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 BESSELL 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 COMPLAINT

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Dated: January 18, 2012

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Defendants Community Health Systems Professional Services Corporation, Deming Hospital Corporation d/b/a Mimbres Memorial Hospital, and Jerry Bossell[1] (referred to collectively as "the Hospital") respectfully submit this Memorandum in support of their Motion To Dismiss the Complaint Under Rules 9(b) and 12(b)(6) of the Federal Rules of Civil Procedure.

INTRODUCTION AND SUMMARY OF ARGUMENT

Relator has brought a False Claims Act ("FCA") lawsuit, but alleges no false claim. Her basic allegations are that the Hospital did not comply with several of the many regulations imposed on laboratories by the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"), 42 U.S.C. § 263a. Even assuming solely for purposes of this motion that those allegations are true, the Tenth Circuit has made clear that the FCA is not a tool to police compliance with government regulations—especially where, as here, CLIA has its own administrative enforcement scheme and the government has conspicuously declined to intervene in Relator's lawsuit. Instead, as the Tenth Circuit has emphasized, the FCA is a tool to stop fraud on the government. To state an FCA claim, Relator must allege how the Hospital's supposed noncompliance led to the knowing submission of false claims. Relator plainly fails to do this. The Complaint does not identify any false claim, and offers only a cursory hypothesis as to how such claims *might* have been submitted. The Complaint thus fails to satisfy minimum pleading standards and should be dismissed with prejudice. In particular:

[1] It is telling that, although she professes to be an insider with detailed knowledge of the Hospital's laboratory operations, Relator does not even get the name of the laboratory's director correct. His last name is "B*o*ssell," not "B*e*ssell."

Count I, alleging violations of the FCA pursuant to its *qui tam* provisions, is foreclosed by *United States ex rel. Conner v. Salina Regional Health Center, Inc.*, 543 F.3d 1211 (10th Cir. 2008). *Conner* holds that a relator does not state an FCA claim under Rule 12(b)(6) merely by alleging noncompliance with government regulations. Instead, because the FCA is concerned specifically with stopping fraud on the government, a claim is stated only if compliance with the regulations is a condition for the defendant to receive government payment. *Conner* dismissed the relator's FCA complaint because the Medicare regulations at issue were enforced through "a detailed administrative mechanism . . . [that] does not require perfect compliance as an absolute condition to receiving Medicare payments." *Id.* at 1221 (emphasis omitted). Therefore, while the regulations were "conditions of program *participation*," they were not "conditions of *payment*." *Id.* at 1220 (emphasis in original). The CLIA regulations Relator claims the Hospital violated, which likewise do not condition payment on perfect compliance, are materially indistinguishable from the regulations in *Conner*.

Count I should also be dismissed for the independent reason that the Complaint does not plead fraud with particularity as required by Rule 9(b). The *sine qua non* of any FCA suit is the submission of a false claim, yet Relator does not identify even a single false claim. The Hospital performed thousands of laboratory tests over the period alleged in the Complaint, yet the Hospital is left to guess as to which claims were allegedly false. Nor does the Relator even come close to pleading the "who, what, when, where and how" of such false claims, as the Tenth Circuit requires. See *United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 726–27 (10th Cir. 2006).

Count III, alleging retaliation in violation of the FCA, fails to state a claim under Rule 12(b)(6). Relator does not allege necessary elements of a retaliation claim: that she engaged in activity protected by the FCA and that the Hospital knew of such activity. Relator alleges only that she investigated whether the Hospital complied with CLIA. But uniform case law holds that investigating regulatory compliance is not protected activity unless it is linked to an investigation of improper billing, fraud, the possibility of FCA litigation, or the like. Here it is not, and Count III therefore fails as a matter of law.

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. Alternatively, the Court should not exercise supplemental jurisdiction over these state causes of action (Counts II and IV) if the Court dismisses the federal claims in Counts I and III.

BACKGROUND

A. Relator's Allegations

Relator Sally Hansen alleges that she observed CLIA violations in the Hospital's laboratory after she began working there in May 2010. Compl. ¶ 28 (ECF No. 1). She claims that the laboratory's Procedures Manual was out of date, in violation of CLIA, because it 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.* ¶ 29. Relator also alleges that the laboratory did not perform quality control testing on certain instruments and equipment used in the laboratory, as required by CLIA. *Id.* ¶ 31. In particular, she alleges that such testing was not sufficiently performed with respect to a diagnostic device called the Vitek 2

Microbial Identifier (*id.* ¶¶ 33–46), culture media and reagents (*id.* ¶¶ 47–57), commercial kit tests (*id.* ¶¶ 58–61), gram stains (*id.* ¶¶ 62–66), and a blood culture analyzer (*id.* ¶¶ 67–71).

Relator alleges that she raised her concerns about these issues to a co-worker (Rene Rivero) and superiors, but that they were not responsive. *Id.* ¶¶ 72–81. She claims that Mr. Rivero and Mr. Bossell harassed her after she continued to press her concerns. *Id.* ¶¶ 82–83. Relator states that she was placed on administrative leave on or about July 22, 2010. *Id.* ¶ 84. She alleges that 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.* ¶ 88.

Relator initiated this action under the FCA and state law in June 2011. See ECF No. 1. Despite Relator's allegations, both the United States and the State of New Mexico declined to intervene. The Court unsealed the Complaint on August 8, 2012. See ECF No. 22.

B. CLIA

CLIA requires laboratories, such as the Hospital'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 testing. Compl. ¶¶ 25–27; 42 U.S.C. §§ 263a(b), (d). A laboratory must have a valid CLIA certificate in order to participate in Medicare or Medicaid. Compl. ¶ 4; 42 C.F.R. §§ 493.1, 493.1808. Here, Relator acknowledges that the Hospital's laboratory has a valid CLIA certificate. Compl. ¶ 27. Relator does not allege that the certificate has been suspended or limited in any way.

CLIA is implemented through exhaustive regulations that set forth quality control and other requirements. Compl. ¶ 26; 42 C.F.R. Part 493. The Centers for Medicare and Medicaid Services ("CMS") enforces CLIA's regulations through a detailed administrative scheme.

Compl. ¶ 24; 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 a sanction that is appropriate in light of the nature of the laboratory's CLIA deficiency. *Id.* § 493.1804.

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 unless "the plaintiff's complaint alone is legally sufficient to state a claim for which relief may be granted." *Smith v. United States*, 561 F.3d 1090, 1098 (10th Cir. 2009) (internal quotation marks omitted).

"FCA claims, which involve averments of fraud, are held to a higher standard. [T]he heightened pleading requirements of [Rule] 9(b) apply to claims brought under the FCA. Rule 9(b) requires that '[i]n alleging fraud . . . a party must state with particularity the circumstances constituting fraud[.]'" *United States ex rel. Lacy v. New Horizons, Inc.*, 348 F. App'x 421, 424 (10th Cir. 2009) (quoting Fed. R. Civ. P. 9(b)).

ARGUMENT

I. Count I Does Not Satisfy Rules 12(b)(6) Or 9(b)

Count I alleges the Hospital violated the FCA by presenting false claims, by making false statements to get such claims paid, and by making false statements to avoid paying money owed

to the government. Compl. ¶¶ 93–95; see also 31 U.S.C. §§ 3729(a)(1)(A)–(B), (G). To state a claim under any of these provisions, Relator must allege (at minimum) 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. The crux of Relator's theory is that the Hospital impermissibly billed Medicare[2] for laboratory tests that were not performed in perfect compliance with every CLIA regulation. Even taking Relator's allegations as true solely for purposes of this motion, they fail by a wide margin to state an FCA violation under Rule 12(b)(6) or to allege fraud with particularity under Rule 9(b).

A. Count I Is Foreclosed By The Tenth Circuit's Decision In *Conner*, Because Relator Alleges Only Regulatory Violations And Not False Claims

The first and, in and of itself, fatal defect of Relator's theory is that it is foreclosed by the Tenth Circuit's decision in *Conner*. *Conner* makes clear that noncompliance with a government regulation is insufficient to give rise to FCA liability. Rather, liability can exist only when compliance with the regulation is a condition of receiving government payment. Because, as we explain below, compliance with CLIA is not a condition of receiving payment, but only a condition of participating in Medicare, the Complaint fails to allege falsity and should be dismissed.

[2] The 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).

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 several 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.

Applying this distinction, the court 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 has discretion (but not an obligation) to 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 the court 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.[3]

2. The CLIA regulations the Hospital allegedly violated are materially indistinct from the regulatory schemes that *Conner*, *Mikes*, and the other cited cases held were conditions of participation, and not of payment. Therefore, even if the Hospital did not comply with the regulations (which we assume solely for the purposes of this motion), such 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). Under the CLIA administrative enforcement process, CMS or approved accreditation agencies are charged with certifying laboratories, inspecting laboratories for compliance with CLIA regulations, and investigating any alleged CLIA violations. 42 C.F.R. § 493.1773. If a deficiency is found, then CMS may impose a range of sanctions, including directing the laboratory to take corrective action, imposing a civil monetary penalty of up to $10,000 *per day* of noncompliance, and—the most severe civil sanction—suspending or revoking a laboratory's CLIA certificate. *Id.*

[3] See also, *e.g.*, *United States ex rel. Williams v. Renal Care Group, Inc.*, 696 F.3d 518, 531–32 (6th Cir. 2012) (noncompliance with condition of participation does not give rise to FCA liability); *United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 307–311 (3d Cir. 2011) (same); *United States ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262, 268–70 (5th Cir. 2010) (same); *United States ex rel. Gross v. AIDS Research Alliance-Chicago*, 415 F.3d 601, 604–05 (7th Cir. 2005) (same); *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1267 (9th Cir. 1996) (same); *Foglia v. Renal Ventures Mgmt., LLC*, 830 F. Supp. 2d 8, 19–20 (D.N.J. 2011) (same); *United States ex rel. Wall v. Vista Hospice Care, Inc.*, 778 F. Supp. 2d 709, 720–21 (N.D. Tex. 2011) (same); *United States ex rel. Landers v. Baptist Memorial Health Care Corp.*, 525 F. Supp. 2d 972, 978–79 (W.D. Tenn. 2007) (same).

§§ 493.1806, 493.1834(d)(2). Intentional violations of CLIA requirements are subject to criminal punishment of imprisonment and fine. *Id.* § 493.1806(e). The regulations afford CMS much discretion to choose a sanction that is appropriate based on a totality of the circumstances, which include the severity of the violation and the laboratory's history of CLIA compliance. *Id.* § 493.1804.

Suspending or terminating 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 CMS suspends or cancels Medicare payments, it must give the laboratory notice and an opportunity to respond. *Id.* §§ 493.1810, 493.1826(b), 493.1828(b), 493.1842(b). If CMS ultimately decides to impose this sanction, it does so only prospectively, and the laboratory may seek an administrative appeal. *Id.* §§ 493.1826(b), 493.1828(a)(3), 493.1842(b), 493.1844(f); see also, *e.g.*, 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, Docket 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). Significantly, no CLIA regulation authorizes CMS to cancel a laboratory's billing privileges retroactively or to seek disgorgement from the laboratory of Medicare payments disbursed for non-compliant laboratory testing. See 42 C.F.R. Part 493.

Only when CMS suspends or revokes a laboratory's CLIA certificate—a severe sanction that, like other CLIA sanctions, lies in CMS's discretion—must CMS restrict a laboratory's Medicare billing privileges. 42 C.F.R. §§ 493.1808, 493.1809, 493.1842(a). And even then, billing privileges are revoked "concurrently" (not retroactively) with cancellation of the certificate and cannot take effect until at least 5 days after the laboratory receives notice from CMS (and at least 15 days if the laboratory's deficiencies do not pose immediate jeopardy to health and safety). *Id.* §§ 493.1808, 493.1810(c)(2), 493.1844(h). Here, Relator acknowledges that the Hospital's laboratory has a valid CLIA certificate to perform all of the testing at issue in this case. Compl. § 27. And Relator does not allege that the laboratory's Medicare billing privileges have ever been suspended, revoked, or limited in any way by CMS or any other agency.

In addition to the CLIA regulations described above, the Medicare regulations also make clear 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"). The section pertaining to laboratory services specifically requires that such services be provided by "a certified laboratory that meets requirements of part 493 [*i.e.*, the CLIA regulations] of this chapter." 42 C.F.R. § 482.27(a). 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 reason."); *id.* § 3.3.2.4 (June 28, 2011) ("NOTE**:** Conditions of participation (COP) are not conditions of payment."); see also *Wall*, 778 F. Supp. 2d at 720–21 (relying on Medicare Program Integrity Manual to conclude that defendant's alleged violation of Medicare regulations for hospice care 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"). Part 424 makes no mention of CLIA regulations, though it identifies in detail numerous other conditions for payment.

The CLIA administrative scheme thus bears all the features that *Conner* and other courts identified as hallmarks of conditions of participation. Put simply, compliance with CLIA can scarcely be considered a *prerequisite* to receiving Medicare payments when noncompliance only *might* lead to cancellation of *future* Medicare payments. As the Third Circuit aptly observed when dismissing a claim similar to Relator's, "considering that the Government has established an administrative mechanism for managing and correcting Medicare marketing violations which includes remedies for violations other than the withholding of payment otherwise due, it is clear that, although the Government considers substantial compliance with the marketing regulations 'a condition of ongoing Medicare participation, it does not require perfect compliance as an absolute condition for receiving Medicare payments for services rendered.'" *Wilkins*, 659 F.3d

at 310 (quoting *Conner*, 543 F.3d at 1221); see also, *e.g.*, *Steury*, 625 F.3d at 270; *Mikes*, 274 F.3d at 701–02.[4]

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 *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 the Tenth Circuit has 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

[4] Relator makes no serious effort to contend that CLIA regulations are conditions of payment whose violation could give rise to an FCA claim. The closest the Complaint comes is its conclusory assertion, made without citation to any legal authority, that "[l]ab services that are performed in violation of CLIA are ineligible for reimbursement." Compl. ¶ 4. This is a quintessential "legal conclusion couched as a factual allegation" that the Court need not accept as true and that, as explained above, is false. *Phillips v. Bell*, 365 F. App'x 133, 139 (10th Cir. 2010) (internal quotation marks omitted); see also *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.").

services performed by a hospital." *Conner*, 543 F.3d at 1221. "If successful," the court 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 42 C.F.R. Part 493. The regulations specify sanctions that CMS may impose for each of the CLIA deficiencies Relator alleges—including Relator's cursory allegation that the Hospital obtained its CLIA certificate through misrepresentation. See 42 C.F.R. §§ 493.1806, 493.1840(a)(1). If CMS, in its expert judgment and based on its extensive experience administering CLIA, believes the Hospital 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, Relator asks the Court to make the same determinations about compliance that CMS would make. And if the Hospital were found noncompliant, then the Court would be required to impose the FCA's punitive remedy of treble damages, even if that penalty 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. Just as in *Conner*, permitting this lawsuit to go forward, where the alleged CLIA violations are not conditions of receiving Medicare payment, would make "a statute intended to protect the government's fiscal interests . . . undermine the government's own regulatory procedures." 543 F.3d at 1222.[5]

B. Count I Fails Because Relator Does Not Plead Fraud With Particularity

1. The Complaint should be dismissed for the independent reason that it does not come close to pleading fraud with the particularity that Rule 9(b) requires. "At a minimum, Rule 9(b) requires that a plaintiff set forth the 'who, what, when, where and how' of the alleged fraud," and "the time, place, and contents of the false representation, the identity of the party making the false statements and the consequences thereof." *Sikkenga*, 472 F.3d at 726–27 (internal quotation marks omitted). As *Sikkenga* makes clear, the Tenth Circuit applies Rule 9(b) rigorously in FCA suits. "Underlying schemes and other wrongful activities that result in the submission of fraudulent claims are included in the 'circumstances constituting fraud and mistake' that must be pled with particularity under Rule 9(b)." *Id.* at 727 (internal quotation marks omitted). "However, unless such pleadings are *linked to allegations, stated with particularity, of the actual false claims submitted to the government*, they do not meet the particularity requirements of Rule 9(b)." *Ibid.* (emphasis added and internal quotation marks omitted). In other words, "Rule 9(b) . . . does not permit a False Claims Act plaintiff merely to

[5] Relator's allegation that the Hospital submitted a reverse false claim in violation of 31 U.S.C. § 3729(a)(1)(G) fails, not only for the reasons stated above, but also because Relator does not allege the Hospital owed any "obligation to pay or transmit money or property to the Government." *Ibid.*

describe a private scheme in detail but then to allege simply and without any stated reason for his belief that claims requesting illegal payment must have been submitted, were likely submitted or should have been submitted to the Government." *Ibid.* (internal quotation marks omitted).

The Tenth Circuit's decision in *United States ex rel. Lacy v. New Horizons, Inc.*, 348 F. App'x 421 (2009), is representative of the court's stringent application of Rule 9(b). The relator there alleged that the defendant impermissibly billed Medicare for services that the defendant had not yet performed. *Id.* at 425. Relying on *Sikkenga*, the court dismissed the claim under Rule 9(b). "Notwithstanding the fact that [the relator's] allegations concern a fairly specific time period (June 1999 to at least April 2004) and an identified class of patients (all patients in the nine operating homes in Oklahoma), she has supplied no specific details concerning *any particular false claim* for payment submitted . . . to the government." *Ibid.* (emphasis in original). Nor did the relator allege a "single instance of a particular false claim . . . that would be representative of the class described." *Ibid.*

The court also dismissed relator's claim that the defendant falsified certain records "to reflect compliance when [defendant was] being evaluated by the State for certification between 1999 and 2004[, including] medical charts, doctors[']' orders, and time sheets for each facilit[y]." *Id.* at 427 (alterations in original). As the court explained, "[t]o satisfy the requirements of the FCA, such falsifications would ultimately have to be tied to a planned or actual false or fraudulent claim for payment. But [relator] makes no attempt to demonstrate the required link." *Ibid.* (internal citation omitted). See also, *e.g.*, *United States ex rel. Schwartz v. Coastal Healthcare Group, Inc.*, 232 F.3d 902 (Table), 2000 WL 1595976, at *6 (10th Cir. 2000).

2. Relator's Complaint does not allege nearly the detail the Tenth Circuit requires. The Complaint is essentially an extended recitation of instances where, in Relator's view, the Hospital did not comply with CLIA. See Compl. ¶¶ 22–88. But such allegations are insufficient as a matter of law unless they are "linked to allegations, stated with particularity, of *the actual false claims submitted to the government.*" *Sikkenga*, 472 F.3d at 727 (emphasis added); see also *United States v. Cheng*, 184 F.R.D. 399, 401 (D.N.M. 1998) ("[T]he Act attaches liability, not to underlying fraudulent activity, but to the 'claim for payment.'" (internal quotation marks omitted)). Of the Complaint's 103 paragraphs, only two refer to any false claim, and do so in the most conclusory fashion. Paragraph 90 asserts, without elaboration, that "[d]efendants submitted false claims to federal and state government agencies, which resulted in the payment by Medicare and Medicaid of reimbursements for ineligible lab services." This "formulaic recitation of the elements of a cause of action" does not satisfy even the notice-pleading requirements of Rule 8(a). *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

Much less does the allegation meet the heightened requirements of Rule 9(b). To start with, Relator does not "link[]" her allegations to even a single "actual false claim[] submitted to the government." *Sikkenga*, 472 F.3d at 727 (internal quotation marks omitted). That failure is dispositive under controlling law. See *id.* at 728 (dismissing complaint under Rule 9(b) because relator does not "allege[] the specifics of any actual claims submitted"); *Lacy*, 348 F. App'x at 425; see also *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 233–35 (1st Cir. 2004) (dismissing complaint under Rule 9(b) where relator alleged details of scheme to defraud but failed to allege any particular false claims); *United States ex rel. Clausen v. Lab.*

Corp. of Am., Inc., 290 F.3d 1301, 1312 (11th Cir. 2002) (same); *United States ex rel. Bell v. Ghaffari*, No. CV 01-1248 MV/KBM, slip op. at 27–28 (D.N.M. Mar. 30, 2007) (same).

Nor does Relator attempt to answer any of Rule 9(b)'s questions. "Who" among the multiple "[d]efendants" (Compl. ¶ 90) submitted false claims? "When," "where," and "how" were false claims submitted? By Relator's count, the Hospital performed hundreds, and probably thousands, of laboratory tests over the period alleged in the Complaint. *Id.* ¶¶ 46, 57 . Which of these tests led to false claims? To which "federal and state government agencies" (*id.* ¶ 90) were the claims submitted? Which of the claims were for laboratory tests performed on Medicare and Medicaid patients, rather than patients who self-pay or have private insurance and thus involve no government funds? See *Karvelas*, 360 F.3d at 234 n.18 (dismissing complaint where relator "does not specify which of the particular [regulatory] violations . . . involved Medicare or Medicaid patients"); *United States ex rel. Wildhirt v. AARS Forever, Inc.*, No. 09 C 1215, 2011 WL 1303390, at *5 (N.D. Ill. Apr. 6, 2011) (same); Compl. ¶ 22 (alleging that only half of the Hospital's revenue is generated from Medicare and Medicaid). And, of the laboratory tests performed on Medicare patients, which were performed on inpatients versus outpatients? The distinction matters because Medicare pays to treat inpatients in lump sum; claims for such payments thus could not give rise to FCA liability because the amount of the payments is not affected by whether a laboratory test (compliant or not) is performed. See, *e.g.*, *Sacred Heart Med. Ctr. v. Sullivan*, 958 F.2d 537, 540–41 (3d Cir. 1992) (explaining Medicare payment process for inpatients).

Relator also fails to allege "what" about the claims was false. Notably, Relator does not allege the Hospital made any factually false statements—*e.g.*, that the Hospital sought

reimbursement for tests it never performed. Nor does Relator allege the Hospital made any legally false statements—*e.g.*, that it falsely certified to the government that it complied with CLIA. Instead, Relator asserts only that the Hospital was not entitled to bill Medicare for noncompliant tests. See Compl. ¶ 89. That is a misstatement of law (see Part I.A, *supra*), but even if it were true, the Tenth Circuit has stated unequivocally that the FCA does not punish fraudulent conduct unless that conduct is tied to actual false claims submitted to the government. *Sikkenga*, 472 F.3d at 727; *Lacy*, 348 F. App'x at 425; see also *Karvelas*, 360 F.3d at 243; *Clausen*, 290 F.3d at 1311. Relator must identify specific claims for payment submitted to the United States and explain what about the claim is false. Yet Relator provides no clues. The only way for the Hospital to defend against the allegations would be to review *every* claim dating back multiple years and *guess* at *which ones* Relator thinks are false and *why* Relator may think that. But "[t]he particularity requirement of Rule 9 is a nullity if Plaintiff gets a ticket to the discovery process without identifying a single false claim by amount." *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, No. 97CV2200, 2001 WL 1867721, at *1 (N.D. Ga. May 16, 2001), aff'd, 290 F.3d 1301 (11th Cir. 2002).

Rather than cure these defects, the Complaint compounds them by adopting an entirely different theory of falsity just one paragraph later. Paragraph 91 does not allege the Hospital submitted any claim that was itself false, but rather used "false information" to cause the Hospital's accrediting agency "to allow Mimbres lab to retain CLIA certification." Therefore, according to Relator, "RRC was able to continue to bill Medicare and Medicaid for lab services only as a result of this same fraud." Compl. ¶ 91.

Relator cannot satisfy Rule 9(b) simply by dressing the Complaint in the garb of a new, fraudulent inducement theory.[6] In the first place, Relator alleges that "RRC" committed the FCA violation, but does not explain what (or who?) "RRC" is. The Hospital is unfamiliar with any "RRC." And the Complaint does not name "RRC" as a defendant or otherwise define or refer to this person or entity. See *Schwartz v. Celestial Seasonings, Inc.*, 124 F.3d 1246, 1252 (10th Cir. 1997) ("The purpose of Rule 9(b) is to afford defendant fair notice of plaintiff's claims and the factual ground upon which [they] are based . . . .") (internal quotation marks omitted).

In any event, the Complaint fails Rule 9(b) for additional reasons. Relator's contention that "Defendants misled the Joint Commission" (Compl. ¶ 91) is utterly conclusory. It lacks all of the required "who, what, when, where and how" of the supposed fraudulent conduct. Relator does not identify what false information the Hospital presented, to whom at the Joint Commission the information was presented, or how the information affected the Joint Commission's certification decision. The only specific false information Relator alleges concerns Rene Rivero's conduct in June 2010 (*id.* ¶ 78), some nine months *after* the October 2009 re-certification (*id.* ¶ 91).

Moreover, Relator's theory of liability depends on the following chain of inferences: (1) that the Hospital's laboratory violated one or more CLIA regulations; (2) that the Hospital falsified information to conceal the violations; (3) that the Hospital presented the falsified information to an accrediting agency; (4) that the accrediting agency relied on the falsified information; (5) that if CMS learned of the misrepresentations, it would have elected to impose a

[6] In addition, Relator's fraudulent inducement theory asserts false statements in connection with the quintessential condition of participation (i.e. retaining the Hospital's CLIA certification) and, accordingly, fails under *Conner* to state a FCA violation. See Part I.A, *supra*.

sanction; and finally (6) that this sanction would have involved the suspension or cancellation of the Hospital's Medicare billing privileges during the time period alleged in the Complaint. Relator alleges *no* facts to support the third through sixth links in the chain, and offers only a single sentence to support the second. See Compl. ¶ 78. *Sikkenga* rejected a comparable theory as "hopelessly speculative" and "woefully short" of Rule 9(b)'s pleading standards. 472 F.3d at 727–28. Here, as there, "[s]uch a generalized daisy chain of causation does not meet the requirements of Rule 9(b)." 472 F.3d at 728 n.34; see also *Lacy*, 348 F. App'x at 427; *United States ex rel. Willard v. Humana Health Plan of Texas Inc.*, 336 F.3d 375, 384–386 (5th Cir. 2003).

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

Count III alleges the Hospital retaliated against Relator 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, Relator fails to allege she was engaged in protected activity or that the Hospital had notice of any such conduct.

The only conduct Relator identifies as the basis for her retaliation claim is that she investigated supposed CLIA violations. Compl. ¶¶ 72–88. 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 merely a corollary to the "well-established principle that the FCA is 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 in *Karvelas* dismissed a retaliation claim much like Relator's. 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 failed to 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.*, *Campion v. Northeast Utilities*, 598 F. Supp. 2d 638, 657 (M.D. Pa. 2009).

Here, as in *Karvelas*, Relator's retaliation claim is based on no more than her investigation of the Hospital's compliance with CLIA. Relator "spoke to Rivero about the outdated Procedures Manual"; "reiterated her concerns about numerous CLIA violations"; "told

Gramer about the violations she had found"; and "cited the inadequate Procedures Manual and lack of quality control testing." Compl. ¶¶ 74–76, 80. These actions concern regulatory compliance; none links such compliance to improper billing of the government (or to any billing), to allegations of fraud, to reporting the noncompliance to the government, or to initiating litigation, much less an FCA suit. As in *Karvelas*, Relator's "conduct, without more, does not constitute protected conduct under the FCA." 360 F.3d at 237. See also, *e.g.*, *Campion*, 598 F. Supp. 2d at 657.

Because Relator does not allege she engaged in protected activity, necessarily she fails to allege the Hospital had notice of such 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 Relator alleges is that she told her superiors she thought the Hospital was not complying with CLIA. Relator does not allege she ever mentioned billing, fraud, or the FCA (or a lawsuit or investigation of any kind), or that she gave the Hospital reason to think she was engaged in protected conduct and was not simply reporting alleged CLIA noncompliance. Count III therefore fails as a matter of law. See, *e.g.*, *Robbins v. Provena Hosps., Inc.*, No. 03 C 1371, 2003 WL 21468588, at *4 (N.D. Ill. June 24, 2003) ("An investigation of regulation violations, without a fraudulent component in the complaints to the employer, does not give the employer notice that [the] employee's activities were done to further a FCA action." (internal quotation marks omitted)); *Campion*, 598 F. Supp. 2d at 657 (same); *Wildhirt*, 2011 WL 1303390, at *1, *6; *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) (same); 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).

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

1. Counts II and IV raise purely 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 the identical factual allegations, that form the basis of 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 that Counts I and III should be dismissed. See *e.g.*, *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).

2. Alternatively, if the Court dismisses the federal claims in Counts I and III, the Court should not exercise supplemental jurisdiction over Counts II and IV. Under 28 U.S.C. § 1367(c), a district court may decline to exercise supplemental jurisdiction if "the district court has dismissed all claims over which it has original jurisdiction." See, *e.g.*, *Koch v. City of Del City*, 660 F.3d 1228, 1248 (10th Cir. 2011); *James v. Chavez*, No. CIV 09–0540, 2011 WL 6013547, at *11 (D.N.M. Nov. 21, 2011). Should the Court elect not to dismiss Counts II and IV for failure to state a proper claim, it should decline to exercise supplemental jurisdiction over these state law counts if it dismisses the federal claims (Counts I and III).

CONCLUSION

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

Respectfully submitted,

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