IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

COMMONWEALTH OF VIRGINIA *ex rel.* HUNTER LABORATORIES, LLC, *et al.*	)	
Plaintiff-Relators,	)	
v.	)	CASE NO. 1:13-CV-1129 (GBL/TCB)
QUEST DIAGNOSTICS, INC., *et al.*	)	
Defendants.	)	

MEMORANDUM ORDER AND OPINION

THIS MATTER is before the Court on Defendants Laboratory Corporation of America Holdings and Laboratory Corporation of America (collectively "LabCorp")'s Motion to Dismiss for Failure to State a Claim (Doc. 73). This case involves allegations that LabCorp (i) overcharged the Commonwealth of Virginia for Medicaid-reimbursable testing and (ii) provided kickbacks to healthcare providers to induce the referral of Medicaid business. Relators Hunter Laboratories, LLC and Chris Reidel (collectively "Relators") bring their allegations as claims under the Virginia Fraud Against Taxpayers Act ("VFATA").

There are three issues before the Court. The first issue is whether the Court should dismiss the Amended Complaint for failure to seal where the original Complaint was sealed and the Amended Complaint alleges the same conduct as the original Complaint but a different regulatory basis for liability and a different set of overcharges. The Court denies the Defendant's Motion to Dismiss the Amended Complaint for failure to seal. Relators have consistently alleged the same underlying conduct and gave the Commonwealth sufficient opportunity to investigate those allegations when they sealed the original Complaint. Because the Commonwealth is well

advised on whether the alleged conduct violates Commonwealth laws and regulations, failure to seal the Amended Complaint is not a basis for dismissal.

The second issue is whether the Court should dismiss the Amended Complaint where Relators allege that LabCorp's entry into a Medicaid participation agreement is a false certification and where Relators do not identify a single false claim for payment. The Court **GRANTS** LabCorp's Motion to Dismiss because Rule 9(b) requires the identification of at least one false claim, and Relators' general allegations that claims for payment were made fail to meet that requirement. Moreover, the Amended Complaint fails to satisfy Rule 8(a) because Relators have not pled facts sufficient to establish that the representations LabCorp made in the participation agreement were a false certification.

The third issue is whether the Court should dismiss the Amended Complaint with prejudice, given that Relators knew of the defects befalling the original Complaint and yet duplicated many of those defects in the Amended Complaint, including the failure to identify a single false claim. The Court **GRANTS** LabCorp's Motion to Dismiss, **DISMISSES** the Amended Complaint **WITH PREJUDICE**, and **DENIES** leave to amend because Relators' failure to remedy their pleading defects, despite notice and an opportunity to remedy, indicates that further attempt at amendment would be futile.

I. BACKGROUND

Relators Hunter Laboratories, LLC ("Hunter") and Chris Reidel ("Reidel") (collectively "Relators") bring this action on behalf of Plaintiff the Commonwealth of Virginia ("Commonwealth") against Defendants Laboratory Corporation of America and Laboratory Corporation of America Holdings (collectively "LabCorp"). LabCorp and Hunter are

commercial reference laboratories operating nationally and in the Commonwealth. (Doc. 71, ¶ 24.) Reidel is Hunter's Chief Executive Officer. (*Id.* ¶¶ 17–18.)

Commercial reference laboratories provide outpatient clinical testing services to aid healthcare providers in medical diagnosis and treatment. (*Id.* ¶ 28.) Commercial reference laboratories bill these services to many types of healthcare providers, including hospitals, private physicians, and state-administered Medicaid programs. The Commonwealth administers its Medicaid program through the Department of Medical Assistance Services ("DMAS"). When a commercial reference laboratory performs a Medicaid-reimbursable test, it bills DMAS directly and is reimbursed by DMAS directly. (*Id.* ¶ 29.)

A. Overcharge and Kickback Theories of VFATA Liability

This action revolves around Medicaid-reimbursement claims submitted by LabCorp to DMAS. Relators allege that the claims are "false" and thus actionable under the Virginia Fraud Against Taxpayers Act ("VFATA") because LabCorp's business practices violated both a state regulation and federal statute. Specifically, Relators allege that LabCorp violated (i) 12 Va. Admin. § 30-120-1040 ("Waiver Regulation") by charging DMAS higher rates than non-Medicaid customers and (ii) 42 U.S.C. § 1320a-7b ("Anti-Kickback Statute") by offering discounts to healthcare providers to induce the referral of Medicaid business.

The Waiver Regulation is a state regulation concerning home and community-based waiver services. It requires "[p]roviders approved for participation [to] . . . [s]ubmit charges to DMAS . . . in amounts not to exceed the provider's *usual and customary charges* to the general public . . . ." 12 Va. Admin. § 30-120-1040(C)(8) (emphasis added). Relators allege that charging lower rates to non-Medicaid customers and higher rates to DMAS violated the Waiver

Regulation because the lower rates constituted LabCorp's "usual and customary charges" and thus should have been charged to DMAS as well.

The Anti-Kickback Statute is a federal statute prohibiting, *inter alia*, the offering or paying of kickbacks. In the Medicaid context, kickbacks are remuneration knowingly and willfully paid or offered to induce the referral of "any item or service for which payment may be made in whole or in part under a Federal health care program." *See* 42 U.S.C. § 1320a-7b(b)(2)(A). Relators allege that the discounts LabCorp gave to referring providers were kickbacks made in violation of the statute.

According to the Amended Complaint, violation of the Waiver Regulation and Anti-Kickback Statute made LabCorp's claims false because they made LabCorp's representations that it would comply with applicable laws and regulations false.[1] LabCorp made these representations when it entered into the Virginia Medicaid Independent Laboratory Participation Agreement. Under the Agreement, LabCorp represented (i) "that charges submitted for services rendered [would] be based on the usual, customary, and reasonable concept" and (ii) that it would "comply with all applicable state and federal laws, as well as administrative policies and procedures of VMAP as from time to time amended." (*Id.* ¶ 11.)

B. Scheme to Overcharge DMAS in Violation of the Waiver Regulation

The Amended Complaint details the underlying schemes to overcharge DMAS and pay kickbacks. For the overcharge scheme, LabCorp maintains both a Patient List Price and Client List Price for its testing services. The Patient List Price is the highest price LabCorp bills private

[1] Although the Amended Complaint appears to pursue a falsity-by-certification theory, in their papers on the Motion to Dismiss, Relators supplemented this theory with a falsity-by-overcharge theory. (*See* Doc. 78, at 20–21.) Relators argued that the falsity of LabCorp's claims lies solely in LabCorp "charg[ing] a higher dollar amount than allowed under a contract, law, or regulation." However, as discussed, *see infra* Section III.C, false-claims liability based on a regulatory, statutory, or contractual violation requires allegation of a false certification.

insurers for testing of privately-insured patients. The Client List Price is the highest price LabCorp bills physicians for testing of uninsured patients. Usually, the Patient List Price for a given service is higher than the Client List Price.

Although the Patient List Prices and Client List Prices are the highest stated prices, private insurers and physicians are not charged at those prices. Instead, LabCorp negotiates discounts for each private insurer and physician, resulting in individually tailored, lower fee schedules. On the other hand, "LabCorp charges Virginia Medicaid solely its Patient List Price—the highest rates charged to any customers." (Doc. 71, ¶ 33.) The Amended Complaint alleges that this billing practice violated a regulatory obligation to charge DMAS only its "usual and customary" rates.

Additionally, Relators allege that between 1997 and 2008, LabCorp submitted 2,730,814 claims to DMAS, and DMAS reimbursed LabCorp a total of $39,367,802. (*Id.* ¶ 45.) Relators allege that "[o]n each of those [2,730,814] claims," LabCorp violated the Waiver Regulation by charging DMAS above its "usual and customary" rates. (*Id.* ¶ 46.) Relators provide a table comparing the discounted prices given to two private insurers, United Healthcare and Premier, with the maximum DMAS reimburses for each service. (*Id.* ¶ 44.) The table does not include the actual rates that LabCorp charged DMAS. Instead, Relators allege that "the Medicaid maximum rates . . . are the minimum that LabCorp charges Medicaid." (*Id.*)

C. Scheme to Pay Kickbacks in Violation of the Anti-Kickback Statute

For the kickback scheme, the Amended Complaint alleges that LabCorp provided below-cost discounts to physicians and private insurers to induce the referral of Medicaid business to LabCorp. (*Id.* ¶¶ 55–56.) A physician is incentivized to secure discounts because the physician can then pocket those discounts. (*Id.* ¶ 52.) LabCorp provides private insurers with discounts

because the insurers can influence in-network physicians to use LabCorp and those physicians can refer Medicaid business to LabCorp. (*Id.* ¶ 56.)

Relators do not allege how many claims were submitted as a result of "kickbacks." Rather, they allege that "LabCorp's average fully-allocated cost per test is approximately $14.11, and its SG&A cost is approximately $3.47 per test." (*Id.* ¶ 66.) "SG&A" refers to the cost of sales as well as general and administrative costs. Relators then include a table listing the prices charged to one non-Medicaid provider, Premier, by service and checking off whether those prices fall below the $14.11-average for a test or the $3.47-average for SG&A. (*Id.* ¶ 67.)

D. Procedural History

Relators filed the Original Complaint in the Circuit Court for Fairfax County on December 17, 2007, against three sets of Defendants: LabCorp, Quest Diagnostics, Inc. ("Quest"), and Specialty Laboratories, Inc. ("Specialty"). (Doc. 1.) On September 9, 2013, all Defendants removed this action to the Eastern District of Virginia. (*Id.*) On October 25, 2013, the Court granted each Defendant's Motion to Dismiss the Original Complaint. (Doc. 56.) Relators filed a motion for leave to amend on November 8, 2013, (Doc. 58), which the Court granted on December 11, 2013, (Doc. 71). In between filing the motion to amend and filing the Amended Complaint, Relators reached a provisional settlement with Quest and Specialty. A stay with respect to Quest and Specialty remains in effect. (Doc. 99.)

II. STANDARD OF REVIEW

A motion to dismiss a complaint under Rule 12(b)(6) of the Federal Rules of Civil Procedure should be granted unless the complaint "states a plausible claim for relief." *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 563 (2007)); *see also* Fed. R. Civ. P. 8(a)(1), 12(b)(6). In considering a Rule 12(b)(6) motion, the Court must

construe the complaint in the light most favorable to the plaintiff, read the complaint as a whole, and take the facts asserted therein as true. *Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1134 (4th Cir. 1993).

In *Bell Atlantic Corp. v. Twombly*, the Supreme Court held that a complaint must "possess enough heft" (that is, "factual matter") to set forth grounds for the plaintiff's entitlement to relief and "to state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 557, 570. The complaint must contain sufficient factual allegations, which if taken as true, "raise a right to relief above the speculative level," *id.* at 555, and "across the line from conceivable to plausible," *id.* at 570. The Court explained further, in *Ashcroft v. Iqbal*, that the standard of facial plausibility requires pleading of "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 556). "A pleading that offers labels and conclusions[,] a formulaic recitation of the elements of a cause of action[,]" or "naked assertions devoid of further factual enhancement" will not suffice. *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 555, 557) (internal quotation marks omitted).

In cases involving fraud, plaintiffs "must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). In the false-claims context, this requires pleading "the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby." *United States ex rel. Wilson v. Kellogg, Brown & Root, Inc.*, 525 F.3d 370, 379 (citing *Harrison,* 176 F.3d at 784) (internal quotations omitted). Failure to comply with Rule 9(b) is treated as failure to state a claim under Rule 12(b)(6). *United States ex rel. Jones v. Collegiate Funding Servs., Inc.*, 469 F. App'x 244, 257 (4th Cir. 2012) (citing *Harrison*, 176 F.3d at 783 n.5).

III. DISCUSSION

The Court **GRANTS** LabCorp's Motion to Dismiss the Amended Complaint for two reasons. First, the Amended Complaint fails to satisfy Rule 9(b) because Relators have not identified a single false claim submitted by LabCorp. Second, the Amended Complaint fails to satisfy Rule 8(a) because Relators have not pled facts sufficient to establish that LabCorp made a false representation when it entered into the Virginia Medicaid Independent Laboratory Participation Agreement. The Court addresses each basis for dismissal but first addresses LabCorp's assertion that the Amended Complaint should be dismissed for failure to comply with a statutory sealing requirement.

A. Sealing Requirement

The Court holds that Relators' failure to seal the Amended Complaint is not a basis for dismissal because the Amended Complaint does not depart so profoundly from the original Complaint as to contain new and substantially different allegations of fraud.

Section 8.01-216.5 of the Virginia Fraud Against Taxpayers Act ("VFATA") imposes filing and service requirements on qui tam relators. One requirement is that "[t]he complaint shall be filed in camera, shall remain under seal for at least 120 days, and shall not be served on the defendant until the court so orders." Va. Code § 8.01-216.5(B). Its purpose is to allow the Commonwealth time to investigate qui tam claims and decide whether to intervene and prosecute the claims itself. *See id.* The VFATA's sealing requirement parallels the sealing requirement of the federal False Claims Act ("FCA"). *Compare* 31 U.S.C. § 3730(b)(2) (requiring qui tam complaints to remain under seal for at least 60 days), *with* Va. Code § 8.01-216.5(B).

LabCorp argues that the VFATA sealing requirement applies not only to original complaints but also to amended complaints if the amended complaints contain "new substantive

claims for relief, or new and substantially different (as opposed to merely more detailed) allegations of fraud." *See United States ex rel. Davis v. Prince*, 766 F. Supp. 2d 679, 683 (E.D. Va. 2011) (internal quotation marks and citation omitted). LabCorp argues that Relators' Amended Complaint contains new and substantially different allegations of fraud because it alleges a new regulatory basis for the "usual and customary" requirement and it alleges a different set of discounts.

The Court will not apply a sealing requirement to the Amended Complaint because the change in legal authority between the Original and Amended Complaints does not fundamentally alter Relators' claims. The Original Complaint alleges that LabCorp failed to charge DMAS "the lower of the state agency fee schedule or actual charge (charge to the general public)." (*See* Doc. 1-1, at ¶ 6 (quoting 12 Va. Admin. § 30-80-30(A)(1))). The Amended Complaint alleges that LabCorp charged DMAS in amounts "exceed[ing] the provider's usual and customary charges to the general public[.]"(*See* Doc. 71, at ¶ 10 (quoting 12 Va. Admin. § 30-120-1040)).

Both theories are based on the same underlying conduct—LabCorp charging DMAS at rates above those charged to non-Medicaid customers. By sealing the original Complaint, Relators gave the Commonwealth an opportunity to investigate whether such conduct violated Commonwealth laws and regulations. Requiring Relators to seal the Amended Complaint would provide no additional benefit to the Commonwealth and would needlessly delay this litigation.

The Commonwealth is well advised on what conduct violates its laws and regulations. If the Commonwealth believed that LabCorp violated an uncited law or regulation, it could have filed its own complaint alleging the proper regulation or statute or amended the complaint. *See* Va. Code § 8.01-216.9 ("[T]he Commonwealth may file its own complaint or amend [a qui tam] complaint . . . to clarify or add detail to any claim . . . and to add any additional claim[.]").

That Relators allege discounts made to two non-Medicaid providers instead of one and made between 2007 and 2010 instead of 2002 and 2004 does not alter this conclusion. First, LabCorp does not explain how knowledge of a different set of discounted prices would have materially affected the Commonwealth's investigation. The Commonwealth understood from the original Complaint that LabCorp might have offered kickbacks to referring physicians. With that knowledge, the Commonwealth had the opportunity to investigate potential violations of the Anti-Kickback Statute and decide whether to intervene.

The purposes behind the sealing requirement were already met by the sealing of the Original Complaint, and the Court will not recognize failure to seal the Amended Complaint as a basis for dismissal.

B. Rule 9(b) Particularity

Although failure to seal is not a basis for dismissal, the Court holds that Relators' (i) failure to identify a single false claim with particularity and (ii) failure to allege a false certification *do* warrant dismissal. Because these pleading defects infest both the overcharge and kickback theories, the Court dismisses the Amended Complaint in its entirety. The Court reviews each basis for dismissal in turn, beginning with the want of Rule 9(b) particularity.

Rule 9(b) requires that a complaint alleging fraud identify "the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby." *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 379 (4th Cir. 2008). Because false-claims liability "arises from the submission of a fraudulent claim to the government, not the disregard of government regulations," *Corsello v. Lincare*, 428 F.3d 1008, 1012 (11th Cir. 2005), it is the false claims which must be alleged with particularity, not the statutory or regulatory violation. "Rule 9(b) does not permit a [false-claims]

plaintiff merely to describe a private scheme in detail but then to allege simply and without any stated reason for his belief that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government." *United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, 707 F.3d 451, 456 (4th Cir. 2013) (citing *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002)); *see also Corsello*, 428 F.3d at 1012 (finding Rule 9(b) not met where the relator "described in detail a private scheme to defraud" but provided no facts to suggest that false claims were submitted).

Although there is a circuit split on the question, several courts of appeals have found that Rule 9(b) is met only where the relator identifies the "who, what, when, where, and how" of at least one false claim. *Compare United States ex rel. Bender v. N. Am. Telecomm., Inc.*, 499 F. App'x 44, 45 (D.C. Cir. 2013); *United States ex rel. Lacy v. New Horizons, Inc.*, 348 F. App'x 421, 425 (10th Cir. 2009); *United States ex rel. Bledsoe v. Cmty. Health Sys. Inc.*, 501 F.3d 493, 510 (6th Cir. 2007); *United States ex rel. Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552, 557 (8th Cir. 2006); *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 233 (1st Cir. 2004); *Clausen*, 290 F.3d at 1312 n.21, *with Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 998 (9th Cir. 2010) (rejecting a categorical approach requiring identification of representative examples but acknowledging that other circuits have adopted such an approach).

The Fourth Circuit has not expressly addressed this issue but its ruling in *United States ex rel. Nathan v. Takeda Pharmaceuticals North America, Inc.*, 707 F.3d 451 (4th Cir. 2013), suggests that it follows those circuits requiring identification of at least one representative claim. In *Nathan*, the Fourth Circuit cited favorably both to *United States ex rel. Clausen v. Lab Corporation of America, Inc.*, 290 F.3d 1301 (11th Cir. 2002), and *United States ex rel. Joshi v. St. Luke's Hospital, Inc.*, 441 F.3d 552 (8th Cir. 2006). *Clausen* and *Joshi* are decisions from the

Eleventh and Eighth Circuits respectively, holding that a qui tam relator must identify at least some representative claims with particularity. *See Nathan*, 707 F.3d at 457. Moreover, the Fourth Circuit cited to *Joshi* specifically for the proposition that a relator must "provide some representative examples of [the defendants'] alleged fraudulent conduct." *See Joshi*, 441 F.3d at 557, *quoted in Nathan*, 707 F.3d at 457.

Here, Relators argue that the Amended Complaint satisfies Rule 9(b) because it "provides specific examples of LabCorp's 'usual and customary' prices" and "specific, particular examples of below-cost discounts." (Doc. 78, at 10, 13.) Relators contend that requiring identification of all of LabCorp's false claims "would be both inefficient and impractical." (*Id.*) Relators' arguments miss the point. Rule 9(b) is not concerned with specifying the prices LabCorp charged or the kickbacks LabCorp provided. The falsity of LabCorp's conduct lies not in the prices it charged or discounts it provided but in the claims it submitted to DMAS. Thus, it is the claims which must be alleged with particularity. Additionally, Rule 9(b) does not require identification of all false claims. It requires only the identification of *some* representative claims. This requirement balances the need not to overburden the relator at the pleading stage with the need to provide notice to the defendant.

Applying Rule 9(b) to the Amended Complaint, the Court finds the Amended Complaint must be dismissed for want of particularity. With respect to the overcharge theory, Relators identify the fee schedules LabCorp used to charge DMAS but do not identify a claim submitted using those fee schedules. Instead, Relators provide general allegations that fee schedules existed and claims were made. Relators engage in summary pleading of the false claims, alleging that between 1997 and 2008, a total of 2,730,814 claims were submitted and that "[e]ach of those

charges violated the False Claims Act, as they exceeded LabCorp's usual and customary charges." (Doc. 71, at ¶ 46.)

With respect to the kickback theory, Relators do not identify what claims were submitted to DMAS as a result of the discounts. Instead, Relators generally allege that kickbacks were paid, referrals were made, and LabCorp submitted claims to DMAS for the referred services. Instead of detailing the contents of an individual claim, the Amended Complaint alleges that "[e]ach one of those claims for payments constitutes a violation of the AKS and the Virginia False Claims Act." (Doc. 71, at ¶ 68.)

The Amended Complaint does not allege the "who, what, when, where, and how" of a single false claim, neither under the overcharge theory nor the kickback theory. Such generalized pleading fails to meet Relators' Rule 9(b) burden.

C. Rule 8(a) Plausibility and Allegation of a False Certification

Next, the Court considers Relators' attempts to meet Rule 8(a)'s plausibility standard. The Court holds that the Amended Complaint fails to satisfy Rule 8(a) for two reasons: (i) Relators must allege a false certification because the falsity alleged in the Amended Complaint stems from a contractual violation and (ii) LabCorp's representations in the Virginia Medicaid Independent Laboratory Participation Agreement ("Participation Agreement") have not been adequately pled as a false certification.

In the Amended Complaint, Relators allege that LabCorp made a false certification when it signed the Participation Agreement. Under the Participation Agreement, "[t]he provider agrees that charges submitted . . . will be based on the usual, customary, and reasonable concept and agrees that all requests for payment will comply in all respects with the policies of VMAP[.]" (*Id.*, at ¶ 11.) Additionally, "[t]he provider agrees to comply with all applicable state and federal

laws, as well as administrative policies and procedures of VMAP as from time to time amended." (*Id.*) Though Relators allege a false certification in the Amended Complaint, in briefing, they argued that a false certification was unnecessary because "where there is an overcharge—i.e., the defendant is alleged to have charged a higher dollar amount than allowed under a contract, law, or regulation—there is no issue of 'certification.' " (Doc. 78, at 15.)

Relators mistakenly focus on the concept of overcharge instead of the concept of legal and factual falsity. As a result, Relators incorrectly argue that a false certification is not necessary to their claims. The Fourth Circuit has noted that a court "will not find liability merely for non-compliance with a statute or regulation." *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 786–87 (4th Cir. 1999). Rather, liability for a statutory, regulatory, or contractual violation exists only if (i) the defendant makes a false certification of compliance with the applicable statute, regulation, or contract and (ii) the government conditions payment on compliance with the statute, regulation, or contract. *See id.* at 787.

Put differently, a false certification is necessary if there is an allegation of legal falsity—i.e., the defendant's claims are false because the defendant violated a regulation, statute, or contract and made representations that no violation occurred. *See United States ex rel. Colucci v. Beth Israel Med. Ctr.*, 785 F. Supp. 2d 303, 311 (S.D.N.Y. 2011). But if there is an allegation of factual falsity, no false certification is needed. "A claim is factually false where the claimant supplies [1] an incorrect description of goods or services provided or [2] a request for reimbursement for goods or services never provided." *Id.* (quoting *Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001)). There is no need for false certification because the falsity arises from the fact the government was billed for something it did not receive. By contrast, a false certification is needed in cases of statutory, regulatory, or contractual violation because the violation, taken

alone, is not an inherently false act. What makes the violation actionable or false is the certification that no violation occurred.

Here, the Amended Complaint clearly alleges a legal falsity—that LabCorp's claims are false because LabCorp violated the Waiver Regulation and Anti-Kickback Statute. There is no allegation that LabCorp billed DMAS for services it did not provide. Accordingly, Relators must plead a false certification. Having examined the Amended Complaint, the Court finds that Relators have not adequately pled the Participation Agreement as a false certification. The Court reaches this conclusion for three reasons: (i) the Commonwealth conditioned Medicaid *participation*, not Medicaid payment, on entering into the Agreement, (ii) no facts establish that the representations in the Agreement were false when made, and (iii) a general representation of compliance with all laws lacks the requisite nexus between the subject matter of the certification and the event triggering the loss—i.e., the kickback and overcharge schemes.

First, to succeed on a theory of false certification, the relator must show, among other things, that "a government contract or program required compliance with certain conditions as a prerequisite to a government benefit, payment, or program[.]" *Harrison*, 176 F.3d at 786. Here, Relators allege no facts suggesting that the Commonwealth made statutory and regulatory compliance a condition for *payment*. Instead, they allege that the Commonwealth made compliance "a condition of *participation* in Virginia Medicaid." (Doc. 71, at ¶ 12 (emphasis added)). This distinction is crucial because "[t]he success of a false certification claim depends on whether it is based on 'conditions of participation' in the [Medicaid] program (which do not support an FCA claim) or on 'conditions of payment' from [Medicaid] funds (which do support FCA claims)." *United States ex rel. Hobbs v. MedQuest Assocs.*, 711 F.3d 707, 714 (6th Cir. 2013).

The name of the Agreement alone—the Virginia Medicaid Independent Laboratory *Participation* Agreement—suggests that noncompliance would have resulted in LabCorp's removal from a list of approved Medicaid participants. It does not suggest that the Commonwealth would have withheld payment for work already performed. *See id.* at 714–15 (finding a certification that the defendant would "abide by the Medicare laws, regulations and program instructions" insufficient because "the certification does not contain language conditioning *payment* on compliance with any particular law or regulation"). Because the facts do not establish that the Commonwealth conditioned *payment* on LabCorp's certification, the Amended Complaint fails to make out a false certification.

Second, to succeed on a theory of false certification, the relator must show that the certification was "an intentional, palpable lie," *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1267 (9th Cir. 1996), at the time it was made since "[t]he falsity of a claim is determined at the time of submission," *Hobbs*, 711 F.3d at 714; *cf. United States ex rel. Quinn v. Omnicare, Inc.*, 382 F.3d 432, 438 (3d Cir. 2004). Here, Relators offer no facts suggesting that, when LabCorp signed the Participation Agreement, it did not intend to be in general compliance with the law or charge what it believed were usual and customary charges. Relators do not allege that LabCorp engineered its scheme of kickbacks or overcharges before signing the Agreement. In fact, Relators have not even alleged *when* LabCorp signed the Participation Agreement, making it impossible to determine whether the certification was false when made.

Lastly, for a certification to be false, it must be a certification of compliance with a particular statute, regulation, or condition of payment. A general certification of compliance does not trigger false-claims liability. *See Mikes*, 274 F.3d at 698 (a claim is false where it "falsely certifies compliance with a *particular* statute, regulation or contractual term, where compliance

is a prerequisite to payment" (emphasis added)); *United States ex rel. Conner v. Salina Reg. Health Ctr., Inc.*, 543 F.3d 1211, 1218–19 (10th Cir. 2008) (finding certification that "the services identified in this cost report were provided in compliance with [the laws and regulations regarding the provision of healthcare services]" too general to create liability). There must be some "relation . . . between the subject matter of the false statement and the event triggering Government's [sic] loss," *United States ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1171 (9th Cir. 2006) (internal quotation marks and citation omitted).

Here, LabCorp made a representation in the Participation Agreement that it would comply with applicable laws and that its charges "[would] be based on the usual, customary, and reasonable concept." (Doc. 71, at ¶ 11.) While LabCorp's "usual and customary" certification bears some relationship to the alleged overcharges, it bears no relationship to the alleged kickbacks. Moreover, to the extent that the certification is a general statement of compliance with applicable laws, it bears an insufficient relationship to both the alleged overcharges and alleged kickbacks.

For these reasons, the Court holds that the Amended Complaint fails to adequately plead a false certification. Additionally, because Relators fail to adequately plead a false certification and fail to identify a single claim with particularity, the Court GRANTS LabCorp's Motion to Dismiss in its entirety.

D. Denying Leave to Amend the Amended Complaint

The remaining question is whether to dismiss the Amended Complaint with prejudice and deny Relators a third opportunity to remedy their pleading defects. Having considered the severity and number of defects and the opportunities for amendment already provided, the Court

DENIES Relators leave to amend and DISMISSES the Amended Complaint WITH PREJUDICE.

"In the Eastern District of Virginia, an amendment may be considered futile where Plaintiffs have previously had two full opportunities to plead their claim." *Iron Workers Local 16 Pension Fund v. Hilb Rogal & Hobbs Co.*, 432 F. Supp. 2d 571, 595 (E.D. Va. 2006) (citation omitted). Here, Relators have had two full opportunities to state a claim, first in filing the Original Complaint and second in amending the Original Complaint. Both times, Relators failed to meet their burden, despite receiving notice of the defects as early as September 2013, when the first Motion to Dismiss was filed, and despite continuing to receive notice through the Court's oral ruling granting all three Motions to Dismiss.

Not only have Relators failed to meet their burden but they have ignored the Court's express instruction to identify at least a single false claim. In orally ruling on the original Motions to Dismiss, the Court stated, "I don't think there's been sufficient identification of the time, place and contents of the false representations . . . . [I]n order to have a False Claims Act claim, I think you must have a single claim, at least a claim that was made that was false[.]" (Doc. 74-1, at 52:6–17.) Relators did not identify a single false claim in their Amended Complaint and in briefing continued to argue that alleging "details of particular claims . . . is unnecessary, and would serve no purpose in this context." (Doc. 78, at 13.)

This failure to meet their burden, despite notice and an opportunity to remedy, suggest that further attempt at amendment would be futile. Affording Relators a third opportunity to state their claims would only subject LabCorp to continued time and expense and "undermine the substantial interest of finality in litigation." *Nathan*, 707 F.3d at 461.

For these reasons, the Court DISMISSES Relators' Amended Complaint WITH PREJUDICE and DENIES leave to amend.

IV. CONCLUSION

For the foregoing reasons, the Court **GRANTS** LabCorp's Motion to Dismiss in its entirety. The Amended Complaint is hereby **DISMISSED WITH PREJUDICE** and leave to amend is **DENIED**.

This Order **CLOSES** the case.

IT IS SO ORDERED.

ENTERED this 13th day of May, 2014.

Alexandria, Virginia
5/13/14

/s/
Gerald Bruce Lee
United States District Judge