UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO

UNITED STATES OF AMERICA and THE STATE OF NEW MEXICO, ex rel. SALLY HANSEN, Plaintiffs, v. DEMING HOSPITAL CORPORATION d/b/a MIMBRES MEMORIAL HOSPITAL, COMMUNITY HEALTH SYSTEMS, INC., COMMUNITY HEALTH SYSTEMS PROFESSIONAL SERVICES CORP., and JERRY BOSSELL Defendants.	)	Case No. 2:11-cv-00566-WPL-CG

DEFENDANTS DEMING HOSPITAL CORPORATION d/b/a MIMBRES MEMORIAL HOSPITAL, COMMUNITY HEALTH SYSTEMS PROFESSIONAL SERVICES CORP., AND JERRY BOSSELL'S MEMORANDUM IN SUPPORT OF THEIR MOTION TO DISMISS RELATOR'S FIRST AMENDED COMPLAINT

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Dated: June 12, 2013

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Defendants Deming Hospital Corporation d/b/a Mimbres Memorial Hospital, Community Health Systems Professional Services Corporation, and Jerry Bossell (collectively, "Mimbres" or the "Hospital") respectfully submit this Memorandum in support of their Motion To Dismiss Relator's First Amended Complaint under Rule 12(b)(6) of the Federal Rules of Civil Procedure.

INTRODUCTION AND SUMMARY OF ARGUMENT

This case exemplifies a danger the Tenth Circuit and numerous other courts have warned against: Stretching the False Claims Act ("FCA") beyond its intended reach by applying it to regulatory violations that are appropriately addressed through administrative means.

Here, Relator Sally Hansen alleges that Mimbres did not comply with several of the regulations that govern laboratories under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"), 42 U.S.C. § 263a. Hansen claims that because Mimbres received government reimbursement for laboratory tests while it was noncompliant, Mimbres did not just violate CLIA, but also the FCA.

The Tenth Circuit has made clear, however, that the FCA is not a tool to enforce government regulations. Instead, it is an anti-fraud statute, meant to stop defendants from using false statements to obtain government payment they are not owed. The Tenth Circuit therefore imposes a common-sense limitation on relators, like Hansen, who seek to base FCA claims on regulatory violations: The FCA claim is viable only if compliance with the regulation is a precondition of receiving government payment—what the Tenth Circuit and other courts call a "condition of payment." *United States ex rel. Conner v. Salina Regional Health Center, Inc.*, 543 F.3d 1211, 1220 (10th Cir. 2008). If, instead, the regulation is not a condition of payment, and thus the government would have paid the defendant despite its noncompliance, then the FCA

claim fails as a matter of law because the defendant has not "submitted a legally fraudulent or false claim." *Id.* at 1217. *Conner* applied this rule to dismiss the relator's FCA claim under Rule 12(b)(6), because the Medicare regulations at issue were not conditions of payment but only "conditions of participation"—*i.e.*, regulations that must be followed for the defendant to participate in Medicare, but that do not require perfect compliance at all times for the defendant to receive Medicare reimbursement. *Id.* at 1217–23.

The CLIA regulations, like the regulations in *Conner*, are classic conditions of participation and therefore do not give rise to an FCA claim as a matter of law. The Medicare regulations expressly identify CLIA as a "Condition of Participation" and not a "Condition for Medicare Payment." 42 C.F.R. Part 424; *id.* § 482.27(a). No CLIA or Medicare regulation requires or even authorizes the government to deny reimbursement for laboratory tests that were performed in noncompliance with CLIA. Hence by definition, the CLIA regulations are not conditions of payment. Instead, the regulations set forth an intricate enforcement scheme that allows the administrative agency, in its expertise and discretion, to select from other remedies that are appropriate in the circumstances. As in *Conner*, withholding Medicare or Medicaid funding is a remedy of last resort that can be imposed only on *future* laboratory testing, and even then only after notice and a chance for the laboratory to object—a sanction that, in any event, the agency has not imposed on Mimbres. To apply the FCA and its inflexible (and harsh) remedies here would thus not only run afoul of Tenth Circuit law, but "would undermine the government's own administrative scheme." 543 F.3d at 1220. That is particularly inappropriate in light of the fact that the state and federal governments have now *twice* declined to intervene in this lawsuit. Accordingly, ***Count I*** should be dismissed because it does not state a claim under Rule 12(b)(6).

Count III, alleging retaliation in violation of the FCA, also fails to state a claim under Rule 12(b)(6). Hansen alleges only that she investigated whether Mimbres was in compliance with the regulatory provisions of CLIA. But to state a retaliation claim, Hansen must allege that she engaged in protected activity and that Mimbres had notice of that activity. Courts have uniformly held that merely investigating possible regulatory violations is not enough; instead, the investigation must concern improper billing, fraud, the possibility of FCA litigation, or the like. Here it does not, and Count III therefore fails as a matter of law.

Finally, ***Counts II and IV*** should be dismissed because they rest on the same conduct underlying Counts I and III and invoke state statutes that are construed similarly to the FCA.

BACKGROUND

A. Procedural History

Hansen filed her original Complaint alleging violations of the FCA and state law on June 27, 2011. ECF No. 1. After investigating Hansen's allegations, both the United States and the State of New Mexico declined to intervene. ECF Nos. 20–21. The Court unsealed the Complaint on August 8, 2012. ECF No. 22. Mimbres moved to dismiss the Complaint under Rules 9(b) and 12(b)(6) of the Federal Rules of Civil Procedure (the "Motion") on January 18, 2013. ECF No. 44.

Hansen did not file a response to the Motion, but instead filed a First Amended Complaint on February 1, 2013. ECF No. 50. After reviewing the amended allegations, both the United States and the State of New Mexico again declined to intervene. ECF Nos. 55–56. The Court then unsealed the First Amended Complaint on April 11, 2013. ECF Nos. 58. Mimbres

now files this renewed motion to dismiss because the First Amended Complaint still fails under Rule 12(b(6).

B. CLIA

CLIA requires laboratories, such as Mimbres's laboratory, to obtain a certificate from the Secretary of the Department of Health and Human Services or an approved accrediting agency in order to perform clinical diagnostic testing on human beings. First Amended Complaint ("Compl.") ¶¶ 25–28 (ECF No. 50); 42 U.S.C. § 263a(b). A laboratory must have a valid CLIA certificate to participate in Medicare or Medicaid. Compl. ¶¶ 27, 34; 42 C.F.R. §§ 493.1808, 493.1842. Here, Hansen acknowledges that Mimbres's laboratory has a valid CLIA certificate. Compl. ¶ 29. Hansen does not allege that the certificate, or Mimbres's right to bill Medicare or Medicaid, have ever been suspended or limited in any way.

CLIA is implemented through comprehensive regulations that set forth quality control and other requirements. Compl. ¶ 28; 42 C.F.R. Part 493. The Centers for Medicare & Medicaid Services ("CMS") enforces CLIA's regulations through a detailed administrative scheme. Compl. ¶ 26; 42 C.F.R. Part 493, Subparts Q (Inspection) and R (Enforcement Procedures). When a laboratory does not comply with one or more CLIA requirements, CMS may impose sanctions of increasing severity, culminating in revocation of a laboratory's certificate (or even criminal penalties, where a violation of CLIA is intentional). 42 C.F.R. §§ 493.1806, 493.1807. The regulations confer on CMS much flexibility and discretion to select the administrative action that is appropriate in light of the nature of the laboratory's CLIA deficiency. *Id.* §§ 493.1800, 493.1804.

C. Hansen's Allegations

Hansen alleges that she observed CLIA violations in Mimbres's laboratory after she began working there in May 2010. Compl. ¶ 9. She contends that the laboratory's Procedure Manuals were out of date, in violation of CLIA, because they contained instructions for equipment and procedures that were no longer in use and did not include instructions for newer equipment and procedures that were in use. *Id.* ¶ 56. Hansen further alleges that defendant Bossell performed the function of laboratory director but was unqualified for that position, and that Mimbres failed to provide required training in laboratory techniques to other laboratory personnel. *Id.* ¶¶ 54, 59. In addition, she claims that Mimbres did not perform quality control testing on certain instruments and equipment used in the laboratory as required by CLIA, *id.* ¶ 63, including the Vitek 2 Microbial Identifier (*id.* ¶¶ 68–83), culture media and reagents (*id.* ¶¶ 84–97), commercial kit tests (*id.* ¶¶ 98–104), gram stains (*id.* ¶¶ 105–13), a blood culture analyzer (*id.* ¶¶ 114–19), the ACL Elite device (*id.* ¶¶ 120–34), and rapid plasma reagin testing (*id.* ¶¶ 135-40). Hansen also alleges that in one instance, laboratory employee Rene Rivero created false quality control records related to microbiology testing. *Id.* ¶ 145.[1]

Hansen charges that Mimbres did not disclose these alleged violations to the Joint Commission, the accrediting organization authorized to certify the Hospital under CLIA, when the Joint Commission conducted biannual inspections of its laboratory in October 2009 and October 2011. *Id.* ¶¶ 36, 141–60. Instead, she alleges Mimbres falsely represented its compliance with CLIA. *Id.* ¶¶ 146–49, 158. She also alleges the Hospital sought and received

[1] Hansen alleges that Rivero's conduct occurred "in advance of the Joint Commission's October 2009 on-site audit" of Mimbres (Compl. ¶ 145), but then inconsistently alleges the conduct occurred sometime in June 2010, long after the audit (*id.* ¶¶ 165–67).

reimbursement from Medicare and Medicaid between 2008 and 2011, while the laboratory was noncompliant with CLIA. *E.g., id.* ¶ 50.

Hansen contends that she raised her concerns about the laboratory's alleged CLIA violations to Mr. Rivero, Mr. Bossell, and others at Mimbres, but they were not responsive. *Id.* ¶¶ 161–70. She asserts Mr. Rivero and Mr. Bossell harassed her after she continued to press her concerns. *Id.* ¶¶ 171–72. Hansen states she was placed on administrative leave on or about July 22, 2010. *Id.* ¶ 173. She alleges she was allowed to return to work in February 2011, but that she had no choice but to quit because she was required to work a different, less desirable shift. *Id.* ¶ 175–76.

STANDARD OF REVIEW

"[T]o withstand a motion to dismiss, a complaint must have enough allegations of fact, taken as true, to state a claim to relief that is plausible on its face." *Kansas Penn Gaming, LLC v. Collins*, 656 F.3d 1210, 1214 (10th Cir. 2011) (internal quotation marks omitted). Dismissal is required where the plaintiff's complaint fails as a matter of law to state a cognizable claim for relief. *Smith v. United States*, 561 F.3d 1090, 1098 (10th Cir. 2009).

ARGUMENT

I. Count I Fails Rule 12(b)(6) Because It Alleges Only Regulatory Violations, And Not False Claims

Count I alleges Mimbres violated the FCA by presenting false claims, making false statements to get such claims paid, and making false statements to avoid paying money owed to the government. Compl. ¶¶ 182–85 (citing 31 U.S.C. §§ 3729(a)(1)(A)–(B), (G)). To state a claim under any of these provisions, Hansen must allege (at least) a false statement or claim. *United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 727 (10th

Cir. 2006) ("[A] defendant's presentation of a false or fraudulent claim to the government is a central element of every False Claims Act case." (internal quotation marks omitted)); *Conner*, 543 F.3d at 1217.

Here, Hansen does *not* allege Mimbres billed the government for laboratory tests or services that were not actually performed—what the Tenth Circuit calls a "factually false claim." *Conner*, 543 F.3d at 1217. Instead, she relies on a theory of "legal falsehood" (*ibid.*): That the Hospital billed Medicare[2] for laboratory tests while the laboratory was not in perfect compliance with CLIA. In particular, she contends Mimbres falsely represented its compliance with CLIA to the Joint Commission, thereby "causing the inspectors to grant CLIA certification to the Mimbres lab when, in fact, it was materially non-compliant." Compl. ¶ 179. She also alleges that only because of its fraudulently obtained CLIA certification was the Hospital "able to continue to bill Medicare and Medicaid for lab services." *Id.* ¶ 181. Therefore, according to Hansen, every single bill Mimbres submitted to Medicare between 2008 and 2011 for laboratory services is a false claim triggering full liability under the FCA.

Even assuming *arguendo* the truth of Hansen's allegations, they fail to state a claim under Tenth Circuit law. In *Conner*, the Tenth Circuit made crystal clear that noncompliance with a government regulation does not by itself give rise to FCA liability. Instead, liability can exist only when compliance with the regulation is a condition of receiving government payment. 543 F.3d at 1217 ("[T]he relator must demonstrate that the defendant has certified compliance

[2] The First Amended Complaint alleges improper billing of both Medicare and Medicaid. "[B]ecause hospitals participating in Medicaid must meet the standards of participation for Medicare," we use "Medicare" to refer to participation in both programs. *Conner*, 543 F.3d at 1216 n.4; see also 42 C.F.R. §§ 482.1(a)(5), 493.1809.

with a statute or regulation *as a condition* to government payment . . . ." (internal quotation marks and alteration omitted; emphasis in original)).[3] Because, as we explain below, compliance with CLIA is not a condition of receiving payment, but only a condition of participating in Medicare, the First Amended Complaint fails to allege falsity and should be dismissed.

1. In *Conner*, as here, the relator alleged that a medical facility violated the FCA by seeking Medicare payments for services rendered in noncompliance with "a host of Medicare regulations and statutes." 543 F.3d at 1214, 1216 n.5 (listing alleged violations). The district court dismissed the complaint under Rule 12(b)(6), and the Tenth Circuit affirmed. The court explained the "significant distinction" between "conditions of program *participation*" and "conditions of *payment*." *Id.* at 1220 (emphasis in original). Conditions of participation "are enforced through administrative mechanisms, and the ultimate sanction for violation of such conditions is removal from the government program." *Ibid.* In contrast, conditions of payment "are those which, if the government knew they were not being followed, might cause it to actually refuse payment." *Ibid.* Only violations of conditions of *payment* can give rise to FCA liability because "[i]f 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 FCA." *Id.* at 1219–20.

[3] More specifically, "legally false certification claims can rest [on] one of two theories—express false certification, and implied false certification. An express false certification theory applies when a government payee falsely certifies compliance with a particular statute, regulation or contractual term, where compliance is a prerequisite to payment." *Conner*, 543 F.3d at 1217 (internal quotation marks and citation omitted). "Under an implied false certification theory, by contrast, courts do not look to the contractor'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." *Id.* at 1218.

Applying this distinction, *Conner* held that the relator had alleged violations of conditions of participation, but not of payment, and therefore did not state an FCA claim. The court reviewed the Medicare regulations at issue, and found significant that "[e]ven if . . . a provider appears noncompliant, the government does not immediately suspend Medicare enrollment or billing privileges." *Id.* at 1220. Instead, the regulations give the provider a chance to cure the deficiency. *Id.* at 1220–21. If the provider does not achieve substantial compliance, then the government may (but not must) terminate the provider's Medicare participation. *Ibid.* "And even in those cases," there was no indication that the government "normally seeks retroactive recovery of Medicare payments for services actually performed on the basis that the noncompliance rendered them fraudulent." *Id.* at 1221. The court therefore concluded: "Based on the fact that the government has established a detailed administrative mechanism for managing Medicare participation, we are compelled to conclude that although the government considers substantial compliance a condition of ongoing Medicare *participation*, it does not require perfect compliance as an absolute condition to receiving Medicare *payments* for services rendered." *Id.* at 1221 (emphasis in original).

In contrast to the regulations in *Conner*, regulations that are conditions of *payment* make clear that compliance is a prerequisite to payment. The Second Circuit's decision in *United States ex rel. Mikes v. Straus*, 274 F.3d 687 (2001)—on which *Conner* relied, see 543 F.3d at 1220—is illustrative. The relator claimed that the defendant violated the FCA by seeking Medicare reimbursement for medical tests that were not performed in accordance with guidelines. 274 F.3d at 694–95. According to the relator, this violated two Medicare statutes. The Second Circuit agreed that violation of the first statute (42 U.S.C. § 1395y(a)(1)(A)) stated

an FCA claim because the statute was a condition of payment: "Because this section contains an express condition of payment—that is, 'no payment may be made'—it explicitly links each Medicare *payment* to the requirement that the particular item or service be 'reasonable and necessary.'" 274 F.3d at 700 (emphasis in original). But *Mikes* rejected relator's argument that the second statute (42 U.S.C. § 1320c-5(a)), which imposed quality-of-care standards on defendant, was a condition of payment. Like *Conner*, the Second Circuit reasoned that noncompliance with this statute did not automatically lead to suspension of payments; instead, a noncompliant provider would be given notice and an opportunity to fix the problems, and the government ultimately had discretion whether to exclude the provider from the Medicare program. 274 F.3d at 701–02. See also, *e.g.*, *United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 307–14 (3d Cir. 2011) (relying on *Conner* to conclude that Medicare marketing regulations were conditions of participation, while the federal Anti-Kickback Statute was a condition of payment).[4]

2. The CLIA regulations that Mimbres allegedly violated are materially indistinct from the regulatory schemes that *Conner*, *Mikes*, and the other cited cases held were conditions

[4] Courts routinely reject FCA claims premised on noncompliance with regulations that are not conditions of payment—a rule "adopted by all courts of appeals to have addressed the matter." *United States ex rel. Siewick v. Jamieson Science and Engineering, Inc.*, 214 F.3d 1372, 1376 (D.C. Cir. 2000). See, *e.g.*, *United States ex rel. Hobbs v. MedQuest Assocs., Inc.*, 711 F.3d 707, 713–19 (6th Cir. 2013); *United States ex rel. Williams v. Renal Care Group, Inc.*, 696 F.3d 518, 531–32 (6th Cir. 2012); *Wilkins*, 659 F.3d at 307–11; *United States ex rel. Vigil v. Nelnet, Inc.*, 639 F.3d 791, 799–800 (8th Cir. 2011); *United States ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262, 268–70 (5th Cir. 2010); *United States ex rel. Gross v. AIDS Research Alliance-Chicago*, 415 F.3d 601, 604–05 (7th Cir. 2005); *Mikes*, 274 F.3d at 701–02; *Siewick*, 214 F.3d at 1376; *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1267 (9th Cir. 1996); *Maa v. Ostroff*, No. 12-cv-200, 2013 WL 1703377, at *17–*19 (N.D. Cal. Apr. 19, 2013); *Foglia v. Renal Ventures Mgmt., LLC*, 830 F. Supp. 2d 8, 19–20 (D.N.J. 2011).

of participation, and not of payment. Therefore, even if the Hospital did not comply with the regulations (which we assume solely for purposes of this motion), that noncompliance would not give rise to FCA liability as a matter of law.

Like the regulations in *Conner* and *Mikes*, the CLIA regulations set forth a "detailed administrative mechanism for managing Medicare participation." *Conner*, 543 F.3d at 1221. See 42 C.F.R. Part 493, Subparts Q (Inspection) and R (Enforcement Procedures); *id.* § 493.1800(a)(2)(iii) (CLIA "[g]rants the Secretary broad enforcement authority"). Under the CLIA administrative enforcement process, CMS or accreditation agencies like the Joint Commission are charged with certifying laboratories, inspecting them for compliance with CLIA, and investigating alleged CLIA violations. 42 C.F.R. § 493.1773. If a deficiency exists but is below the "condition" level,[5] then CMS merely requires the laboratory to submit an acceptable plan of correction. *Id.* § 493.1816. If there is a condition-level deficiency, then CMS may choose from a range of sanctions, including directing the laboratory to take corrective action, requiring on-site government monitoring, imposing a civil monetary penalty of up to $10,000 *per day* of noncompliance, and—the most severe civil sanction—suspending, limiting, or revoking a laboratory's CLIA certificate. *Id.* §§ 493.1806, 493.1834(d)(2). In addition, intentional violations of CLIA requirements are subject to criminal punishment of imprisonment and fine. *Id.* § 493.1806(e). The CLIA regulations afford CMS much discretion to choose a sanction that is appropriate in the circumstances, including the severity of the violation and the

[5] "Condition level requirements" are general requirements laboratories must meet under CLIA. See 42 C.F.R. § 493.2; Compl. ¶ 32 & n.1. Condition level requirements are further subdivided into "standards," which supply more specificity and detail to the "conditions."

laboratory's history of CLIA compliance. *Id.* § 493.1804(d) (listing factors CMS considers in choosing a sanction).

Suspending or cancelling a laboratory's Medicare billing privileges is just one potential sanction that CMS may (or may not) impose in its discretion. *Id.* § 493.1807. Before doing so, CMS must give the laboratory notice and an opportunity to respond. *Id.* §§ 493.1810(a)–(b), 493.1826(b), 493.1828(b), 493.1842(b). If CMS is not persuaded by the response, it must give the laboratory additional notice that it is imposing the sanction, the rationale for the sanction, and the sanction's effective date. *Id.* §§ 493.1810(c), 493.1844(g); *Oakland Med. Grp., P.C. v. Sec'y of Health & Human Servs., Health Care Fin. Admin.*, 298 F.3d 507, 509 (6th Cir. 2002). Significantly, the effective date must be at least five days *after* the notice of the sanction's imposition (and at least 15 days if the CLIA deficiency does not pose immediate jeopardy). 42 C.F.R. §§ 493.1810(c)(2), 493.1844(h)(2). In other words, the sanction operates prospectively only; between the date of the CLIA violation and the effective date of the sanction, a laboratory may continue seeking and receiving Medicare reimbursement.

Also significantly, no CLIA regulation authorizes CMS to cancel a laboratory's billing privileges retroactively or to order the laboratory to disgorge Medicare payments it received for noncompliant testing. See generally 42 C.F.R. Part 493; 57 Fed. Reg. 7218, 7221 (Feb. 28, 1992) ("Cancellation of a laboratory's Medicare approval means that Medicare payment for the laboratory's services will not be made *after the effective date of cancellation* and the laboratory's Medicare participation has, therefore, been canceled." (emphasis added)); *Lyle Griffith, M.D. Laboratory v. CMS*, Decision No. CR1496, No. C-05-145, at §§ I, IV (HHS Dept'l Appeals Bd. Aug. 31, 2006) (sustaining CMS's decision to cancel laboratory's approval to receive Medicare

payments for services performed on or after January 6, 2005, based on CLIA violations occurring from 2002–04).[6]

Here, Hansen acknowledges that Mimbres's laboratory possesses a CLIA certificate to perform all of the testing at issue in this case. Compl. ¶ 29. And Hansen does not allege that the laboratory's Medicare billing privileges have ever been suspended, cancelled, or limited in any way.

Furthermore, and removing any doubt, the Medicare regulations explicitly state that compliance with CLIA is a condition of participation, and not of payment. Medicare conditions of participation are set forth in 42 C.F.R. Part 482, entitled "Conditions of Participation for Hospitals." This section specifically provides that compliance with CLIA is a condition of participation. See 42 C.F.R. § 482.27(a) (requiring, as a condition of participation in Medicare, that laboratory services be provided by "a certified laboratory that meets requirements of part 493 of this chapter [*i.e.*, the CLIA regulations]"). Significantly, violation of a condition of participation is *not* a basis to withhold Medicare payment. See Medicare Program Integrity Manual, No. 100-08, at § 3.1(A) (June 28, 2011), available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c03.pdf ("[Contractors] shall not expend Medicare Integrity Program . . . resources analyzing provider compliance with Medicare rules that do not affect Medicare payment. Examples of such rules include violations of conditions of participation . . . ."); *ibid.* ("If during a review, any contractor believes that a provider does not comply with conditions of participation, the reviewer shall not deny payment solely for this

[6] Copies of administrative decisions are included in the Appendix for the convenience of the Court. They are also available online at http://www.hhs.gov/dab/search.html.

reason."); *id.* § 3.3.2.4 ("NOTE**:** Conditions of participation (COP) are not conditions of payment."); see also *United States ex rel. Wall v. Vista Hospice Care, Inc.*, 778 F. Supp. 2d 709, 720–21 (N.D. Tex. 2011) (relying on Medicare Program Integrity Manual to conclude that defendant's alleged violation of Medicare regulations was a condition of participation, and therefore dismissing FCA claim under Rule 12(b)(6)).

In contrast, Medicare conditions of payment are codified in an entirely different part. See 42 C.F.R. Part 424 (entitled "Conditions for Medicare Payment"). This Part imposes on hospitals numerous requirements that, if not met, will cause Medicare payment to be denied to the hospital. See, *e.g.*, 42 C.F.R. § 424.5(a) (enumerating conditions that "must be met" "[a]s a basis for Medicare payment"); *id.* § 424.5(b) (identifying additional conditions). Not surprisingly, Part 424 makes no mention of CLIA regulations.

The CLIA statute and regulations thus bear all the features that *Conner* and other courts identified as hallmarks of conditions of participation:

- They are enforced through "a detailed administrative mechanism." *Conner*, 543 F.3d at 1221. See also, *e.g.*, *Wilkins*, 659 F.3d at 310; *Mikes*, 274 F.3d at 701–02.

- Where a violation exists, the "government does not immediately suspend Medicare enrollment or billing privileges," but rather does so only in its discretion and based on a laboratory's substantial noncompliance. *Conner*, 543 F.3d at 1220–21. See also, *e.g.*, *Wilkins*, 659 F.3d at 309–10; *Steury*, 625 F.3d at 269–70; *Mikes*, 274 F.3d at 701–02.

- "And even in those cases," the government does not "normally see[k] retroactive recovery of Medicare payments for services actually performed on the basis that the noncompliance rendered them fraudulent" (*Conner*, 543 F.3d at 1221)—a statement that applies even more strongly here because *no* CLIA regulation authorizes the government to cancel Medicare billing privileges retroactively. See also *Wilkins*, 659 F.3d at 310; *United States ex rel. Willard v. Humana Health Plan of Tex. Inc.*, 336 F.3d 375, 382–83 (5th Cir. 2003).

And, the Medicare regulations expressly define compliance with CLIA as a condition for participating in the Medicare program, but not a condition for receiving any particular Medicare payment. Accordingly, under Tenth Circuit precedent, Hansen's claim fails as a matter of law.

3. The Tenth Circuit and other courts have emphasized the important policy reasons for respecting the difference between a condition of participation and a condition of payment. Failing to do so would turn every violation of a government regulation into a full blown FCA suit subject to that statute's draconian penalties. The FCA, however, "'was not designed for use as a blunt instrument to enforce compliance with all medical regulations.'" *Wilkins*, 659 F.3d at 307 (quoting *Mikes*, 274 F.3d at 699); see also *Hobbs*, 711 F.3d at 717 (same); *Williams*, 696 F.3d at 532 (same); *Hopper*, 91 F.3d at 1266 (same).

To expand the FCA to cover all medical regulations would not only distort the statute beyond its intended purpose, but would greatly interfere with agencies' ability to enforce the administrative schemes entrusted to them. As *Conner* cautioned, such a view of the FCA would allow "[a]n individual private litigant, ostensibly acting on behalf of the United States, [to] prevent the government from proceeding deliberately through the carefully crafted remedial process and could demand damages far in excess of the entire value of Medicare services performed by a hospital." 543 F.3d at 1221. "If successful," the Tenth Circuit explained, "the consequences of such an action would likely be catastrophic for hospitals that provide medical services to the financially disadvantaged and the elderly." *Ibid.* Moreover, "rather than relying on the experience of state agencies to survey compliance, such a broad reading of the FCA . . . would burden the federal courts with deciding whether medical services were performed in full

compliance with a host of Medicare statutes and regulations." *Ibid.* See also, *e.g.*, *Wilkins*, 659 F.3d at 310–11 (same); *Mikes*, 274 F.3d at 700 (same).

This lawsuit exemplifies the concerns of *Conner* and other courts. The CLIA regulations, spanning more than 100 single spaced pages, are a model of intricate federal regulations subject to "a complex monitoring and remedial scheme that ends Medicare payments only as a last resort." *Conner*, 543 F.3d at 1222; see generally 42 C.F.R. Part 493. The regulations specify sanctions that CMS may impose for each of the CLIA deficiencies Hansen alleges. See 42 C.F.R. §§ 493.1806, 493.1807, 493.1840. If CMS, in its expert judgment and based on its extensive experience administering CLIA, believes Mimbres was somehow deficient, then CMS can bring an enforcement action and, in its discretion, impose a sanction commensurate to the violation, which may or may not include limiting *future* Medicare billing privileges.

By seeking to enforce the regulations through this FCA lawsuit, however, Hansen asks the Court to make the same determinations about compliance that CMS would make. And if Mimbres were found noncompliant, then Hansen would require that the Court impose the FCA's punitive remedy of penalties and treble damages, even if that sanction is entirely disproportionate to the Medicare funds paid to the Hospital, and even if CMS (or the Court, for that matter) were to agree the remedy is inappropriate under the circumstances and would unfairly injure the Hospital's patients. For example, Hansen alleges a host of paperwork errors unrelated to the laboratory tests actually performed, such as inadequate procedure manuals (Compl. ¶ 56) and insufficient documentation of lab personnel qualifications (*id.* ¶ 59). Yet Hansen asserts Mimbres billed Medicare in violation of the FCA more than *ten thousand* times between 2008 and 2011, and asks the Court to award penalties of $11,000 for *each violation, in addition to*

treble the total amount of reimbursements Mimbres received. *Id.* at p. 49 ¶ A (Count I). Just as in *Conner*, permitting this lawsuit to go forward—where the alleged CLIA violations are not conditions of payment, where CMS has not limited Mimbres's Medicare billing privileges in any way, and where both the United States and the State of New Mexico have twice declined to intervene in Hansen's lawsuit—would make "a statute intended to protect the government's fiscal interests . . . undermine the government's own regulatory procedures." 543 F.3d at 1222.

4. Hansen does not seriously deny that the CLIA regulations are conditions of participation, and not of payment. She alleges in passing that "lab services that are performed in violation of CLIA are ineligible for reimbursement." Compl. ¶ 12; see also *id.* ¶ 177 (same). But tellingly, she cites no authority whatsoever—statute, regulation, treatise, administrative decision, agency manual or policy statement, *anything*—in support of that legal conclusion, which is both wrong and not entitled to deference. See *Phillips v. Bell*, 365 F. App'x 133, 139 (10th Cir. 2010) (unpublished) (courts may reject "legal conclusion[s] couched as a factual allegation" when deciding a motion to dismiss (internal quotation marks omitted)); *Foglia*, 830 F. Supp. 2d at 19–20 (dismissing complaint where "Relator asserts in merely conclusory fashion that compliance with these licensing regulations is a condition of payment by the federal government. The amended complaint is devoid of reference to any rule, regulation, or other source that would provide factual support for Relator's assertion.").[7]

[7] Hansen's bald assertion that a laboratory may not seek Medicare reimbursement unless it is in perfect compliance with CLIA is not just wrong as a matter of law, but is contrary to common sense. According to her view, if a laboratory fails to comply with even one of CLIA's hundreds of requirements, then the laboratory would have no right—indeed, would violate not just CLIA *but the FCA*—if it sought Medicare reimbursement for services actually performed. Hansen's failure to provide any support for that extreme proposition is particularly inexcusable in light of

Instead, the First Amended Complaint resorts to two other bases of liability, both of which fail. First, Hansen quotes several certifications that Mimbres allegedly made to the federal and state governments when applying for Medicare and Medicaid and when seeking reimbursements thereunder. Compl. ¶¶ 44–46, 48. But these certifications cannot sustain an FCA claim because the CLIA regulations are only conditions of participation. See *Conner*, 543 F.3d at 1217–18. Further and independently, none of the certifications mentions CLIA at all; instead, their catch-all language refers broadly to "all Medicare regulations, program instructions and Title XVIII of the Social Security Act" (Compl. ¶ 44) or, even more broadly, to "all federal, state, and local laws, rules and regulations" period (*id.* ¶ 46). *Conner* rejected a similar certification because "it contains only general sweeping language and does not contain language stating that payment is conditioned on perfect compliance with any particular law or regulation." 543 F.3d at 1219.[8]

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the fact that Mimbres, in its motion to dismiss Hansen's original Complaint, explained at length (as we do above) why the proposition is false. See ECF No. 45 at 9–15. Indeed, Hansen's failure to muster supporting authority speaks volumes when viewed against the balance of the First Amended Complaint, which is replete with citations to CLIA regulations.

[8] Hansen's attempt to rely on this initial general certification by Mimbres fails for a multitude of other reasons. The "falsity of a claim is determined at the time of submission," and Hansen does not allege that Mimbres "intended to violate Medicare regulations at the time it applied." *Hobbs*, 711 F.3d at 714–15 (rejecting FCA claim premised on Medicare enrollment certification); see also *Hopper*, 91 F.3d at 1267; *Wall*, 778 F. Supp. 2d at 721. For that matter, Hansen does not allege the date (or even the year) the certification was made, nor any other details about it. Hansen thus fails to satisfy Rule 9(b)'s requirement of pleading fraud with particularity, in addition to failing to state a claim under Rule 12(b)(6). See *Sikkenga*, 472 F.3d at 726–27 (Rule 9(b) applies to FCA suits and requires relators to "set forth the 'who, what, when, where and how' of the alleged fraud" (some internal quotation marks omitted)); *United States ex rel. Lacy v. New Horizons, Inc.*, 348 F. App'x 421, 425 (10th Cir. 2009) (unpublished).

Second, Hansen contends that if Mimbres had disclosed the alleged CLIA violations to the Joint Commission during and between its biannual inspections of the laboratory in 2009 and 2011, then the Joint Commission would have denied re-certification to the laboratory. Compl. ¶¶ 179–80. Without CLIA certification, Hansen alleges, the Hospital would not have received Medicare payments. *Ibid.*; see also *id.* ¶ 27. This theory is just an attempt to plead around the fact that the CLIA regulations are not conditions of payment. And not surprisingly, the theory fails in the face of the regulations' plain text. CMS has expressly accounted for the scenario where it finds that a laboratory's owner or employee has "[b]een guilty of misrepresentation in obtaining a CLIA certificate," "[f]ailed to comply with the certificate requirements and performance standards," or "[v]iolated or aided and abetted in the violation of any provisions of CLIA and its implementing regulations." 42 C.F.R. § 493.1840(a)(1), (3), and (6); see also Compl. ¶ 33 (acknowledging these provisions). Then, CMS may limit the laboratory's Medicare billing privileges, but as always may do so only prospectively. See 42 C.F.R. §§ 493.1808, 493.1840(d)–(e), 493.1844(g)–(h).[9] Thus, even if CMS were to have found that Mimbres violated any of the above regulations (which Hansen does not allege), and even if CMS were to have decided to restrict the laboratory's billing privileges prospectively (which Hansen does not allege), then Mimbres *still* would have been perfectly entitled to retain Medicare reimbursements it had already received. Thus, those reimbursements are not false or fraudulent under the FCA.

[9] See also, *e.g.*, *Cervera v. CMS*, Decision No. CR939, No. C-99-797, at §§ I, IV.D (HHS Dept'l Appeals Bd. Aug. 1, 2002) (sustaining CMS's decision to cancel laboratory's approval to receive Medicare payments after August 1999 for misrepresentations made in CLIA application in January 1999).

Hansen's allegations are similar to those the Ninth Circuit rejected in *Hopper*. There, the relator alleged the defendant school district had falsely certified that it would abide by the Individuals with Disabilities Education Act. 91 F.3d at 1263. She claimed that the school district subsequently violated the statute, and therefore that all claims the school district had submitted for special education funding were false. *Id.* at 1265. The Ninth Circuit rejected the argument, reasoning that "[m]ere regulatory violations do not give rise to a viable FCA action" where there were "administrative and other remedies" for such violations and where certification was not a condition of payment. *Id.* at 1267. See also *Conner*, 543 F.3d at 1221–22 (discussing *Hopper* approvingly). Hansen's allegations fail for the same reasons.

5. Finally, Hansen alleges without elaboration that Mimbres submitted a reverse false claim in violation of 31 U.S.C. § 3729(a)(1)(G). Compl. ¶ 185. That allegation fails for the reasons above, and also because Hansen does not allege the basic predicate of a reverse false claim, that the Hospital owed any "obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(1)(G). See also *United States ex rel. Bahrani v. Conagra, Inc.*, 465 F.3d 1189, 1195–97 (10th Cir. 2006). Further, the allegation contains no detail whatsoever, and thus does not satisfy the basic pleading requirements of Rule 8(a), much less the heightened ones of Rule 9(b).

For all these reasons, Count I does not satisfy Rule 12(b)(6) and should be dismissed.[10]

[10] In an apparent effort to tarnish Mimbres's name, Hansen repeatedly suggests that the conduct of the laboratory injured the Hospital's patients. *E.g.*, Compl. ¶¶ 9 (Hospital "ignored the risks to patient health and safety"), 11 ("Defendants have placed, and continue to place, patients at great risk"), 12 (Hospital's conduct "threaten[ed] patient safety"). Yet Hansen does not identify a single such patient or provide any evidence that such injury actually occurred, much less explain how these allegations are at all relevant to an FCA case. Indeed, Hansen's irresponsible

II. Count III Does Not Satisfy Rule 12(b)(6) Because Hansen Does Not Allege She Engaged In Protected Activity Or That Mimbres Had Notice Of Such Activity

Count III alleges that Mimbres retaliated against Hansen in violation of the FCA, 31 U.S.C. § 3730(h), but fails to plead necessary elements of that claim. To state a retaliation claim, "a plaintiff must show that 1) the employee's conduct was protected under the FCA; 2) the employer knew that the employee was engaged in such conduct; and 3) the employer discharged or discriminated against the employee because of his or her protected conduct." *United States ex rel. Bespalko v. Sandia Corp.*, No. 99cv1466 WJ/RLP, slip op. at 3 (D.N.M. June 17, 2005). Here, Hansen does not allege she was engaged in protected activity or that Mimbres had notice of any such conduct.

The only conduct Hansen identifies as the basis for her retaliation claim is that she investigated supposed CLIA violations. Compl. ¶¶ 161–76. But the case law is clear that protected activity does not encompass '"an employee's investigation of nothing more than his employer's non-compliance with federal or state regulations.'" *Hutchins v. Wilentz, Goldman & Spitzer*, 253 F.3d 176, 187–88 (3d Cir. 2001) (quoting *United States ex rel. Yesudian v. Howard Univ.*, 153 F.3d 731, 740 (D.C. Cir. 1998)). Instead, to amount to protected activity, the employee's investigation must be tied in some way to "trying to recover money for the government"—*i.e.*, to "investigating fraud." *Hopper*, 91 F.3d at 1269. This limitation on the scope of protected activity is just a corollary to the "well-established principle that the FCA is

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statements illustrate why courts require relators to comply with the strictures of Rule 9(b): To "protect[t] defendants from harm to their goodwill and reputation." *United States ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 921 (4th Cir. 2003); see also *S2 Automation LLC v. Micron Tech., Inc.*, 281 F.R.D. 487, 494 (D.N.M. 2012) (same). That Hansen is evidently upset with Mimbres, which no longer employs her, is no excuse to make wild, unsubstantiated allegations and try to stoke concern in the community the Hospital serves.

not a vehicle for regulatory compliance." *Luckey v. Baxter Healthcare Corp.*, 2 F. Supp. 2d 1034, 1045 (N.D. Ill. 1998), aff'd, 183 F.3d 730 (7th Cir. 1999).

Applying these principles, the First Circuit dismissed a retaliation claim much like Hansen's. *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220 (1st Cir. 2004), abrogated on other grounds by *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662 (2008). There, as here, the relator worked in a hospital and claimed he was retaliated against after reporting to his superiors violations of Medicare and Medicaid regulations. 360 F.3d at 237. The First Circuit held these allegations did not state a claim because "such activities [did not] constitute protected activity." *Ibid.* "[Relator's] statement that he reported his supervisors' destruction of incident reports of medical errors suggests a cover-up of regulatory failures but does not allege investigation or reporting of false or fraudulent claims knowingly submitted to the government." *Ibid.* The same was true of relator's reporting "the hospital's alleged failure to comply with patient care standards." *Ibid.* "Although '[c]orrecting regulatory problems may be a laudable goal,' it is 'not actionable under the FCA in the absence of actual fraudulent conduct."' *Ibid.* (quoting *Hopper*, 91 F.3d at 1269). See also, *e.g.*, *Hopper*, 91 F.3d at 1269 (relator not engaged in protected activity despite her "numerous written complaints, seventy letters and over fifty telephone calls," because she "was merely attempting to get the School District to comply with Federal and State regulations," and not "trying to recover money for the government").

Here, as in *Karvelas*, Hansen's retaliation claim is based only on her investigation of Mimbres's compliance with CLIA. Hansen "raised concerns about CLIA violations promptly and repeatedly to Mimbres management"; "told Gramer [the Human Resources Director] about

the violations [Hansen] had found"; "wrote a letter to William Quitmeyer [Mimbres' Chief Executive Officer] . . . cit[ing] the inadequate Procedures Manual and lack of quality control testing"; and "contacted the New Mexico Department of Health about testing procedures that were not being done properly." Compl. ¶¶ 161–63, 165, 169. These actions surface possible regulatory compliance issues; none links such compliance to improper billing of the government (or to any billing), to allegations of fraud, or to initiating litigation, much less an FCA suit. As in *Karvelas*, Hansen's "conduct, without more, does not constitute protected conduct under the FCA." 360 F.3d at 237. See also, *e.g.*, *Campion v. Northeast Utilities*, 598 F. Supp. 2d 638, 657 (M.D. Pa. 2009).[11]

Because Hansen does not allege she engaged in protected activity, necessarily she fails to allege Mimbres had notice of that activity. See *Karvelas*, 360 F.3d at 238 ("[T]he kind of knowledge the defendant must have mirrors the kind of activity in which the plaintiff must be engaged." (internal quotation marks omitted)). All Hansen alleges is that she told her superiors she thought the Hospital was not complying with CLIA. Hansen does not allege she ever mentioned billing or the FCA (or a lawsuit of any kind), or that she gave Mimbres reason to

[11] Even if Hansen had alleged she investigated improper billing, she still would not have engaged in protected activity. Because the CLIA regulations are conditions of participation only, her investigation had no "distinct possibility" of leading to a viable FCA action. *Glynn v. EDO Corp.*, 710 F.3d 209, 216–18 (4th Cir. 2013) (investigating false certification of compliance with government contracts, where certification is not material to government's payment decisions, is not protected activity).

think she was investigating fraud and was not simply reporting alleged CLIA noncompliance. Count III therefore fails as a matter of law.[12]

III. Counts II And IV Fail For The Same Reasons Under State Law

Counts II and IV raise state law claims under the New Mexico Medicaid False Claims Act ("NMFCA"), N.M.S.A. §§ 27–14–1 *et seq.*, and the Fraud Against Taxpayers Act ("FATA"), N.M.S.A. §§ 44–9–1 *et seq.* They arise from the same conduct and factual allegations as do the federal claims in Counts I and III, respectively. Because the NMFCA and FATA parallel the federal FCA, Counts II and IV should be dismissed for the same reasons Counts I and III should be dismissed. See *New York v. Amgen Inc.*, 652 F.3d 103, 109 (1st Cir. 2011) (the NMFCA "may be construed consistently with the federal [FCA]"); *Hill v. Vanderbilt Capital Advisors, LLC*, 834 F. Supp. 2d 1228, 1262 (D.N.M. 2011) (stating that "[t]he FATA is analogous to the [federal FCA]" and construing the FATA by reference to FCA cases); see also *United States ex rel. Conrad v. GRIFOLS Biologicals Inc.*, No. RDB 07-3176, 2010 WL 2733321, at *6 (D. Md. July 9, 2010).

In addition, Hansen fails to plead that the New Mexico Department of Human Services has issued a written determination that there is substantial evidence that a violation occurred. Absent that written determination, the NMFCA requires that Hansen's state law claim be

[12] See, *e.g.*, *Robbins v. Provena Hosps., Inc.*, No. 03 C 1371, 2003 WL 21468588, at *4 (N.D. Ill. June 24, 2003); *Campion*, 598 F. Supp. 2d at 657–58; *United States ex rel. Wildhirt v. AARS Forever, Inc.*, No. 09 C 1215, 2011 WL 1303390, at *1, *6 (N.D. Ill. Apr. 6, 2011); *United States ex rel. Kennedy v. Aventis Pharm., Inc.*, No. 03 C 2750, 2008 WL 4371323, at *1–*3 (N.D. Ill. Feb. 11, 2008); see also *Lacy*, 348 F. App'x at 429 (dismissing FCA retaliation claim); *Sikkenga*, 472 F.3d at 728–29 (same); *United States ex rel. Ramseyer v. Century Healthcare Corp.*, 90 F.3d 1514, 1522–23 (10th Cir. 1996) (same).

dismissed. See N.M. Stat. § 27–14–7(C), (E)(2); *United States ex rel. Streck v. Allergan, Inc.*, 894 F. Supp. 2d 584, 603–04 (E.D. Pa. 2012).

CONCLUSION

For all these reasons, the Court should dismiss the First Amended Complaint with prejudice.

Respectfully submitted,

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Dated: June 12, 2013

APPENDIX

CASE | DECISION | JUDGE | FOOTNOTES

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division

IN THE CASE OF

SUBJECT:

Carlos A. Cervera, M.D.,

Petitioner,

- v -

Centers for Medicare & Medicaid Services

DATE: August 1, 2002

Docket No.C-99-797
Decision No. CR939

DECISION ...TO TOP

DECISION

I sustain the determination of the Centers for Medicare & Medicaid Services (CMS) to prohibit Carlos A. Cervera, M.D. (Petitioner) from owning or operating a laboratory for at least two years. I find that Petitioner was a "laboratory director" of the San Fernando Diagnostic Laboratory, Inc. (San Fernando), whose Clinical Laboratory Improvement Amendments of 1988 (CLIA) certificate was revoked. CMS is therefore authorized to prohibit Petitioner's ownership or directorship of any CLIA laboratory for a period of two years from the issuance date of this decision.

I. Background

This case emanates from sanction determinations that CMS (formerly known as the Health Care Financing Administration or "HCFA") made against San Fernando. The sanctions that CMS imposed against San Fernando include revocation of San Fernando's CLIA certificate. San Fernando has not requested a hearing to contest those sanctions. Petitioner requested a hearing in order to challenge CMS's determination that, as a consequence of being San Fernando's laboratory director, he was precluded from owning, operating, or directing a clinical laboratory for at least two years.

San Fernando was a clinical laboratory seeking certification to perform clinical

testing under CLIA. On January 8, 1999, San Fernando filed with the Laboratory Field Services, State of California Department of Health Services (LFS): 1) an application for a clinical laboratory license; 2) a laboratory testing declaration; 3) a laboratory personnel report form; and 4) a clinical laboratory application (CLIA application). HCFA Exs. 1, 2, 3, 4. The Application for Clinical Laboratory License and Laboratory Testing Declaration (HCFA Exs. 1, 2) were signed by Petitioner as "Laboratory Director." Furthermore, the Laboratory Personnel Report Form and the Clinical Laboratory Application both list Petitioner as San Fernando's "laboratory directory." HCFA Exs. 3, 4. San Fernando's CLIA application was approved and became effective as of April 23, 1999. The CLIA certificate was issued to Petitioner on May 18, 1999. HCFA Ex. 13; Hearing Transcript (Tr.) at 56-57.

In the latter part of May 1999, upon review of Petitioner's State license and CLIA applications by LFS, CMS was informed of a discrepancy between the total annual test volume in San Fernando's State licensing application and that provided in the CLIA application. *Id.*, at 52-53. By letter dated June 17, 1999, CMS advised Petitioner of inconsistencies. Specifically, Petitioner was advised that the CLIA application contained the testing volume total (45,000) which was lower than the State application total (485,000), and that it was the lower estimation which established the fee assessment amount to be charged and paid by San Fernando. CMS informed Petitioner that sanctions would be imposed, which included revocation of San Fernando's CLIA certificate for one year, cancellation of San Fernando's approval to receive Medicare and Medicaid payments, and prohibition of the owner and operator (laboratory director) from owning, operating, or directing a laboratory for at least two years from the date of revocation. HCFA Ex. 5.

Petitioner requested a hearing to contest CMS's findings and remedy determinations. This matter was assigned to me for a hearing and decision. I held an in-person hearing in Los Angeles, California on August 28, 2000. The parties each called witnesses to testify. CMS offered, and I accepted, into evidence exhibits identified as HCFA Exhibits (HCFA Exs.) 1-13.[(1)] Petitioner offered, and I accepted, into evidence exhibits identified as Petitioner's Exhibits (P. Exs.) 1-15.

II. Applicable Law

CLIA establishes requirements for all laboratories that perform clinical diagnostic tests on human specimens and provides for federal certification of such laboratories. Pub. L. No. 100-578, amending Section 353 of the Public Health Service Act, codified at 42 U.S.C. § 263a et seq. The purpose of CLIA is to ensure the accuracy and reliability of laboratory tests, and hence the

public health of all Americans. *See* H.R. Rep. No. 899, 100th Cong. 2d Sess. 8, 18 (1988), reprinted in 1988 U.S.C.C.A.N. 3828, 3839. CMS certification of a laboratory under CLIA is dependent upon whether the laboratory meets the conditions for certification set out in the statute and regulations. 42 U.S.C. § 263a(f)(1)(E); 42 C.F.R. § 493.1 et seq. Pursuant to CLIA, the Secretary of Health and Human Services (Secretary) has broad enforcement authority, including the ability to suspend, limit, or revoke the certificate of a laboratory that is out of compliance with one or more requirements for certification.

The Secretary has exercised his authority under 42 U.S.C. § 263a(f) and issued regulations implementing CLIA. *See* 42 C.F.R. Part 493. The regulations specify standards and the specific conditions of certification that a laboratory must meet to achieve compliance. The regulations confer broad authority on CMS to ensure that laboratories perform as Congress intended, including authority to inspect and sanction laboratories that fail to comply with the regulatory requirements. CMS has the delegated authority to suspend, limit, or revoke the CLIA certificate of a laboratory that is out of compliance with one or more CLIA conditions, and may also impose alternative sanctions such as a directed plan of correction or monitoring by the state. 42 C.F.R. § 493.1806.

CLIA provides the following with respect to the owners and operators of non-compliant laboratories in addition to sanctions which may be imposed directly against a laboratory:

> (3) Ineligibility to own or operate laboratories after revocation.
>
> No person who has owned or operated a laboratory which has had its certificate revoked may, within 2 years of the revocation of the certificate, own or operate a laboratory for which a certificate has been issued under this section.

42 U.S.C. § 263a(i)(3). The Secretary's regulations specify that a "laboratory director" is considered an "operator" of a laboratory:

> Operator means the individual or group of individuals who oversee all facets of the operation of a laboratory and who bear primary responsibility for the safety and reliability of the results of all specimen testing performed in that laboratory. The term includes-(1) A director of the laboratory if he or she meets the stated criteria . .

42 C.F.R. § 493.2.

The regulations also require that any laboratory conducting moderate or high complexity testing have a laboratory director who meets specific qualifications and has clear and specific responsibilities. 42 C.F.R. §§ 1403, 1405, 1407. The

regulations specify that:

> The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate [sic], and proficiently and for assuring compliance with the applicable regulations.

42 C.F.R. § 493.1407.

The applicable law and regulations provide that adverse actions may be taken against a laboratory's owner, operator, or one of its employees where such individual is guilty of misrepresentations in obtaining a CLIA certificate. *See* 42 U.S.C. § 263a(i)(1); 42 C.F.R. § 493.1840(a)(1). Such adverse actions include suspension, limitation, or revocation of the party's CLIA certificate. *Id*.

Any laboratory that has, as its owner or operator (which includes laboratory director), an individual who owned or operated a laboratory that had its CLIA certificate revoked within the previous two years is subject to adverse action, including suspension and/or revocation pursuant to 42 C.F.R. § 493.1840(a)(8).

CLIA further provides, at 42 U.S.C. § 263a(i)(1), that a laboratory's certificate may be suspended, revoked, or limited only after reasonable notice and opportunity for hearing to "the owner or operator of the laboratory . . ." The Secretary's regulations provide that a laboratory or prospective laboratory dissatisfied with an initial determination, as delineated at 42 C.F.R. § 493.1844(b), is entitled to a hearing before an administrative law judge (ALJ). 42 C.F.R. § 493.1844(a). The hearing procedures found in subpart D of Part 498 are incorporated by reference. 42 C.F.R. § 493.1844. The "suspension, limitation or revocation of the laboratory's CLIA certificate . . . because of noncompliance . . . ." is the first listed initial determination subject to hearing before an ALJ. 42 C.F.R. § 493.1844(b)(1).

Where a party requests a hearing, before an ALJ, of CMS's initial determination, the two-year prohibition will not commence until the issuance of a decision by the ALJ. 42 C.F.R. § 493.1844(d)(2) (. . . suspension, limitation, or revocation of a CLIA certificate is not effective until after a hearing decision by an ALJ is issued.).

III. Issues

The threshold issue in this matter is whether Petitioner has an appeal right as to CMS's actions. Prior Departmental Appeals Board (DAB) case law has determined that laboratory directors in such cases as this one do have a right to appeal. *See RNA Laboratories, Inc., and Ter-Zakarian Medical Clinic*, DAB

CR829 (2001); *Eugene R. Pocock, M.D.*, DAB CR527 (1998); *Sentinal Medical Laboratories, Inc.*, DAB No. 1762 (2001). Since the threshold issue is answered in the affirmative, then the subsequent issues are:

- Whether Petitioner was in fact the laboratory's director at the time of the alleged misrepresentation contained in the application forms; and

- Whether Petitioner was properly subject to sanction by CMS.

IV. Findings, Conclusions and Analysis

I make findings of fact and conclusions of law (Findings) to support my decision in this case. I set forth each Finding below as a separate heading. I discuss each Finding in detail.

A. *The information contained in the State licensure and CLIA application forms was a misrepresentation of information and, therefore, subject to sanctions by CMS.*

The basis for the actions taken by CMS against San Fernando, and collaterally against Petitioner, was the discrepancy in the test volume estimates contained in both the California State licensing application (State application) and the CLIA application. HCFA Ex. 5, at 1. The estimations are essential for the assessment of fees to be paid by the applicant prior to the issuance of a CLIA registration certificate. *See* 42 C.F.R. § 493.643(c). The estimates in the CLIA application were substantially lower than those reported in the State application. Tr. at 52-53; HCFA Exs. 2, 4. Had the higher estimation been provided in the CLIA application, San Fernando would have fallen into a different capacity category, which would have resulted in a higher fee assessment. Tr. at 68-69.

Petitioner argues that, since the regulations do not specifically define the term "misrepresentation," CMS has applied an inaccurate definition to the term and, therefore, has applied an incorrect interpretation to 42 C.F.R. Part 493. Petitioner's Post-Hearing Brief (P. Br.) at 6. Petitioner further asserts that CMS has failed to meet "the legal requirements and conditions necessary to support a charge of "misrepresentation . . . " *Id.*, at 10. Petitioner argues that the regulation's omission in providing a definition for "misrepresentation" leaves the term subject to interpretation. On this point, I am in agreement with Petitioner. However, I do not agree with Petitioner's particular interpretation on this subject. Petitioner's elucidation suggests that the appropriate definition in this instance would result in "misrepresentation" being synonymous with the term "fraud." Petitioner suggests that Black's Law Dictionary, as published by the Lawbook Exchange, provides the appropriate definition. In essence, Petitioner's reference source states the following:

> False and fraudulent misrepresentation is by representation contrary to the fact made by a person with knowledge of its falsehood and being the cause of the other party's entering into a contract.

Id., at 6.

However viable a definition this may be, it is not one I would use in this case. Upon review of another Black's Law Dictionary, Centennial Edition, I find a somewhat broader definition of "misrepresentation." The Centennial Black's defines "misrepresentation" as:

> Any manifestation by words or other conduct by one person to another that, under the circumstances, amounts to an assertion not in accordance with the facts. An untrue statement of fact. An incorrect or false representation. That which, if accepted, leads the mind to an apprehension of a condition other and different from that which exists . . .

Black's Law Dictionary, Abridged Sixth Edition, 692 (1991).

I agree with CMS's argument that neither the statute nor the regulations require ***specific*** intent for the misrepresentation. Clearly, 42 U.S.C. § 263a(i)(1)(A) prescribes:

> (1) In general
>
> Except as provided in paragraph (2), the certificate of a laboratory issued under this section may be suspended, revoked, or limited if the Secretary finds, after reasonable notice and opportunity for hearing to the owner or operator of the laboratory, that such owner or operator or any employee of the laboratory -
>
> (A) has been guilty of misrepresentation in obtaining the certificate.

Nowhere in this provision does it indicate that the misrepresentation must be **deliberate** or **intentional**. If I were to follow Petitioner's particular line of thinking, I would be forced to conclude that by "misrepresentation," the regulations are applicable only to intentional efforts to provide misinformation. I do not comprehend the regulations to be so narrow. In that the term "misrepresentation" is extremely broad and subject to numerous interpretation, I believe that it was Congress' intent to be broad and to mean any inaccurate information contained in an application for certification which, if relied upon by a state or federal agency, would result in certification issuance. Clearly, the misrepresentation could be unintentional or intentionally fraudulent. Based upon the evidence before me, it is clear that CMS has not argued nor attempted to prove that Petitioner intentionally provided misinformation on the

State and CLIA applications. However, CMS has more than substantiated that there was a misrepresentation of information provided in both applications, albeit arguably unintentional.

B. *Petitioner was the laboratory director for San Fernando at the time of the submission of the State and CLIA applications.*

Once the question as to whether there has been a misrepresentation has been answered in the affirmative, the next issue to be addressed is whether Petitioner is one of the individuals delineated in the statute and regulations. Specifically, was Petitioner an owner, operator, or an employee of the laboratory when the misrepresentation occurred.

Petitioner challenges CMS's allegation that he was the laboratory director of San Fernando at the time of execution of the State and CLIA applications. Petitioner also accuses CMS of violating "the well-established legal principle of form over substance" in the alleged attempt to make 'laboratory director' and 'owner/operator,' as delineated at 42 U.S.C. § 263a synonymous. P. Br. at 22. The regulations at 42 C.F.R. § 493.2 define "operator" as:

> . . . . the individual or group of individuals who oversee all facets of the operation of a laboratory and who bears primary responsibility for the safety and reliability for the results of all specimen testing performed in that laboratory. The term includes --
>
> (1) A director of the laboratory if he or she meets the stated criteria . . .

It is clear on its face that at the signing of the State application form, Petitioner held himself out to be the laboratory director for San Fernando. Without Petitioner's affirmation that he was serving in such a capacity, San Fernando's application would not have been processed by the State agency. Tr. at 82. Furthermore, this was not Petitioner's first encounter with clinical laboratories or with the functions associated with being a laboratory director. According to evidence and testimony, Petitioner had been a director of, at least, two known laboratory facilities prior to his involvement with San Fernando. *See* HCFA Ex. 4, at 4. Therefore logic would dictate that Petitioner would have some knowledge of the intricacies of being a laboratory director.

However, Petitioner contends that at the time of the signing and submission of the State application forms, he was not qualified to act as a laboratory director. P. Br. at 19. The regulations prescribe the standard by which an individual is qualified to serve as a laboratory director. The regulations delineate, among other things:

> The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests

> and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part.(a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and(b) The laboratory director must --(1)(i) Be a doctor of medicine or doctor . . . . licensed to practice medicine . . . . in the State in which the laboratory is located; and (ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (ii) Have had laboratory training or experience consisting of: (A) At least one year directing or supervising non-waived laboratory testing, ...

42 C.F.R. § 493.1405(a), (b)(1), (b)(2)(i), (b)(2)(ii)(A).

Neither party has argued nor presented evidence which would question whether Petitioner did or did not meet the educational/professional qualifications stipulated in section 493.1405. However, the testimony of Alyce Brydon, Section Chief, LFS, substantiates Petitioner's eligibility to serve as a laboratory director pursuant to 42 C.F.R. § 493.1405. Tr. at 203-204. It is not the initial qualifications that Petitioner disputes. But rather, he argues that his disqualification to serve as a laboratory director is the result of an internal investigation by LFS of Petitioner's prior involvement with two other laboratories. Petitioner particularly asserts that:

> Petitioner made no "misrepresentation" to HCFA as the Laboratory Director . . . . at the time the application was made because . . . . Petitioner was not be [sic] qualified to be a laboratory director under California State regulations.

P. Br. at 19.

Petitioner contends that, because of an ongoing investigation by Ms. Bryden's office six months prior to the submission of the State and CLIA applications, it was known well in advance that Petitioner was not eligible to serve as the laboratory director of San Fernando. Petitioner's argument would have merit had there been an ultimate determination made during the six months prior as to Petitioner's ineligibility to serve as San Fernando's laboratory director. On cross examination, Ms. Bryden testified that the investigation in essence was the result of her office's repeated attempts to acquire records from Petitioner relating to the two other facilities in which he was the laboratory director. Ms. Bryden stated:

> . . . . because we were beginning to investigate these laboratories, we needed records from the laboratories. These were requested from [Petitioner] in December of 1998. He did not respond. We requested them again in January of '99. He did not respond. We requested them again in February of '99. He did not respond. Then we wrote him a letter of intent to impose sanctions upon him for not responding.
>
> His answer to that was, "I wasn't laboratory director at that time and I never saw any of the letters." So after some discussion on this he produced letters of his - his letters of resignation for these two laboratories. We sent the issue to our legal department for a decision since we did not have copies of those letters, although he had said he had sent them to us. And at that time, our legal department finally in about November [1999] said, "Well, we'll give him the benefit of the doubt that these are legitimate letters and we won't impose sanctions . . . .

Tr. at 225-226.

It is clear from the testimony of Ms. Bryden that no adverse determination against Petitioner resulted from the investigation. And even if I were to find that LFS's determination did in fact result in a determination that Petitioner was ineligible to be a laboratory director, such information was never conveyed to CMS for consideration. As Ms. Bryden testified, the matter under investigation dealt was a state licensure issue and such information would have never been relayed to CMS. Tr. at 227. Therefore,

Petitioner's argument that an individual under investigation for "any alleged or actual wrong doing" is unacceptable as a laboratory director is without merit. Therefore, I find that as of January 8, 1999, the date of the signing of the applications, Petitioner was the laboratory director of San Fernando.

Even if I concluded that Petitioner was not the laboratory director subsequent to January 8, 1999, he was the laboratory director at the time of execution of the four application documents and submission to LFS. *See Edward Ming-Che Lai, M.D.*, DAB CR848 at 7 (2001). In *Ming-Che Lai*, there was a question of whether the petitioner was a laboratory director eight months after submission of the initial application documentation, which included the CLIA application. The ALJ in that case concluded that it was clear from the executed documents that the petitioner was functioning as the laboratory director as of the date of the documents; However, rebuttal evidence supported the argument that petitioner was not serving as the laboratory director as of May 2000, eight months after the execution date. Such an analogy is applicable to the facts of the present case. Petitioner has not presented any compelling evidence to support his contention that he was not serving, nor had he agreed to serve, as the laboratory director as of January 8, 1999 when the application forms were

executed and filed with LFS.

C. *Petitioner's arguments relating to his alleged status as an "employee" laboratory director are without merit.*

Petitioner next asserts that, even though he may have been considered a laboratory director for San Fernando, he was an "employee of the organization and as such cannot be held liable for the actions of the employer." P. Br. at 24. Petitioner also suggests that he would have been an employee of San Fernando only if the facility had opened for business. *Id*. Petitioner sums up his argument by concluding that, since 42 C.F.R. § 1840(A)(8) "singles out one employee to be punished" and is not applicable to all employees, then the regulatory provision is unconstitutional. *Id*.

It is significant that, in order for San Fernando to acquire and maintain certification for performing moderate complexity testing, it had to have a laboratory director who provided "overall management and direction" of the laboratory, in accordance with 42 C.F.R. § 493.1407, and who met the qualification requirements of 42 C.F.R. § 493.1405. These regulations draw no distinctions regarding a laboratory director who has status as an employee, as opposed to being a contractor, an owner entitled to an equity share, a volunteer, or one who serves in some other status.

The purpose of CLIA is to ensure the accuracy and reliability of laboratory tests, and thus, the public health of all Americans. *See* H.R. Rep. No. 899, 100th Cong. 2d Sess. 8, 18 (1988), reprinted in 1988 U.S.C.C.A.N. 3828, 3829. The Secretary's purpose in treating a laboratory director of a laboratory which has its CLIA certificate revoked as an operator for purposes of the two-year ban on owning or operating another laboratory is consistent with the legislative intent of CLIA. 57 Fed. Reg. 7226 (1992).

Petitioner's unique interpretation of the regulations, whereby he is shielded from his responsibilities as a laboratory director and the sanctions contemplated by the statutes and regulations, is unreasonable and inconsistent with the purposes of CLIA. I have concluded that, by accepting the title of "laboratory director" of a laboratory having or seeking a CLIA certificate, the director accepts all of the specified regulatory responsibilities and is subject to the authority of CMS and any sanctions specified by law, regardless of the actual employment status of the director.

D. *Petitioner is properly subject to the two-year prohibition on owning, operating or directing a laboratory.*

San Fernando did not contest the sanctions imposed by CMS and, therefore, its certification was revoked effective August 16, 1999. The revocation of San Fernando's certification triggers 42 U.S.C. § 263a(i)(3), which is applicable to

Petitioner for the reasons previously discussed. Section 263a(i)(3) provides that "[n]o person who has owned or operated a laboratory which has had its certificate revoked may, within two years of the revocation of the certificate, own or operate a laboratory for which a certificate has been issued under this under this section. Section 493.1840(a) of 42 C.F.R. is also triggered, which requires CMS to initiate adverse actions to suspend, limit or revoke the CLIA certificate of any laboratory if it is found that an owner or operator owned or operated a laboratory that had its CLIA certificate revoked within the last two years. CMS has no discretion and, in fact, takes no action under 42 U.S.C. § 263a(i)(3); the two-year ban on owning and operating is automatic. Similarly, CMS has little discretion under 42 C.F.R. § 493.1840(a)(8) as it must initiate action against the offending laboratory.

> E. *I do not have the authority to address Petitioner's assertion that the regulations at issue are unconstitutional.*

Even if I had entertained Petitioner's constitutional arguments as they relate to 42 C.F.R. § 1840(a)(8), I would be unable to utilize them in my deliberations on this matter. I do not have the authority to decide these issues. Administrative law judges have no statutory or regulatory authority to find invalid or refuse to follow federal statutes or regulations. *Wayne E. Imber, M.D.*, DAB CR661, *aff'd*, DAB No. 1740 (2000); *Richard A. Fishman, D.O.*, DAB CR100 (1990) (administrative law judges do not have authority to declare federal statutes unconstitutional); *Sentinel Medical Laboratories, Inc.*, DAB No. 1762 (2001) ([i]t is well established that administrative forums, such as this Board and the Department's ALJs, do not have the authority to ignore unambiguous statutes or regulations on the basis that they are unconstitutional).

As a result of these explicit jurisdictional prohibitions, Departmental Appeals Board ALJs lack authority to review the constitutionality of statutes. Petitioner may not use this administrative appeals process to obtain redress for both his alleged constitutional harms. *See Serban I. Cocioba, M.D.*, DAB CR654 (2000) (finding no jurisdiction to rule on constitutional claims); *Morton Markoff, D.O.*, DAB CR538 (1998) (administrative law judges lack authority to decide constitutional claims).

V. Conclusion

Based upon the foregoing, I affirm CMS's determination and conclude that Petitioner is prohibited from owning, operating or directing a laboratory for two years pursuant to 42 U.S.C. § 263a(i)(3), due to the revocation of San Fernando's CLIA certification of which he served as laboratory director during the relevant period of time. The two-year prohibition will commence to run from the issuance date of this decision.

JUDGE

...TO TOP

Alfonso J. Montano

Administrative Law Judge

FOOTNOTES

...TO TOP

1. CMS's exhibits were identified with the acronym "HCFA" and, therefore, I will refer to them by that acronym in order to avoid confusion.

CASE | DECISION |JUDGE | FOOTNOTES

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division

IN THE CASE OF

SUBJECT:

Lyle Griffith, M.D. (Laboratory),

DATE: August 31, 2006

Petitioner,

- v -

Centers for Medicare & Medicaid Services.

Docket No.**C-05-145**
Decision No. **CR1496**

DECISION ...TO TOP

DECISION

The Petitioner in this case, Lyle Griffith Laboratory (Petitioner or lab) is a California clinical laboratory owned and operated by Lyle Griffith, M.D. It has been certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a *et seq*. Petitioner appeals the decision of the Centers for Medicare & Medicaid Services (CMS) to revoke its CLIA certificate, cancel its approval to receive Medicare payments, and impose a substantial civil money penalty (CMP).

The parties have filed cross-motions for summary judgment. For the reasons discussed below, I deny Petitioner's motion for summary judgment, and grant CMS's motion, sustaining its determinations and the imposition of penalties.

I. Background

In order to ensure the accuracy and reliability of laboratory tests, and thus the health and safety of those tested, CLIA creates a federal certification process for laboratories that perform clinical diagnostic tests on human specimens. Pub. L. No. 100-578, *amending* section 353 of the Public Health Service Act, codified at 42 U.S.C. § 263a *et seq.*; *see* H.R. Rep. No. 100-899, at 8 (1988), *reprinted in* 1988 U.S.C.C.A.N. 3828, 3829. To be certified, a laboratory must meet the

conditions of certification set out in the statute and regulations. 42 U.S.C. § 263(a)(f)(1)(E); 42 C.F.R. § 493.1 *et seq.* The statute gives the Secretary of Health and Human Services (Secretary) broad enforcement authority, including the authority to suspend, limit, or revoke the certificate of a laboratory that is out of compliance with one or more conditions. Each condition represents a major division of laboratory services or required environmental protections, and standards are specific components of the conditions. *RNA Laboratories, Inc.*, DAB No. 1820, at 3 (2002).

The Secretary has delegated to CMS the responsibility for CLIA enforcement. CMS or its designee conducts periodic inspections to determine a laboratory's compliance with CLIA requirements. 42 C.F.R. § 493.1777. CMS may suspend, limit, or revoke the CLIA certificate of a laboratory that is out of compliance with one or more CLIA conditions, and may also impose alternative sanctions such as a directed plan of correction, state monitoring, or a CMP. 42 C.F.R. § 493.1806; *RNA Laboratories*, DAB No. 1820, at 3; *Ward General Practice Clinic*, DAB No. 1624, at 2 (1997).

Here, following a recertification survey completed August 25, 2004, the California Department of Health Services, Laboratory Field Services (State Agency) determined that the lab was out of compliance with seven CLIA conditions and various standard-level requirements. CMS Exhibit (Ex.) 1. By letter dated September 17, 2004, the State Agency instructed the lab to correct all of its condition-level deficiencies, affording it ten days in which to submit acceptable evidence of correction and a credible allegation of its compliance. CMS Ex. 4, at 2. The letter warned that, if the lab failed to correct its condition-level deficiencies, the State Agency would recommend that CMS impose sanctions, including revocation of the lab's CLIA certificate. CMS Ex. 4, at 2-3. At Petitioner's request, the State Agency allowed the lab an additional ten days for response. CMS Ex. 4, at 4.

Petitioner submitted its response, which the State Agency determined did not include acceptable evidence that the lab had corrected its deficiencies, and was not a credible allegation of compliance. In a letter dated December 16, 2004, the State Agency so advised Petitioner, and recommended that CMS impose sanctions. CMS Ex. 4, at 5-6.

CMS agreed with the State Agency's findings and recommendations, and, after allowing the lab an additional opportunity to show why sanctions should not be imposed (CMS Ex. 5), imposed the following sanctions: 1) revocation of the lab's CLIA certificate;[(1)] 2) a $3,000 per day CMP for each day of noncompliance, effective January 6, 2005; 3) a directed plan of correction, directing the lab to cease all testing effective January 6, 2005, and to submit to CMS a list of the names and

addresses of clients who had used the lab's services since October 2002 (so that CMS could inform them of the lab's noncompliance); and 4) cancellation of the lab's approval to receive Medicare payments for any services performed on or after January 6, 2005. CMS Ex. 6.

Petitioner appeals. The parties have filed cross-motions for summary disposition accompanied by witness declarations and other exhibits.[(2)] CMS asks that I consider 14 of its 21 proposed exhibits, CMS Exs. 1-9, and 17-21. CMS Opp. Br., at 1. With its motion, Petitioner has filed seven exhibits (P. Exs. 1-7). For the purpose of resolving these motions, I admit into evidence CMS Exs. 1-9 and 17-21 and P. Exs. 1-7.

II. Issues

I first consider whether summary disposition is appropriate.

On the merits, the question is whether Petitioner failed to comply with one or more CLIA conditions of participation, thereby giving CMS the authority to impose remedies, including the revocation of Petitioner's CLIA certificate and the cancellation of Petitioner's approval to receive Medicare payments.

Because I find at least one condition-level deficiency, CMS may impose sanctions (42 C.F.R. § 493.1804(b)), and its choice of alternative sanctions, including the amount of a CMP, is not an initial determination reviewable in this forum. 42 C.F.R. § 493.1844(c)(4). *See* discussion below.

III. Discussion

A. Summary disposition is appropriate where, as here, Petitioner has not demonstrated any dispute regarding genuine issues of material fact. [(3)]

Summary disposition is appropriate where there are no disputed issues of material fact and where the only questions that must be decided involve either questions of law or the application of the law to the undisputed facts. *Livingston Care Center*, DAB No. 1871, at 6 (2003). A party opposing summary disposition must allege facts that, if true, would refute the facts relied upon by the moving party. *See, e.g.*, Fed. R. Civ. P. 56(c); *Garden City Medical Center*, DAB No. 1763 (2001); *Everett Rehabilitation and Medical Center*, DAB No. 1628, at 3 (1997) (in-person hearing required where only non-movant shows there are material facts in dispute that require testimony). A party may not simply state that it disputes allegations of fact in order to avoid the entry of summary disposition; it must describe the asserted facts credibly in order to establish a dispute.

CMS is requesting summary affirmance here, asserting that no material facts

are in dispute with respect to two of the cited condition-level deficiencies: 1) the lab did not successfully participate in an approved proficiency testing (PT) program (42 C.F.R. § 493.803); and 2) the laboratory director did not fulfill his responsibilities under 42 C.F.R. § 493.1403. CMS alleges, and presents evidence to establish, that, for one routine analyte,[(4)] the lab failed to achieve satisfactory PT scores during the first and third testing events of 2003. CMS also alleges, and presents evidence to establish, that the lab director, Dr. Griffith, was not even aware of the lab's PT errors, did not follow up on the problems, and thus failed to provide the lab with the necessary management and administration. *See* discussions below.

Petitioner has not challenged these assertions. *See, e.g.*, P.'s Hearing Request; CMS Ex. 7. Instead, it questions the agencies' motives in imposing these sanctions, and complains about the quality of the state survey, and the refusals by the State Agency and CMS either to accept its plan of correction or to assist the lab in addressing its deficiencies. I find that these, at best, marginally relevant accusations are simply not material to the question of the lab's compliance with CLIA conditions. Inasmuch as Petitioner has alleged no material fact in dispute on this critical question, CMS is entitled to summary judgment if it establishes that, based on the undisputed facts, it is entitled to judgment as a matter of law. I now address that question of law.

B. Petitioner was not in substantial compliance with 42 C.F.R. § 493.803 because, for two out of three consecutive testing events, it failed to achieve a satisfactory score for each analyte tested.

A laboratory that holds a CLIA certificate of accreditation may perform moderate and high complexity tests, but it must participate in a proficiency testing program as outlined in 42 C.F.R. Part 493, Subpart H. This is a condition-level requirement. *See* 42 C.F.R. § 493.2 (any of the requirements identified as "conditions" in subparts G through Q of Part 493 is a condition-level requirement). Under the provisions of Subpart H, each laboratory must enroll in an approved PT program that meets specific criteria set out at Subpart I of Part 493. 42 C.F.R. § 493.801. A laboratory performing high complexity testing "must successfully participate" in an approved PT program for each "specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA." 42 C.F.R. § 493.803(a). If a laboratory fails to participate successfully, CMS must impose sanctions. 42 C.F.R. § 493.803(b).

The undisputed evidence establishes that, for the years 2002, 2003, and 2004, Petitioner was enrolled in a PT program administered by the American Academy of Family Practitioners, and participated in three PT events per year. CMS Exs. 17; 18;[(5)] 19, at 4-5 (Myler Declaration (Decl.)); 21 (Mitchell Decl.). Results of its PT tests show that, for the first and third testing events of 2003, the lab received scores of 0% and 40%, respectively, for the analyte alanine aminotransferase (ALT/SGPT), part of the routine chemistry subspecialty. CMS

Exs.17, at 2, 16; 18; 19, at 5 (Myler Decl.); and 21, at 3 (Mitchell Decl.).

Failure to attain a score of at least 80 % of acceptable responses for each analyte in each testing event is unsatisfactory performance for the testing event. 42 C.F.R. § 493.841(a). Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. 42 C.F.R. § 493.841(g). Thus, because Petitioner failed to achieve a satisfactory score for two out of three consecutive testing events, it was not in substantial compliance with the CLIA condition governing proficiency testing, 42 C.F.R. § 493.803.

C. Petitioner did not comply with the requirements of 42 C.F.R. § 493.1403 because its laboratory director failed to provide the lab with adequate management and administration.

A laboratory must have a director who meets the qualifications set forth in 42 C.F.R. § 493.1405, and who provides overall management and direction in accordance with 42 C.F.R. § 493.1407. 42 C.F.R. § 493.1403. The lab director is responsible for the overall operation and administration of the lab, which includes employing personnel competent to perform test procedures, and record and report test results promptly, accurately, and proficiently, and for assuring compliance with applicable regulations. 42 C.F.R. § 493.1407. Among the director's specific responsibilities, he/she must ensure that the laboratory is enrolled in an approved PT program, that the PT samples are tested as required, and that PT results are reviewed in order to identify problems. 42 C.F.R. §§ 493.1407(e)(4),[(6)] 493.1445; *see Oakland Medical Group, P.C.*, DAB No. 1755, at 21-22 (2000).

Petitioner acknowledges its significant deficiencies and the laboratory director's responsibility for them. Nevertheless, it points out that there were personnel changes in the lab, including the departure of a prior lab technician and the lab's office manager, and that the lab relocated during this time. P. Hearing Request, at 3 (December 21, 2004) (CMS Ex. 7); P. Opp. Br. at 4. The lab director, Dr. Griffith, also complains that, prior to the CLIA inspection, his lab technician had not told him that his proficiency testing was not passing standards. P. Ex. 1, at 5 (Griffith Decl.). These assertions only underscore Petitioner's noncompliance with 42 C.F.R. § 493.1403. That the lab director was not even aware that his lab had failed its PT events demonstrates the absence of oversight. That his staff were not performing adequately is no defense since the lab director is responsible for employing competent personnel. Delegation of his duties does not relieve the director of responsibility. 42 C.F.R. § 493.1445(b); *see also Preferred Family Clinic*, DAB CR 975, at 11 (2002).

The undisputed evidence thus establishes a pervasive absence of oversight

and direction, sufficient to render unmet, at the condition level, the regulatory requirement for lab director.

D. I have no authority to review Petitioner's other complaints.

Petitioner has admitted its laboratory failures, but raises other issues:

> Specifically, I wish to appeal the process that has transpired leading to the rejection of my corrective action response . . . . I fully accept that the systems, which I believed were in place in my laboratory appear to have broken down, and that in the end the responsibility for the running of my laboratory rests squarely on my shoulders. I do not, however, understand why I have not been given the opportunity to fix these problems and bring my laboratory back into compliance with the applicable state and federal regulations.

P. Hearing Request, at 1 (December 21, 2004) (CMS Ex. 7). Petitioner also complains that it was misled into believing that the State Agency would assist in correcting the lab's problems, and points out the steps it took to develop a plan of correction and to bring itself into compliance. Petitioner also points out that its owner/operator has not been charged with any fraud, and complains that, in light of the lab's level of cooperation, the sanctions are too severe. I have no authority to resolve these issues.

First, with respect to the sanctions imposed, since Petitioner failed to comply with conditions of participation, CMS is authorized to impose principal sanctions, including revocation of the laboratory's CLIA certificate. 42 C.F.R. § 493.1806(a), (b). CMS may also cancel the laboratory's approval to receive Medicare payment for its services. 42 C.F.R. § 493.1807. CMS's determination to impose a CMP, and the amount of the CMP imposed are not initial determinations and thus are not reviewable in this forum. 42 C.F.R. § 493.1844(c).

The agencies' decisions not to accept Petitioner's plan of correction are not "initial determinations," and therefore are not reviewable. 42 C.F.R. § 493.1844.

Finally, Petitioner's complaints about agency motives and purported deception are simply irrelevant to the question of the lab's compliance.

IV. Conclusion

For all of these reasons, I sustain CMS's determination to revoke Petitioner's CLIA certificate for at least one year, to cancel its approval to receive Medicare payment for its services, and to impose a CMP.

JUDGE ...TO TOP

Carolyn Cozad Hughes

Administrative Law Judge

FOOTNOTES ...TO TOP

1. Because Petitioner filed an appeal, the revocation of the lab's CLIA certificate does not become effective until the date of an administrative law judge decision upholding the basis for the remedy. 42 C.F.R. §§ 493.1840(e), 493.1844(d)(2).

2. CMS has submitted a Brief in Support of Summary Disposition (CMS Br.) and, responding to Petitioner's Motion for Summary Judgment, a document titled CMS's Opposition to Petitioner's Cross-Motion for Summary Judgment (CMS Opp. Br.). Petitioner has filed a Motion for Summary Judgment (P. Br.) and a document titled Petitioner's Opposition to CMS's Brief in Support of Summary Disposition (P. Opp. Br.). I note that Petitioner's submissions are virtually identical to each other. Its brief in opposition does not so much respond to CMS's arguments as simply repeat verbatim its initial arguments.

3. I make findings of fact and conclusions of law to support my decision. I set forth each finding, below, in bold and italics, as a separately numbered or lettered heading.

4. An analyte is a substance or constituent for which the laboratory conducts testing. 42 C.F.R. § 493.2.

5. CMS Ex. 18 is an Oscar Report, showing the lab's PT profile for the years 2002, 2003, and 2004. It lists the analytes for which the lab completed PT for these years, and provides the PT scores for each testing event. Failing scores are marked by an asterisk. Although CMS does not base its summary judgment motion on all of the PT failures, the document shows more than a dozen failed tests over a relatively short period (seven testing events, from the third event of 2002 through the third event of 2004).

6. Noncompliance with 42 C.F.R. § 493.1407(e)(4)(iii) was separately cited as a standard-level deficiency. CMS Ex. 1, at 38-39.