b)(2). This express provision is a total variance with Section 410.32(b)(1)'s definition of a physician. In addition, the Secretary's regulation, Section 410.33(b)(2) expressly directs the Medicare carrier, here CIGNA, to "establish[]" the requirements for a "supervision physician" at an IDTF who "must personally furnish the level of supervision" for tests described Section 410.32(b)(3)(ii) and (iii) that also require "direct supervision." Id.

Medicare administrators cite Section 410.33 as the governing regulations for IDTF, as reflected in the earlier quotation from CMS's manual: "Under 42 CFR

§410.33(b)(1), an IDTF must have one or more supervising physicians who are responsible for: The direct and ongoing oversight of the quality of the testing performed." (Docket Entry No. 150-11 at 5). CIGNA's LRMP that is cited by the Defendants, also cites Section 410.33(b) on "Physician Supervision" at an IDTF 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 hospital or physician's office. **The diagnostic tests in an IDTF must be performed by licensed, certified nonphysician personnel under appropriate physician supervision**.
>
> * * *
>
> **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)[17] (emphasis added). Moreover, during the time at issue, MedQuest's chief compliance officer cited 42 U.S.C.§ 410.33 as the governing regulation for IDTFs. Supra at 29.

Defendants argue that Section 410.33 refers to Section 410.32 as an indication that Section 410.32 governs IDTFs. Section 410.33(b)'s reference to Section 410.32(b)(3)(ii) and (iii) is to the requirement of direct or personal supervision for certain tests where the physician must be physically present at the testing. This interpretation is consistent with CMS's manual:

> **Under 42 CFR §410.33(b)(2), if a procedure requires the direct or personal supervision of a physician as set forth in 42 CFR §410.32(b)(3), the carrier shall ensure that the IDTF's supervisory physician furnishes this level of supervision.**

[17] Absent a national policy, LMRP are regional coverage determinations that govern as an adjunct to a national policy. *See* 68 Fed.Reg. 63,692, 63,693 (Nov. 7, 2003).

> The carrier's enrollment staff shall be familiar with the definitions of personal, direct and general supervision set forth at 42 CFR §410.32(b)(3), and shall ensure that the applicant has checked the highest required level of supervision for the tests being performed.

(Docket Entry No. 150-11 at 7) (emphasis added). To be sure, for payment of diagnostic X-ray tests, Section 410.32(b)(1) refers to the term "physician" as defined in 42 U.S.C. § 1861r of the Social Security Act, but Section 410.33 does not refer to subsection 410.32(b)(1). In a word, Section 410.33 refers to 410.32(b)(3)(ii) and (iii), but does not incorporate the definition of physician that is in Section 410.32(b)(1). Section 410.32 does not mention an IDTF in any of its provisions and thus, does not govern IDTFs.

Finally, contrary to Defendants' insistence, there is not any conflict among Medicare carriers on the requirement of a radiologist to provide direct supervision. First, CIGNA, Medicare's designated carrier for Tennessee, actually approved MedQuest's application for Dr. Tan, a non-radiologist physician with relevant training[18] to serve as a supervising physician at MedQuest's Nashville area IDTFs. The undisputed facts are that other carriers adopt similar proficiency standards as CIGNA and the other Medicare carriers also approve non-radiologists as supervising physicians at IDTFs for contrast studies. See supra at 32-33.

In sum, the Court concludes that the Medicare statute and regulations expressly govern the Defendants' conduct at issue on the United States's and Relator's FCA claims. The Court's conclusions are not based on CMS or CIGNA manual or forms. Those manual and forms are

[18] There are some references to Dr. Tan's training as limited to general supervision, but Defendants concede that Dr. Tan received training on all levels of supervision at an IDTF. (Docket Entry No. 210 at 14).

interpretive guides that reinforce the language and meaning of the regulation. Under Chevron, the Court must defer to these administrative interpretations.

3. The FCA Violations

The purpose of the Federal Claims Act is "to provide for restitution to the government of 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 present 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) (emphasis added). As the Sixth Circuit observed, a violation of Section 3729(a)(1) occurred where "Pratt's false statement had the potential to influence the government's decision to sign the contract and thus, to pay the invoices under the contract." United Technologies, 626 F.3d at 320.

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 to be spent or used on the Government's behalf . . . and if the United States Government 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)(i)(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 or regulation for medical payment. United States ex rel. A+ Homecare, Inc. v. Medshares Mgmt. Group, Inc., 400 F.3d 428, 451 (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). See also United States v. Stevens, 605 F. Supp. 2d 863, 867(W.D. Ky. 2008) ("a physician demonstrates 'reckless disregard' when he fails to take reasonable steps to ensure that his clinic's claims for governmental reimbursement are accurate.") (citing Krizek, 111 F.3d at 942). As the Sixth Circuit observed under the FCA, health care providers "'must turn square corners when they deal with the Government.'" Century Health, 289 F.3d at 413 (internal quotations omitted).

Here, the United States asserts the "express certification" and "implied certification" theories[19] under the FCA. The express certification is that MedQuest '"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."[20] Conner, 543 F.3d at 1217 (quotation and emphasis

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[19] Defendants contend that the United States never asserted this theory of liability. There is some language to support this contention. (Docket Entry No. 66 at 12). In subsequent filings by both parties, however, this issue was fully briefed. (Docket Entry No. 158, United States Memorandum at 14, asserting both explicit and implied theories of certification); (Docket Entry No. 171, Defendants' Response Memorandum at 21-22, contending that the Government's theory is at best implied), and (Docket Entry No. 185, United States Memorandum at 18-23,arguing implied certification in detail). Thus, the Court considers this theory of liability.

[20] The Court earlier concluded that the requisite physician supervision is a condition of payment of claims for MedQuest's IDTFs diagnostic testing with contrasts. (Docket Entry No. 94, Memorandum at 15-19). In its earlier ruling, the Court declined Defendants' contentions that the radiologist or proficiency requirement for an IDTF's supervising physician was a condition of participation, not a condition of payment. To be sure, conditions of participation in the particular government program, cannot give rise to a FCA claim. Id. at 12-18. Yet, reviewing all relevant Medicare regulations, the Court concluded that the radiologist or its equivalent requirement was predominantly a condition of payment. Id. at 15-18. By its express language, Section 410.33(b)(2) presents a condition for payment: "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** … **or an independent diagnostic testing facility (IDTF)**." This conclusion is underscored by Sections 410.32(b)(1) and (3) that refer to physician supervision as necessary for tests "**and payable under the physician fee schedule**." (emphasis added). Without such a qualified person performing the tests, the entity cannot be compensated by the Medicare program. (Docket Entry No. 49 at Exhibit R). These sections of Section 410.33, when read as a whole, establish that appropriate physician supervision is a condition of payment under the FCA.

omitted). Accord United States ex rel. Mikes v. Straus, 274 F.3d 687, 698 (2d Cir. 2001) and United States ex rel. Siewick v. Jamieson Sci. & Eng'g, Inc., 214 F.2d 1372, 1376 (D.C. Cir. 2000). In Medshares, the Sixth Circuit adopted the implied certification theory, "which holds a defendant liable for violating the 'continuing duty to comply with the regulations on which payment is conditioned.'" 400 F.3d at 454 n. 20; accord Augustine, 289 F.3d at 415 (liability can attach if a defendant "violates its continuing duty to comply with regulations on which payment is conditioned."). The "implied certification" theory here is that MedQuest made an implied certification that the Medicare claims submitted for testing at its Nashville area IDTFs were based upon diagnostic testing that conformed to the Medicare regulations and policies for a Medicare approved physician for such testing.

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 (citation omitted); 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.

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). Here, CIGNA has the statutory and regulatory authority to set qualifications of IDTF providers for whose services CIGNA will pay. Pursuant to these regulations, CIGNA so instructed IDTFs. If CIGNA knew that the providers listed in MedQuest's applications were not providing the services at issue and knew that CIGNA had not approved any of these providers at MedQuest's Nashville IDTFs, then CIGNA would not have paid those claims. These facts satisfy the legal standard cited by Defendants. "If the government would have paid the claims despite knowing that the contractor has failed to comply with certain regulations then there is no false claim for purposes of the FC." Wilkins, 2011 WL 2573380 at *8 (quoting Connor, 543 F.3d at 1219-20).

Supp. 2d at 979 (quoting United States ex rel. Mikes v. Straus, 274 F.3d 687, 697 (2d Cir. 2001)).

a. MedQuest's Nashville Area IDTFs' Testing

Here, at MedQuest's Nashville area IDTFs, Defendants have a documented and undisputed history of extensive use of physicians who lacked Medicare approval to provide any supervision at an IDTF. These physicians are not shown to possess the certification or specialized training required by CIGNA. Moreover, MedQuest's Nashville area IDTF technical staff had constant difficulties with securing any physicians for coverage of contrast testing that requires direct physician supervision. As a result, the proof establishes that MedQuest's technical non-physician staff members actually injected contrast and conducted contrast studies of Medicare beneficiaries without **any** physician supervision that Section 410.33 does not authorize. MedQuest submitted Medicare claims for payment for all of those testings and by doing so, MedQuest violated its first express certification that the physicians[21] listed in its application would supervise such testing and later, in submitting billings implicitly certified that those tests were provided in accordance with applicable Medicare regulations and by physicians approved by Medicare.

As to the knowingly or reckless disregard element, MedQuest is an experienced IDTF provider that operates in thirteen states. MedQuest has been in this market since 1998 and is now the leading IDTF firm in this market. MedQuest has a trained staff on CMS 855 form and

[21] Defendants contend that Medicare billing forms do not require the name of the individual physician who performed the testing. This fact underscores the importance of listing the physicians who will perform the testing on the IDTF's application for Medicare enrollment and the regulation requiring notice of any changes in an IDTF's application, 42 C.F.R. 410.33(g)(2). Otherwise Medicare would not have any assurance of the physician "demonstrated capability to supervise the testing at an IDTF. 42 U.S.C,§ 1395ddd(c)(1); 42 C.F.R. 410.33(b)(2).

related instructions. This supervising physician coverage for the diagnostic tests with contrast was well known to MedQuest upper management and managers of its Nashville area IDTFs. Yet, the Defendants instructed their staffs to select any doctor without regard to that doctor's "proficiency in the performance and interpretation of each type of diagnostic procedure" at the Defendants' facilities. MedQuest had a clear alternative to submit physicians who were not radiologists to be supervising physicians, but who had appropriate training as with Dr. Tan, an internist. The Court concludes that the proof establishes that MedQuest's failure to provide adequate supervising physician coverage for the diagnostic tests with contrast was so significant that MedQuest's technical staff at its Nashville area IDTFs actually conducted the diagnostic testing without **any** physician supervision.

For these reasons, the Court concludes that MedQuest's use of non-Medicare approved physicians for contrast studies represents a reckless disregard of Medicare's program integrity statute, Medicare regulations and CIGNA's requirements (expressly authorized by the Secretary's regulation) for physicians with the demonstrated capability to provide direct coverage of these tests and approved by Medicare. Defendants' extensive use for contrast studies of physicians who were neither trained nor approved by their Medicare carrier is also evidence of Defendants'reckless conduct establishing violations of the FCA. Thus, the Court concludes that the United States's proof establishes Defendants' liability under FCA precedents.

Defendants' policy argument about the rationality of CIGNA's proficiency requirement cannot set aside the Secretary's regulation, Section 410.33(b) that serves the express statutory purpose set forth in Section 1395ddd(c)(1) of the Medicare Act requiring Medicare providers possess the "demonstrated capability to carry out [its contractual] activities." 42 U.S.C. 1395ddd(c)(1). The Secretary's regulation Section 410.33 designated the Medicare carrier to

determine the qualification. The issue is not a physician's ability to provide treatment if a medical problem arises from these tests, but consistent with 42 U.S.C.§1395ddd (c)(1), the controlling issue is whether a designated physician can assure the Medicare program of his or her possession of the "demonstrated capability" or competence in all aspects of these diagnostic tests at an IDTF for Medicare beneficiaries. It must be remembered that among the "primary purposes of Medicare is to promote beneficiary access to high-quality medical care while preventing fraudulent suppliers from providing items or services to Medicare beneficiaries or billing the Medicare program or its beneficiaries." Fayad v. Sebelius, No. 09-14119 2011 WL 1120036 at *5 (E.D. Mich. March 25, 2011)(citing 71 Fed. Reg. 20754).

For these collective reasons, the Court concludes that the United States should be awarded summary judgment on each of these theories of liability under the FCA.

b. MedQuest's Medicare Billings with Dr. Witt's Billing Number

The United States' second FCA claim actually has two components: MedQuest's failure to give notice of its acquisition of Dr. Witt's Charlotte facility and MedQuest's use of Dr. Witt's Medicare billing number for MedQuest's testing of Medicare beneficiaries at the Charlotte center.

The United States and Relator assert that MedQuest's billings of Medicare for payment of its testing of Medicare patients at the Charlotte facility using Dr. Witt's Medicare billing number violates the FCA. Defendants argue that MedQuest's Charlotte facility would have been classified as an IDTF effective with the date of Dr. Witt's stock transfer and this classification would not have affected its Medicare 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 or the Charlotte Center to enroll as an IDTF.

Forty-two C.F.R. § 410.33(a)(1) prescribes the "rules [that] apply when an IDTF furnishes diagnostic procedures in a physician's office." For Medicare payment of services by a qualified physician for certain contrast procedures 42 C.F.R. § 410.33(a)(1) requires 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 . . . . 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) (emphasis added).

The IDTF regulation, 42 C.F.R. § 410.33(g)(2), requires an approved IDTF or applicant for an IDTF status to provide, in pertinent part, notice of **"Changes in ownership**, changes of location, **changes in general supervision … [that] must be reported to the Medicare fee-for-service contractor on the Medicare enrollment application within 30 calendar days of the change**. **All other changes** to the enrollment application **must be reported within 90 days**.[22] (emphasis added). The IDTF regulation also requires the IDTF to operate in conformity with state law. 42 C.F. R.§410. 33(g)(1)(Medicare provider agrees to "Operate[] its business in compliance with all applicable Federal and State licensure and regulatory requirements for the health and safety of patients.")

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[22] Medicare regulations allows the assignment of a Medicare provider's services within a period of time for the acquiring entity to be certified, and in the interim, the acquiring company can operate under the acquired provider's Medicare billing number to avoid a disruption of services to beneficiaries. 42 C.F.R. § 489.18 lists the providers subject to that regulation, but IDTFs, distinct providers with a separate regulation, are not among the providers listed.

Significant here is that MedQuest purchased Dr. Witt's Certificate of Need from Tennessee health officials for the Charlotte diagnostic testing facility at that location. Under Tennessee law, any transfer of a Certificate of Need for a health care facility is null and void unless there is a transfer of ownership, Scott v. Ashland Healthcare Center, Inc., 49 S.W.3d 281, 287 (Tenn. 2001). This exception is in Tenn. Code Ann. § 68-11-1620 (a) that "nothing in this section shall prohibit the transfer of a certificate of need, other than a certificate of need for the establishment of a new health care institution, **if the certificate of need is transferred as part of the transfer of ownership** of an existing health care institution." (emphasis added). Although Defendants contend that the Certificate of Need was for construction of the facility and had expired, nonetheless MedQuest requested this transfer. Under Tennessee law, when William S.Witt, Inc. transferred his Certificate of Need to MedQuest, there was a change of ownership, thereby vesting ownership of the certificate in MedQuest. Thus, this change of ownership would trigger the notice provisions of 42 C.F.R. § 410.33(g)(2).

MedQuest acquired Dr. Witt's practice in January 2004, but failed to notify or to apply for enrollment as an IDTF and for its Medicare billing number until June 2005. As the designated Medicare provider at the Charlotte location, Dr. Witt had a duty to report the change of ownership of that facility to Medicare, but as a Medicare provider and new owner of the Charlotte facility, MedQuest also owed a legal duty to report the change of ownership. This duty is reflected in CMS's directive to MedQuest to submit a CMS 855 change of information form. The CMS 855 form also requires certain changes in the providers' information, (Docket Entry No 140-1, Blank deposition at 11, 12), including a change of provider's business name and location; tax identification number of the provider/supplier; ownership interest and/or managing control; contact person(s) for the provider; payment information; the name of the authorized

official for provider; and the authorized official's signature and certification. (Docket Entry No. 176 at ¶ 51). Thus, the Court concludes that the United States's proof establishes MedQuest's reckless disregard of the notice requirements in Medicare regulations and instructions on the CMS form for its second FCA theory.

Moreover, 42 C.F.R. § 410.33(i)(1) addresses the commencement date of an IDTF's billing of Medicare.

> (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.

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." [23]

Yet, the Medicare policy, cited by the Defendants as allowing backbilling, provides that "**An applicant that has purchased the assets of an existing IDTF is not automatically allowed to continue billing. It must apply as a new IDTF and may back bill once enrolled.** Obviously, use of the same personnel and equipment as the previously enrolled IDTF can facilitate the determination that the new IDTF can bill as of the date of the sale". (Docket Entry No. 150-11 at 1) (emphasis added). Moreover, the IDTF regulation requires an IDTF to

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[23] Once submitted, Medicare approved MedQuest's application for its Charlotte facility eliminating any administrative proceedings. There are several remedies for violations of Medicare regulations and policies. United States ex rel. Schuhardt v. Washington University, 228 F. Supp. 2d 1018, 1024 (E.D. Mo. 2002). In addition to administrative sanctions, the remedies include the enforcement of the FCA that is committed to the Attorney General. Id. The Court lacks the authority to require a choice of those remedies.

"[p]rovide[] complete and accurate information on its enrollment application. **Changes in ownership**, changes of location, changes in general supervision, and adverse legal actions **must be reported to the Medicare fee-for-service contractor on the Medicare enrollment application within 30 calendar days of the change**." 42 C.F.R. § 410.33(g)(2) (emphasis added).

The use of another provider's Medicare billing number can give rise to a FCA violation. United States v. Mackby, 339 F.3d 1013, 1015 (9th Cir. 2003) (where the non-physician partner in a partnership provider service, who was not qualified to perform the services, used the Medicare billing number of his partner who was qualified to provide services resulting in a FCA violation).

Here, Dr. Witt testified that with MedQuest's acquisition of William S. Witt Inc,, his physician practice ended. Under his reading contract with MedQuest, Dr. Witt who was to provide coverage at all three of MedQuest's Nashville area IDTFs, was unavailable for coverage of contrast tests for significant times. Such lack of availability posed difficulties for MedQuest's Nashville area IDTFs' staffs to secure physician coverage of contrast studies. MedQuest's Nashville area staff had to use physicians who were not approved by Medicare at their IDTFs for contrast tests of Medicare beneficiaries. At some local IDTFs, staff actually performed these tests of Medicare beneficiaries without **any** physician coverage. MedQuest leased this location from Dr. Witt; hired the center's managers and regional managers for the Charlotte center; obtained necessary insurance; and required that employees at the Charlotte center sign MedQuest's compliance policy. MedQuest's chief compliance officer admitted that during this time from January 2004 through June 2005, the Charlotte center was operating as an IDTF.

These facts lead the Court to conclude that the Charlotte facility was not a physician's practice so as to justify the Charlotte's center's use of Dr. Witt's Medicare billing number.

Eighteen (18) months lapsed before MedQuest informed CMS of the change of ownership of the Charlotte location, Defendants billed the Medicare program for diagnostic services performed at the Charlotte center using Dr. Witt's Medicare physician provider number. Once Aetna informed CIGNA of the Charlotte center's actual owner, CIGNA required MedQuest to submit a change of information for the Charlotte facility to secure Medicare's approval. During this time period MedQuest was operating IDTFs and had to be aware of the applicable Medicare regulation that requires: " Changes in ownership … must be reported to the Medicare fee-for-service contractor on the Medicare enrollment application within 30 calendar days of the change". 42 C.F.R. §410.33(g)(2). In face of this clear regulation, for eighteen months after this purchase, MedQuest did not inform Medicare of this change of ownership nor apply to enroll the Charlotte center in Medicare as an IDTF.

Under the Medicare backbilling policy, to backbill, MedQuest had to submit an application and be certified by a Medicare carrier. For this 18 months period, the Charlotte center did not apply and thus, was also not certified to operate as an IDTF. If this omission involved a "mom and pop" operation of an IDTF, the Court would take a different view, but MedQuest is a highly sophisticated and experienced IDTF provider with operations in 13 states. The facts on the United States's second theory prove MedQuest's reckless disregard of 42 C.F.R. § 410.33(g)(2) and the Medicare backbilling policy.

4. Damages and Penalties

As to the award of damages and penalties for these FCA violations, 31 U.S.C. § 3729(a) provides that for a FCA violation, the Defendant "is liable to the United States Government for a

civil penalty of not less than $5,000 and not more than $10,000 … **plus** 3 times the amount of damages which the Government sustains because of the act[.]"[24] (emphasis added). Yet, the award of treble damages and penalties under the FCA is limited by the Eighth Amendment's excessive fines clause. See United States v. Mackby, 339 F.3d 1013, 1016 (9th Cir. 2003).

Given the Court's legal conclusions and factual findings, the Court deems the Government's damages proof to warrant an award of damages. The supervising physician logs of the Defendants' Nashville area IDTFs reflect diagnostic contrast testing of Medicare beneficiaries by physicians without Medicare approval that caused 474 false claims submitted by MedQuest and paid by Medicare from January 15, 2004 through September 12, 2006 for a total of $343,758.22. From January 15, 2004 to June 30, 2005, for these same improper testings, MedQuest used Dr. Witt's Medicare billing number for Medicare payments to submit 995 claims for which Medicare paid $493,185.46 to MedQuest.

As to the appropriate measure for a penalty award, "the court must determine '[w]ith what act did the defendant submit his demand or request and how many such acts were there?' Thus, separate penalties are to be assessed for each request for payment, rather than for each false statement." United States ex rel. Augustine v. Century Health Services, Inc., 136 F. Supp. 2d 876, 895 (M.D. Tenn. 2000) (quoting and citing United States v. Krizek, 111 F.3d 934, 939-40 (D.C. Cir. 1997)). In Century Health, the FCA violations were submissions of cost reports.

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[24] Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461; Public Law 104-410), the minimum penalty for False Claims Act violations has been raised from $5,000 to $5,500 and the maximum penalty has been raised from $10,000 to $11,000. See 28 C.F.R. § 85.3(a)(9).

Medicare pays claims only for services provided to an "eligible individual." See 42 U.S.C. § 1395x, 1395b-3, 1395w-21 and 1395w-28. Here, Defendants provided testing services to eligible Medicare beneficiaries. As the Sixth Circuit observed "[u]nder the Medicare regulatory regime, service providers are paid for 'the reasonable cost of services **provided to beneficiaries'**." Medshares Management, 400 F.3d at 456 (quoting 4 C.F.R. § 413.64(a)) (emphasis added). In an action under the False Claims Act, the Supreme Court stated:

> To equate the number of forfeitures with the number of contracts would in a case such as this result almost always in but a single forfeiture, no matter how many fraudulent acts the subcontractor might have committed. This result would not only be at odds with the statutory language; it would also defeat the statutory purpose.

United States v. Bornstein, 423 U.S. 303, 311 (1976); ISee also United States ex rel. Kreindler & Kreindler v. United Technologies Corp., 985 F.2d 1148, 1157 (2d Cir. 1993).

Thus, the Court concludes each claim submitted by MedQuest for each contrast testing of a Medicare beneficiary without an approved Medicare physician, represents the appropriate basis for the award of penalties under the FCA. MedQuest is an experienced provider of IDTF services with an extensively trained staff. MedQuest is the leading IDTF firm in the nation that operates in thirteen states. MedQuest had a clear alternative to submit physicians who were not radiologists, but who had the appropriate training, as with Dr. Tan, but elected not to do so. This supervising physician coverage for the diagnostic tests with contrast was well known to MedQuest's upper management and managers of its Nashville area IDTFs. The proof establishes that this lack of supervising physician coverage for the diagnostic tests with contrast at MedQuest Nashville area IDTFs was so significant that MedQuest's technical staff actually conducted the diagnostic testing without any physician supervision. Damages are not sought or awarded for those acts. Thus, in these circumstances, the Court deems the $11,000 penalty

appropriate for each of the false claims involving the use of non-Medicare approved physicians submitted by MedQuest to Medicare for payment from January 15, 2004 through September 12, 2006.

For MedQuest's Charlotte billings with Dr. Witt's Medicare billing number, 42 C.F.R. § 410.33(g)(2) allows a thirty day window for submission of any change in ownership of an approved provider. The Court deems the $5,500 penalty appropriate for the claims submitted for 17 months. The Government's proof in the Charlotte facility (Docket Entry No. 138 at 7, Haines Affidavit) does not reflect the dates of those billings. The total billings minus the 30 days after the change in ownership of the Charlotte facility should be readily ascertainable and should not be subject to dispute. If so, the parties should be able to stipulate the number of such billings for the 17 month period.

IV. Relief

For these collective reasons, the Court concludes that the United States's motion for summary judgment on its FCA claims should be granted (Docket Entry No. 127); the Defendants' motion for summary judgment (Docket Entry No. 128) should be granted on Relator's retaliation claim, but otherwise denied; Defendants' motion to dismiss Relator's amended complaint (Docket Entry No. 148) should be granted on her retaliation claim, but otherwise denied; and the Defendants' motion for summary judgment on the United States's FCA claims should be denied. (Docket Entry No. 149). With these conclusions, the Court deems the Government's common law claims to be moot. An Order awarding damages will be entered upon the parties' stipulation or proof on the billings at the Charlotte facility after the 30 days window for notice of change of ownership in 42 C.F.R. 410.33(g)(2).

An appropriate Order is filed herewith.

ENTERED this the _____ day of August, 2011.

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WILLIAM J. HAYNES, JR.
United States District Judge