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UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

UNITED STATES OF AMERICA, ex rel.; KAREN J. HOBBS,
Plaintiffs-Appellees,

STATE OF TENNESSEE, ex rel.,
Plaintiff,

v.

MEDQUEST ASSOCIATES, INC.; BIOIMAGING AT CHARLOTTE, INC.; BIOIMAGING OF COOL SPRINGS, INC.; BIOIMAGING AT HARDING, INC., nka BioImaging at Edmondson,
Defendants-Appellants.

No. 11-6520

Appeal from the United States District Court
for the Middle District of Tennessee at Nashville.
No. 3:06-CV-1169—William J. Haynes, Jr., District Judge.

Argued: November 29, 2012

Decided and Filed: April 1, 2013

Before: KEITH, CLAY, and ROGERS, Circuit Judges.

COUNSEL

ARGUED: Jeffrey S. Bucholtz, KING & SPALDING LLP, Washington, D.C., for Appellants. Christine N. Kohl, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Appellees. **ON BRIEF:** Jeffrey S. Bucholtz, Paul A. Mezzina, KING & SPALDING LLP, Washington, D.C., Britt King Latham, BASS, BERRY & SIMS, Nashville, Tennessee, Rebekah N. Plowman, Kristen Pollock McDonald, NELSON, MULLINS, RILEY & SCARBOROUGH, LLP, Atlanta, Georgia, for Appellants. Christine N. Kohl, Thomas M. Bondy, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Appellees. Paul W. Kim, OBER KALER GRIMES & SHRIVER, Baltimore, Maryland, for Amicus Curiae.

OPINION

ROGERS, Circuit Judge. MedQuest Associates, Inc. and three of its subsidiaries (collectively "MedQuest") appeal an $11,110,662.71 judgment against them for filing false claims for reimbursement under Medicare Part B in this False Claims Act (FCA) *qui tam* action. The claims fall into two categories: (1) claims that were false because MedQuest used physician supervisors who were not approved by the local Medicare carrier, and (2) claims that were false because they were submitted by an independent diagnostic testing facility (IDTF) that was not properly enrolled in the Medicare program and were filed using another physician's billing number.

The regulatory scheme does not support FCA liability for failure to comply with the supervising-physician regulations, and the district court's grant of summary judgment against MedQuest on this issue must be reversed. With respect to the second set of claims, MedQuest's failure to satisfy the enrollment regulations and its use of a billing number belonging to a physician's practice it controlled do not trigger the hefty fines and penalties created by the FCA. Summary judgment on this set of claims must also be reversed.

I.

MedQuest is a diagnostic testing company that operates more than ninety testing facilities in thirteen states. This case concerns its compliance with certain Medicare regulations in three of its Nashville, Tennessee-area facilities, known as the Charlotte Center, the Cool Springs Center, and the Harding Center.

In December 2006, Karen Hobbs, a former MedQuest employee, brought this *qui tam* suit against MedQuest alleging violations of the FCA. Over two years later, the United States intervened and took over the litigation of the suit. The suit alleged—and the district court held on summary judgment—that MedQuest violated the FCA in two significant respects: (1) in two testing facilities, MedQuest used supervising physicians

who had not been approved by the Medicare program and the local Medicare carrier to supervise the range of tests offered at the sites, and (2) after acquiring the Charlotte Center, MedQuest failed to properly re-register the facility to reflect the change in ownership and enroll the facility in the Medicare program, instead using the former owner's payee ID number. *United States ex rel. Hobbs v. MedQuest Assocs., Inc.*, 812 F. Supp. 2d 821 (M.D. Tenn. 2011). In this appeal, MedQuest argues that its violations, if any, run afoul of the conditions of participation in the Medicare program—not conditions of payment for tests and services. This is significant because only the latter may form the basis of an FCA action.

A. Regulatory Scheme

While the FCA provides the vehicle for suit, Medicare statutes and regulations define the requirements for Medicare claims and form the basis of much of the dispute in this case. Medicare Part B—the portion of the program that covers the costs of physician services, supplies, and tests—only covers tests that are "reasonable and necessary." 42 U.S.C. § 1395x(s)(3) (2003); *id.* § 1395y(a)(1)(A) (2003). For a diagnostic test to be "reasonable and necessary," it "must be furnished under the appropriate level of supervision by a physician." 42 C.F.R. § 410.32(b)(1) (2003). Medicare requires entities that seek reimbursement from the program to first enroll and gain approval from their local Medicare carrier. A carrier is the claims-processing and -regulating entity that contracts with the Centers for Medicare and Medicaid Services (CMS), the body created by the Department of Health and Human Services (HHS) to administer the Medicare program. In this case, CIGNA is the applicable carrier.

For organizations like MedQuest, the enrollment process begins with the submission of a CMS-855B Application ("Enrollment Application"). This particular application enables an entity to enroll as an Independent Diagnostic Testing Facility (IDTF). "An IDTF must have one or more supervising physicians who are responsible for" providing general supervision of procedures at the facility. 42 C.F.R. § 410.33(b)(1) (2003). For "procedure[s] requiring . . . direct or personal supervision," the "IDTF's supervising physician must personally furnish this level of supervision."

Id. § 410.33(b)(2) (2003). The Enrollment Application requires an IDTF to identify its "supervising physicians." The form concludes with a certification that if the signor "become[s] aware that any information in this application is not true, correct or complete, [he] agree[s] to notify the Medicare program contractor of this fact immediately." CMS regulations also require that CMS be notified of any addition, deletion, or change to the list of physicians. While the application requires that each physician attest that he or she is proficient in all tests to be supervised at the facility, CMS has interpreted this requirement to mandate only that, as a whole, the group of supervising physicians has the combined expertise to provide proficient supervision for all tests. "The basic requirement . . . is that all the supervisory physician functions must be properly met at each location, regardless of the number of physicians involved. . . . The physicians used need only meet the proficiency standards for the tests they are supervising."

In its own set of policies, called Local Medical Review Policies (LMRPs), CIGNA sets out specific qualifications required to perform and supervise individual procedures. For example, a certified radiologist must perform a CT scan with contrast under the "direct supervision" of a physician, who must also be a radiologist, or else provide evidence of medical education or certification "specific to the skills involved in performing that test."

Once enrolled, the provider submits CMS-1500 forms to the carrier to obtain payment for services provided to Medicare patients. These forms reflect the treatment or services provided and identify the provider or supplier who provided them. Tests, supplies, and services are correlated to a series of unique numbers, called CPT codes, which quickly convey to the carrier what reimbursable expenses the provider has incurred. The CMS-1500 form requires the provider to "certify that the services listed above were medically indicated and necessary to the health of this patient and were personally furnished by me or my employee under my personal direction."

B. MedQuest's Actions

1. MedQuest used non-supervising physicians to directly supervise contrast tests.

In two of its facilities, the Harding Center and the Cool Springs Center, MedQuest listed board-certified radiologists (and, in one case, a non-radiologist who had been approved by CIGNA) on its CMS enrollment forms as the "supervising physicians" for the facility. These three physicians, Dr. Witt, Dr. Cooney, and Dr. Tan, were listed in the appropriate place on MedQuest's IDTF enrollment forms. In addition, MedQuest hired other physicians to provide patient services. However, Medicare regulations require that certain procedures be conducted under direct or personal supervision—namely, for purposes of this case, contrast MRI and CT scans. CMS requires that these scans be directly supervised by one of the IDTF's supervising physicians, and CIGNA imposes an additional requirement that the scans be approved by a specialist in radiology.

The Government alleges that the centers used physicians besides those approved by CIGNA to provide direct supervision for contrast procedures, some of whom did not specialize in radiology. MedQuest concedes that some of these procedures were not supervised by the approved physician personnel, although it maintains that all procedures received supervision by a physician, approved or otherwise. MedQuest also notes that its stated policy was to limit direct supervisory responsibility to those physicians listed on its enrollment forms, as memorialized in a 2003 memo to center managers stating, "[t]he 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" (emphasis in original).

2. MedQuest purchased a physician's practice and operated it as an independent diagnostic testing facility, without registering as an IDTF, and instead used the former practice's billing number on claims forms.

In a third Nashville-area clinic, the Charlotte Center, MedQuest submitted claims for eighteen months using the billing number of Dr. William S. Witt. This pattern arose after MedQuest bought all of the shares in Dr. Witt's physician's practice and began operating the center as a MedQuest facility. According to Dr. Witt, his practice effectively ended at the time of the buyout. However, Dr. Witt continued to provide patient services at all three of the Nashville-area centers at issue in this case. MedQuest characterizes the resulting arrangement as one in which William S. Witt, Inc. became a MedQuest subsidiary, and it justifies the use of Witt's billing code on that basis. Appellant Br. at 46. MedQuest's use of the code ended on July 1, 2005, when MedQuest re-enrolled the Charlotte Center as an IDTF. MedQuest attributes this change in enrollment to an effort to consolidate the Nashville centers under one tax ID. However, MedQuest's chief compliance officer testified that the earlier failure to register happened because "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."

C. The District Court's Judgment

Following discovery, both sides moved for summary judgment. On August 23, 2011, the district court published a lengthy decision granting summary judgment in favor of Hobbs and the Government on both express and implied certification theories. *United States v. MedQuest Assocs., Inc.*, 812 F. Supp. 2d 821 (M.D. Tenn. 2011). The district court determined that the Enrollment Application "included a certification and in effect, an agreement that the physicians listed . . . would provide the direct supervision for applicable testing." *Id.* at 852. The court further concluded that "[t]he 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." *Id.*

The district court found that MedQuest incurred FCA liability for its use of non-supervising personnel to monitor contrast testing, and the court concluded, "MedQuest submitted Medicare claims for payment for all of those [contrast] testings and by doing so, MedQuest violated its first express certification that the physicians 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." *Id.* at 864. In an intermediate order denying MedQuest's motion to dismiss, the court accepted the Government's theory that "Defendants submitted false claims for payment of diagnostic tests with CPT codes that Defendants knew to be false given the express Medicare regulation requiring appropriately qualified physician supervision as a condition of payment for IDTF's claim for diagnostic services with contrasts." *United States ex rel. Hobbs v. MedQuest Assocs., Inc.*, 702 F. Supp. 2d 904, 918 (M.D. Tenn. 2010). The district court determined that MedQuest's position as a large-scale testing-center operator put its upper-level management in a position where they either knew or recklessly disregarded the noncompliant actions at the Nashville centers. *MedQuest*, 812 F. Supp. 2d at 864–65.

The district court concluded that MedQuest's failure to update CMS enrollment forms upon the transfer of ownership of Dr. Witt's practice constitutes a false certification, although its precise theory is unclear. *See id.* at 866–67 (citing the legal duty to submit a CMS-855 change of information form and "conclud[ing] that the United States's proof establishe[d] MedQuest's reckless disregard of the notice requirements in Medicare regulations and instructions on the CMS form"). The district court also found an FCA violation in the use of Dr. Witt's billing number. *Id.* at 867–68.

MedQuest moved for reconsideration on Eighth Amendment grounds related to the damages and penalties, but on October 21, 2011, the district court denied the motion and entered judgment for the Government in the amount of $11,110.662.71. *United States ex rel. Hobbs v. MedQuest Assocs., Inc.*, No. 3:06-01169, 2011 WL 5027504, at *5 (M.D. Tenn. Oct. 21, 2011). This total included 343 claims for contrast testing

supervised by non-approved physicians and 945 claims filed using Dr. Witt's billing number. *Id.* The Government was entitled to treble damages on each claim. *Id.* The court assessed fines of $11,000 for each supervising-physician violation and $5,500 per billing-number violation. *Id.* The court found that "one half of the total mandatory treble damages awarded" were compensatory. *Id.* at *7. The remaining half were therefore punitive. *Id.*

MedQuest now challenges the district court's grant of summary judgment as to both types of claims and renews its Eighth Amendment objection to the damages and penalties the court awarded.

II.

MedQuest's actions at the Nashville-area centers clearly were at odds with the goals and aims of the Medicare program in several respects, and the Government has raised reasonable arguments in support of its claims. We have little sympathy for MedQuest, which sometimes skirted and appears to have often ignored applicable regulations in the conduct of its centers. However, because these regulations are not conditions of payment, they do not mandate the extraordinary remedies of the FCA and are instead addressable by the administrative sanctions available, including suspension and expulsion from the Medicare program.

This Court reviews a district court's grant of summary judgment de novo, *Ventas, Inc. v. HCP, Inc.*, 647 F.3d 291, 324 (6th Cir. 2011), applying the same standards as the district court. *Natron Corp. v. STMicroelecs., Inc.*, 305 F.3d 397, 403 (6th Cir. 2002). Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact" such that "the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a).

A. MedQuest's use of non-approved supervising physicians for contrast procedures does not constitute an adequate basis for an FCA claim because it violated only conditions of participation.

The FCA creates civil liability for any person who "knowingly presents, or causes to be presented" to the government "a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1) (2006). The statute requires only that the false or fraudulent claim be presented by a person with actual knowledge of the information submitted and who acts in deliberate ignorance, or with reckless disregard as to the veracity of that information. *Id.* § 3729(b). Suit may be filed directly by the government or, as here, may be brought as a *qui tam* action in which the government may intervene. *Id.* § 3730. Treble damages are prescribed by statute, and civil penalties range from $5,500 to $11,000 per false claim. *Id.* § 3729(a); 28 C.F.R. § 85.3(a)(9) (2011).

In addition to obvious cases of fraud, as where a provider bills for procedures or services that were not rendered or not necessary, a claim may be false under a "false certification" theory, as "when the claimant knowingly falsely certifies that it has complied with a statute or regulation the compliance with which is a condition for Government payment." *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 305 (3d Cir. 2011); *see also Chesbrough v. VPA, P.C.*, 655 F.3d 461, 467 (6th Cir. 2011). The success of a false certification claim depends on whether it is based on "conditions of participation" in the Medicare program (which do not support an FCA claim) or on "conditions of payment" from Medicare funds (which do support FCA claims). *Wilkins*, 659 F.3d at 309; *United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1220 (10th Cir. 2008); *United States ex rel. Mikes v. Straus*, 274 F.3d 687, 701–02 (2d Cir. 2001).

False certifications may be express or implied. *Wilkins*, 659 F.3d at 305. In an express false certification, the defendant is alleged to have signed or otherwise certified to compliance with some law or regulation on the face of the claim submitted. Under an implied certification theory, a facially truthful claim can be construed as false if the claimant "violates its continuing duty to comply with the regulations on which payment

is conditioned." *Chesbrough*, 655 F.3d at 468 (quoting *United States ex rel. Augustine v. Century Health Servs., Inc.*, 289 F.3d 409, 415 (6th Cir. 2002)). Courts do not look to the claimant's actual statements; rather, the analysis focuses on "the underlying contracts, statutes, or regulations themselves to ascertain whether they make compliance a prerequisite to the government's payment." *Conner*, 543 F.3d at 1218. A false-certification theory only applies where the underlying regulation is a "condition of payment," meaning that the government would not have paid the claim had it known the provider was not in compliance. *See Chesbrough*, 655 F.3d at 468. Of course, a regulation may in some cases be both a condition of payment and a condition of participation. *See United States ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1176 (9th Cir. 2006).

The Government alternatively uses the express and implied false-certification theories to allege FCA liability against MedQuest for its failure to comply with the requirement that "[i]n 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." 42 C.F.R. § 410.33(b)(2) (2003). Neither theory supports FCA liability in this case.

1. Express Certification

The Government cannot point to an express certification made by MedQuest that it was in compliance with the supervising-physician requirements. MedQuest's statements in its Enrollment Application do not constitute certifications that would support an FCA action. The Enrollment Application required certification that the centers would "abide by the Medicare laws, regulations and program instructions." Reliance on this provision as an express certification violating the FCA is misplaced. The falsity of a claim is determined at the time of submission. *United States ex rel. Quinn v. Omnicare, Inc.*, 382 F.3d 432, 438–39 (3d Cir. 2004). The Government has not argued or provided evidence that MedQuest intended to violate Medicare regulations at the time it applied. Moreover, the certification does not contain language conditioning *payment* on compliance with any particular law or regulation.

MedQuest did not make any express certifications of compliance with physician-supervision requirements in its CMS claim forms that would support an FCA action. The only express certification on the CMS-1500 claim form is that the services listed on the form were "medically indicated and necessary for the health of the patient." The medical need for the contrast scans has not been contested.

2. Implied Certification

The Government's implied certification theory rests on the assertion that MedQuest implicitly certified compliance with the supervising-physician requirements—which it characterizes as conditions of payment—each time it submitted a claim for Medicare payment. Because the supervising-physician requirements are not conditions of payment, this theory fails. A conclusion that compliance with the supervising-physician requirements is a condition of payment is only possible by weaving together isolated phrases from several sections in the complex scheme of Medicare regulations. This cut-and-paste approach is not supported by the structure of the regulatory scheme, and it is not reasonable to expect Medicare providers to attempt such an approach to statutory interpretation in their efforts to comply with the FCA.

The Government contends that the claims submitted by MedQuest violate conditions of payment because the tests were not "reasonable and necessary" and therefore do not satisfy the primary prerequisite to Medicare payment. However, the natural reading of the relevant regulations supports only a conclusion that contrast testing is not reasonable and necessary if it is not performed under direct supervision by a physician. Although MedQuest was not in complete regulatory compliance, the claims at issue were supervised directly by physicians; for this reason, the claims meet the "reasonable and necessary" requirement and satisfy the conditions for payment. Additional rules pertaining to the roles and duties of supervising physicians at IDTFs and to additional certifications required for contrast testing procedures are found in separate regulations that do not refer to the "reasonable and necessary" standard; therefore, interpreting them as relating to the "reasonable and necessary" conditions comes only from a strained reading of the regulatory scheme.

42 U.S.C. § 1395y states that Medicare will not make payment for services that are not "reasonable and necessary." 42 U.S.C. § 1395y(a)(1)(A) (2003); *see also* 42 C.F.R. § 411.15(k)(1) (2003). This standard is elucidated in certain CMS regulations, like 42 C.F.R. § 410.32, which applies the standard to diagnostic testing. For diagnostic tests to be "reasonable and necessary," they "must be furnished under the appropriate level of supervision by a physician as defined in [42 U.S.C. § 1395x(r)]."[1] 42 C.F.R. § 410.32(b)(1) (2003). The regulations set out three levels of supervision: general, direct, and personal. *Id.* § 410.31(b)(3) (2003). "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." *Id.* § 410.32(b)(3)(i) (2003). An intermediate level of supervision, "direct supervision," requires a physician to be "present in the office suite and . . . available to furnish assistance" but does not necessarily require the physician to be in the room where the procedure is performed. *Id.* § 410.32(b)(3)(ii) (2003). "Personal supervision," the highest level, "means a physician must be in attendance in the room during the performance of the procedure." *Id.* § 410.32(b)(3)(iii) (2003). Relevant to this case, though most diagnostic testing requires only general supervision, CIGNA requires "contrast testing" to be done with direct supervision. Under these requirements, contrast testing is reasonable and necessary only if it is directly supervised by a physician. Because MedQuest provided this level of supervision in the procedures it billed to Medicare, it did not violate this condition of payment.

Although other Medicare regulations applied to MedQuest, only physician supervision at an appropriate level (i.e., general, direct, or personal) is relevant to the "reasonable and necessary" inquiry. Among these other requirements, CIGNA's Local Policies (LMRP) provide that the supervising physician must be certified in radiology.

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[1]This provision defines a physician in basic terms: "The term 'physician', when used in connection with the performance of any function or action, means (1) a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action . . . ." 42 U.S.C. § 1395x(r). The definition also encompasses doctors of dental surgery, doctors of podiatric medicine, doctors of optometry, and chiropractors so long as they are acting within the scope of their licenses and/or authorizations to practice. *Id.*

This LMRP requirement, however, does not purport to supplement the "reasonable and necessary" conditions contained in § 410.32.

Moreover, the LMRP appears to have expressly limited its "reasons for denial" in an LMRP section with that title. According to that section, payment may be denied when the test is "performed for indications other than those listed in the 'Indications and Limitations of Coverage and/or Medical Necessity' section of this policy and applicable [LMRPs]," "[w]hen the services are performed for screening purposes," "[w]hen the medical record does not verify that the service described . . . was provided," and "[w]hen the patient's record lacks evidence that the treating physician did not [sic] order the test." In contrast to those situations, the appendix stated that because some IDTFs might "not currently meet the . . . credentialing criteria," it would "allow up to one year from the date the applicant enrolled as an IDTF for the applicable certification/licensure to be obtained." The implication is that the LMRP does not forbid payment when there are regulatory violations like the ones at issue here.

Other CMS regulations specifying supervisory procedures specific to IDTFs do not relate to the "reasonable and necessary" language in § 410.32 in such a way as would create a condition of payment. 42 C.F.R. § 410.33, titled "Independent diagnostic testing facility," sets out characteristics of and requirements for IDTFs. These include the requirement that each facility have one or more supervising physicians. *Id.* § 410.33(b) (2003). After stating the general duties and qualifications of the supervising physician, the regulation provides that "[i]n 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 furnish this level of supervision." *Id.* § 410.33(b)(2) (2003). While it creates additional requirements for IDTFs, this provision does not mean that services lose "reasonable and necessary" status when furnished by a physician who is not a supervising physician. Section 410.32 fully provides the conditions of payment for diagnostic testing—that a test is reasonable and necessary only when performed under the adequate level of supervision. Because the requirements in § 410.33 are

conditions of participation and not conditions of payment, violations are punishable only by administrative remedies including expulsion from the Medicare program.

Nor does § 410.33 independently create conditions of payment. The Government points to the opening words of the regulation, which state that "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, . . . or an independent diagnostic testing facility (IDTF)." *Id.* § 410.33(a) (2003). Although this provision appears to create a condition of payment with the language "will pay . . . only when," the condition in this context is that the provider be an IDTF. *Id.* The Government does not produce any evidence to support an argument that the Charlotte Center was not an IDTF at the time it billed Medicare, whether or not it was in full compliance with § 410.33(b)(2).

Our conclusion regarding the absence of conditions of payment is aligned with decisions in this and other circuits interpreting the appropriate scope of FCA liability. Recently, this court reaffirmed its view that "[t]he False Claims Act is not a vehicle to police technical compliance with complex federal regulations" when it determined that statements and requirements in a dialysis provider's Medicare application did not permit suit under the FCA. *Williams*, 696 F.3d at 532. Like our sister circuits, we recognize the need for an "active role" to be played by actors outside the federal government in the enforcement of the Medicare statute, *see Mikes*, 274 F.3d at 699–700, and we recognize that the FCA (through *qui tam* suits or otherwise) retains an important role in the Medicare context. But where, as in this case, the violations would not "natural[ly] tend[] to influence" CMS's decision to pay on the claims, *United States ex rel. A+ Homecare, Inc. v. Medshares Mgmt. Grp., Inc.*, 400 F.3d 428, 444–45 (6th Cir. 2005), the "blunt[ness]" of the FCA's hefty fines and penalties makes them an inappropriate tool for ensuring compliance with technical and local program requirements like the special supervision requirements at issue in this case. *See Mikes*, 274 F.3d at 699. Such compliance may of course be enforced administratively through suspension, disqualification, or other remedy.

B. MedQuest did not violate conditions of payment when it used Dr. Witt's billing number after the transfer of stock ownership.

The district court's reasons for assessing liability against MedQuest on the Charlotte Center claims were based on a combination of laws not in effect at the time of MedQuest's actions[2] and on conditions of participation. Although the Goverment offers authority for its assertion that MedQuest should have notified Medicare and/or re-enrolled the Charlotte Center after it took ownership, the only condition of payment identified by the Government is the provision in 42 C.F.R. § 410.33(a) that "carriers will pay for diagnostic procedures under the physician fee schedule only when performed by a physician, a group practice of physicians, . . . or an [IDTF]." However, the Government has not alleged that MedQuest was not operating the Charlotte Center as an IDTF, nor has it supported its assertion that "IDTF" means "approved and enrolled IDTF." For this reason, FCA liability on this claim is untenable.

The Government states, "When MedQuest purchased Dr. Witt's practice in 2004, the Charlotte facility was no longer a physician's practice. Nor was it an IDTF because it was not enrolled as such in the Medicare program." Government Br. at 51 (citing 42 U.S.C. § 1395cc(j)) (2003). The Government argues that "under [§ 413.33(a)(1)], MedQuest was not entitled to be paid for tests at the Charlotte facility until it was an enrolled and approved IDTF." The Government is likely correct that the facility would no longer have been classified by Medicare as a physician's practice following the transfer of ownership from Dr. Witt to MedQuest, but the remainder of its assertions lack merit.

Enrollment and approval are not required for an entity to be an IDTF. No provision in the relevant statutes, regulations, or interpretive rules establishes this

[2]In their briefs, the parties agree that 42 C.F.R. § 410.33(g), which addresses the procedures associated with an IDTF's change of ownership, was not part of the applicable regulations until it was enacted in 2006, several years after the actions at issue in this claim.

requirement.[3] The Government's sole reliance on 42 U.S.C. § 1395cc(j), which directs the HHS Secretary to promulgate regulations related to enrollment, is misplaced because the statute cannot possibly be interpreted to mean that an IDTF cannot exist without Medicare enrollment. This is the only legal basis offered on appeal for this supposed enrollment/approval requirement.

Moreover, the Government's assertion that this is a failure-to-enroll problem ignores the fact that Witt's practice, which MedQuest purchased, was already enrolled in the Medicare program. This case, at most, represents a failure to update enrollment information, which we have held is not a violation of a condition of payment. The Government contends that "Dr. Witt's corporate practice was never a MedQuest subsidiary; the practice ended when Dr. Witt sold all his shares to MedQuest and he became an 'independent contractor' at the three Nashville IDTFs, with no other relationship to MedQuest." Appellee's Br. at 55. The Government does not, however, offer any rational reason to conclude that the predominant effect of the stock purchase was to dissolve Dr. Witt's corporation. Nor does it explain why an incorporated physician's practice cannot be effectively purchased by an outside entity. While Dr. Witt's practice may no longer have been appropriately classified as a physician's practice, the evidence belies the assertion that it "ceased to exist" in the manner implied by the Government. The Government does not contest that the facility used the same or similar personnel to provide the same or similar services with the same facilities, supplies and assets—one of which was a billing number.

We are cognizant of Medicare's need to monitor its providers, and the Government has provided ample documentation to support its assertion that MedQuest was, or should have been, aware of the program's interest in monitoring its providers and assuring quality patient care. However, the Government cites no regulation governing MedQuest's conduct in the facts of this case. Doubtless, providers should, in good faith,

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[3]Medicare advises suppliers of a four-factor test to determine if an entity is properly classified as an IDTF and therefore, the requirement is less concrete. Further, Medicare allows a facility that belatedly enrolls as an IDTF to back-bill for procedures conducted before it was enrolled so long as the pre-enrollment procedures met the substantive requirements imposed on IDTFs.

endeavor to be as responsive as possible to the known goals of the Medicare program. However, the FCA does not impose liability for providers' failure to anticipate needs of the program that have not been promulgated in regulations conditioning payment on compliance, in addition to providers' obligations to navigate the already-complicated scheme of regulations. In the absence of a regulation conditioning payment on an accurate, updated enrollment form reflecting current ownership, and without support for the proposition that a purchaser of a corporate practice is not legally entitled to use that corporation's billing number, MedQuest cannot be held liable under the FCA.

III.

FCA liability is not warranted on either of the claims in this case, and therefore we reverse the district court's judgment. Because we reverse the judgment in full, we have no need to reach MedQuest's Excessive Fines arguments.