IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
Wheeling

UNITED STATES ex rel. LOUIS LONGO,

Plaintiff,

v.

Civil Action No. 5:19-CV-192
Judge Bailey

WHEELING HOSPITAL, INC.,
R&V ASSOCIATES, LTD., and
RONALD L. VIOLI,

Defendants.

MEMORANDUM OPINION AND ORDER
DENYING MOTIONS TO DISMISS

Pending before this Court are three motions to dismiss: Defendant Wheeling Hospital's Motion to Dismiss the Government's Complaint in Intervention [Doc. 104]; Defendant R&V Associates, Ltd.'s Motion to Dismiss Government's Complaint in Intervention [Doc. 106]; and Defendant Ronald L. Violi's Motion to Dismiss Government's Complaint in Intervention [Doc. 108]. All three motions have been fully briefed and are ripe for decision.

Background

On December 22, 2017, Louis Longo ("Longo" or "Relator"), filed this *qui tam* action under seal in this Court. On March 25, 2019, the United States intervened in this action and filed its Complaint in Intervention ("Complaint") [Doc. 19].[1]

[1]The parties have agreed that this action will proceed solely on the Government's Complaint in Intervention. *See* ***United States ex rel. Wride v. Stevens-Henager College,***

In 2006, R&V Associates, Ltd. ("R&V") was hired to manage the hospital. Violi, one of R&V's two partners, served as the hospital's CEO. That arrangement continued until May of this year. The Government alleges that during their tenure, R&V and Violi oversaw the hospital's hiring of dozens of physicians at inflated salaries to capture revenues from those doctors' patient referrals. To that end, Wheeling Hospital routinely entered into physician contracts that resulted in violations of two laws that defendants repeatedly promised to comply with: the physician self-referral law (commonly known as the "Stark Law"), 42 U.S.C. § 1395nn, and the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b). It is alleged that this scheme led to thousands of false claims to the Medicare program, tens of millions of dollars in profit for the hospital, and millions in management fees for R&V and Violi.

To recover for this fraud, the United States has asserted claims against defendants under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-33, and the federal common law.

Each of the three defendants filed separate motions to dismiss. Each claims that:

1. The Complaint fails to meet the heightened standards of pleading required by Rule 9(b) Fed. R. Civ. P.; and

2. The Complaint does not and cannot satisfy the materiality requirement of the FCA.

R&V and Violi also claim that the Government has engaged in impermissible "shotgun" pleading and that the Government has failed to sufficiently plead scienter.

Finally, R&V contends that the Government has failed to allege with sufficient

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Inc., 2019 U.S. Dist. LEXIS 6783 at *59-89 (D. Utah Jan. 14, 2019).

particularity that R&V submitted or caused to be submitted false claims.

"Originally passed during the Civil War in response to overcharges and other abuses by defense contractors, Congress intended that the False Claims Act, 31 U.S.C.A. §§ 3729–3733 (West Supp.1998), and its *qui tam* action would help the government uncover fraud and abuse by unleashing a 'posse of *ad hoc* deputies to uncover and prosecute frauds against the government.' ***United States ex rel. Milam v. Univ. of Tex. M.D. Anderson Cancer Ctr.***, 961 F.2d 46, 49 (4th Cir. 1992)." ***Harrison v. Westinghouse Savannah River Co.***, 176 F.3d 776, 784 (4th Cir. 1999). *See also* ***United States ex rel. Escobar v. Universal Health Services, Inc.***, 842 F.3d 103, 106 (1st Cir. 2016), quoting ***United States v. Bornstein***, 423 U.S. 303, 309 (1976).

In ***United States ex rel. Drakeford v. Tuomey Healthcare System, Inc.***, 675 F.3d 394 (4th Cir. 2012), Judge Duncan, writing for the majority, described the statutory framework:

> The FCA is a statutory scheme designed to discourage fraud against the federal government. 31 U.S.C. § 3729(a)(i) provides, in relevant part, that "any person who ... knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval ... is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000 ... plus 3 times the amount of damages which the Government sustains because of the act of that person. Section 3729(b)(1) defines the term "knowingly" to "mean that a person, with respect to information ... has actual knowledge of the information; (ii) acts in deliberate ignorance of the

truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information," with the additional provision that "no proof of specific intent to defraud" is required. Section 3729(b)(2) further defines, in relevant part, the term "claim" as "any request or demand, whether under a contract or otherwise, for money or property ... that ... is presented to an officer, employee, or agent of the United States."

The Stark Law was enacted to address overutilization of services by physicians who stood to profit from referring patients to facilities or entities in which they had a financial interest. The Stark Law, and regulations promulgated pursuant thereto ("Stark Regulations") prohibit a physician who has a "financial relationship" with an entity—such as a hospital—from making a "referral" to that hospital for the furnishing of certain "designated health services" for which payment otherwise may be made by the United States under the Medicare program. 42 U.S.C. § 1395nn(a)(1); 42 C.F.R. § 411.353(a). A hospital may not submit for payment a Medicare claim for services rendered pursuant to a prohibited referral. 42 U.S.C. § 1395nn(a)(1)(B); 42 C.F.R. § 411.353(b). The United States may not make payments pursuant to such a claim, and hospitals must reimburse any payments that are mistakenly made by the United States. 42 U.S.C. § 1395nn(g)(1); 42 C.F.R. § 411.353(c), (d). However, when a physician initiates a service and personally performs it, that action does not constitute a referral under the Stark Law. 42 U.S.C. § 1395nn(h)(5); 42 C.F.R. § 411.351.

The Stark Law and Stark Regulations define a "financial relationship" to include "a compensation arrangement" in which "remuneration" is paid by a hospital to a referring physician "directly or indirectly, overtly or covertly, in cash or in kind." 42 U.S.C. §§ 1395nn(a)(2), (h)(1); 42 C.F.R. § 411.354. An indirect financial relationship exists if, inter alia, there is an indirect compensation arrangement between the referring physician and an entity that furnishes services. An indirect compensation arrangement exists if, inter alia, the referring physician receives aggregate compensation that **"varies with, or takes into account**, the volume or value of referrals or other business generated by the referring physician for the entity furnishing" services. 42 C.F.R. § 411.354(c)(2)(ii) (emphasis added).

The Stark Regulations provide that certain enumerated compensation arrangements do not constitute a "financial relationship." 42 C.F.R. § 411.357. Significantly for our purposes, a subset of indirect compensation arrangements do not constitute a financial relationship if the compensation received by the referring physician is (1) equal to the "fair market value for services and items actually provided"; (2) "not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician" for the hospital; and (3) "commercially reasonable." 42 C.F.R. § 411.357(p). Subsection 411.357(p) is known as the "indirect compensation arrangements exception." See, e.g., 72 Fed.Reg. at 51,014.

675 F.3d at 397-98.

"There are two categories of false claims under the FCA: a factually false claim and a legally false claim. ***U.S. ex rel. Conner v. Salina Reg'l Health Ctr., Inc.***, 543 F.3d 1211, 1217 (10th Cir. 2008). A claim is factually false when the claimant misrepresents what goods or services that it provided to the Government and a claim is legally false when the claimant knowingly falsely certifies that it has complied with a statute or regulation the compliance with which is a condition for Government payment. ***Id***. A legally false FCA claim is based on a 'false certification' theory of liability. *See* ***Rodriguez v. Our Lady of Lourdes Med. Ctr***., 552 F.3d 297, 303 (3d Cir. 2008), *overruled in part on other grounds by* ***U.S. ex rel. Eisenstein v. City of New York***, 556 U.S. 928 (2009). On this appeal, we are concerned only with allegedly legally false claims related to appellees' eligibility to receive payment, as appellants do not contend that appellees did not deliver the services for which they sought payment.

"There is a further division of categories of claims as the courts have recognized that there are two types of false certifications, express and implied. *See, e.g.,* ***Conner***, 543 F.3d at 1217. Under the 'express false certification' theory, an entity is liable under the FCA for falsely certifying that it is in compliance with regulations which are prerequisites to Government payment in connection with the claim for payment of federal funds. ***Rodriguez***, 552 F.3d at 303. There is a more expansive version of the express false certification theory called 'implied false certification' liability which attaches when a claimant seeks and makes a claim for payment from the Government without disclosing that it violated regulations that affected its eligibility for payment. ***Id***. Thus, an implied false

certification theory of liability is premised 'on the notion that the act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a precondition to payment.' ***Mikes v. Straus***, 274 F.3d 687, 699; *see also* ***United States v. Sci. Applications Int'l Corp.***, 626 F.3d 1257, 1266 (D.C. Cir. 2010) ('Courts infer implied certifications from silence where certification was a prerequisite to the government action sought.' (internal quotation marks and citation omitted))." ***United States ex rel. Wilkins v. United Health Group, Inc.***, 659 F.3d 295, 305 (3d Cir. 2011).

That the implied false certification theory is a viable cause of action was determined in ***Universal Health Services, Inc. v. United States and Commonwealth of Mass. ex rel. Escobar***, ___ U.S. ___, 136 S.Ct. 1989, 1999 (2016). However, "the implied certification theory of liability should not be applied expansively." ***Wilkins***, *supra*, at 307.

Pleading

As noted above, the defendants seek dismissal on the basis that the Government has failed to meet the heightened standards of Rule 9(b). To meet that standard, "an FCA plaintiff must, at a minimum, describe '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.' ***Harrison I***, *supra*, 176 F.3d at 784 (internal quotations omitted). These facts are often 'referred to as the "who, what, when, where, and how" of the alleged fraud.' ***United States ex rel. Willard v. Humana Health Plan of Texas Inc.***, 336 F.3d 375, 384 (5th Cir. 2003) (quoting ***United States ex rel. Thompson v. Columbia/HCA Healthcare Corp***., 125 F.3d 899, 903 (5th Cir. 1997))."

To plead the submission of false claims, the United States may either "identify[]

specific false claims or alleg[e] a scheme that **necessarily** resulted in the submission of false claims." ***United States ex rel. Szymoniak v. Am. Home Mortgage Servicing, Inc.***, 679 F. App'x 299, 303 (4th Cir. 2017) (emphasis in original). Where specific claims are identified, a sample suffices, including to plead a widespread fraud. *See* ***United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc.***, 707 F.3d 451, 457 (4th Cir. 2013) (citing ***United States ex rel. Joshi v. St. Luke's Hosp., Inc.***, 441 F.3d 552, 557 (8th Cir. 2006), for the proposition that a relator must "provide **some** representative examples" (emphasis in ***Joshi***)); *see also*, ***United States ex rel. Lutz v. Berkeley Heartlab***, 225 F.Supp.3d 487, 499 (D.S.C. 2016) (denying motion to dismiss where "[t]he allegedly false claims include the entire universe of claims" tainted by alleged kickback scheme, and while "[i]dentifying each specific claim from this universe is unnecessary," "the Government does specifically identify several physicians who allegedly received" kickbacks); ***United States ex rel. Schuhardt v. Wash. Univ***., 228 F.Supp.2d 1018, 1034 (E.D. Mo. 2002) (denying motion to dismiss complaint that included representative claims, and observing that "[b]ecause of the breadth of the allegations – possibly hundreds of doctors and thousands of claims over several years – the complaint need not cite specifics for every transaction"); ***United States ex rel. Baklid-Kunz***, 2012 WL 921147 (M.D. Fla. March 19, 2012) (plaintiff not required to provide allegations relevant to affirmative defenses).

With respect to its Stark Law allegations, the Complaint alleges that R&V and Violi caused Wheeling Hospital to enter into compensation arrangements with: Dr. Adam Tune, a pain-management physician; dozens of employed physicians, with thirteen examples identified by name; and the physicians of Radiology Associates, Inc., with one example

identified by name. The Complaint further alleges that all of those physicians made DHS referrals to Wheeling Hospital. With respect to the AKS, the Complaint alleges that (1) Wheeling Hospital, acting through R&V and Violi, offered and paid remuneration to Dr. Tune; (2) they did so to induce Dr. Tune to refer patients to Wheeling Hospital for the furnishing of services; (3) those services were payable under Medicare; and (4) defendants acted knowingly and willfully.

To bolster even further its allegations that Wheeling Hospital systematically entered into improper compensation agreements, the Complaint describes with specificity a spreadsheet created by the hospital in 2012 that detailed the compensation terms for all of the hospital's employed physicians at that time. Of the 59 physicians listed, 36 were described as receiving compensation that allegedly took into account those physicians' referrals. The Complaint adds that the hospital entered into similarly problematic arrangements with other physicians who would not have appeared on the 2012 spreadsheet, as they left the hospital earlier or joined later, and offers a basis for that allegation.

The Complaint also pleads that Wheeling Hospital's systematically improper compensation arrangements resulted in the submission of false claims. It does not merely allege "a scheme that necessarily resulted in the submission of false claims," as permitted. Instead, it meets the stricter standard by detailing fifteen examples of Medicare claims – one referred by each of the fifteen physicians named in the Complaint. For each sample claim, the Complaint lists the referring physician, the inpatient diagnostic related group or outpatient diagnosis, date(s) of service, and amount of Medicare reimbursement paid.

Although Rule 9(b) states that "[m]alice, intent, knowledge, and other conditions of

a person's mind may be alleged generally," an FCA plaintiff still "must set forth specific facts that support an inference of fraud." ***Willard***, 336 F.3d at 385 (internal quotations omitted); ***United States ex rel. Wilson v. Brown & Root, Inc.***, 525 F.3d 370 (4th Cir. 2008). At the pleading stage "the Government need not prove scienter, it need only allege it." ***Berkeley Heartlab***, 225 F.Supp.3d at 500; *See* ***United States v. Halifax Hosp. Med. Ctr.***, 2012 WL 921147, at *6 (M.D. Fla. March 19, 2012 ((rejecting defense argument of insufficiently pleaded scienter in FCA case premised on Stark Law violations).

The Government has not merely alleged defendants' scienter as a general matter. Rather, it has set forth pages of supporting factual content. For starters, R&V and Violi (and therefore Wheeling Hospital) were well-acquainted with the laws they allegedly violated. From around 1998 to 2005, Violi served as the president and CEO of a Pittsburgh-area children's hospital. R&V's website emphasized its (specifically Violi's) health care experience and expertise and the firm's familiarity with "government regulation." R&V took over management of nearby Weirton Medical Center beginning in 2012. These are not, as R&V misstates, "benign allegations of R&V's background and experience in the industry." Rather, given the prominence of these statutes in the health care industry, defendants' touting of that experience corroborates that their acts in contravention of these statutes were not mere oversights.

The Complaint does not simply rely on defendants' experience alone in pleading scienter. R&V and Violi required all Wheeling Hospital employees to undergo training on the Stark Law and AKS. Based on those trainings, the hospital's former COO understood the AKS to prohibit "kickbacks or payments for driving business to your hospital," and that,

under the Stark Law, "the amount of facility fees would not be related to [a physician's] compensation." Having overseen that training, Violi and R&V understood those restrictions, too. In fact, shortly after arriving at Wheeling Hospital, Violi cited Stark Law compliance as the basis for negotiating higher rental rates (i.e., rates consistent with fair market value) in certain physician lease arrangements. In 2008, the COO sent the hospital's general counsel a memorandum concerning the interpretation of the Stark Law. All three defendants were familiar with nearby Ohio Valley Medical Center's 2011 settlement with the United States of FCA claims premised on alleged Stark Law violations. In 2012, the hospital's CFO sent its then-COO and Relator (then-Executive Vice President) a link to an article about a Stark Law investigation that the United States was conducting in Florida.

Given their past familiarity with, and ongoing attention to, these statutes, it is at least plausible that defendants knew precisely what they were agreeing to when they repeatedly certified in Wheeling Hospital's cost reports and enrollment forms, that they had complied and would continue to comply with the Stark Law, AKS, and FCA. But despite R&V's responsibility for legal and regulatory compliance, defendants failed to put into place protocols that would ensure that Wheeling Hospital's financial relationships with its referring physicians and the submission of resulting claims actually did comply with those statutes. The Government alleges that was by design, as capturing revenues through physician retention was a critical piece of R&V's and Violi's strategy for making money at the hospital. According to the Government, defendants ignored concerns raised internally about the legality of the hospital's physician compensation arrangements. Violi (and therefore R&V and Wheeling Hospital) repeatedly disregarded such concerns raised by Relator between 2012 and 2015.

In addition, the Complaint chronicles defendants' conduct with respect to Wheeling Hospital's contract with Dr. Tune. Violi initially told Dr. Tune that Wheeling Hospital was not interested in an arrangement with Dr. Tune unless the hospital could bill for technical fees referred by Dr. Tune. Later, after the parties reached an agreement under which the hospital improperly paid Dr. Tune a portion of those technical fees, the hospital's CFO expressed concern about that provision's legality. The hospital continued making those payments nonetheless. Then, in 2015, the hospital's general counsel told Dr. Tune that the parties would need to amend their agreement to remove that problematic language. Yet Wheeling Hospital continued to pay Dr. Tune under the existing arrangement for months, with Violi even executing two extensions of that contract. As the chief decision maker on physician retention and compensation, and as the signatory to all of the hospital's contracts with Dr. Tune, Violi knew about these concerns. The parties eventually restructured Dr. Tune's compensation to remove the language at issue, but in a way that continued paying him compensation that took into account the value of his prior referrals and exceeded fair market value.

The above allegations are sufficient, if not more than sufficient, to meet the above pleading standards.

Materiality

"To be actionable, a false claim must be material to the government's decision to pay the claim. *See, e.g.*, ***Escobar II***, 136 S.Ct. at 2001; *see also* ***United States ex rel. Loughren v. Unum Grp.***, 613 F.3d 300, 307 (1st Cir. 2010). The Act itself defines 'material' to mean 'having a natural tendency to influence, or be capable of influencing, the

payment or receipt of money or property.' § 3729(b)(4)." ***United States ex rel. Escobar v. Universal Health Services, Inc.***, 842 F.3d 103, 106 (1st Cir. 2016).

More precisely, under the implied certification theory, "in order for False Claims Liability to attach, these misleading omissions must be material to the government's decision to pay the claim. Whether the regulatory, statutory or contractual requirement in question is a precondiction for payment was not necessarily dispositive of whether the requirement is material to the decision to pay, the Court concluded. ***Id***. at 2001. Rather, "[w]hat matters is ... whether the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision." ***Escobar***, 842 at 109, quoting ***Escobar II***, at 1996.

"The language that the Supreme Court used in ***Escobar II*** makes clear that courts are to conduct a holistic approach to determining materiality in connection with a payment decision, with no one factor being necessarily dispositive. As the Court observed, 'materiality cannot rest "on a single fact or occurrence as always determinative."' ***Escobar II***, 136 S.Ct. at 2001 (quoting ***Matrixx Initiatives, Inc. v. Siracusano***, 563 U.S. 27, 39 (2011)). Because the materiality requirement in the Act descends from 'common-law antecedents,' ***id***. at 2002 (quoting ***Kungys v. United States***, 485 U.S. 759, 769 (1988)), under both the FCA and under the common law, materiality 'look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.' ***Id***. at 2002–03 (citing **Williston on Contracts** § 69:12 (4th ed. 2003) and the **Restatement (Second) of Torts**, § 538). Materiality is more likely to be found where the information at issue goes 'to the very essence of the bargain,' ***Escobar II***, 136 S.Ct. at 2003, n. 5 (quoting ***Junius***

Constr. Co. v. Cohen, 257 N.Y. 393, 400, 178 N.E. 672 (1931) (Cardozo, C.J.))." ***Escobar***, 842 F.3d at 109-110.

"'The materiality standard is demanding,' as the False Claims Act is not "'an all-purpose antifraud statute" or a vehicle for punishing garden-variety breaches of contract or regulatory violations.' ***Escobar II*** at 2003 (internal citation omitted). Materiality 'cannot be found where noncompliance is minor or insubstantial.' ***Id***. 'Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance.' ***Id***." ***Escobar***, 842 F.3d at 110.

"The Court then laid out several specific factors that might contribute to determining materiality:

> [p]roof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement. Conversely, if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.

Escobar II at 2003-04. In a case decided after (and citing) ***Escobar II***, this Court concluded that in assessing materiality in connection with a different section of the False

Claims Act, the fundamental inquiry is 'whether a piece of information is sufficiently important to influence the behavior of the recipient.' ***United States ex rel. Winkelman et al. v. CVS Caremark Corp***., 827 F.3d 201, 211 (1st Cir. 2016)." ***Escobar***, 842 F.3d at 110.

Escobar did not set a new standard for materiality. ***United States v. Palin***, 874 F.3d 418, 422 (4th Cir. 2017). Of course, in considering a motion to dismiss, the issue is not whether materiality has been proven, but rather whether materiality has been plausibly alleged. ***United States ex rel. Wood v. Allergan, Inc.***, 246 F.Supp.3d 772, 818 (S.D. N.Y. 2017), *rev'd on other grounds*, 899 F.3d 163 (2d Cir. 2018).

The defendants use the holding in ***Escobar II***, at 2003, that "if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material" to argue that since the Government continued paying federal program payments to Wheeling Hospital after the relator filed suit, the alleged violations by the Hospital are not material. This Court cannot accept this argument. The filing of a *qui tam* action does not equate to actual knowledge on the part of the Government. The Government must be given time to investigate and determine whether the accusations have merit and whether to intervene in the action. It is the date of intervention which could be considered actual notice to the Government at this stage of the proceedings.

This Court doubts that the hospital industry would warmly welcome a rule that required the Government to cut off hospital funding whenever a *qui tam* action is filed or forfeit its right to seek reimbursement. "The Government does not enjoy the luxury of

refusing to reimburse health care claims the moment it suspects there may be wrongdoing. To this day, defendants claim they did not have the requisite scienter to violate the FCA. All the evidence defendants have put forth in support of their scienter cuts against their materiality argument that the Government was aware of AKS/FCA violations as early as 2011 but nonetheless continued to pay claims." ***United States ex rel. Lutz v. Berkeley Heartlab, Inc.***, 2017 WL 4803911 (D. S.C. Oct. 23, 2017).

While the courts are directed to utilize a holistic approach to determining materiality, some courts have found that AKS and Stark violations border on *per se* material. In ***Allergan***, *supra,* the Southern District of New York found that the standard medicare provider documents all "require compliance with 'applicable Federal or State laws,' *see, e.g.*, [***United States ex rel.***] ***Smith*** [***v. Yale University***], 415 F.Supp.2d [58] at 63–64 [(D. Conn. 2006)] (discussing CMS Form 1500), a universe that plainly encompasses the AKS. The fact that they do not explicitly reference the AKS is of no moment. Indeed, 'the conclusion that [AKS] compliance is a precondition of payment is rendered inescapable when the purpose of the [AKS] is considered within the context of' these healthcare statutes. [***United States ex rel.***] ***Westmoreland*** [***v. Amgen, Inc.***], 812 F.Supp.2d [39] at 53 [(D. Mass. 2011]. After all, "[k]ickbacks are designed to influence providers' independent medical judgment in a way that is fundamentally at odds with the functioning of the system as a whole.... If providers could demand payment for claims resulting from kickback violations, then the [AKS] would be meaningless." ***Id***. at 53–54; *accord* ***United States ex rel. Thomas v. Bailey***, 2008 WL 4853630, at *8 (E.D. Ark. Nov. 6, 2008) (noting that "case law supports the proposition that compliance with [the AKS] is a condition of

payment under" federal health care programs); [***United States ex rel. Fry v.***] ***The Health All. of Greater Cinn.***, 2008 WL 5282139, at *11 [(S.D. Ohio Dec. 18, 2008)] (similar)." 246 F.Supp.3d at 817.

The ***Allergan*** opinion continues:

> The sole remaining question, then, is whether compliance with the AKS is "material" to a payment decision by the Government. *See* ***Escobar***, 136 S.Ct. at 2002. The ***Escobar*** Court did not adopt a precise definition of materiality; instead, the Court instructed that, "[u]nder any understanding of the concept, materiality looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation." ***Id***. (internal quotation marks omitted). Applying that "holistic" approach here, *see* ***United States ex rel. Escobar v. Universal Health Servs., Inc.***, 842 F.3d 103, 109 (1st Cir. 2016), the Court has no trouble concluding that compliance with the AKS is a "material" condition of payment. First, violation of the AKS is a far cry from an "insubstantial" regulatory violation like, say, requiring "that [government] contractors buy American–made staplers" rather than foreign staplers. *See* ***Escobar***, 136 S.Ct. at 2004. Indeed, Congress has made it a felony offense punishable by up to five years in prison, *see* 42 U.S.C. § 1320a–7b, and, as noted, the law now provides explicitly that "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim," id. § 1320a–7b(g). Second, Medicare Part D Provider Agreements and the majority of state Medicaid Provider Applications

> expressly designate AKS compliance as a condition of payment. . . .. And third, neither Allergan nor PhRMA points to evidence that the Government pays Medicaid or Medicare claims "in full despite its actual knowledge" of AKS violations. ***Escobar***, 136 S.Ct. at 2003. In fact, the Government has actively pursued FCA actions and criminal proceedings to deter and punish AKS violations and recoup funds. *See, e.g.*, ***United States ex rel. Bilotta v. Novartis Pharm. Corp.***, 50 F.Supp.3d 497, 506 (S.D. N.Y. 2014); [***United States v.***] ***McClatchey***, 217 F.3d at 829–34 [(10th Cir. 2000)]. These considerations, by themselves, are enough to establish that compliance with the AKS is plausibly a material condition of payment under the federal health care programs at issue in this case.

246 F.Supp.3d at 817-18.

Under this framework, the United States has pleaded material violations. The Government's decision to identify a provision as a condition of payment is evidence of materiality, even if not dispositive. ***Escobar***, 136 S.Ct. at 2003. CMS has classified compliance with the Stark Law and AKS as conditions of payment, including on the enrollment forms that defendants signed. In fact, the Stark Law prohibits CMS from paying Medicare claims submitted in violation of the statute. Thus, Congress did not merely label the Stark Law a condition of payment, but imposed it as a mandatory condition, which is the strongest possible indication of materiality. This statutory language is echoed by the accompanying regulations, which require an entity to refund promptly any Medicare payments it has received in violation of the Stark Law. 42 C.F.R. § 411.353(d). The AKS,

for its part, is a felony statute requiring specific intent, the violation of which renders a claim per se false under the FCA.

The Complaint explains why compliance with the Stark Law and AKS goes to the "essence of Medicare's bargain with participating healthcare providers," as "[b]oth play a key role in ensuring that services are reasonable and necessary, and not provided merely to enrich the parties to an unlawful arrangement at the expense of federal health programs and their beneficiaries." It describes why defendants' alleged systemic violations were "not minor or insubstantial," as they "implicate the core concerns of those statutes, including because defendants directly incentivized and paid physicians in return for increased referrals to Wheeling Hospital." It also sets forth a number of instances in which the Government has settled and litigated violations of these statutes, including in the Fourth Circuit. For these and other reasons, courts have repeatedly held that alleged violations of the Stark Law and AKS were material, including after ***Escobar***. *See* ***Berkeley Heartlab***, 2017 WL 6015574, at *2; ***United States ex rel. Wood v. Allergan, Inc.***, *supra*; ***United States ex rel. Emanuele v. Medicor Assoc.***, 242 F.Supp.3d 409, 431 (W.D. Pa. 2017).

In a later decision in ***United States ex rel. Lutz v. Berkeley Heartlab, Inc.***, 2017 WL 6015574 (D.S.C. Dec. 4, 2017), Judge Gergel held that "[t]he 'holistic' materiality analysis the Supreme Court set forth in ***Escobar*** demonstrates that AKS compliance is per se material. In ***Escobar***, the Supreme Court held that several factors are considered in determining materiality: (1) whether compliance with a statute is a condition of payment, (2) whether the violation goes to "the essence of the bargain" or is "minor or insubstantial," (3) whether the Government consistently pays or refuses to pay claims when it has

knowledge of similar violations, and (4) whether the Government would likely refuse payment had it known of the violation. 135 S.Ct. at 2003-04." 2017 WL 6015574 at *2.

Judge Gergel elaborated:

> Each factor demonstrates the per se materiality of AKS compliance. Courts have long held that AKS compliance is a condition of payment. See ***[United States ex rel.***] ***Kester [v. Novartis Pharmaceuticals***], 41 F.Supp.3d at 330 [S.D. N.Y. 2014] (collecting cases). Violation of the AKS is not a de minimis regulatory violation, nor is it a mere technical violation of adhesive fine print in Government contracts. It is a felony punishable by five years in prison, and it requires the violator to act "knowingly and willfully." 42 U.S.C. § 1320a-7b. The Government routinely punishes AKS violations through criminal proceedings and civil proceedings to recoup funds. *See, e.g.*, ***United States v. McClatchey***, 217 F.3d 823 (10th Cir. 2000); ***Wood***, 246 F.Supp.3d 772; ***United States ex rel. Williams v. Health Mgmt. Assocs. Inc.***, No. 3:09-CV-130 (M.D. Ga. Nov. 3, 2016); ***United States ex rel. McGuire v. Millennium Laboratories, Inc.***, No. 12-cv-10132 (D. Mass. Aug. 19, 2016) (and related cases); ***United States ex rel. Doe v. Institute of Cardiovasular Excellence, PLLC***, Case No. 5:11-CV-406-OC-KRS (M.D. Fla. May 17, 2016) (and related cases); ***United States ex rel. Bilotta v. Novartis Pharm. Corp.***, 50 F.Supp.3d 497 (S.D.N.Y. 2014). The U.S. Department of Health and Human Services has issued "special fraud alerts" specifically warning about AKS violations in reimbursement requests for

> laboratory services for over twenty years. *See* **Special Fraud Alert: Laboratory Payments to Referring Physicians** (June 25, 2014), reprinted at 79 Fed. Reg. 40,115 (July 11, 2014); **Special Fraud Alert: Arrangements for the Provision of Clinical Laboratory Services** (Oct. 1994), reprinted at 59 Fed. Reg. 65,372 (Dec. 19, 1994). There can be no question that the Government would likely refuse to pay a claim that it actually knows is the result of an AKS violation.

2017 WL 6015574 at *2. *See also, e.g.*, ***Allergan***, 246 F.Supp.3d at 818 ("[a]pplying th[e] 'holistic' approach" described in ***Escobar***, reasoning that "violation of the AKS is a far cry from an 'insubstantial' regulatory violation," and "concluding that compliance with the AKS is a 'material' condition of payment"); *see also* ***United States v. Rogan***, 517 F.3d at 452 (AKS and Stark Law violations are material within the context of the FCA).

Similarly, in ***United States ex rel. Emanuele v. Medicor Associates***, the defendants moved for summary judgment, arguing that the relator had not developed sufficient evidence that the Stark Law violations at issue in that case were material under ***Escobar***. The court denied that motion, emphasizing that CMS is statutorily prohibited from paying violative claims, and concluding that "the ***Escobar*** factors" made "clear that the alleged violations at issue here are material." 242 F.Supp.3d at 431. Later, the court specifically rejected the defendants' argument that relator had fallen short of the materiality standard by failing to show that the United States would not have paid claims had it known about the defendants' Stark Law violations. *See* ***United States ex rel. Emanuele v. Medicor Associates***, 2017 WL 3675921, at *6 (W.D. Pa. Aug. 25, 2017).

A final factor, absent in ***Escobar***, is that in this case the Government has intervened seeking reimbursement. This final factor strongly militates in favor of materiality. ***United States ex rel. Badr v. Triple Canopy, Inc.***, 857 F.3d 174, 177 (4th Cir. 2017).

Based upon the foregoing, this Court finds that the Government has established materiality as a matter of law.

Individual Liability

Finally, the defendants criticize the Government for a "shotgun" pleading approach, arguing that the Complaint makes allegations against the defendants as a group without specifically identifying which defendant did what.

Under the facts of this case, such differentiation is unnecessary. Wheeling Hospital hired R&V to manage the Hospital. R&V then became the agent for Wheeling Hospital. R&V then provided Violi to act as the CEO of the Hospital. As a result, Violi was the agent of R&V and the agent of Wheeling Hospital. All of the actions described in the Complaint were committed in the course and scope of employment. Therefore, any misdeeds committed by Wheeling Hospital under the guidance of Violi are imputed to Violi and to R&V. R&V could only act through its two principals, Violi and Vince Deluzio. Therefore any misdeeds by them are imputed to Violi and to the Hospital. Finally, any misdeeds committed by or at the direction of Violi are imputed to both R&V and Wheeling Hospital.

Conclusion

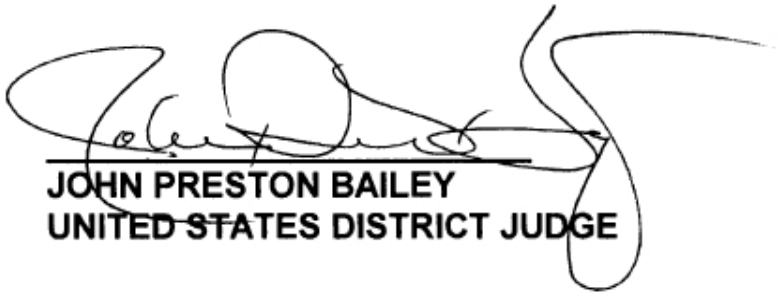
For the reasons stated above, Defendant Wheeling Hospital's Motion to Dismiss the Government's Complaint in Intervention [**Doc. 104**] is **DENIED**; Defendant R&V Associates, Ltd.'s Motion to Dismiss Government's Complaint in Intervention [**Doc. 106**] is **DENIED**;

and Defendant Ronald L. Violi's Motion to Dismiss Government's Complaint in Intervention [**Doc. 108**] is **DENIED**.

It is so **ORDERED**.

The Clerk is directed to transmit copies of this Order to all counsel of record herein.

DATED: September 18, 2019.



JOHN PRESTON BAILEY
UNITED STATES DISTRICT JUDGE