IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA
ATHENS DIVISION

UNITED STATES OF AMERICA *ex rel.* RALPH D. WILLIAMS,	)	
BRINGING THIS ACTION ON BEHALF OF THE UNITED STATES OF AMERICA AND THE STATE OF GEORGIA	)	
Plaintiffs and Relator,	)	CIVIL ACTION NO. 3:09-cv-130 (CDL)
v.	)	
HEALTH MANAGEMENT ASSOCIATES, INC., et al.,	)	
Defendants.	)	

SC/ATL DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO DISMISS

LATHAM & WATKINS LLP
Roger S. Goldman (pro hac petition forthcoming)
Abid R. Qureshi (pro hac petition forthcoming)
555 Eleventh Street, NW, Suite 1000
Washington, DC 20004-1304
(202) 637-2200

ALSTON & BIRD LLP
William H. Jordan
Georgia Bar Number 405112
bill.jordan@alston.com
Samuel R. Rutherford
Georgia Bar Number 159079
1201 West Peachtree Street
Atlanta, GA 30309-3424
Telephone: (404) 881-7000
Fax: (404) 881-7777

Counsel for Defendants Tenet Healthcare Corporation, Tenet HealthSystem GB, Inc., North Fulton Medical Center, Inc., Tenet HealthSystem Spalding, Inc., and Hilton Head Health System, L.P.

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INTRODUCTION

This is a *qui tam* action arising under the False Claims Act, 31 U.S.C. §§ 3729-33 ("FCA") and the Georgia Medicaid False Claims Act, Ga. Code Ann. §§ 49-4-168.1 to -168.6 ("Georgia Medicaid FCA"), directed at a series of affiliation and service agreements entered into between four hospitals operated by Tenet Healthcare Corporation ("Tenet")—Atlanta Medical Center ("AMC"), North Fulton Regional Medical Center ("NF"), and Spalding Regional Medical Center ("Spalding") in the metro Atlanta area, and Hilton Head Health System ("HH") in South Carolina, (together "the Hospitals" and with Tenet the "SC/Atl Defendants")—and Hispanic Medical Management ("HMM" or "Clinica"),[1] an entity that operated clinics in Georgia and South Carolina dedicated to providing prenatal care to uninsured and underinsured Spanish-speaking women. The agreements were entered into to provide a swiftly growing but underserved Hispanic population in Georgia and South Carolina with much needed prenatal care and to secure translation services critical to providing the patients with a culturally accommodating environment during delivery.

Ralph D. Williams ("Relator") and the State of Georgia ("the State") allege in separate complaints that the Hospitals violated the federal Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), by entering into these affiliation and services agreements with Clinica. According to Relator and the State, this violation of the AKS constitutes actionable conduct under the FCA and the Georgia Medicaid FCA. Relator and the State allege a scheme to ensure

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[1] HMM is the corporate name for a now-dissolved Georgia corporation that was operated by Ed and Tracey Cota. HMM operated prenatal clinics under the trade name Clinica de la Mama. After the Cotas divorced in the late 2000s, the Cotas partitioned the clinics between themselves. The clinics retained by Mr. Cota are operated by Cota Medical Management Group, Inc. t/a Clinica de la Mama. The Clinics retained by Mrs. Cota were operated by International Clinical Management Services, Inc. t/a Clinica del Bebe. For simplicity, all these entities will be referred to as "HMM" or "Clinica."

that pregnant mothers would deliver their babies at the Hospitals, ignoring the undisputed fact that the Hospitals paid Clinica fair market value to provide actual translation and administrative services for which the hospitals had a legitimate business need. At their core, the complaints attack defendants for attracting and helping, previously unserved or underserved Hispanic mothers—and their unborn American babies—receive desperately needed health care that benefitted the community as a whole through improved outcomes for the babies.

Neither complaint alleges that the services for which the Hospitals contracted were not performed (which they were) or that the services for which the Hospitals contracted were not provided for a fair market value price (which they were).[2] Instead, Relator and the State claim that the service agreements, and the services provided under those agreements, were only a part of the relationship between the Hospitals and Clinica. Instead, they allege that the "real" reason the Hospitals entered into the agreements was to generate new deliveries for the Hospitals. The complaints allege that the Medicaid claims submitted by the Hospitals to the government for the services rendered to the Hispanic mothers and their American children were therefore "false" as a result of the alleged AKS violations, despite the fact that the Hospitals undisputedly provided medically necessary services.

Not only do the complaints ignore completely that the services contracted for were provided at fair market value and were actually performed, but both the State and Relator ignore

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[2] *See* State Complaint Exhibit G at A-1, ECF No. 55 (providing that Clinica "shall provide sufficient certified bilingual Company Staff twenty-four hours per day and seven days per week as may be reasonably necessary to enable Hospital physicians and staff medical and clerical personnel to understand Hispanic speaking patients so that they can perform medical services on the Hispanic patients at the [Hospital]"); *id.* (providing that Clinica will "[o]btain all necessary patient information to determine the eligibility of Hispanic children patients for Peachcare or Permanent Medicaid and admit Hispanic patients for emergency medical assistance ("EMA"), Permanent Medicaid and Medically Needy Medicaid from the State or from any other applicable third party payor to cover Hospital Services."); *see also* State Complaint Exhibits O, P, Q.

the larger picture of the enormous health benefits provided to a fast-growing number of Hispanic women and their children as a direct result of the program at issue in this case.[3] The relationship between Clinica and the Hospitals brought these unserved women (and their babies) into the healthcare system in the first instance "to provide an alternative for uninsured mothers-to-be, many of whom [we]re undocumented."[4] The attempt was to "bridge the gap between the American health-care system and this growing population."[5] As a direct result of the agreements between Clinica and the Hospitals, instead of presenting to the Hospitals to deliver their babies having had no prenatal care whatsoever, the Clinica patients "received nine months of prenatal care, including laboratory tests, ultrasound exams, counseling and regular office visits."[6] One of the primary impacts of this relationship was to improve healthcare for a population that was otherwise being ignored.

Ironically, despite the State's condemnation of the relationship between Clinica and the Hospitals, the Federal Government (through the Centers for Medicare and Medicaid Services) has recently announced the "Strong Start for Mothers and Newborns Initiative," which is an "initiative to test and evaluate enhanced prenatal care interventions for women enrolled in Medicaid … who are at risk for having a preterm birth."[7] CMS's goal is to "reduce the rate of

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[3] The Court is not limited to the four corners of the complaint at the Rule 12(b)(6) stage and may take judicial notice of facts contained in other documents, such as news media, so long as the extrinsic documents are undisputed in terms of authenticity. *See, e.g., Long v. Slaton*, 508 F.3d 576, 578 n.3 (11th Cir. 2007); *Maxcess, Inc. v. Lucent Techs., Inc.*, 433 F.3d 1337, 1340 n.3 (11th Cir. 2005).

[4] Peter Frost, *Clinic Helps Hispanic Mothers Who Lack Health Insurance*, The Island Packet Nov. 20, 2006, *available at* http://www.lowcountrynewspapers.net/archive/node/110052.

[5] *Id.*

[6] *Id.*

[7] *See* Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Strong Start for Mothers and Newborns Initiative: Enhanced Prenatal Care Models*,

preterm births, improve the health outcomes of pregnant women and newborns, and decrease the anticipated total cost of medical care during pregnancy, delivery and over the first year of life for children born to mothers in Medicaid."[8]

These are the very benefits associated with the Clinica program. As explicitly recognized by the health director for the State of South Carolina at the time the Hilton Head Clinic opened: "[i]f we can get a healthy infant delivered in a healthy environment, it reduces the overall cost and financial impact to the community."[9]

This case is thus fundamentally different than a typical kickback case. Here, the Hospitals contracted with Clinica to create a continuum of care that would allow them collectively to attract a population that traditionally had limited or no access to medical care for pregnancy and birth. Fears arising from immigration status and language barriers are long term, substantial obstacles to healthcare access for this underserved population. For the Latino community, "[t]here's a fear of accessing any kind of government program or anything that feels like a government program … because there's a prevailing feeling in the community that it's going to have a negative impact on … immigration status."[10] In addition to this fear, immigrant Hispanic women historically had "limited access to culturally competent and linguistically appropriate care."[11] By contracting with Clinica to provide both pre-admission and translation

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http://innovation.cms.gov/initiatives/Strong-Start-Strategy-2/index.html (last visited on Nov. 7, 2013).

[8] *Id.*

[9] Frost, *supra* note 4.

[10] J. Lester Feder, *Falling Through The Cracks: Why Hispanics find it especially difficult to access health care*, Newsweek, June 7, 2010 (*available at* http://www.thedailybeast.com/newsweek/2010/06/07/falling-through-the-cracks.html).

[11] National Latina Institute For Reproductive Health, *Prenatal Care Access Among Immigrant Latinas*, Dec. 2005, *available at* http://latinainstitute.org/sites/default/files/publications/PrenatalCare-2_0.pdf).

services during delivery, the Hospitals were able to provide better care and a welcome environment that conveyed to these women that the Hospitals' chief concern was not their immigration status but rather their well-being and the well-being of their babies. In doing so, the Hospitals were able to remove some of the barriers to healthcare access that plague this population.[12]

At bottom, the complaints ignore the reality of the relationship between Clinica and the Hospitals and seek to sanction the Hospitals for the efforts to attract new patients into the system. Both complaints are fatally flawed—and should be dismissed—for at least three reasons. First, neither Relator nor the State adequately alleges the elements of an AKS violation. Second, as to claims submitted prior to 2010, neither complaint adequately alleges that the Hospitals submitted a false certification of compliance with the AKS. Finally, neither complaint adequately alleges that the Hospitals knowingly submitted a false claim. In short, both Relator and the State have failed to state a claim against Tenet or the Hospitals. The complaints should be dismissed.

BACKGROUND

In the late 1990s and the early 2000s, Georgia and South Carolina both experienced a significant influx of uninsured, undocumented Hispanic immigrants.[13] This population has historically been unserved or underserved, as undocumented immigrants are not eligible for

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[12] "[C]ommunication is central to the process of health care delivery and has profound effects on patient–provider relationships and on the health care people receive. Studies have found that language barriers between providers and patients may result in excessive ordering of medical tests, lack of understanding of medication side effects and provider instructions, decreased use of primary care, increased use of the emergency department, and inadequate follow-up." José J. Escarce & Kanika Kapur, Access to and Quality of Health Care, *Hispanics and the Future of America*, (National Research Council (US) Panel on Hispanics in the U.S. et al. eds. 2006), *available at* http://www.ncbi.nlm.nih.gov/books/NBK19910/.

[13] *See* Frank Hobbs & Nicole Stoops, U.S. Census Bureau, U.S. Department of Commerce, *Demographic Trends in the 20th Century: Census 2000 Special Reports* (Nov. 2002), *available at* http://www.census.gov/prod/2002pubs/censr-4.pdf.

coverage under traditional state Medicaid programs, and language barriers and the fear of being discovered and deported often prevents them from seeking medical care.[14] Nonetheless, Hospitals are obligated by the federal Emergency Medical Treatment and Labor Act ("EMTALA") to stabilize and treat anyone coming to the emergency department, regardless of their citizenship status or ability to pay. 42 U.S.C. § 1395dd. That obligation extends to pregnant mothers who are about to deliver a child.

Many states, including Georgia and South Carolina, provide some coverage for undocumented immigrants under the Emergency Medical Assistance ("EMA") program. State Complaint ¶21. EMA covers certain emergency health conditions, including childbirth. *Id.* ¶18. EMA reimburses the hospitals at which these undocumented patients deliver for labor and delivery, and their babies are eligible for Newborn Medicaid. Relator Third Amended Complaint ¶¶13-15, ECF No. 47 ("Relator Complaint"). Because EMA is not an ongoing coverage plan, hospitals can be reimbursed for this mandated care only upon the submission of a completed enrollment application, which requires the collection of information from the patient and the patient's treating physician.[15]

Defendant Clinica operates OB-GYN clinics that focus on providing prenatal care to undocumented, Spanish-speaking immigrants. It also contracts with hospitals to provide translation services, assistance in completing the paperwork necessary to obtain EMA coverage

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[14] *See, e.g.*, Division of Family and Children Services, Georgia Department of Human Services, *Emergency Medical Assistance*, http://dfcs.dhs.georgia.gov/emergency-medical-assistance (last visited Nov. 7, 2013); Georgia Department of Human Services, *Medicaid Manual* § 2054: Emergency Medical Assistance (revised July 23, 2013), *available at* http://www.odis.dhr.state.ga.us/3000_fam/3480_medicaid/MAN3480.doc ("Georgia Medicaid Manual"); Jeffrey T. Kullgren, *Restrictions on Undocumented Immigrants' Access to Health Services: The Public Health Implications of Welfare Reform*, 93 Am. J. Pub. Health 1630, 1630-33 (Oct. 2003), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1448024/pdf/0931630.pdf.

[15] *See* Georgia Medicaid Manual § 2054 (Basic Considerations).

for patients when they deliver, and other related services, including education and marketing. State Complaint ¶¶10, 112. The pre-natal services that Clinica provides are not covered by Medicaid, and Clinica's patients pay for those services out-of-pocket. Clinica arranges for local physicians and midwives and nurse practitioners to see patients in Clinica's clinics, and those physicians and midwives typically deliver babies for patients who have been seen at Clinica in local hospitals.

FACTUAL ALLEGATIONS

On December 1, 2009, Relator filed this lawsuit on behalf of the United States and Georgia under the *qui tam* provisions of the FCA against Clinica, its owners, and several hospitals with which Clinica had arrangements to provide services. Four of those hospitals are affiliated with Tenet and one hospital, Walton Regional Medical Center, is operated by another hospital system, Health Management Associates, Inc. ("HMA").[16] On September 18, 2012, Relator amended his complaint to add the State of Georgia as a plaintiff. On March 5, 2013, Relator filed his Second Amended Complaint. On April 30, 2013, the United States Government filed a notice of its decision not to intervene explaining that "the United States hereby respectfully notifies the Court that it is not intervening at this time." On May 30, 2013, Relator filed his Third Amended Complaint.

Relator worked only for the HMA Hospital, Walton Regional, in Winder, Georgia. He never worked for or had any relationship with the Hospitals in metro Atlanta or South Carolina. Consequently, his allegations against them are based solely on information and belief. Thus, his specific factual allegations are sparse. Relator alleges in a conclusory fashion that "Clinica recruits pregnant, undocumented Hispanic women to its prenatal clinics" and then "directs this

[16] Relator was the Chief Financial Officer at Defendant HMA. Relator has never held any position at Tenet or any of the Tenet-affiliated Hospitals.

vulnerable and malleable population of patients who will be Medicaid beneficiaries when they deliver their babies, from its clinics to the … Hospitals … who pay for the referrals." Relator Complaint ¶11. Relator further alleges that "under contracts purportedly for Spanish interpreter and other services," the Hospitals paid Clinica to recruit pregnant undocumented Hispanic women and refer them to the Hospitals for their deliveries. *Id.* ¶¶97, 98. Relator nowhere alleges that Clinica did not provide these contracted-for services, that the Hospitals did not have a legitimate business need for these services, or that the Hospitals paid something other than fair market value compensation for the services. Similarly, Relator fails to acknowledge that Clinica employees, as non-physicians, could not have made "referrals" to the Hospitals as that term is used in the AKS. Nonetheless, Relator generically alleges that the Hospitals' corporate offices and the Hospitals "worked together to knowingly and intentionally pay for referrals" in violation of the federal Anti-kickback Statute, resulting in the submission of false or fraudulent Medicaid claims in violation of the FCA. *Id.* ¶¶99, 103.

Notably, Relator ignores the fact that thousands of previously unserved pregnant women and their babies received important prenatal care and hospital services that they might never have received without these arrangements. More significantly, and as more fully set forth below, Relator fails to even allege a number of the factual elements critical to establishing an FCA violation based on a violation of the AKS.

On July 31, 2013, the State of Georgia intervened and filed its complaint.[17] The State likewise alleges that "Clinica recruited undocumented, pregnant Hispanic women to its prenatal clinics" and "directed this population whose deliveries (and their newborns' care) were paid for

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[17] Although Relator's complaint names as a defendant Hilton Head Hospital in South Carolina, the State has not named Hilton Head as a defendant. *See* State Complaint ¶¶2-9 (naming the parties).

by Medicaid" to the Hospitals. State Complaint ¶10. Just as Relator does, the State alleges that "under cover of contracts purportedly for Spanish interpreter, management, consulting, marketing, and other services, since March 15, 2000," the Hospitals paid illegal remuneration to Clinica to recruit pregnant undocumented Hispanic women and refer them to the Hospitals for their deliveries and care for their newborns at Medicaid expense. *Id.* ¶112. Like Relator, the State does not allege what payments constitute the allegedly illegal remuneration since the only monies paid were for services that were, in fact, provided. Indeed, the State does not (and cannot) allege that Clinica did not provide these contracted-for services, that the Hospitals did not have a legitimate business need for these services, or that the Hospitals paid something other than fair market value compensation for the services.[18] Critical factual allegations are entirely lacking. And, like Relator, the State ignores the tremendous benefits provided to the pregnant mothers and their babies as a result of receiving prenatal care and appropriate hospital services.

Tenet and the Hospitals now move to dismiss for failure to state a claim on which relief may be granted under Rule 12(b)(6), and for failure to plead fraud with the requisite particularity under Rule 9(b).

SUMMARY OF ARGUMENT

Both complaints fail to state a claim under Rule 12(b)(6) and fail to allege fraud with the required specificity under Rule 9(b).

First, all counts of both complaints are premised on violations of the AKS, but neither Relator nor the State adequately alleges the critical elements of an AKS violation: remuneration, an intent to induce referrals, or a knowing and willful violation of the AKS.

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[18] In contrast, both the State and the Relator's complaints allege that HMA's Monroe Hospital entered into a contract with Clinica in March 2008 to provide translation and eligibility services (State Complaint ¶78), but that such services were not provided, despite Monroe's payment for them (*id.* ¶¶90-94).

Second, the complaints fail adequately to allege that the Hospitals submitted a false certification of compliance with the AKS. As set forth more fully below, with respect to claims field before March 2010, a putative violation of the AKS is actionable under the FCA only if the Hospitals certified compliance with the AKS as a prerequisite to payment under a government program. The certifications identified in the complaints either do not expressly certify compliance with the AKS or they are not conditions of payments under Medicaid. Accordingly, the complaints do not allege that the Hospitals submitted a false certification upon which any false claim would be predicated.

Third, Relator's complaint fails to allege that any false claims were made by Hilton Head Health System.

Fourth, the complaints fail to allege that the Hospitals submitted a claim knowing it was false.

Put simply, despite myriad pages of rhetoric designed to suggest—falsely—that the Hospitals were engaged in a scheme to defraud government health care programs, neither complaint adequately alleges that the Hospitals knowingly submitted a false claim. As a result of these pleading deficiencies, the Hospital defendants respectfully request that the Court dismiss both complaints.

ARGUMENT

I. STANDARD OF REVIEW

Claims brought under the FCA must comply with the particularity requirements of Rule 9(b) for claims of fraud. Rule 9(b) provides: "In alleging fraud … a party must state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). Thus, at a minimum, Rule 9(b) requires that a plaintiff set forth the 'who, what, when, where, and how' of the alleged fraud. *United States ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1310 (11th Cir. 2002).

"A dismissal for failure to plead fraud with particularity under Rule 9(b) is treated as a dismissal for failure to state a claim under Rule 12(b)(6)." *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 901 (5th Cir. 1997).

When ruling on a motion to dismiss for failure to state a claim under Rule 12(b)(6), the Court must look to the complaint to determine whether it pleads each of the elements of each cause of action as required by Federal Rule of Civil Procedure 8. The plaintiff is "obligat[ed] to provide the 'grounds' of his 'entitle[ment] to relief' [by providing] more than labels and conclusions, [because] a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555-56 (2007) (citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986)). "Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 557).

Legal conclusions and conclusory allegations that merely recite the elements of a claim are not entitled to the presumption of truth afforded to well-pled facts. *See Randall v. Scott*, 610 F.3d 701, 709-10 (11th Cir. 2010). Therefore, after excising the allegations not accepted as true, the Court must decide whether the remaining factual allegations plausibly suggest entitlement to relief. *Id.* In other words, the complaint must contain allegations that plausibly give rise to an entitlement to relief. *Id.*

Further, the complaint's factual allegations must be sufficient to plausibly suggest each material element necessary to sustain a recovery under the legal theory advanced by the plaintiff. *Fin. Sec. Assurance, Inc. v. Stephens, Inc.*, 500 F.3d 1276, 1282-83 (11th Cir. 2007) (complaints must "'contain either direct or inferential allegations respecting all the material elements necessary to sustain a recovery under some viable legal theory'" (citation omitted)).

II. THE AKS CLAIMS SHOULD BE DISMISSED BECAUSE BOTH THE STATE AND THE RELATOR FAIL ADEQUATELY TO ALLEGE THE ELEMENTS OF THE STATUTE

This is not a typical False Claims Act case. Neither Relator nor the State make any allegation that any defendant submitted a claim to the government that sought payment for services not actually rendered or that misrepresented the nature of the services provided. There is no dispute that the services for which the Hospitals sought payment—the delivery of newborn babies—were actually provided by the Hospitals to the patients. Instead, all of Relator's and the State's claims are premised on liability theories tethered to alleged violations of the AKS.

The AKS imposes criminal liability and penalties on any person who knowingly and willfully offers or pays remuneration to induce or reward referrals of items or services reimbursable by a federal health care program. *See* 42 U.S.C. §§ 1320a-8, -7b(b). To make out a prima facie case that a defendant violated the AKS, a complaint must allege that the defendant offered or paid remuneration with the intent to induce referrals, and knew that its conduct was wrongful. *See, e.g., McNutt ex rel. United States v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1258-60 (11th Cir. 2005). Furthermore, the AKS is an intent-based statute with two separate heightened intent elements. Accordingly, Relator and the State must allege that the Hospitals acted both "knowingly and willfully," *i.e.*, with intent to violate the law, and with intent to offer or pay remuneration in exchange for referrals. *See United States ex rel. Singh v. Bradford Reg'l Med. Ctr.*, 752 F. Supp. 2d 602, 640 (W.D. Pa. 2010).

The particularity requirement of Rule 9(b) is satisfied only if the complaint alleges "'facts as to time, place, *and substance of the defendant's alleged fraud*,' specifically 'the details of the defendants' allegedly fraudulent acts, when they occurred, and who engaged in them.'" *Hopper v. Solvay Pharm., Inc.*, 588 F.3d 1318, 1324 (11th Cir. 2009) (emphasis added) (citations omitted); *United States ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1310 (11th Cir.

2002); *United States ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1357 (11th Cir. 2006). Both complaints fail adequately to allege remuneration or the requisite intent.

A. The Complaints Do Not Adequately Allege Remuneration

The AKS prohibits the "solicit[ation] or recei[pt] … [of] remuneration (including any kickback, bribe, or rebate)" in exchange for the referral of government program business. 42 U.S.C. § 1320a-7b(b)(1). As multiple courts have noted, the AKS defines "remuneration" to include "'transfers of items or services for free or other than fair market value.'" *See, e.g., United States ex rel. Jamison v. McKesson Corp.*, No. 2:08CV214-SA-DAS, 2009 U.S. Dist. LEXIS 89807, at *28 (N.D. Miss. Sept. 29, 2009) (quoting 42 U.S.C. § 1320a-7a(i)(6)); *United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am.*, 565 F. Supp. 2d 153, 162 (D.D.C. 2008) (same).

For this reason, to adequately plead remuneration, Relator and the State must specifically allege facts showing both the fair market value of the services provided by Clinica and how the amounts paid to Clinica differed from fair market value. *See Klaczak ex rel. United States v. Consolidated Med. Transp.,* 458 F. Supp. 2d 622, 678-79 (N.D. Ill. 2006) (granting summary judgment in favor of defendant, finding that relators had failed to prove remuneration under the AKS because they had not shown how amounts paid differed from fair market value); *United States ex rel. Goodstein v. McLaren Reg'l Med. Ctr.*, 202 F. Supp. 2d 671, 674 (E.D. Mich. 2002) (dismissing FCA claims after bench trial finding that lease rate was at a fair market value, "effectively eliminat[ing] the Government's claims"); *United States ex rel. Obert-Hong v. Advocate Health Care*, 211 F. Supp. 2d 1045, 1049 & n.3 (N.D. Ill. 2002) ("The Anti-kickback [Statute] does not prohibit hospitals from acquiring medical practices, nor does it preclude the seller-doctor from making future referrals to the buyer-hospital, provided there are no economic inducements for those referrals. To comply with the statute, the hospital must simply pay fair

market value for the practice's assets."); *United States ex rel. Perales v. St. Margaret's Hosp.*, 243 F. Supp. 2d 843, 850 (C.D. Ill. 2003) (granting summary judgment to defendant because relator failed to demonstrate what fair market value was or how the compensation paid exceeded it); *United States ex rel. Woods v. N. Ark. Reg'l Med. Ctr.*, No. 03-3086, 2006 U.S. Dist. LEXIS 63870, at *7-8 (W.D. Ark. Sept. 7, 2006) (dismissing AKS-based FCA case with prejudice for failure to identify fair market value of leased office space and to identify what was paid outside of the fair market value range).

Courts have found complaints with far more detail about remuneration than alleged here to lack the requisite specificity under 9(b). For example, in *United States ex rel. Dennis v. Health Management Associates*, No. 3:09-cv-00484, 2013 WL 146048, at *2 (M.D. Tenn. Jan. 14, 2013), the Court dismissed an AKS claim for insufficiently alleged remuneration. The relator alleged that the defendants provided "substantial" in kind benefits to a practicing physician in exchange for his continuing high volume of referrals to UMC, specifically the provision of free office space and $60,000 in annual pay for services as "Group Director." *Id*. at *4. The relator alleged that the $60,000 paid to the physician was "far in excess of the fair market value" of the services provided, and that the remuneration was paid to him "in exchange for large volumes of referrals." *Id.* at *13. In dismissing the complaint, the court explicitly noted that the complaint said nothing about what the physician's duties were or why $60,000 per year would exceed fair market value compensation for those duties.

The pleadings at issue in this case provide even less information about the remuneration paid to Clinica or how that remuneration somehow exceeded fair market value for the services provided by Clinica. Neither complaint alleges any facts or details about the remuneration the Hospitals paid to Clinica. Relator's sole allegation regarding remuneration is that "under

contracts purportedly for Spanish interpreter and other services, Tenet paid Defendant Clinica to recruit pregnant undocumented Hispanic women and refer them to Tenet hospitals for their deliveries at public (Medicaid) expense." Relator's Complaint ¶97. Aside from this one conclusory statement that merely recites the elements of an AKS violation, Relator's complaint is entirely devoid of *any* information—let alone specific details—regarding the amounts the Hospitals paid under the contracts.[19] Rule 9(b) requires far more. *See e.g., Ziemba v. Cascade Int'l, Inc.*, 256 F.3d 1194, 1202 (11th Cir. 2001) (noting that the purpose of Rule 9(b) is to alert[ ] defendants to the precise misconduct with which they are charged and protect[ ] defendants against spurious charges"). Rule 9(b) requires that plaintiffs provide some facts to demonstrate that the service contracts for translation and Medicaid enrollment services were somehow not exactly what they purported to be: unremarkable service contracts designed to ensure that Hispanic mothers could communicate with the health care professionals treating them at the Hospitals, that their babies received the Medicaid benefits they were entitled to receive, and that the Hospitals complied with laws and regulations regarding Limited English Proficiency ("LEP") patients.[20] *See, e.g., Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1013 (11th Cir. 2005) (per curiam) (affirming the dismissal of an FCA complaint on Rule 9(b) grounds because the complaint "failed to allege when, where, and what violations of the False Claims Act occurred").

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[19] Dismissing Relator's complaint for failure to plead facts with any specificity as opposed to just the elements of the cause of action is in keeping with the public policy underpinnings of Rule 9(b). "When a plaintiff does not specifically plead the minimum elements of [his] allegation, it enables [him] to learn the complaint's bare essentials through discovery and may needlessly harm a defendant's goodwill and reputation by bringing a suit that is, at best, missing some of its core underpinnings, and at worse … baseless allegations used to extract settlement." *Clausen*, 290 F.3d at 1313 n.24.

[20] Title VI of the Civil Rights Act of 1964, 42 U.S.C. § 2000d, and Executive Order 13166, 65 Fed. Reg. 50,121 (Aug. 16, 2000), ("Improving Access to Services for Persons with Limited English Proficiency") requires hospitals and providers receiving certain federal funds, such as Medicaid, to take reasonable steps to ensure that LEP individuals are able to have meaningful access to vital programs and services. *See* 45 C.F.R. § 80.3(b)(2).

The State's complaint fares no better. The State makes the conclusory allegation that the contracts between the Hospitals and Clinica "were and are vehicles for illegal kickbacks paid to the Clinica defendants as remuneration for the recruitment and referral of Georgia Medicaid patients to hospitals owned and controlled by Defendants." State Complaint ¶3; *see also* ¶112. The State provides no additional details about the amounts paid under the contracts. And, critically, the complaints do not allege that Clinica did not provide the services for which they were contracted. Entering into contracts for needed services with a referral source is entirely legal, and it is certainly not, as the State's complaint seems to assert, a *per se* violation of the AKS. Indeed, while the AKS applies to referrals between providers and referral sources, it is not a strict liability statute. *See, e.g., Klaczak*, 458 F. Supp. 2d at 688 (noting that the AKS does not impose strict liability).

The absence of any facts demonstrating that the amounts allegedly paid to Clinica for the services provided by Clinica to the Hospitals were not at fair market value (which they were) is also fatal to the complaints. Put simply, absent sufficient allegations demonstrating that the services were not compensated at fair market value, the complaints do not allege remuneration, and thus the AKS-based FCA claims must be dismissed. *See, e.g., Obert-Hong*, 211 F. Supp. 2d at 1049 (dismissing AKS-based FCA claim where relator failed adequately to allege that defendant paid above fair market value to acquire physician practices); *see also Klaczak*, 458 F. Supp. 2d at 679 (granting summary judgment to defendant because "Relators cannot prove that the Hospital Defendants received remuneration—something of value—without comparing contracted rates with fair market value"); *Perales*, 243 F. Supp. 2d at 851 (relator "failed to demonstrate what the fair market value of the practices in question was").

B. The Complaints Fail to Allege That the Hospitals Possessed the Heightened Scienter Requirements of the AKS.

1. Neither Complaint Properly Alleges That the Hospitals Acted With the Intent to Induce Referrals

To survive a motion to dismiss, the complaint must allege that the Hospitals offered remuneration to Clinica *with an intent to induce referrals*. *See* 42 U.S.C. § 1320a-7b(b)(2); *United States v. Starks*, 157 F.3d 833, 840 (11th Cir. 1998) ("intent to *induce referrals*" is an essential element of an AKS charge). The phrase "to induce" has been interpreted to mean "the intent to gain influence over the reason or judgment of a person making referral decisions." *United States v. McClatchey*, 217 F.3d 823, 834 (10th Cir. 2000).

Relator's complaint is devoid of any factual allegations regarding the Hospitals' intent to induce referrals. Relator alleges that "Tenet w[as] financially motivated to enter into the contracts with Clinica to induce Clinica to refer pregnant patients to the Defendants Hospitals." Relator's Complaint ¶182. But a conclusory allegation regarding "financial motivation" falls substantially short of alleging the requisite intent.

The State relies on the fact that Hospital personnel referred to Clinica in documents as a "referral source" (State Complaint ¶116), that "Tenet counted on and tracked revenue from the Clinica Medicaid newborns, …, in addition to the Clinica deliveries" (*id.* ¶117), that "Tenet corporate asked AMC and NF about their clinics' volumes over the past three months, specifically asking about 'overall deliveries, not %.'" (*id.* ¶121), and that when deliveries were lower, Defendant Hospital executives expressed dissatisfaction with the Clinica relationship (*id.* ¶¶122-24). But these allegations as pled are completely consistent with the notion that, by providing services to make pregnant Hispanic women feel more comfortable during delivery,

these women would come to the Hospitals for their deliveries.[21] Courts have held that "a hope, expectation or belief that referrals may ensue from remuneration" does not violate the AKS, *United States v. Rogan*, 459 F. Supp. 2d 692, 714 (N.D. Ill. 2006); *aff'd*, 517 F.3d 449 (7th Cir. 2008) ("[A] hope, expectation or belief that referrals may ensue from remuneration for legitimate services is not a violation of the [AKS]." (citation omitted)); *cf. McClatchey*, 217 F.3d at 834 (approving of a jury instruction which stated that defendants "cannot be convicted merely because they hoped or expected or believed that referrals may ensue from remuneration that was designed wholly for other purposes").

Indeed, one would expect to find the discussions identified by the State regarding the Hospitals' interest in tracking the volume of patients from Clinica given the contracts at issue. The Hospitals contracted for certain amounts of translation, marketing, and pre-admission services from Clinica. By tracking volumes of patients, the Hospitals were ensuring that they had contracted for an appropriate number of translators and were paying for effective marketing services. Indeed, the Hospitals used these statistics to negotiate later iterations of the contracts at issue to ensure they received the right amount of services at fair market value.

And as for the State's reliance on the Hospitals' occasional expression of discontent with the volume of patients, those statements are entirely consistent with the notion that, providing these services, the Hospitals anticipated and believed that they would attract new patients. Absolutely nothing in the discussions relied upon by the State suggests that the Hospitals paid Clinica more than the services were worth in exchange for Clinica agreeing to refer patients to the Hospitals. In short, these facts are not plausibly indicative of an intent to induce. *See, e.g.,*

[21] The State and Relator do not—and cannot—allege that cooperative relationships between clinics and hospitals to attract new patients are inherently unlawful. Indeed, such relationships are common in the Atlanta area and elsewhere.

Iqbal, 556 U.S. at 677 (requiring factual allegations plausibly suggesting (not merely consistent with) a right to relief).

The Complaints are also woefully deficient in detail with respect to any explanation of how Clinica "referred" patients to the Hospitals within the meaning of the AKS. The Complaints make the bald allegations that Clinica "directed" or "referred" patients to the Hospitals, but contain no factual allegations that would explain how the non-physician owners of a clinic—who are by definition not members of the medical staff of any hospital and have no ability to admit the patient to the hospital—could have effectuated such referrals. In similar situations, courts have found that lay-persons who engaged in promotional activities designed to attract patients to a particular provider do not "refer" patients within the meaning of the AKS. Rather, "referrals" are made by physicians who exercise their independent medical judgment and who have the authority to select where their patients will be treated. *See United States v. Miles*, 360 F.3d 472, 480 (5th Cir. 2004) (overturning criminal AKS conviction of lay-persons engaged to market and advertise the services of home health agency because "[t]he payments … were not made to the relevant decisionmaker as an inducement or kickback for sending patients").

2. The Complaints Do Not Adequately Plead That the Hospitals Knowingly and Willfully Violated the AKS

Not only are there no proper allegations of remuneration paid with the intent to induce referrals, there are also no allegations that anyone associated with the Hospitals acted with the requisite intent to violate the law. Relator and the State are required to allege that someone at the Hospitals knew that the AKS prohibited the offering or payment of remuneration to induce referrals, and had the "specific intent to do something the [AKS] forbids, that is with a bad purpose, either to disobey or disregard the law." *Starks*, 157 F.3d at 837-38.

Here, Relator has merely asserted that "Tenet's corporate offices and individual facilities worked together to knowingly and intentionally pay for referrals of Medicaid beneficiaries from Clinica for obstetrical services provided at Tenet hospitals."[22] Relator's Complaint ¶99. Even Relator's sparse allegations have no indicia of reliability because he has no firsthand knowledge of Tenet or the Tenet-affiliated Hospitals as he only worked for HMA. In nearly identical language that is equally conclusory, the State likewise states that "Tenet's corporate office and the individual hospital facilities worked together to knowingly and intentionally pay for referrals of Medicaid beneficiaries from Clinica for obstetrical services and infant care provided at Tenet hospitals."[23] State Complaint ¶118. Neither complaint anywhere alleges facts that show that any individual associated with Tenet or the Hospitals ever believed that the Hospitals were violating the law by contracting with Clinica for necessary services or by working to attract new patients into the healthcare system. The complaints should be dismissed on this basis as well.

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[22] The Relator's failure to plead any facts related to Tenet's alleged intent is not surprising, as it is apparent from his complaint that the Relator has no first-hand knowledge whatsoever about the Hospitals' relationship with Clinica, much less knowledge of any fact that would allow a finding that the Hospitals' employees entered into the agreements with Clinica knowing that such agreements violated the law. The State's failure to plead such facts is even more telling, as the State has conducted its own investigation and has been made aware that Tenet consulted with counsel in connection with each and every Clinica contract. If this matter survives past the pleading stage, Tenet will present evidence that its employees consulted with counsel with respect to the contracts at issue and thus lacked the requisite intent to violate the AKS. *See United States v. Stevens*, 771 F. Supp. 2d 556, 565-66 (D. Md. 2011) ("Good faith reliance on the advice of counsel, when proven, negates the element of wrongful intent of a defendant that is required for a conviction.").

[23] To properly allege an AKS violation, the State and Relator are required to identify a specific individual at the Hospitals who had the requisite specific intent to violate the AKS. Although Rule 9(b) does not require a plaintiff to allege state of mind, it does require the State and Relator to identify "who" had the nefarious intent. Yet neither complaint identifies a single individual at the Hospitals in metro Atlanta or South Carolina who allegedly had the intent to do something that the law forbids.

At bottom, Relator and the State premise all of their claims (FCA and state law) on alleged violations of the AKS. Because they cannot demonstrate an AKS violation, their FCA claims must fail. However, even if the Court determines that the AKS claims may be viable (which they are not), the Relator and the State fail to sufficiently allege a violation of the FCA.

III. THE COMPLAINTS FAIL TO ALLEGE THAT ANY CLAIMS SUBMITTED BY THE HOSPITALS PRIOR TO MARCH 2010 WERE RENDERED FALSE BY ANY POTENTIAL AKS VIOLATION

The gist of Relator's and the State's claims is that the Hospitals' alleged violations of the AKS rendered "false" their subsequent claims for payment for services in connection with the delivery of Medicaid-eligible babies. Determining whether a violation of the AKS can render a subsequent claim "false" for FCA purposes with respect to claims submitted before 2010[24] is the subject of a substantial body of law around the country that draws a critical distinction between conditions of payment and conditions of participation—only the failure to comply with a condition of payment can render a claim false. And because a review of the complaints demonstrates that neither the various provisions of the Georgia Medicaid program nor the various forms referred to by the State and Relator demonstrate that AKS compliance was a condition of payment under the Medicaid program, the complaints must be dismissed with respect to all claims submitted prior to March, 2010.

[24] There is a distinction in the law between claims submitted before passage of the Affordable Care Act ("ACA") on March 23, 2010 and those submitted after ACA. The amendments to the AntiKickback Statute by the ACA establish that allegations of express or implied certifications are no longer required to support an FCA cause of action premised on underlying kickbacks for claims submitted after March 23, 2013 (ACA's effective date). This amendment has no effect on claims submitted prior to the ACA's enactment, which comprise the vast majority of the claims at issue here beginning in 2001. Nothing about this aspect of ACA was intended by Congress to be some kind of "clarification" of existing law, and it would be contrary to the Constitution for the Court to apply these provisions retroactively.

Before turning to a detailed analysis of Plaintiffs' allegations, it is useful to review the analytical framework used by courts to determine whether violations of regulatory requirements are sufficient to render claims false.

A. Legally and Factually False Claims

Courts recognize two types of actionable false claims: factually false and legally false. In a case predicated on a factually false claim, the claim is false because the contractor submitted an "incorrect description of goods or services provided or a request for reimbursement for goods and services never provided." *United States ex rel. Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001)). Legally false claims, sometimes also referred to as claims based on false certifications, differ in that the claim presented to the government is not false or overstated on its face, i.e., the services were actually rendered, but the defendant otherwise violated a statutory or regulatory provision that renders the claim not payable. The premise of a false certification theory is that the defendant has made "false certifications of statutory or regulatory compliance, or of the existence (or non-existence) of certain conditions, which are alleged to be a prerequisite to the government's payment." John T. Boese, *Civil False Claims and Qui Tam Actions* § 1.06(C) (4th ed. last updated 2013). Both complaints allege only legally false certification claims—that is, neither the Relator nor the State allege that the Hospitals failed to provide necessary obstetric services related to the payments at issue.

B. Express and Implied False Certifications

Legally false certification claims fall into two categories: express false certifications and implied false certifications. *See, e.g., United States ex rel. Blundell v. Dialysis Clinic, Inc.*, No. 5:09-CV-00710 (NAM/DEP), 2011 U.S. Dist. LEXIS 4862, at *38-39 (N.D.N.Y. Jan. 19, 2011). The 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." *Mikes*, 274 F.3d at 698. This certification may be any false statement that relates to the claim, as long as it is made through express means. *United States ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1172 (9th Cir. 2006). The complaints make clear that both the State and the Relator are proceeding on an express certification theory.

C. Conditions of Payment v. Conditions of Participation

Conditions of payment are requirements that must be satisfied before the government will pay a claim. *See United States ex rel. Gross v. AIDS Research Alliance-Chicago*, 415 F.3d 601, 604 (7th Cir. 2005). They are distinct from conditions of participation in a government program (such as Medicaid), which are often codified in separate and distinct sections of the relevant regulatory framework from conditions of payment. Failure to comply with a condition of payment may properly form the basis for an FCA suit under the theory that payment would not have been made on the claim absent compliance with the condition of payment. *Mikes*, 274 F.3d at 700. Therefore, if the false certification clearly relates to a condition of payment, courts generally have found that the claim satisfies the "falsity" element of the FCA. *Blundell*, 2011 U.S. Dist. LEXIS 4862, at *39-40.

In *McNutt*, the Eleventh Circuit found that compliance with the AKS was a "condition of payment by the Medicare program," and thus could form the basis of an FCA suit related to Medicare payments. 423 F.3d at 1259. In that case, the defendants were parties to a provider agreement that made explicit compliance with the AKS "a condition for receipt of payments from the Medicare program." *Id.* at 1258. The fatal problem for the Relator's and the State's complaints here is that the ***Medicare*** agreement provisions that led to the *McNutt* court's conclusion are very different from the provisions in the ***Medicaid*** program at issue and referenced in the complaints here.

In *McNutt*, the government alleged that the defendants had violated the FCA by seeking Medicare reimbursement for medical supplies sold by defendants to patients who had been procured by the defendants in violation of the AKS by paying kickbacks to entities that had referred the patients to the defendants. *Id.* at 1258; *see also McNutt ex rel. United States v. Haleyville Med. Supplies, Inc.*, 01-AR-3156-J, slip op. at 1 (N.D. Ala. July 2, 2004). The defendants moved to dismiss. In denying the motion, the District Court noted that the defendant had executed a Medicare enrollment form that contained the following language:

> I agree to abide by the Medicare laws, regulations, and program instructions applicable to DMEPOS supplier. … I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark Law), and on the supplier's compliance with all applicable conditions of participation in Medicare.

Id. at 3 (emphasis omitted).

In other words, the court focused on the fact that the defendants had explicitly agreed through their Medicare provider agreement on the critical legal issue: that compliance with the AKS was a condition of *payment* by Medicare. While the district court denied the motion, it certified the question of whether an alleged AKS violation could form the basis of an FCA claim. *Id.*

On appeal, the Eleventh Circuit held that the government had alleged a valid FCA claim. *McNutt*, 423 F.3d at 1257. Given the language in the form noted above, it is not surprising that the court pointed out that "[n]either party disputes that compliance with federal health care laws, including the [AKS], is a condition of payment by the Medicare program." *Id*. at 1259. Thus, failure to comply with the AKS precluded the defendants from receiving Medicare payments,

and the court held that the knowing submission of claims which that were thus ineligible for payment rendered the claims false under the FCA.

In contrast to circumstances like those present in *McNutt*, if the condition or requirement that has not been satisfied is not a condition for **payment**, but rather a condition of **participation**, courts routinely conclude that such violations do not render claims false, as a claim may be eligible for payment even if a provider is out of compliance with one or more conditions of participation at the time the claim is submitted. *See, e.g., Mikes*, 274 F.3d at 702 (discussing conditions of participation versus payment in an implied certification context); *United States ex rel. Landers v. Baptist Mem'l Health Care Corp.*, 525 F. Supp. 2d 972, 978 (W.D. Tenn. 2007) (holding that "Conditions of Participation are not the equivalent of Conditions of Payment" and thus that the alleged failure to comply with Medicare conditions of participation does not amount to a false or fraudulent claim under the FCA). FCA liability thus requires a clear violation of a condition of payment, and not simply a condition of participation.

The Sixth Circuit recently affirmed that the failure to comply with a condition of participation cannot be the predicate act for a false claim. *See United States ex rel. Hobbs v. MedQuest Assocs.*, 711 F.3d 707 (6th Cir. 2013). In *MedQuest*, the Sixth Circuit reversed the district court's entry of summary judgment because the liability was based on regulatory non-compliance that was a "condition of participation" in Medicare, but not a "condition of payment" of Medicare claims. *Id.* at 714. The government argued that the claims for payment to Medicare were false because MedQuest had failed to comply with certain Medicare requirements regarding approved physicians that were specified in the regulations. In its enrollment application with Medicare, MedQuest had expressly certified that it would "'abide by the Medicare laws, regulations and program instructions.'" *Id.* The court observed that neither this regulation—nor

any other identified by the government—made compliance with the "approved physician" requirement a condition of payment. *Id.* at 715. The court applied the same analysis and reached the same result with respect to the government's second claim that MedQuest submitted false claims when it used a former owner's facility billing number after a transfer of ownership. *Id.* at 717-18. The court held that at most, MedQuest failed to update its enrollment information after the transfer of stock ownership of the facility, but this failure was not a condition of payment. *Id.* at 718-19.

Although the court characterized the Medicare program violations as "clearly … at odds with the goals and aims of the Medicare program in several respects," *id.* at 713, the court ruled that the government cannot use the FCA to enforce or punish that type of conduct and instead should use available administrative remedies, *id.* at 717. The Sixth Circuit made clear that regulatory violations that are violations of "conditions of participation"—even if serious and intentional—are not enough to establish an FCA violation and do not "mandate the extraordinary remedies of the FCA." *Id.* at 713.

Consistent with this framework, courts have found violations of the AKS actionable under the FCA only when the defendant has certified that it complied with the law, and when that certification of compliance was a prerequisite to payment under a government program. *United States v. Medina*, 485 F.3d 1291, 1305 (11th Cir. 2007); *see also United States ex rel. Bennett v. Medtronic, Inc.*, 747 F. Supp. 2d 745, 783-85 (S.D. Tex. 2010) (dismissing FCA claims "[b]ecause the relators have not alleged that Medtronic caused any hospital or physician to certify compliance with the anti-kickback statute"); *United States ex rel. Kennedy v. Aventis Pharm., Inc.*, 610 F. Supp. 2d 938, 946 (N.D. Ill. 2009) (dismissing FCA claims because "relators have identified no express false certification of compliance with the anti-kickback

statute"); *United States ex rel. Barmak v. Sutter Corp.*, No. 95 CIV.7637 KTD RLE, 2002 WL 987109, at *6 (S.D.N.Y. May 14, 2002) (dismissing FCA claims where "plaintiffs have not alleged any certification of compliance with the anti-kickback statute, or that the Government relied on such certification in making payments to Defendants").

It is significant that the distinction between conditions of payment and conditions of participation in the FCA context has been established for a number of years. The State of Georgia therefore has had many years to change its forms if it wanted to mandate that compliance with the AKS was a condition of payment. Georgia has not done so, and its decision not to do so must be given effect.

D. The State and Relator Rely On Certifications That Do Not Expressly Certify Compliance With the AKS And/Or Are Not Conditions For Payment Under Medicaid

As noted above, Relator and the State rely on an express certification theory. *See* State Complaint ¶26 ("[T]he Defendant Hospitals have falsely and expressly certified to Georgia Medicaid that they were in compliance with the Medicare and Medicaid Patient Protection Act." (citation omitted)); Relator's Complaint ¶46. However, the allegations in the complaints are plainly insufficient to support a FCA claim based on such a theory.

Specifically, the State and Relator have relied exclusively on certifications that either (i) on their face do not certify compliance with the AKS and/or (ii) are not conditions of payment under Georgia Medicaid. Because neither the State nor the Relator identifies any certification of compliance with AKS that constitutes a condition of payment under Georgia Medicaid, both complaints must be dismissed with respect to all claims filed before March 2010. Each of the certifications identified in the complaints is discussed below.

E. Certifications Made to Medicare are Irrelevant

The first category of certifications identified by the State relate to the Medicare program. But every claim in this case is a state ***Medicaid***—not Medicare—claim. Accordingly, the Medicare provisions have no applicability and cannot provide the basis for alleging that claims submitted to Medicaid—an entirely different program with different requirements—are false.

In order to satisfy their obligation to demonstrate that the Hospitals have certified compliance with the Anti-Kickback Statute as a condition of payment, the State and Relator rely on several different sources, including Hospital Insurance Benefit Agreements, Medicare Enrollment Applications for Institutional Providers, and Cost Report Applications. None of these, however, does what is required to adequately plead a claim here – that is, none of the sources shows that the Hospitals' certified compliance with the Anti-Kickback Statute as a condition of *payment*.

1. Hospital Insurance Benefit Agreement

Relator and the State both rely on Hospital Insurance Benefit Agreements, which are applications submitted to CMS in connection with the Medicare program, in alleging their FCA theories. State Complaint ¶¶33-34; *see also* Relator Complaint ¶43-44. But as the State's complaint itself asserts, the Hospital Insurance Benefit Agreement is a condition of "*participation* in the Medicare program"—not a condition of payment. State Complaint ¶33 (emphasis added). More importantly, because the Insurance Agreement relates to Medicare—an entirely different program and does not even condition payment of Medicare claims on compliance with its terms, the certifications made in them cannot be the basis of a false certification theory with respect to Georgia Medicaid claims.

2. Medicare Enrollment Application for Institutional Providers

Both complaints next rely on the Medicare Enrollment Application, called a CMS Form 855A. This is the same Medicare form relied on by the *McNutt* court. But this Medicare form is inapplicable to a Medicaid-only case involving only Medicaid claims. State Complaint ¶¶35-36; Relator Complaint ¶¶45-46. There are separate Medicaid applications in Georgia. *See* Centers for Medicare & Medicaid Services, Department of Health and Human Services, CMS Form 10115, *available at* http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms10115.pdf. Yet neither complaint even attempts to explain how a certification of compliance with Medicare rules that is not submitted to the State could possibly be a condition of payment under Georgia Medicaid. The lack of a citation to any such payment rule speaks volumes.

3. Cost Report Certifications

Both the State and Relator also attempt to rely on Medicare cost report certifications. The State alleges that "As a ***necessary condition to payment by Medicare***, CMS requires hospitals to submit on an annual basis a form CMS-2552, more commonly known as the "Hospital Cost Report." State Complaint ¶39 (emphasis added); *see also* Relator's Complaint ¶¶47-48.

Once again, the plaintiffs conflate federal Medicare and state Medicaid program requirements, relying on certifications submitted to ***Medicare***, on cost reports that at best must be submitted in order for hospitals to receive ***Medicare*** reimbursement. And once again, neither complaint alleges that these certifications made to Medicare are or could somehow be conditions for payment of claims under Georgia's ***Medicaid*** program. While the State does allege that copies of these Medicare cost reports must be and were submitted to Georgia Medicaid, State Complaint ¶40, there is no allegation that the mere act of supplying these cost reports is a

condition of payment under the Georgia Medicaid program, much less that the substance of any certification made to Medicare was somehow a condition of payment by the State.

F. The Georgia Medicaid Program Explicitly Labels Compliance With Anti-Kickback Provisions as a Condition of Participation Not a Condition of Payment

The State next attempts to plead false certification by relying on the Georgia Medicaid Regulations and the Provider Agreement which references them. As set forth below, a review of the very regulations cited by the State demonstrates that the Georgia Medicaid program explicitly recognized the distinction between conditions of participation and conditions of payment, and made the choice to consider compliance with the anti-kickback provisions as a condition of participation.

1. The Georgia Medicaid Regulations Include Specific Conditions of Payment

The Georgia Medicaid regulations identify expressly the provisions that the State considers as conditions for payment—and this does not include the AKS. *See* Division of Medical Assistance, Georgia Department of Community Health, *Part I Policies and Procedures for Medicaid/Peachcare for Kids* (Apr. 1, 2011), *available at* https://advocacy.gha.org/Portals/1/Documents/Advocacy/Finance/MedicaidPeachcare.pdf ("Georgia Medicaid Procedures"). For example, with respect to beneficiaries that are covered by both Medicare and Medicaid, the regulations require coordination of benefits with Medicare and provide: "When a Medicaid member is also covered by Medicare, the following conditions must be met in order for Medicaid benefits to be paid…." *Id.* § 302.1. Indeed, the State in its complaint refers to Section 106.1 of the Georgia Medicaid regulations and the associated Attestation of Compliance, provisions where the State makes clear that compliance with a

different federal statute (42 U.S.C. § 1396a(68)) is not merely a condition of participation but is a condition of payment. That section provides:

> As further terms and conditions of participation, and in compliance with [42 U.S.C. §1396(a)(68)], all entities that receive annual Medicaid payments of at least $5 million shall, as a condition of receiving such payments, establish written policies for all employees (including management), and of any contractor or agent of the entity, that include detailed information about the False Claims Act and the other provisions named in [42 U.S.C. §1396(a)(68)(A)].

Georgia Medicaid Procedures § 106.1

The regulations go on to require the execution of an Attestation of Compliance, an example of which is attached to the State's complaint as Exhibit D. Here again, the Attestation form itself is explicit that compliance with these provisions is a condition of payment and not a mere condition of participation. *See* Georgia Medicaid Procedures, Appendix K ("I hereby attest that, as a condition for the above-identified Covered Entity to receive payments under the Georgia Medicaid/PeachCare for Kids Program ….").

2. The Attestation of Compliance Does Not Condition Payment on Compliance with the AKS

While the Attestation of Compliance is expressly labeled a condition of payment, the content of that attestation does not in any way certify compliance with the AKS or any state anti-kickback provisions. The very language cited in the State's complaint makes clear that the required certification is simply that the Provider maintains written policies and procedures regarding various state and federal laws. The Attestation in no sense certifies compliance with any of the underlying statutory provisions—only that the Provider maintains policies that address these statutes and that such policies are provided to employees and contractors. *See* State Complaint, Exhibit D (Attestation of Compliance, Georgia Medicaid Procedures, Appendix K).

The State has not alleged that any of the Hospitals failed to create and maintain the required policies and procedures. Thus, although these provisions are conditions of payment, the Attestations of Compliance do not render any claims submitted by the Hospitals false.

3. The Georgia Provider Agreements and Medicaid Regulations Do Not Condition Payment on AKS Compliance

The State next refers to the Georgia Provider Agreements. But the provisions cited in the complaint do not contain any agreement that payment is conditioned on compliance with the AKS along the lines of the enrollment application cited in *McNutt*. *See* State Complaint ¶¶47-48. Indeed, the State complaint points to no provisions in the Georgia Provider Agreement that references the AKS (or any other specific statute). *See id.* Instead, the State complaint simply refers to broad provisions in the Agreement that specify prospective compliance with all requirements including those set forth in the Georgia Medicaid regulations.[25] *Id.*

As noted above, however, those regulations explicitly draw the distinction between conditions of payment, such as compliance with 42 U.S.C. §1396(a)(68), on the one hand and conditions of participation on the other. Thus, while as noted in the State's complaint, the regulations prohibit kickbacks as defined as "[a]ny offer … for remuneration … in return for the referral of a Medicaid … member," the State regulators considered the anti-kickback issue and chose to address it as one of some thirty-eight "General Conditions of Participation," not a condition of payment. State Complaint ¶51. Similarly, the broad provision in the regulations cited in the State's complaint, that providers "[c]omply with all State and Federal laws and

[25] The statements in these applications are forward-looking and include only promises to comply with health care laws in the future. They do not certify past compliance and are not submitted in connection with any later-submitted claims. Thus, at most these agreements acknowledge that a provider has read and understood the conditions of participating in the program, but they cannot support an FCA claim. *See United States ex rel. Graves v. ITT Educ. Servs., Inc.*, 284 F. Supp. 2d 487, 500-02 (S.D. Tex. 2003) (certifications of future compliance do not give rise to FCA liability), *aff'd*, 111 F. App'x 296 (5th Cir 2004).

regulations related to furnishing Medicaid/ Peachcare for Kids service" is candidly labeled by the State in its Complaint as a one of the "General Conditions of Participation"—not a condition of payment. *Id.*

There is no dispute that the State in its regulations distinguishes between conditions of payment and conditions of participation. There is also no dispute that the State addressed compliance with anti-kickback provisions and chose to label such compliance as a condition of participation. The State Medicaid regulations and the associated Provider Agreements thus provide no support for the State's theory that alleged non-compliance with AKS or any state anti-kickback provisions rendered any claims submitted by the Hospitals false.

4. Electronic Funds Transfer Certifications of Compliance

The State next relies on the compliance certification for electronic funds transfer ("EFT"). But like the Attestation discussed above, the EFT Agreement cannot be the basis of an FCA claim because the Certificate of Compliance in the EFT Agreement nowhere certifies compliance with the AKS, and the State alleges no other factual basis upon which such certification is allegedly false.

5. Power of Attorney Certifications

Finally, the State turns to the Power of Attorney Certifications that are executed when the Defendant Hospitals employ a third party "Billing Service," to undertake and process the electronic Medicaid claims submission. State Complaint ¶¶61, 63. The Power of Attorney Certifications cannot be the basis of an FCA claim. The certification nowhere mentions the AKS, nor does it certify compliance with it as a condition of payment. At most, the certification is an acknowledgment that submission of a false claim is a crime.

IV. RELATOR'S COMPLAINT FAILS TO ALLEGE THAT HILTON HEAD HEALTH SYSTEM SUBMITTED A FALSE CLAIM

Relator fails to identify any false or fraudulent claim submitted by Hilton Head Health System to the government and, therefore, Relator's allegations against Hilton Head should be dismissed in their entirety.

The "'central question'" in a claim brought under the False Claims Act is "'whether the defendant ever presented a "false or fraudulent claim" to the government.'" *Hopper*, 588 F.3d at 1326 (quoting *Clausen*, 290 F.3d at 1311). "Without the presentment of such a claim, … there simply is not actionable damage to the public fisc as required under the False Claims Act." *Clausen*, 290 F.3d at 1311. Here, Relator has failed to identify a single false claim made by Hilton Head Hospital. Although Relator purports to identify eleven such claims made by AMC, North Fulton, and Spalding, *see* Relator Complaint ¶¶105-15, any such claims about Hilton Head are conspicuously absent.

Nor do Relator's allegations carry any indicia of reliability that might otherwise excuse his failure to identify specific claims submitted by Hilton Head. *See United States ex rel. Schubert v. All Children's Health Sys., Inc.*, No. 8:11–cv–1687–T–27EAJ, 2013 WL 1651811 (M.D. Fla. Apr. 16, 2013). Relator did not work "'in the very department where [he] allege[s] the fraudulent … scheme occurred.'" *Id.* at *4 (citation omitted). In fact, he did not work for any of the Hospitals in any capacity at any time. Thus, Relator's complaint lacks any indicia of reliability and the allegations against Hilton Head should be dismissed as a result. *See United States ex rel. Sanchez v. Lymphatx, Inc.*, 596 F.3d 1300, 1303 (11th Cir.2010) ("Despite her assertion that she had direct knowledge of the defendants' billing and patient records, however, Sanchez failed to provide any specific details regarding either the dates on or the frequency with which the defendants submitted false claims, the amounts of those claims, or the patients whose

treatment served as the basis for the claims. Without these or similar details, Sanchez's complaint lacks the 'indicia of reliability' necessary under Rule 9(b) ...." (citation omitted)).

V. BOTH COMPLAINTS FAIL TO ALLEGE THAT THE HOSPITALS KNOWINGLY SUBMITTED A FALSE CLAIM

The Eleventh Circuit has held that "in a health care fraud case, the defendant must be shown to have known that the claims submitted were in fact, false." *Medina*, 485 F.3d at 1297. "'For a certified statement to be "false" under the Act, it must be an intentional, palpable lie' … known to be a lie when it is made." *Hendow*, 461 F.3d at 1172 (citations omitted). Relator is required to allege—with particularity under Rule 9(b)—that the Hospitals' certifications of compliance were "knowingly false when made." *Id.*; *United States ex rel. Parato v. Unadilla Health Care Ctr., Inc.*, 787 F. Supp. 2d 1329, 1340 (M.D. Ga. 2011) (dismissing FCA claim where relator did not allege that defendant's "assurances and certifications were known to be false at the time they were made"). The complaints fail to state that the Hospital employees signing the certifications knew about the alleged remuneration scheme and therefore knew that the certifications were false when submitted.

Under Rule 9(b), a complaint that alleges fraud by a corporate defendant must allege "who" at the Company engaged in the alleged fraud, and "the role these individuals played in the alleged fraud." *United States ex rel. Williams v. Martin-Baker Aircraft Co.*, 389 F.3d 1251, 1257 (D.C. Cir. 2004). Neither the State nor Relator identifies any individual Hospital employees who were supposedly at fault for the Hospitals' conduct. Neither complaint contains any allegation that any individual knew of the allegedly fraudulent scheme. Because the Complaint fail to plead facts as to "'who engaged in'" the "'allegedly fraudulent acts,'" *Hopper*,

588 F.3d at 1324 (citation omitted), the FCA claims fails to satisfy Rule 9(b) and should be dismissed on this basis as well.[26]

VI. THE STATE'S COMMON LAW CLAIMS SHOULD ALSO BE DISMISSED

A. Fraud and Deceit (Count V)

The State's common law claim for fraud and deceit should also be dismissed. Under Georgia law, a claim for fraud and deceit has five essential elements: (1) a false representation, (2) "'scienter, the intent to deceive,'" (3) an intent to induce the plaintiff to act "'in reliance upon the representation,'" (4) justifiable reliance, (5) "'damages directly and proximately caused by the reliance.'" *Harrouk v. Fierman*, 291 Ga. App. 818, 822 (2008) (quoting *Middleton v. Troy Young Realty, Inc.*, 257 Ga. App. 771, 772 (2002)). The State's generic assertions reflect an awareness of these elements, but the Complaint fails to include the specific allegations that Rule 9(b) requires to state such a claim. The State not only fails to identify with specificity the actual false representations made or the way in which those representations were untrue, it cannot sufficiently allege reliance on such representations or damage caused by that reliance because (as discussed in Section III above) none of the alleged false certifications (which are the only candidate representations in the Complaint) were a condition for payment by Medicaid. Additionally, the State's Complaint lacks any allegation identifying anyone who acted with the intent to deceive in making any representation to the State, much less anyone who did so with the intent that the State rely on it to pay any of the Medicaid claims at issue in this case. Finally, the fundamental basis of the State's fraud claim is an AKS violation, which as demonstrated above,

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[26] The State's claims for violations of the Georgia False Medicaid Claims Act (Counts I and II), the Georgia Medical Assistance Act (Count III), and Civil Conspiracy under the Georgia False Medicaid Claims Act (Count IV) should all be dismissed on the same grounds as the Relator's claims for violations of the Federal Medicaid Act as those claims each require the same elements of proof.

the State has failed to adequately allege. Therefore, the State's fraud claim must also be dismissed.

B. Breach of Contract (Count VI)

The State's breach of contract claim is based on the State's allegation that "Georgia alleges that it entered into provider agreements with the Defendants Hospitals for the provision of medical services to Medicaid and EMA recipients, and that these provider agreements included, as material terms, the Defendants' Hospitals' agreements not to pay kickbacks for Medicaid patient referrals." State Complaint ¶176. The State alleges that "the Defendant Hospitals paid kickbacks to Defendant Clinica for the referral of Medicaid and EMA patients." *Id.* ¶177. Although the State's breach of contract claim is pled in the alternative to its Medicaid claims, it nonetheless bases this claim on its allegations that the Hospitals paid kickbacks. But as explained above, the complaint fails to allege that Clinica never provided the services for which the Hospitals paid it or that the services were not paid for at fair market value. *See infra* at X. If the Hospitals contracted for services from Clinica at fair market value and the services were provided under the contracts, the State cannot sustain its putative breach of contract claim. Thus, Georgia has not adequately alleged a breach of the provider agreements.

C. Payment By Mistake (Count VII)

Similarly, the State's claim for payment by mistake of fact must also be dismissed. The State alleges that it "paid the hospital defendants for claims for health services rendered to patients who had been referred as a result of illegal kickbacks without knowledge of material facts, and under the mistaken belief that the hospital defendants were entitled to receive payment for such claims, which were not eligible for payment. The State of Georgia's mistaken belief was material to its decision to pay the hospital defendants for such claims." State Complaint ¶182. Again, the complaint fails to adequately allege that Clinica never provided the services for

which the Hospitals paid it or that the services were not paid for at fair market value, and thus has not adequately alleged that any kickbacks were paid. Accordingly, the State's claim for payment by mistake must fail as well.

D. Fraudulent Concealment (Count VIII)

Finally, the State's fraudulent concealment claim is also based on the Hospitals' alleged kickback scheme that has not been adequately alleged. "To establish a prima facie case of fraudulent concealment, plaintiffs must prove, *inter alia*, that the "defendant made a false representation of a material fact or concealed a material fact when under a duty to disclose" and that the "defendant knew the representation to be false or omission to be true when he made it." *McLendon v. Georgia Kaolin Co.*, 837 F. Supp. 1231, 1239 (M.D. Ga. 1993). The State's complaint fails to allege either of these elements. It has not adequately alleged a kickback scheme and this has failed to allege that the Hospitals made a false representation of material fact. And the State's complaint fails to identify a single individual who knew that any claims made to the State were false when they were made. In sum, the State's entire complaint must be dismissed.

VII. THE COMPLAINTS SHOULD BE DISMISSED WITH PREJUDICE

Neither the State nor Relator should be permitted to amend their complaints. Under Federal Rule of Civil Procedure 15(a), a court should give leave to amend freely "when justice so requires." Fed. R. Civ. P. 15(a)(2). The district court, however, need not "allow an amendment … where amendment would be futile." *Corsello*, 428 F.3d at 1014 (citation omitted); *id.* (holding that the district court did not abuse its discretion when it determined that allowing plaintiff "to amend his complaint would have been futile"). In *Corsello*, the Court noted that the complaint did not have the indicia of reliability necessary for the plaintiff to plead fraud with particularity because although the plaintiff had worked in sales for the defendant he

did not have access to the information necessary to meet the specificity required by Rule 9(b). *Id.* at 1015. Thus, any further amendment of the complaint would be futile. Here, the Relator, who was never employed at Tenet, has amended his complaint three times in four years and still provides no detail whatsoever regarding the factual allegations as they relate to Tenet or the Hospitals. Just as in *Corsello*, Relator should not be permitted to amend his complaint. "[T]he *Qui Tam* Act was not enacted in order give the relator an unlimited opportunity to perfect its complaint." *Id.* at 1011. Neither should the State be permitted to amend its complaint. Although the State had access to ample discovery prior to intervening in this case, its complaint was nonetheless deficient in a number of ways. There is nothing to suggest that the State will be able to cure the deficiencies in its complaint either.

CONCLUSION

For the foregoing reasons, the SC/Atl Defendants respectfully request that the Court dismiss all counts of both complaints with prejudice and without leave to amend.

Respectfully submitted,

/s/ William H. Jordan

ALSTON & BIRD LLP
William H. Jordan
Georgia Bar Number 405112
bill.jordan@alston.com
Samuel R. Rutherford
Georgia Bar Number 159079
sam.rutherford@alston.com
Matthew L.J.D. Dowell
Georgia Bar Number 236685
matt.dowell@alston.com
1201 West Peachtree Street
Atlanta, GA 30309-3424
Telephone: (404) 881-7000
Fax: (404) 881-7777

LATHAM & WATKINS LLP
Roger S. Goldman (pro hac petition forthcoming)
Abid R. Qureshi (pro hac petition forthcoming)
555 Eleventh Street, NW, Suite 1000
Washington, DC 20004-1304
(202) 637-2200

David J. Schindler (pro hac petition forthcoming)
355 South Grand Avenue
Los Angeles, CA 90071-1560
(213) 485-1234

Katherine A. Lauer (pro hac petition
forthcoming)
600 West Broadway, Suite 1800
San Diego, CA 92101-3375
(619) 236-1234

Counsel for Defendants Tenet Healthcare Corporation,
Tenet HealthSystem GB, Inc., North Fulton Medical Center, Inc.,
Tenet HealthSystem Spalding, Inc., and Hilton Head Health System, L.P.

CERTIFICATE OF SERVICE

I hereby certify that I have this day served a true and correct copy of the within and foregoing **SC/Atl Defendants' Memorandum of Law in Support of Their Motion to Dismiss** using the Clerk of Court's CM/ECF system, which will automatically send email notifications of such filing to the attorneys of record in this case.

This 8th day of November, 2013.

/s/ Samuel Rutherford
Samuel Rutherford