UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
OWENSBORO DIVISION

CIVIL ACTION NO. 4:20-CV-00066-JHM

UNITED STATES OF AMERICA **PLAINTIFF**

V.

KISHOR N. VORA, M.D., OWENSBORO MEDICAL PRACTICE, PLLC, and OWENSBORO HEART AND VASCULAR **DEFENDANTS**

MEMORANDUM OPINION AND ORDER

This matter is before the Court on Defendants' Motion to Dismiss for Failure to State a Claim. [DN 12]. Fully briefed, this matter is ripe for decision. For the following reasons, Defendants' motion is **DENIED IN PART AND GRANTED IN PART**.

I. BACKGROUND

According to the Complaint, Dr. Kishor N. Vora ("Dr. Vora") is a physician in private practice in Owensboro, Kentucky. [DN 1 ¶ 12]. He is the president and sole member of Owensboro Medical Practice, PLLC, which operates under the assumed name Owensboro Heart and Vascular. [*Id*. at ¶¶ 9–11].

Dr. Vora began communicating with a sales representative from Natural Molecular Testing Corporation ("NMTC") in January 2012. [*Id*. at ¶¶ 3, 29]. Prior to these conversations, Dr. Vora had occasionally referred some laboratory tests to NMTC, but NMTC wanted him to refer more tests to the lab, specifically pharmacogenomics tests.[1] [*Id*. at ¶ 28]. The NMTC sales representative enticed Dr. Vora with "financial rewards" if he referred large numbers of

[1] Pharmacogenomics is the study of "how genes affect a person's response to drugs." U.S. Nat'l Libr. of Med., *What is pharmacogenomics?*, NAT'L INST. OF HEALTH (last updated Aug. 17, 2020), https://ghr.nlm.nih.gov/primer/genomicresearch/pharmacogenomics.

pharmacogenomics tests to the NMTC laboratory. [*Id*. at ¶¶ 30–31]. After significant discussion, Dr. Vora and NMTC ultimately agreed to enter into a "PRIDE Registry Agreement" on April 17, 2012. [*Id*. at ¶ 18]. The PRIDE Registry Agreement was a "data use agreement," under which Dr. Vora agreed to refer 150 pharmacogenomics tests to NMTC each month in exchange for $150 per referral. [*Id*. at ¶¶ 20–22].

Dr. Vora referred significantly more pharmacogenomics tests to NMTC while the PRIDE Registry Agreement was in place. Before the agreement, Dr. Vora referred 47 pharmacogenomics tests to NMTC for Medicare beneficiaries in the eleven-month period between March 1, 2011, and January 31, 2012. [*Id*. at ¶ 28]. In March 2012, the first month Dr. Vora thought the PRIDE Registry Agreement was active, he referred 537 tests for Medicare beneficiaries in a single month. [*Id*. at ¶ 40]. But the PRIDE Registry was not yet active, and Dr. Vora's orders dropped significantly as a result—he referred only 48 tests to NMTC in April 2012. [*Id*. at ¶ 50]. During this time, Dr. Vora sent several messages to NMTC stating he would "not . . . send any samples" until they finalized the PRIDE Registry Agreement. [*Id*. at ¶¶ 43–49]. The PRIDE Registry became active in May 2012, and Dr. Vora's test referrals increased again—he referred 1,206 tests to NMTC of Medicare beneficiaries between May 2012 and March 31, 2013. [*Id.* at ¶¶ 51–52]. NMTC submitted a claim to Medicare for each test. [*Id*. at ¶ 71].[2] During this eleven-month period, NMTC paid Dr. Vora $335,700 through the PRIDE Registry Agreement. [*Id*. at ¶ 15].

In March 2013, NMTC allegedly notified Dr. Vora it was reducing per-test payment from $150 to $105. [*Id*. at ¶ 53]. In response, Dr. Vora "significantly reduced the number of orders" he referred to NMTC, and substantially reduced his overall referrals of pharmacogenomics testing

[2] In support of this allegation, the Complaint alleges two specific claims submitted to the government. [DN 1 ¶ 71, Exhibit R, Exhibit S].

to any lab. [*Id*. at ¶¶ 53–54]. After 2013, he never referred more than 32 total pharmacogenomics tests of Medicare beneficiaries in any year. [*Id*. at ¶¶ 54–55].

On April 30, 2020, the United States of America ("Government") brought this civil action against Dr. Vora, Owensboro Medical Practice, and Owensboro Heart and Vascular (collectively, "Defendants") for violations of the False Claims Act, 31 U.S.C. §§ 3729–3732. The Government alleges that the PRIDE Registry Agreement amounted to an illegal kickback scheme between Dr. Vora and NMTC. [DN 1 ¶¶ 70–72]. As a result, according to the Government, Defendants are liable under two separate theories of False Claims Act ("FCA") liability.

Under the first theory, Dr. Vora is liable under the Anti-Kickback Statute ("AKS") because he "referred pharmacogenomics testing orders to NMTC, at least in part, because NMTC paid renumeration." [*Id*. at ¶ 26]. Since AKS violations are "false claims" for purposes of the FCA, *see* 42 U.S.C. § 1320a-7b(g), the Government alleges all 1,206 claims NMTC submitted for reimbursement are "false claims" under the FCA. [DN 1 ¶ 72]. Dr. Vora is liable because he "caused" NMTC to submit the false claims. [*Id.* at ¶ 73].

Under the second theory, Dr. Vora is liable because certain tests did not comply with Medicare regulations and therefore were "medically unnecessary." Specifically, the Complaint alleges Dr. Vora ordered pharmacogenomics testing without an individualized assessment of need, [*id*. at ¶¶ 74–82], did not use the pharmacogenomics test results in patient treatment, [*id*. at ¶¶ 83–110], and used pharmacogenomics testing to predict warfarin responsiveness in patients that did not meet Medicare testing criteria. [*Id*. at ¶¶ 111–112].

The Government brings four causes of action against the Defendants; each cause of action separately incorporates both theories of liability. Counts I through III are brought under the FCA and allege that the Defendants "knowingly caused to be presented false or fraudulent claims to

Medicare for payment or approval," 31 U.S.C. § 3729(a)(1)(A) (Count I), "knowingly made, used, or caused to be made or used, false records or statements material to false or fraudulent claims," 31 U.S.C. § 3729(a)(1)(B) (Count II), and "conspired to commit a violation of [the FCA]." 31 U.S.C. § 3729(a)(1)(C) (Count III). Count IV alleges a common law unjust enrichment claim. [DN 1 ¶ 162].

In response to the Government's Complaint, Defendants moves to dismiss this action for failure to state a claim, contesting all four of the Government's causes of action.

II. LEGAL STANDARDS

A. Motion to Dismiss: Standard of Review

On a motion to dismiss for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6), a court "must construe the complaint in the light most favorable to plaintiff[ ]," *League of United Latin Am. Citizens v. Bredesen*, 500 F.3d 523, 527 (6th Cir. 2007), "accept all well-pled factual allegations as true," *id.*, and determine whether the "complaint states a plausible claim for relief." *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009). Under this standard, the plaintiff must provide the grounds for his or her entitlement to relief, which "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). A plaintiff satisfies this standard only when he or she "pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. A complaint falls short if it pleads facts "'merely consistent with' a defendant's liability," *id.* at 678 (quoting *Twombly*, 550 U.S. at 557), or if the alleged facts do not "permit the court to infer more than the mere possibility of misconduct." *Id.* at 679. Instead, the allegations must "show[ ] that the pleader is entitled to relief." *Id.* at 679 (quoting FED. R. CIV. P. 8(a)(2)).

When, as here, a claim is brought under the FCA, the complaint also must satisfy the Federal Rule of Civil Procedure 9(b) heightened pleading standard. Rule 9(b) states "[i]n alleging fraud . . . a party must state with particularity the circumstances constituting fraud . . . [m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." FED. R. CIV. P. 9(b). A plaintiff must "allege the time, place, and content of the alleged misrepresentation on which he or she relied; the fraudulent scheme; the fraudulent intent of the defendants; and the injury resulting from the fraud." *Coffey v. Foamex L.P.*, 2 F.3d 157, 161–62 (6th Cir. 1993) (internal citations omitted). Additionally, in an FCA action, the plaintiff must "allege specific false claims" actually submitted to the government to satisfy the Rule 9(b) standard, because the fraudulent *submission* of a claim is "the *sine qua non* of a False Claims Act violation." *United States ex rel. Bledsoe v. Cmty. Health Sys., Inc*., 501 F.3d 493, 504 (6th Cir. 2007).

B. Applicable Legal Standards

1. Medicare

The Medicare statutory scheme provides the basis for this FCA action. Under Medicare Part B, the portion of Medicare at issue here, the government reimburses health care providers for providing covered medical treatment to Medicare beneficiaries. However, the government does not reimburse for covered services that are "not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). The implementing regulations provide additional clarity on what services are "reasonable and necessary." One provision relevant here is 42 C.F.R. § 410.32(a), which states:

> [A]ll . . . diagnostic laboratory tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the

> management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary.

Federal courts have come to refer to such provisions as "conditions of payment" because § 1395y(a)(1)(A) explicitly states the government will not pay for services that do not meet these requirements because they are not "reasonable and necessary." *See, e.g.*, *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2001 (2016).

Comparatively, many Medicare regulations are not explicitly defined as conditions of payment. For example, 42 C.F.R. § 410.32(d)(2)(i) provides that "the physician . . . who orders the [diagnostic laboratory test] must maintain documentation of medical necessity in the beneficiary's medical record." Since this provision does not condition payment on compliance with its terms, a provider's noncompliance does not necessarily mean that Medicare will deny payment. However, a provider must comply with the provisions to become a Medicare-approved provider. Therefore, these provisions sometimes are referred to as "conditions of participation" in the Medicare system. *See United States ex rel. Hobbs v. MedQuest Assocs., Inc.*, 711 F.3d 707, 714 (6th Cir. 2013) (delineating conditions of participation from conditions of payment).

2. False Claims Act

The FCA "is an anti-fraud statute that prohibits the knowing submission of false or fraudulent claims to the federal government." *Bledsoe*, 342 F.3d at 640. The applicable provisions create civil penalties against any person who:

> **(A)** knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
> **(B)** knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
> **(C)** conspires to commit a violation of subparagraph (A), (B) . . .

31 U.S.C. § 3729(a)(1)(A)–(C). The statute authorizes treble damages against anyone found liable, making the penalties "essentially punitive in nature." *United States v. Brookdale Senior*

Living Cmtys., Inc., 892 F.3d 822, 826 (6th Cir. 2018) (quoting *Escobar*, 136 S. Ct. at 1996). Notably, all three relevant subsections rely on the "false or fraudulent claim" element—if a claim is not "false or fraudulent," then there is no liability under any subsection.

3. Anti-Kickback Statute

The AKS is a criminal statute that makes it a felony offense to "knowingly and willfully solicit[ ] or receive[ ] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—in return for purchasing, leasing, ordering . . . any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(1)(B). While the AKS primarily is a criminal statute, it explicitly authorizes civil enforcement under the FCA for any AKS violation: "In addition to the penalties provided for in this section . . . a claim that includes items or services resulting from a violation of this section *constitutes a false or fraudulent claim* for purposes of [the False Claims Act]." 42 U.S.C. § 1320a-7b(g) (emphasis added).

III. DISCUSSION

The Government's Complaint alleges four counts against Defendants: three violations of the FCA and one common law unjust enrichment claim. All three FCA causes of action rely on two distinct theories of liability: (1) Dr. Vora caused false claims to be submitted because he engaged in an illegal kickback scheme with NMTC that violated the Anti-Kickback Statute ("AKS theory"), and (2) Dr. Vora caused false claims to be submitted because he referred medically unnecessary testing through NMTC ("Medical Necessity theory"). The Government uses these two theories as alternative methods to establish the "false or fraudulent claim" element of the FCA. *See* 31 U.S.C. § 3729(a)(1)(A)–(C). If the allegations in either theory do not amount to a "false or fraudulent claim," then all three FCA counts fail to the extent they rely on that theory.

Both parties argue the two distinct theories separately. Therefore, the Court will consider each theory in turn.

A. Counts I–III: FCA Anti-Kickback Theory of Liability

The Government's first theory of liability is based on the AKS—the claims that NMTC submitted to Medicare were "false or fraudulent" because they were tainted by illegal kickbacks. Since AKS violations "constitute[ ] a false or fraudulent claim" under the FCA, 42 U.S.C. § 1320a-7b(g), the Complaint must sufficiently allege (1) Defendants' actions violated the AKS (therefore making it a "false or fraudulent claim") and (2) Defendants' actions satisfy all other elements of the FCA causes of action.

Since the entire AKS theory falls apart if there is no AKS violation, the Court will first consider whether the Complaint sufficiently pleads an AKS violation. If so, the Court will then analyze whether the Complaint adequately alleges the remaining elements of the three FCA causes of action.

1. Underlying AKS Violation

AKS liability attaches against any person who "knowingly and willfully . . . receives any remuneration . . . in return for . . . ordering . . . any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(1)(B). To prove an AKS violation, therefore, the government must prove the following: (1) defendant received renumeration, (2) in return for ordering a good or item paid for through government health care program, and (3) done knowingly and willfully. *See United States ex rel. McDonough v. Symphony Diagnostic Servs., Inc.*, 36 F. Supp. 3d 773, 777 (S.D. Ohio 2014).

Defendants contest two elements of the underlying AKS allegations: (1) the Complaint failed to allege "Dr. Vora . . . ordered the tests willfully for the purpose of receiving renumeration

from NMTC," [DN 12 at 18]; and (2) the tests were medically required for Dr. Vora's patients, so it does not matter whether there was an AKS violation. [*Id*.]. Defendants' first argument, however, actually raises two separate issues—the intent required to violate the AKS and whether the Complaint sufficiently alleges the Defendants acted "knowingly and willfully."

a. AKS: Intent

Defendants first argue the Complaint failed to allege Dr. Vora referred the tests "in return for" renumeration from NMTC. The Government only alleges Dr. Vora referred tests through NMTC "at least in part" because NMTC provided renumeration [DN 1 ¶ 26]—Defendants claim partial intent to receive renumeration does not violate the AKS.

Defendants' contention primarily is a legal question—does a defendant violate the AKS when illegal kickbacks were "one purpose" for the referral, but not the sole purpose? [*See* DN 12 at 17, 19–20; DN 13 at 5]. The issue is salient because the Complaint expressly relied on the "one purpose" theory of liability—it stated Defendants' referral decisions were motivated "at least in part" by renumeration. [*See* DN 1 ¶ 26]. Defendants argue mixed motives are insufficient to allege AKS liability—Dr. Vora must have been motivated solely by illegal renumeration for his conduct to violate the AKS. To support the claim that Dr. Vora was not motivated totally by renumeration, Defendants point out that Dr. Vora referred pharmacogenomics testing to NMTC before the alleged kickback scheme began, [*see* DN 1 ¶ 28], and he continued to refer tests after the alleged scheme ended. [*Id*. at ¶ 53].

The Government does not contend Defendants' sole purpose was renumeration. It implicitly agrees with Defendants that the Complaint only alleges the "one purpose" theory of liability, but it claims the AKS is violated whenever "*one purpose* of renumeration [is] to obtain

money for the referral of services." [DN 13 at 5] (emphasis added). If the "one purpose" theory is not enough, the Complaint does not state a claim for relief.

The Court is convinced the "one purpose" test is a more accurate depiction of the law. While the Sixth Circuit has not decided the issue, every circuit court to address the question has determined a defendant violates the AKS when "one purpose" of referral decisions is to receive renumeration. *United States ex rel. Ruscher v. Omnicare, Inc.*, 663 F. App'x 368, 374 (5th Cir. 2016); *United States v. Borrasi*, 639 F.3d 774, 781–82 (7th Cir. 2011); *United States v. McClatchey*, 217 F.3d 823, 835 (10th Cir. 2000); *United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 30 (1st Cir. 1989); *United States v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989); *United States v. Greber*, 760 F.2d 68, 72 (3d Cir. 1985).

Furthermore, the "one purpose" test appears to align best with the Sixth Circuit's general approach to the scienter requirement under the AKS. The Sixth Circuit has stated that, under the AKS, renumeration is received "in return for" an order if the recipient is "duly induced or moved" by the renumeration. *Jones-McNamara v. Holzer Health Sys.*, 630 F. App'x 394, 401 (6th Cir. 2015); *see also United States ex rel. Robinson-Hill v. Nurses' Registry & Home Health Corp.*, No. 5:08-145, 2015 WL 4394203, at *5 (E.D. Ky. July 15, 2015) (determining that an AKS violation depended on whether "remuneration was provided with the intent to induce or reward referrals"). In defining "inducement," the *Jones-McNamara* court endorsed an Office of Inspector General ("OIG") guidance document, which defined "induce" as "the necessary intent 'to lead or move by influence or persuasion.'" 630 F. App'x at 401 (quoting OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952, 35938 (July 29, 1991)). Neither "influence" nor "persuasion" imply a complete purpose to take a particular action—both words instead suggest that it only must be enough to move a person from one course of action to another course of action. *See Influence*,

Merriam-Webster Online, https://www.merriam-webster.com/dictionary/influence; *Persuade*, Merriam-Webster Online, https://www.merriam-webster.com/dictionary/persuade. Therefore, a person is "induced" if renumeration is persausive enough to cause them to alter their behavior. A partial purpose is enough.

The OIG guidance that the Sixth Circuit relied on supports this interpretation. In the next paragraph after the definition quoted by the *Jones-McNamara* court, the OIG guidance endorsed the *Greber* and *Kats* decisions for the principle that a defendant violates the AKS if "one purpose of the payment is to induce future referrals." OIG Anti-Kickback Provisions, 56 Fed. Reg. at 35938 (quoting *Greber*, 760 F.2d at 69). The Sixth Circuit's reliance on OIG guidance when interpreting the statutory language is insightful for how it would analyze the provision's scope.

While there is some disagreement among lower courts in the Sixth Circuit, *compare United States v. Millennium Radiology, Inc*., No. 1:11cv825, 2014 WL 4908275, at *7 (S.D. Ohio Sept. 30, 2014) (permitting an AKS allegation to survive a motion to dismiss when the plaintiff alleged referrals were "one purpose of the arrangement"), *with United States ex rel. Villafane v. Solinger*, 543 F. Supp. 3d 678, 698 (W.D. Ky. 2008) (declining to adopt the "one purpose" test), this Court is convinced the "one purpose" test is a more accurate depiction of the law. The Government's Complaint is sufficient if it alleges that Defendants were partially motivated by referrals.

Defendants also contend, however, that the Government's word choice requires dismissal because the Government used "at least in part" to describe Defendants' purpose for referring tests through NMTC, rather than "one purpose." [*See* DN 12 at 18–19, DN 17 at 13]. Defendants cite no authority in support of this conclusion, and the Court is not aware of any. Instead, it appears that courts use a variety of language choices to convey the idea that a defendant acts "in return for" renumeration if renumeration is "one purpose" for the action. *See, e.g.*, *United States ex rel.*

Bilotta v. Novartis Pharm. Corp., 50 F. Supp. 3d 497, 520–21 (S.D.N.Y. 2014) ("plausible opposing inference"); *Millennium Radiology*, 2014 WL 4908275, at *7 ("plausible alternative motives"); *U.S. ex rel. Daugherty v. Bostwick Labs.*, No. 1:08-CV-354, 2013 WL 3270355, at *32 (S.D. Ohio June 26, 2013) ("one purpose"). While "one purpose" is the most common terminology, it is not the only acceptable terminology.

Here, the Government alleges the following: "During the relevant time period, Defendants referred pharmacogenomics testing orders to NMTC, at least in part, because NMTC paid renumeration." [DN 1 ¶ 26]. This allegation, supported by numerous detailed factual allegations, sufficiently alleges that renumeration was "one purpose" of the Defendants' referrals to NMTC.

b. AKS: "Knowing and Willful"

The AKS's "willful" requirement requires allegations that a defendant acted with a purpose to commit a wrongful act but does not require knowledge of the statute or intent to violate the statute. *McDonnell v. Cardiothoracic & Vascular Surgical Assocs., Inc.*, No. C2-03-79, 2004 WL 3733402, at *8 (S.D. Ohio July 28, 2004). Circumstantial evidence can prove willfulness. *See United States ex rel. Derrick v. Roche Diagnostics Corp.*, 318 F. Supp. 3d 1106, 1113 (N.D. Ill. 2018) ("[W]illful conduct can be proven circumstantially.").

The Complaint includes numerous specific factual allegations that support an inference the Defendants acted "willfully." For example, the Government alleges the following:

- Defendants ordered 47 pharmacogenomics tests through NMTC during the eleven-month period before the alleged scheme began, then increased their orders to 1,206 tests during the eleven-month period NMTC was paying $150 per test. [DN 1 ¶¶ 28, 51–52].
- Defendants "significantly reduced the number of orders" when NMTC reduced payment to $105 per test. [*Id.* at ¶ 53].
- Defendants ordered 537 tests during March 2012, when Dr. Vora believed NMTC was paying $150 per test. [*Id.* at ¶ 40]. When he found out that was not yet the case, he sent a text message stating "I'm going to tell my staff not to send any samples to the company until all this is clarified." [*Id.* at ¶ 43].

- There were numerous meetings and emails between Dr. Vora and NMTC describing the PRIDE Registry Agreement and potential renumeration. [*Id*. at ¶¶ 34–38].

Taken as true and combined with allegations that Dr. Vora was aware of the AKS, [*id*. at ¶¶ 118–120], the Complaint sufficiently alleges that Dr. Vora acted "with a purpose to commit a wrongful act"—a purpose to refer pharmacogenomics testing to NMTC because he was receiving kickbacks.

This conclusion accords with the Southern District of New York's rationale in *Bilotta*, 50 F. Supp. 3d at 520–21. In *Bilotta*, the government sued a group of doctors for receiving kickbacks from a pharmaceutical company in exchange for prescribing Novartis drugs. *Id*. at 501–02. The complaint conceded the doctors wrote prescriptions for Novartis drugs before the kickback scheme began, but alleged the doctors wrote significantly more prescriptions after they started receiving kickbacks. *See id*. at 502–03, 520–21. The doctor defendants argued the government did not sufficiently allege that kickbacks influenced the doctors because the doctors prescribed the same drug before the renumeration began. *Id*. at 520. The court rejected that argument, stating that the significant increases in the doctors' Novartis prescriptions were "sufficient to allege that the doctors were prescribing Novartis drugs in exchange for kickbacks." *Id*. at 521.

Here, the Government's Complaint features similar allegations of extreme disparities in Dr. Vora's pharmacogenomics test referrals through NMTC during the relevant time period. These allegations, combined with the specific allegations relating to Dr. Vora's behavior during that time period, adequately alleges Dr. Vora ordered testing through NMTC in exchange for kickbacks. *See id*.

The Complaint makes sufficiently detailed allegations that Defendants acted with intent to receive kickbacks, and that the Defendants were aware of the AKS's prohibitions. The Complaint sufficiently pleads that Defendants acted "knowingly and willfully" in violation of the AKS.

c. AKS: Medical Necessity

Next, Defendants suggest the underlying AKS violation fails because the Government "wholly failed to allege how [NMTC's] claims were anything other than medically necessary for Dr. Vora's patients." [DN 12 at 18]. Defendants misstate the law. Medical necessity is not relevant for the AKS theory of liability. *United States v. Eggleston*, __ F. App'x __, 2020 WL 4548119, at *3 (6th Cir. 2020) ("The [AKS] makes no distinction between kickbacks earned from medically necessary services and those earned from unnecessary ones."). When determining whether Defendants violated the AKS (and therefore the FCA), the question is *not* whether Dr. Vora ordered medically unnecessary tests for purposes of receiving renumeration. The question is whether Dr. Vora ordered tests *because of renumeration*.

Since the Defendants' AKS arguments all fail, the Court finds that the Government has sufficiently pled a "false or fraudulent claim" based on AKS violations. Therefore, the Court will now analyze whether the Government alleged all elements of the three FCA causes of action.

2. Count I

Count I alleges that Defendants "knowingly caused to be presented false or fraudulent claims," in violation of the AKS and § 3729(a)(1)(A) of the FCA. [DN 1 ¶¶ 145–146]. Since the underlying AKS violation established the "false or fraudulent claim" prong, *see* 42 U.S.C. § 1320a-7b(g), the remaining question is whether Defendants "caused" the false claim "to be presented" to the government for payment.

Defendants argue that the Government's allegations leave out a required element of a § 3729(a)(1)(A) claim. In addition to the "false or fraudulent claim" and "presentment" elements, they argue, the Government also needed to "allege a specific certification of compliance with the

AKS." [DN 17 at 11]. Since the Complaint does not allege NMTC or Dr. Vora "submitted a claim certifying compliance with the AKS," Defendants claim Count I must be dismissed. [DN 12 at 17].

The Court disagrees. As part of the Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, 124 Stat. 119 (2010), Congress amended the AKS to state "a claim that includes items or services resulting from a violation of this section *constitutes a false or fraudulent claim* for purposes of [the False Claims Act]." 42 U.S.C. § 1320a-7b(g) (emphasis added). The word "constitutes" is important—it shows that an AKS violation automatically meets all requirements of a "false or fraudulent claim," as the term is defined in the FCA. *See Guilfoile v. Shields*, 913 F.3d 178, 190 (1st Cir. 2019) ("The [AKS's] use of the term 'constitutes' would be meaningless if courts had to engage in a materiality analysis—for example, by inquiring into whether the entity submitting the claim had certified its compliance with the AKS—after establishing that a claim resulted from an AKS violation."). Therefore, certification simply is not an element when proceeding under an AKS theory of liability.

This interpretation of § 1320a-7b(g)'s plain text is consistent with the views of most courts that have considered the issue. *See, e.g.*, *United States v. Cath. Health Initiatives*, 312 F. Supp. 3d 584, 594 (S.D. Tex. 2018) ("Due to an amendment in the ACA, liability under the FCA for AKS violations does not require the defendants to have expressly certified their compliance with the AKS."); *Bilotta*, 50 F. Supp. 3d at 529 (certification only required for AKS violations before the 2010 AKS amendment); *United States ex rel. Parikh v. Citizens Med. Ctr.*, 977 F. Supp. 2d 654, 664 n.3 (S.D. Tex. 2013) (no certification required for post-2010 claims).[3]

[3] Many defendants have also chosen not to contest the certification requirement for AKS violations after 2010. *See United States ex rel. Kester v. Novartis Pharm. Corp.*, 43 F. Supp. 3d 332, 364 (S.D.N.Y. 2014) (stating that the defendants "do not argue" the false certification issue for claims submitted after March 2010, because § 1320a-7b(g) stated that a reimbursement claim automatically implied AKS compliance, "even in absence of any express certification of compliance"); *United States v. Millennium Radiology, Inc.*, No. 1:11CV825, 2014 WL 4908275, at *10 n.5 (S.D. Ohio Sept. 30, 2014) (revealing that defendants "do not dispute" that "it is not necessary to allege certification for [an AKS] cause of action under the FCA based on claims submitted after March 23, 2010").

The 2010 amendment to the AKS created a categorical rule that all elements of the "false or fraudulent claim" inquiry are satisfied when the plaintiff pleads an AKS violation. Therefore, submitting a claim for Medicare reimbursement *always* certifies AKS compliance—no special certification is required.

Defendants cite several cases to support their claim that false certification is required to allege an AKS violation. None are prevailing. For example, Defendants cite *United States v. Teva Pharmaceuticals*, but the opinion expressly states that "there is no need for an independent of assessment of materiality" for all claims submitted after March 23, 2010 (the date of the AKS amendment) because "Congress has decreed these claims to be 'fraudulent.'" *United States v. Teva Pharm. USA, Inc.*, 13 Civ. 3702, 2019 WL 1245656, at *28 (S.D.N.Y. Feb. 27, 2019). Furthermore, an earlier opinion in *Teva Pharmaceuticals* squarely held that "after March 2010, the act of submitting a claim for reimbursement itself implied compliance with the AKS." *United States v. Teva Pharm. USA, Inc.*, 13 Civ. 3702, 2016 WL 750720, at *20 (S.D.N.Y. Feb. 22, 2016) (quoting *United States ex rel. Kester v. Novartis Pharm. Corp.*, 43 F. Supp. 3d 332, 364 (S.D.N.Y. 2014)). In another case cited by Defendants, the plaintiff in *United States ex rel. Bruno v. Schaeffer* did allege that the defendants "falsely certif[ied] compliance with the Anti-Kickback Statute"—the court found these allegations sufficient to state a claim under § 3129(a)(1)(A). 328 F. Supp. 3d 550, 557–59 (M.D. La. 2018). But this case does little to bolster Defendants' argument because alleging false certification clearly is acceptable—it just is not *necessary* to allege an FCA violation on an AKS theory of liability.[4]

[4] In *United States ex rel. Benaissa v. Trinity Health*, No. 4:15-cv-159, 2018 WL 684362 (D.N.D. Dec. 31, 2018), another case Defendants cite, a court dismissed a relator's FCA complaint because the relator "failed to plead *any* representative examples of claims for reimbursement." 2018 WL 6843624, at *12 (emphasis added). The relator's "certificates, cost reports, and forms" were insufficient because they were not "claims" under the meaning of § 3729, not because it lacked express certification. *Id*. However, to the extent that the court in *Thornton v. Nat'l Compounding Co.*, No. 8:15-cv-2647-T-36JSS, 2019 WL 2744623 (M.D. Fla. July 1, 2019) required the plaintiff to plead false certification to survive a motion to dismiss, this Court respectfully disagrees.

In its Complaint, the Government pled ample facts to allege NMTC submitted pharmacogenomics testing claims, referred by Dr. Vora, to Medicare. [DN 1 ¶¶ 70–71, Ex. G (claims data)]. It also pled two specific examples of allegedly kickback-tainted patient claims submitted to Medicare. [DN 1 ¶ 71, Exhibit R, Exhibit S]. These specific examples of allegedly false claims are sufficient to meet the Rule 9(b) heightened pleading standard. *See United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 501 F.3d 493, 510 (6th Cir. 2007). And since the alleged timeframe for the fraud was after 2010, [*see* DN 1 ¶ 3], the submission of the claims alone was enough to certify AKS compliance. If Defendants submitted the claims while NMTC and Dr. Vora were engaged in an illegal kickback scheme, Defendants violated the False Claims Act.

The Court concludes the Government did not need to plead facts alleging false certification by NMTC. Defendants' motion to dismiss will be **DENIED** for Count I, to the extent the Government relies on the AKS theory of liability.

3. Count II

Count II of the Complaint alleges violations of 31 U.S.C. § 3729(a)(1)(B), which subjects a person to liability if he "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." The AKS portion of the Complaint alleges the Defendants violated § 3729(a)(1)(B) because they submitted "false records and statements," including "false certifications on Medicare provider enrollment forms and false and misleading representations on claim forms that claims for pharmacogenomics testing submitted to Medicare by NMTC complied with the Anti-Kickback Statute, when in fact, those claims violated the Anti-Kickback Statute." [DN 1 ¶ 152].

In the AKS portion of Count II, the Government substantively alleges two types of false records. First, the Government alleges that Defendants caused NMTC to submit false claim forms

to Medicare. [DN 1 ¶ 152]. Second, the Government alleges that Defendants made false statements on Medicare provider enrollment forms. [*Id.*]. Defendants challenge both categories of records. [*See* DN 12 at 20–23]. The Court will address both the "claim forms" and "Medicare provider enrollment forms" separately.

a. Claim Forms

The Complaint's substantive allegations related to false claim forms based on AKS violations are as follows:

> 142. Each claim submitted by NMTC for Dr. Vora's orders of pharmacogenomics tests included a statement whereby NMTC certified that the information on the claim form was "true, accurate and complete."
> 143. As explained in Section II(A)(ii) above, this statement is false, because the claims were tainted by kickbacks.

[DN 1 ¶¶ 142–143].

In response, Defendants attack the underlying allegations, claiming the Government failed to plead the underlying AKS claims with "particularity." [DN 12 at 21]. But, for the reasons discussed above, the Government adequately pled the AKS violations with particularity, *see supra* Section III.A.1, and the same allegations have enough particularity to satisfy § 3729(a)(1)(B). [*See* DN 1, Exhibit R, Exhibit S].

b. Medicare Provider Enrollment Forms

The Government's allegations that Dr. Vora made a "false record or statement" on the Medicare provider enrollment forms warrants closer attention. Unlike Count I and the "claim form" allegations in Count II, these provider enrollment form allegations do not rely on Dr. Vora

"causing" false claims to be submitted through NMTC. Instead, these allegations assert that Dr. Vora made a "false record or statement" *himself*. [DN 1 ¶¶ 151–152, DN 13 at 20].

The substantive allegations assert that Dr. Vora has been a Medicare provider since 2001. [DN 1 ¶¶ 113–114]. As part of his Medicare enrollment form in 2001, Dr. Vora signed paperwork stating he "understood that payment of a claim by Medicare . . . is conditioned on the claim and the underlying transactions complying with such laws, regulations and program instructions (including the anti-kickback statute . . .), and on a provider/supplier being in compliance with any applicable conditions of participation . . . . " [*Id*. at ¶ 118]. Dr. Vora also asserted he understood the penalties for falsely certifying AKS compliance, [*id*. at ¶ 119], and stated he would "not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare or other federal health care programs." [*Id*. at ¶ 120].

Defendants assert that Dr. Vora's statements in a 2001 Medicare enrollment form cannot possibly create liability for an alleged fraud that took place more than a decade later. [DN 12 at 21–23]. In response, the Government disclaims reliance on the 2001 Medicare enrollment form. Instead, it points to the "revalidat[ion]" forms Dr. Vora must submit every five years. [DN 13 at 20]. The revalidation form asserts Dr. Vora has "read the [Medicare] requirements and understand[s] them." [DN 13 at 20; DN 1 Exhibit AA, at 8–9]. The Government did not include these allegations in the Complaint, but the 2019 revalidation form was attached as Exhibit AA.

To satisfy the Rule 9(b) particularity standard, the Government needed to allege a specific example of a false statement representative of its § 3729(a)(1)(B) allegations. *See* FED. R. CIV. P. 9(b). The Government apparently solely relies on the 2019 provider enrollment form to satisfy that standard. The question, therefore, is whether the 2019 provider enrollment form is a sufficient representative example of a false or fraudulent claim.

A § 3729(a)(1)(B) claim has three elements: "(1) [T]he defendant makes a false statement, (2) the defendant knows that the statement is false, and (3) the false statement is material to a false claim for payment." *United States ex rel. Brooks v. Stevens-Henager Coll., Inc.*, 359 F. Supp. 3d 1088, 1109 (D. Utah 2019). There is no "presentment" requirement in § 3729(a)(1)(B), but the plaintiff must assert a "connection between the alleged fraud and an actual claim made to the government." *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 473 (6th Cir. 2011).

In *Brooks*, a relator attempted to allege § 3729(a)(1)(B) liability against a college that submitted documents asserting compliance with a host of legal requirements. 359 F. Supp. 3d at 1108. The court dismissed the complaint because the allegedly false documents were "nothing more than a set of statements or assertions." *Id*. at 1109. The connection between the documents, which were not requests for payment, and the allegedly false claim was too attenuated to form a basis for liability. *Id.*

Here, the Government's allegations are deficient for the same reason as in *Brooks*. *See id.* at 1108–10. The Government wholly fails to allege how a 2019 generic revalidation form that never requested reimbursement is material to Medicare's decision to reimburse false, kickback-tainted claims that NMTC submitted in 2012 and 2013. *See id.* at 1109.[5] The revalidation forms are far too attenuated to form a basis for liability. *See Chesbrough*, 655 F.3d at 473.

To summarize, therefore, Defendants' motion to dismiss Count II will be **DENIED** to the extent the Complaint relies on the AKS theory and alleges that Defendants "caused" NMTC to make a false record or statement material to false claim forms. Defendants' motion to dismiss

[5] Unlike the discussion in Section III.A.2, which recognized AKS violations always are material in the government's payment decision, "materiality" remains relevant to determine whether the *false statement* was material to the false claim. The revalidation form's materiality, *not* the AKS violation's materiality, is lacking here.

Count II will be **GRANTED** to the extent the Complaint relies on the AKS theory and alleges Defendants' false statements on provider enrollment forms provide the basis for liability.

4. Count III

Count III alleges the Defendants "knowingly entered into one or more conspiracy to present or cause to be presented, false and fraudulent claims for payment or approval to the United States, including those claims for reimbursement of pharmacogenomics tests that violated the AKS and FCA." [DN 1 ¶ 157]. Defendants only contest the underlying AKS allegations. [DN 12 at 23].

As discussed above, the Complaint sufficiently alleges an AKS violation. Therefore, Defendants' motion to dismiss will be **DENIED** on Count III, to the extent Count III relies on the AKS theory.[6]

B. Counts I–III: Medical Necessity Theory of Liability

As noted earlier in this Opinion, the Government's second theory under the FCA is that Dr. Vora is liable because certain tests did not comply with Medicare regulations and therefore were "medically unnecessary." According to the Complaint, Dr. Vora (1) did not make individualized assessments of need before referring pharmacogenomics testing, (2) did not use the test results in treatment, (3) did not document patient need for pharmacogenomics testing in their medical records, and (4) ordered pharmacogenomics tests for patients receiving warfarin treatment who did not meet the Medicare coverage criteria. [DN 1 ¶¶ 74–112, DN 13 at 11]. The Government alleges these actions violated a host of Medicare laws and regulations, making the tests "not reasonable and necessary" and therefore a false claim *per se*. [DN 1 ¶¶ 123–136; DN 13 at 18–19].

[6] Defendants make the same argument regarding the unjust enrichment claim in Count IV—the unjust enrichment claim must fail because the underlying claims are not "false." Since the Court has already rejected that argument for the AKS theory of liability, Defendants' motion to dismiss Count IV necessarily fails as well.

Defendants contest this theory, arguing the Government's Complaint fails to allege why pharmacogenomics testing for the patients was not medically necessary. [DN 12 at 13; *see also* DN 17 at 4–10]. While Defendants are correct that "a theory of alleged lack of medical necessity is simply absent from the complaint," [DN 17 at 8], that is not the theory of liability on which the Government relies. According to the Government's theory of liability, Dr. Vora knew Medicare required certain actions to make a claim reimbursable, he knowingly did not take those actions, and he knowingly "caused" those claims to be submitted to Medicare anyway. The *actual* medical necessity of the tests is not relevant under the Government's theory of liability. For example, 42 C.F.R. § 410.32(a) provides that diagnostic laboratory tests are "not reasonable and necessary" if not ordered by the treating physician. For Medicare purposes, therefore, it does not matter if the patient actually needed a diagnostic lab test. The noncompliance with § 410.32(a) makes the tests unnecessary as a matter of law.

Unlike the AKS theory, this second theory proceeds on the "false certification" theory—Defendants are liable because they caused certain claims to be submitted to Medicare without meeting Medicare's reimbursement requirements. However, not all forms of Medicare noncompliance give rise to FCA liability. To the Defendants point, "[t]he False Claims Act is not a vehicle to police technical compliance with complex federal regulations." *United States ex rel. Williams v. Renal Care Grp., Inc.*, 696 F.3d 518, 532 (6th Cir. 2012). The Sixth Circuit previously analyzed false certification claims based on whether Medicare designated the condition as a "'condition[ ] of participation' in the Medicare program (which do not support an FCA claim) or [a] 'condition[ ] of payment' from Medicare funds (which do support FCA claims)." *United State ex rel. Hobbs v. MedQuest Assocs., Inc.*, 711 F.3d 707, 714 (6th Cir. 2013). But the Supreme Court overruled the Sixth Circuit's standard in 2016. *Universal Health Servs., Inc. v. United States*

ex rel. Escobar, 136 S. Ct. 1989, 2001–04 (2016). In *Escobar*, the Supreme Court rejected a firm distinction between conditions of payment and participation in favor of a holistic standard that considered whether a provision was "material" to the government's payment decision. *Id*. at 2001–03. Under this standard, a "condition of payment" designation is "relevant, but not automatically dispositive" to the materiality analysis. *Id.* at 2001. Instead, the materiality analysis considers the following:

> (1) "[T]he Government's decision to expressly identify a provision as a condition of payment"; (2) whether "the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement" or if, with actual knowledge of the non-compliance, it consistently pays such claims and there is no indication that its practice will change; and (3) whether the "noncompliance is minor or insubstantial" or if it goes "to the very essence of the bargain." None of these considerations is dispositive alone, nor is the list exclusive.

United States v. Brookdale Senior Living Cmtys., Inc., 892 F.3d 822, 831 (6th Cir. 2018) (quoting *Escobar*, 136 S. Ct. at 2001–04 & n.5). A plaintiff must plead enough facts to support a finding of materiality in the complaint to survive a motion to dismiss. *See Escobar*, 136 S. Ct. at 2004 n.6.

While some of the statutes and regulations cited by the Government make compliance a condition of payment, *see* 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. § 410.32(a), this fact only establishes the first *Escobar* factor. Most post-*Escobar* cases suggest that, at minimum, the plaintiff must plead at least two *Escobar* factors. *See, e.g.*, *United States ex rel. Doe v. Heart Sol., PC*, 923 F.3d 308, 318 (3d Cir. 2019); *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 489–90 (3d Cir. 2017); *United States ex rel. Lynch v. Univ. of Cincinnati Med. Ctr., LLC*, No. 1:18-CV-587, 2020 WL 1322790, at *21 (S.D. Ohio Mar. 20, 2020) (holding that a relator sufficiently pled a FCA violation based on allegations that the applicable provisions were conditions of payment, the government would not have paid if it was aware of noncompliance, and

the payment provision is integral to the agreement); *see also United States ex rel. Janssen v. Lawrence Mem'l Hosp.*, 949 F.3d 533, 544–45 (10th Cir. 2020) (granting defendant's motion for summary judgment despite a relator's assertion that multiple statutes "required express reporting as a condition of payment" because the other *Escobar* factors were not satisfied).

Because the Defendant did not specifically challenge the materiality of the false statements, this issue has not been adequately briefed by the parties. Thus, the Court is reluctant to decide it now. Therefore, based on the arguments made thus far by the Defendant, its motion to dismiss Counts I–IV based on the Government's second theory is **DENIED.**

IV. CONCLUSION

For the reasons set forth above, **IT IS HEREBY ORDERED** that Defendants' Motion to Dismiss for Failure to State a Claim is **DENIED IN PART AND GRANTED IN PART**.

Joseph H. McKinley Jr., Senior Judge
United States District Court

September 21, 2020

cc: Counsel of Record