United States District Court
for the
Southern District of Florida

United States of America and others, ex rel. Amber Watt, Plaintiffs,	)	
	)	Civil Action No. 19-61084-Civ-Scola
v.	)	
VirtuOx, Inc., Defendant.	)	

Order Granting Motion to Dismiss

The Plaintiff in this qui tam action, Relator Amber Watt, complains Defendant VirtuOx, a Medicare-approved independent diagnostic testing facility, fraudulently billed federal and state payors, including Medicare, for various services and goods related to at-home oxygen testing. (Am. Compl. ("Compl."), ECF No. 41.) Watt describes four general schemes from which her False Claims Act allegations arise: (1) VirtuOx misidentified San Francisco, California, as its location, in its billing claims, rather than its Coral Springs, Florida, location; (2) VirtuOx billed for unnecessary or redundant "spot check" oximetry testing, in conjunction with overnight oximetry testing; (3) VirtuOx unlawfully promoted an off-label, non-Food and Drug Administration approved use of a device; and (4) VirtuOx used kickbacks to induce durable medical equipment companies to refer data-interpretation work to VirtuOx. (*Id.* ¶¶ 3–8.) Watt's first count arises under the federal False Claims Act while her other twenty-nine counts arise under various state versions of the FCA. After the United States declined to intervene (ECF No. 49), the Court unsealed the initial complaint (ECF No. 50) and, thereafter, the individual plaintiff states declined to intervene as well (ECF No. 51). VirtuOx's motion to dismiss followed. (Def.'s Mot. to Dismiss, ECF No. 53.) In its motion, VirtuOx argues, among other things, that the complaint fails to state a claim upon which relief may be granted, under Federal Rule of Civil Procedure 12(b)(6), and fails to comply with the heightened pleading requirements for alleging fraud, under Rule 9(b). Watt has responded (Pl.'s Resp., ECF No. 74) and VirtuOx has timely replied (Def.'s Reply, ECF No. 76.) After careful consideration, the Court **grants** VirtuOx's motion to dismiss with prejudice (**ECF No. 53**).

1. Background and Facts[1]

VirtuOx operates facilities that analyze patients' oxygen levels, based on data collected from oximetry devices shipped to them at their homes, throughout the United States. (Compl. ¶¶ 19, 95, 97–98, 150.) The patients are prescribed at-home, self-administered testing so that a physician can determine whether they need certain oxygen-related therapies to treat various respiratory ailments. (*Id.* ¶¶ 94, 150.) The data from the devices is typically collected by another type of service provider—a durable medical equipment company—and then transmitted to an independent diagnostic testing facility, like VirtuOx. (*Id.* ¶ 97.) The testing facility—here, VirtuOx—then analyzes the data and provides a report to the ordering physician. (*Id.* ¶ 98.) VirtuOx, as one of these testing facilities, thereafter bills government payors, including Medicare, for the various analyses and testing procedures. (*Id.* ¶ 99.)

A. Reimbursements Vary by Location

Watt says the amount Medicare pays for these services varies "based on where the [testing facility] services are located." (*Id.* ¶ 100.) For example, the amount Medicare pays for these services is significantly higher for San Francisco, California than it is for Florida—sometimes almost double. (*Id.* ¶¶ 100–102.) Watt maintains that the "location of the [testing facility] services [VirtuOx] provides is Coral Springs, Florida," but that VirtuOx represents to its various governmental payors "that the location of services for reimbursement purposes is [its] San Francisco location." (*Id.* ¶¶ 104, 114.)

VirtuOx's corporate office and principal place of business is in Coral Springs. (*Id.* ¶ 104.) Further, patient calls, patient healthcare inquiries, and insurance billing activities are all handled in Coral Springs. (*Id.* ¶ 105.) Finally, all order forms for VirtuOx's services are faxed to its Florida office. (*Id.* ¶ 113.) In contrast, VirtuOx leases a "small space" in San Francisco, where "virtually no [testing] services are being performed" and where the "entire staff consists of a receptionist and office manager." (*Id.* ¶¶ 108–09.) A San Francisco telephone number that Medicare provides to its beneficiaries, to contact VirtuOx, yielded only a busy signal when called. (*Id.* ¶ 111.) Indeed, the only VirtuOx number that gets answered is the number for VirtuOx's Florida office. (*Id.* ¶ 112.)

Based on her review of just a couple years' worth of data, regarding a handful of billing codes, Watt calculates that VirtuOx has received millions of dollars in additional reimbursements, just based on that limited data set, by

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[1] The Court accepts Watt's factual allegations as true for the purposes of evaluating the Defendant's motions to dismiss. *Brooks v. Blue Cross & Blue Shield of Fla., Inc.*, 116 F.3d 1364, 1369 (11th Cir. 1997).

identifying its service location as in San Francisco rather than in Florida. (*Id.* ¶¶ 115–20.)

B. Spot Checks

Physicians can determine a patient's oxygen level using different tests. (*Id.* ¶¶ 123–24.) One test can monitor and record a patient's blood-oxygen saturation levels, along with heart rate, throughout the night. (*Id.* ¶ 123.) Another test a physician can order is a "spot check." (*Id.* ¶ 124.) This test involves placing a pulse oximeter on a patient's finger to check oxygen and heart-rate levels at a moment in time. (*Id.*) Watt says that "[t]here is no reason to perform a spot check at the same time as an overnight study" because "[t]he overnight study would encompass what would be learned from a spot check." (*Id.* ¶ 125.)

VirtuOx provides physicians with forms to prescribe these tests. (*Id.* ¶ 126.) Watt describes the forms as being printed in such a way that "the physician is misled into prescribing both" tests. (*Id.*) VirtuOx prefilled the "Diagnostic Orders" section of the prescription form with the following language: "Awake Oximetry CPT 94760 [the code for the spot-check test] & Overnight Oximetry CPT 94762 [the code for the overnight testing]: Immediately and repeat in 30/60/90 other: _____ to validate oxygen settings." (*Id.* ¶ 127.) According to Watt, this forces a physician to order both tests, rather than choosing one or the other. (*Id.* ¶ 128.)

Once a physician checks the box for the tests, VirtuOx can provide both the overnight service, along with the spot check and then bill the government payors for both. (*Id.* ¶ 129.) The amount Medicare paid VirtuOx for spot-check tests, in 2016 alone, was over $65,000. (*Id.* ¶ 117.)

C. Capnograph At-Home Use

VirtuOx offers a device to durable medical equipment companies it calls the "VPOD CapOx," a capnograph that tests oximetry and carbon dioxide levels overnight. (*Id.* ¶¶ 134–35, 140.) VirtuOx provides a video online, showing patients how to use the device at home. (*Id.* ¶ 136.) At the conclusion of the overnight testing, the durable medical equipment company sends the data collected to VirtuOx for interpretation, the results of which determine whether a patient qualifies for home-oxygen or -ventilation therapy—both costly and risky therapies. (*Id.* ¶¶ 141, 143.) VirtuOx can then submit a claim, for Medicare or Medicaid patients, to a government payor for having analyzed the data. (*Id.* ¶ 142.) If one of the therapies is indicated, the equipment company can then charge Medicare over $1,000 a month, for example, for the ventilation

therapy—therapy that, once prescribed, is often required for the rest of a patient's life. (*Id.* ¶¶ 145–46.)

The Department of Health & Human Services indicates the device VirtuOx offers "is adaptable to adult and pediatric usage in a hospital environment" and "is intended to be used only under regular supervision of clinical personnel." (*Id.*, Ex. 25, ECF No. 41, 147.) Watt complains VirtuOx, without FDA approval, has promoted the device for at-home use without clinical supervision. (*Id.* ¶¶ 136, 38.) Not only have governmental payors reimbursed VirtuOx for analyzing the data measured by this device, but they have also, in turn, paid the equipment companies for administering any resulting therapies that may thereafter be prescribed based on VirtuOx's analyses. (*Id.* ¶¶ 142, 145.)

D. Oximeters Given to Durable Medical Equipment Companies

When a doctor prescribes an overnight pulse oximetry study for a patient, the doctor generally transmits the prescription to a durable medical equipment company which then, in turn, provides the patient with the equipment necessary for the study. (*Id.* ¶¶ 150–52.) The equipment—the pulse oximeter—is oftentimes owned by the equipment company. (*Id.* ¶ 153.) After the patient uses the device, overnight, the patient returns it to the equipment company which then downloads the data. (*Id.* ¶¶ 154–155.) The equipment company can't itself interpret the data but, instead, sends it to a testing facility, like VirtuOx, for analysis. (*Id.* ¶¶ 155–56, 158.) The equipment company doesn't get reimbursed for its part of this service, including the use of the device. (*Id.* ¶ 159.) Rather, the equipment company only generates revenue for providing overnight-oxygen-therapy services and supplies to the patient, once, or if, the testing facility determines such therapies are actually indicated. (*Id.* ¶¶ 160–61.)

VirtuOx provides various durable medical equipment companies with free pulse oximeters, offsetting a large upfront cost the equipment companies would otherwise have to pay for themselves. (*Id.* ¶ 162.) Watt says VirtuOx provides the devices to the equipment companies in exchange for the companies' then choosing VirtuOx to perform their data interpretation. (*Id.* ¶ 163.)

E. Watt's Knowledge of the Alleged Schemes

Watt owns her own independent diagnostic testing facility. (*Id.* ¶ 165.) She has researched data available on Data.CMS.gov for 2016 which indicated VirtuOx was not identifying its service location as Florida. (*Id.* ¶¶ 166–69.) She says she was able to confirm that VirtuOx was using San Francisco as its "Location of Service" when a family friend was prescribed an overnight oxygen

study by her doctor. (*Id.* ¶¶ 170.) That doctor used VirtuOx's pre-printed prescription form, which Watt says forced the doctor to order both the spot-check test as well as the overnight study. (*Id.* ¶ 171.) A Medicare representative also told Watt directly that VirtuOx listed the place of service as San Francisco. (*Id.* ¶ 174.)

Watt says, based on her work in the industry and her research, she knows VirtuOx is (1) simultaneously billing for both the spot-check test and the overnight sleep study; and (2) billing Medicare for the use of a device not approved by the FDA. (*Id.* ¶ 181.) She has also been told directly by representatives from durable medical equipment companies that VirtuOx is offering and providing these companies with free pulse oximeters in exchange for the companies' using VirtuOx's diagnostic services. (*Id.* ¶ 182.) Further, employees from a company that manufactures pulse oximeters told Watt that certain durable medical equipment companies have declined buying their devices because they are able to get them from VirtuOx for $1. (*Id.* ¶ 185.) Ordinarily the devices sell for about $30. (*Id.*)

2. Legal Standards

When considering a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), the Court must accept all the complaint's allegations as true, construing them in the light most favorable to the plaintiff. *Pielage v. McConnell*, 516 F.3d 1282, 1284 (11th Cir. 2008). Under Federal Rule of Civil Procedure 8, a pleading need only contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). The plaintiff must nevertheless articulate "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 56 U.S. 662, 678 (2009). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* Thus, a pleading that offers mere "labels and conclusions" or "a formulaic recitation of the elements of a cause of action" will not survive dismissal. *Id.* In applying the Supreme Court's directives in *Twombly* and *Iqbal*, the Eleventh Circuit has provided the following guidance to the district courts:

> In considering a motion to dismiss, a court should 1) eliminate any allegations in the complaint that are merely legal conclusions; and 2) where there are well-pleaded factual allegations, assume their veracity and then determine whether they plausibly give rise to an entitlement to relief. Further, courts may infer from the factual

> allegations in the complaint obvious alternative explanation[s], which suggest lawful conduct rather than the unlawful conduct the plaintiff would ask the court to infer.

Kivisto v. Miller, Canfield, Paddock & Stone, PLC, 413 F. App'x 136, 138 (11th Cir. 2011) (citations omitted).

"In an action under the False Claims Act, Rule 8's pleading standard is supplemented but not supplanted by Federal Rule of Civil Procedure 9(b)." *Urquilla-Diaz v. Kaplan Univ.*, 780 F.3d 1039, 1051 (11th Cir. 2015). Under Rule 9(b), "a party must state with particularity the circumstances constituting fraud or mistake," although "conditions of a person's mind," such as malice, intent, and knowledge, may be alleged generally. Fed. R. Civ. P. 9(b). "The 'particularity' requirement serves an important purpose in fraud actions by alerting defendants to the precise misconduct with which they are charged and protecting defendants against spurious charges of immoral and fraudulent behavior." *W. Coast Roofing & Waterproofing, Inc. v. Johns Manville, Inc.*, 287 F. App'x 81, 86 (11th Cir. 2008) (citations omitted). "When a plaintiff does not specifically plead the minimum elements of their allegation, it enables them to learn the complaint's bare essentials through discovery and may needlessly harm a defendant's goodwill and reputation by bringing a suit that is, at best, missing some of its core underpinnings, and, at worst, [grounded on] baseless allegations used to extract settlements." *U.S. ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1313 n.24 (11th Cir. 2002). Thus, the Rule's "particularity" requirement is not satisfied by "conclusory allegations that certain statements were fraudulent; it requires that a complaint plead facts giving rise to an inference of fraud." *W. Coast Roofing & Waterproofing*, 287 F. App'x at 86. "To satisfy this heightened-pleading standard in a False Claims Act action, the relator has to allege facts as to time, place, and substance of the defendant's alleged fraud, particularly, the details of the defendants' allegedly fraudulent acts, when they occurred, and who engaged in them." *Urquilla-Diaz*, 780 F.3d at 1051 (cleaned up).

3. Discussion

To recap, Watt alleges VirtuOx conducted four unlawful schemes which resulted in its submitting, or causing to be submitted, false claims to government payors for reimbursement. She contends VirtuOx (1) misidentified where VirtuOx's services are located; (2) billed for unnecessary services; (3) marketed a device for a use that is not FDA approved; and (4) used kickbacks to induce durable medical equipment companies to refer data-interpretation work to VirtuOx. (Compl. ¶¶ 3–8.)

Generally, "[a] claim is considered false under the False Claims Act if it is either factually or legally false." *United States v. Space Coast Med. Associates, L.L.P.*, 94 F. Supp. 3d 1250, 1259 (M.D. Fla. 2015). "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.* The Court agrees with VirtuOx that Watt has failed to state a claim under the FCA based on any of the four alleged schemes.

A. Watt fails to allege a False Claims Act claim based on VirtuOx's identifying San Francisco, rather than Florida, as the location of the services it provides.

VirtuOx makes three basic arguments in urging the Court to dismiss Watt's claims based on VirtuOx's identification of San Francisco as its location of service. (Def.'s Mot. at 9–14.) First, VirtuOx contends Watt fails to plead falsity with respect to claims VirtuOx submitted from its California office. In support, VirtuOx points to Watt's failure to identify any statute, regulation, or rule that would render VirtuOx's identification of San Francisco as false; the Supreme Court's prohibition of liability premised on sub-regulatory guidance; and internal governmental guidance that advises its attorneys not to rely on guidance documents to lodge enforcement actions. Second, VirtuOx maintains Watt fails to plead VirtuOx's knowledge that identifying its location of service as San Francisco was false. And, third, VirtuOx argues that Watt fails to plead that its identification of its California office as its billing location was material to the various governments' reimbursement decisions.

In response, Watt says she does not need to identify any statute, regulation, rule, or sub-regulatory guidance that VirtuOx violated because VirtuOx's misidentification of the "location where its services were rendered" is factually false. (Pl.'s Resp. at 6 –11.) Watt also maintains that the Supreme Court case that VirtuOx relies on, *Azar v. Allina Health Services*, is inapplicable to this case. 139 S. Ct. 1804 (2019). In further support of her argument that VirtuOx's identifying San Francisco as the location of service is false, Watt points to (1) a summary report prepared for a patient in Kansas on which VirtuOx's Coral Springs address is printed; and (2) VirtuOx's failure to have a working telephone number at its San Francisco office. Watt maintains she has sufficiently alleged scienter by showing that VirtuOx explicitly misidentified San Francisco as the location of service. This misidentification, she continues, is material because the government payors reimbursed VirtuOx for a higher rate than they would have had VirtuOx listed its service location as being in

Florida. Lastly, Watt avers that she has also sufficiently alleged a False Claims Act violation under a false certification theory. After careful review, the Court agrees with VirtuOx that Watt's claims based on VirtuOx's alleged misidentification of its location of services should be dismissed because Watt has failed to properly allege either factual or legal falsity.

(1) *The complaint fails to allege factual falsity with respect to VirtuOx's identifying San Francisco as its location of service.*

Watt maintains VirtuOx's representations are factually false because VirtuOx "is claiming its [independent diagnostic testing facility] services are being provided in San Francisco, CA, when they are actually being performed in Coral Springs, FL." (Pl.'s Resp. at 7.) Watt additionally argues that VirtuOx's claims are factually false because its San Francisco location "does not even qualify as an [independent diagnostic testing facility] pursuant to the Medicare requirements." (Pl.'s Resp. at 8.) But, as both parties agree, "[a] factually false claim occurs, for example, when a supplier submits a claim that misidentifies the goods supplied or requests reimbursement for goods that it never provided." *United States ex rel Phalp v. Lincare Holdings, Inc.*, 116 F. Supp. 3d 1326, 1344 (S.D. Fla. 2015) (Williams, J.), *aff'd as modified sub nom. United States ex rel. Phalp v. Lincare Holdings, Inc.*, 857 F.3d 1148 (11th Cir. 2017). In other words, factual falsity is shown when a "supplier falsely bills the government for something not received." *Id.*

Here, though, Watt fails to allege that either VirtuOx dispensed goods or services different than that for which it sought reimbursement or that VirtuOx sought reimbursement for goods or services that were not provided at all. Misidentifying the location where its services were provided or failing to qualify its San Francisco location under Medicare requirements does not amount to a factually false identification of the provision of the actual goods or services themselves—regardless of whether this misidentification or noncompliance resulted in a heightened rate of reimbursement. Instead, determining whether or not VirtuOx's representation of its "location of service" is false depends on how that term is defined and whether VirtuOx complied with the Medicare requirements Watt identified. Contrary to Watt's position otherwise, this does not amount to a claim that is a "fairly straightforward" application of the False Claims Act (Pl.'s Resp. at 6); instead, it leads the Court to inquire whether VirtuOx's claims were legally, as opposed to factually, false. *See United States ex rel. Schimelpfenig v. Dr. Reddy's Labs. Ltd.*, CV 11-4607, 2017 WL 1133956, at *4 (E.D. Pa. Mar. 27, 2017) (noting that plaintiffs "cannot circumvent the requirements for proving legal falsity under the FCA by repurposing their

claims as ones for factual falsity" where the plaintiffs only alleged the defendants' failure to comply with various statutory requirements).

(2) *The complaint fails to allege legal falsity with respect to VirtuOx's identifying San Francisco as its location of service.*

The Court turns next, then, to Watt's alternative argument, that VirtuOx's claims are also legally false. "Where a claimant falsely certifies that it has complied with a federal statute or regulation, compliance with which is a condition of Government payment, the payee's claim is legally false and actionable under the FCA." *Id.* Such false certification can be either express or implied. *Id.* Express certification involves a provider's explicitly certifying compliance with applicable law and regulations as part of the claims-submission process. *U.S. ex rel. Keeler v. Eisai, Inc.*, 568 F. App'x 783, 798 (11th Cir. 2014). Implied certification, on the other hand, implicates a provider's submitting claims for payment when they knowingly violated a law, rule, or regulation which was a condition for receiving payment from the Government. *U.S. ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 313 (3d Cir. 2011). Watt never specifies which theory she believes supports her claim but it is clear she has not alleged a claim for express false certification—her complaint does not set forth any allegation that VirtuOx certified compliance with any rules as part of its actual claims-submission process. Rather, Watt's theory of legal falsity appears to be based on implied false certification.

In support of her theory of false certification, Watt points to, first, VirtuOx's agreement, upon enrolling in Medicare as a participant, that it would abide by Medicare's rules. (Pl.'s Resp. at 10.) She further points out that, within that agreement, VirtuOx also acknowledged it understood that payment of its claims was conditioned upon the claim and the underlying transaction's complying with such rules. (*Id.*) Watt then says that VirtuOx "falsely certif[ied] that its San Francisco, CA location meets the Medicare [independent diagnostic testing facility] requirements." (*Id.*) Her position that the San Francisco location fails to meet Medicare's enrollment standards is based, in turn, on her allegations that that site does not have a working phone number, as required by Medicare. (Pl.'s Resp. at 9; Compl. ¶¶ 110–12.) She maintains that these "fraudulent representations"—that the San Francisco location met the enrollment requirements, when it did not—"were material to Medicare's decision to pay the claims" because Medicare would not have enrolled VirtuOx's San Francisco location, to begin with, had it known VirtuOx did not meet the Medicare requirements for an independent diagnostic testing facility. (*Id.* at 11.) And if Medicare hadn't enrolled VirtuOx in the first place, it would

never have reimbursed VirtuOx at the higher San Francisco rate. (*Id.*) The Court finds Watt's argument misses the mark.

One problem with Watt's analysis is that she fails to identify any factual allegations supporting her claim that VirtuOx's San Francisco location's lack of a working phone and therefore, its failure to meet Medicare's requirements of a qualified independent diagnostic testing facility, was a condition of payment. Her conclusory and unsubstantiated insistence that VirtuOx's compliance with this requirement was "material to Medicare's decision to pay the claims" is not enough. (Pl.'s Resp. at 11.) By way of example, Watt fails to allege facts showing that VirtuOx "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" at issue here. *Universal Health Services, Inc. v. United States*, 136 S. Ct. 1989, 2003 (2016). Instead, she simply maintains that "Medicare would have obviously not reimbursed Defendant at the San Francisco higher reimbursement rate" if it had known VirtuOx's "services were not being rendered [there]." (Pl.'s Resp. 7.) But "[t]he False Claims Act is not an all-purpose antifraud statute or a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Universal Health Services*, 136 S. Ct. at 2003 (cleaned up); *see also Phalp*, 857 F.3d at 1154 ("[T]he fact that there may have been a violation of the laws governing Medicare is not enough, standing alone, to sustain a cause of action under the False Claims Act.") (cleaned up). And so, even if the Court finds Watt has sufficiently alleged that VirtuOx's failure to have a working telephone number for its San Francisco location is a violation of Medicare's enrollment requirements, her remaining factual allegations fall short of establishing that that failure was material to the Government's decision to pay VirtuOx's claims.

Further, Watt's general complaints about VirtuOx's identification of its San Francisco office as its location of service as being a false claim also fail. She repeatedly maintains that VirtuOx falsely represents to the Government that its location is San Francisco rather than its "actual location in Florida." (Pl.'s Resp. at 7.) Without more, though, this fails to identify any statute, regulation, rule, standard, or even guideline, that VirtuOx has actually violated by identifying its location of service as San Francisco.[2] To succeed in

[2] The parties devote much of their briefing to the applicability of the United States Supreme Court's decision in *Azar*, 139 S. Ct. 1804. Because Watt concedes her complaint "does not rely on sub-regulatory guidance to support [her] claim that a provider cannot submit a claim to Medicare for a service it did not provide, or submit a claim falsely stating that a service took place in a location where it did not actually take place," the Court finds that decision immaterial here. Accordingly, the Court declines to evaluate whether it is applicable or not. Additionally, although Watt does not substantively discuss it, she appends Medicare guidance, captioned "Transmittal: 166" and dated July 22, 2005, to her complaint. (Ex. 2, ECF No. 41,

establishing implied legal falsity, Watt must, at a minimum, identify a specific "statutory, regulatory, or contractual requirement" that VirtuOx failed to comply with. *Universal Health Services*, 136 S. Ct. at 1999. Without that, her argument is circular: VirtuOx's claims are false, she reasons, because the claims fail to comply with Medicare requirements; and the claims do not comply with Medicare requirements, she maintains, because they are false.

Certainly, it appears, reading the allegations in the light most favorable to Watt, VirtuOx purposely and knowingly identified San Francisco, rather than Coral Springs, Florida, as the location of its services to take advantage of the increase in allowable reimbursements between to the two locales. In doing so, VirtuOx appears to have exploited a loophole that has resulted in considerably higher payments from government payors. But allegations of dubious business practices alone, however, do not implicate a legally false claim. Without more, the Court finds Watt has failed to state a claim based on VirtuOx's identifying San Francisco as its location of service.

B. VirtuOx's billing for "spot checks" does not result in false claims or otherwise amount to improper conduct.

The second scheme Watt alleges has to do with what she refers to as "spot checks." This service measures a patient's oxygen and heart-rate levels at a moment in time. (Compl. ¶ 5.) In her complaint, Watt says "there is no reason to perform a spot check at the same time as an overnight study" because "[t]he overnight study would encompass what would be learned from a spot check." (*Id.* ¶¶ 6, 125.) But, she alleges, VirtuOx prints prescription forms in such a way that doctors are misled into ordering both tests. (*Id.* ¶¶ 6, 125, 171.) Once prescribed, Watt says, VirtuOx can then provide both the overnight service as well as the "spot check," billing the government for both. (*Id.* ¶ 129.) Watt says that, in 2016 alone, VirtuOx billed Medicare $67,570.20 for these "spot checks" and that the "spot checks" were always billed concurrently with the overnight testing service. (*Id.* ¶¶ 131–32, 180.) Watt also alleges, without elaboration, that VirtuOx "submitted claims for 'spot check' services it did not perform." (*Id.* ¶ 189.)

Watt maintains she has alleged both factual as well as legal falsity with respect to VirtuOx's "spot check" claims. (Pl.'s Resp. at 11–15.) To support her factual-falsity argument, she says she has sufficiently alleged facts that would

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78–83.) One sentence of this document is arguably related to Watt's location-of-service claim: "The carrier jurisdiction for the overnight pulse oximetry test is the location of the [independent diagnostic testing facility] to which the test results are transmitted." (Ex. 2 at 80.) Because Watt does not contend this language renders VirtuOx's location-of-service designation a false claim, the Court declines to consider it here.

establish that VirtuOx billed for but did not actually perform the "spot check" service. (*Id.* at 11–13.) At the same time, to support her legal falsity claim, Watt insists providing a "spot check" measurement, concurrently with overnight testing, is not permitted by Medicare guidance. (*Id.* at 13–15.) VirtuOx, in urging dismissal of Watt's "spot check" claim, argues Watt has failed to allege facts supporting either factual or legal falsity. (Def.'s Mot. at 14–15; Def.'s Reply at 6–7.) After careful review, the Court agrees with VirtuOx.

(1) *The complaint fails to allege factual falsity with respect to VirtuOx's billing for "spot checks."*

Watt's factual falsity argument hinges on her contention that VirtuOx never performed the "spot check" tests it billed Medicare for. (Pl.'s Resp. at 11.) But there is a notable paucity of allegations relating to this lack of performance in her complaint. Indeed, in her complaint, Watt mentions this lack of service only once: "Defendant . . . submitted claims for 'spot check' services it did not perform to Federal and State payors." (Compl. ¶ 189.) This bare allegation, that VirtuOx failed to ever perform the "spot check" tests it billed for, fails to articulate "enough facts to state a claim to relief that is plausible on its face," *Twombly*, 550 U.S. at 570, never mind comply with the particularity requirements of Federal Rule of Civil Procedure 9(b). At bottom, Watt's bald contention that VirtuOx did not perform services for which it billed amounts to nothing more than "an unadorned, the-defendant-unlawfully-harmed-me accusation." *Iqbal*, 556 U.S. at 678 (cleaned up).

Watt's reliance, in her response, on a "Pulse Oximetry – Summary Report," attached to her complaint as Exhibit 29, does not save her claim. (Pl.'s Resp. at 12 (citing Compl., Ex. 29, ECF No. 41, 158–59.) This report simply shows the results of one patient's overnight pulse-oximetry test. It does not reveal any information that would allow the Court to surmise that VirtuOx did not, in addition, perform a "spot check" test as well. Nor does Watt's reliance on the "Overnight Oximetry Order Form" help. (Ex. 29, ECF No. 41, 157.) First, it is largely illegible. Second, Watt's assertions about that form, even if true, fail to allow the Court to infer VirtuOx never performed a "spot check" test for this patient. For example, Watt says "there is nothing checked [on the form] to indicate that the physician ordered a spot check" and "[t]here is no language regarding a spot check test." (Pl.'s Resp. at 12.) According to Watt, though, one portion of this form reads as follows: "Diagnostic Orders: Awake Oximetry CPT 94760 & Overnight Oximetry CPT 94762: immediately and repeat in 30/60/90/other _____ to validate oxygen settings." (*Id.* (emphasis and blank in original).) And so, even if what Watt says is true, she fails to explain what needed to be "checked" in order to show that the doctor did or didn't order the

test. In sum, Watt has failed to allege factual falsity as it relates to the VirtuOx's billing for "spot checks."

(2) *The complaint also fails to allege legal falsity with respect to VirtuOx's billing for "spot checks."*

Alternatively, Watt maintains that VirtuOx's billing for both "spot checks" and overnight pulse oximetry services did not comply with Medicare requirements. Again, though, the allegations in her complaint do not support her position.

In her complaint, Watt alleges that "[t]here is no reason to perform a spot check at the same time as an overnight study" because "[t]he overnight study would encompass what would be learned from a spot check." (Compl. ¶¶ 6, 125.) In her opposition brief, to support her position that this alleged redundancy is contrary to Medicare guidance, she points to Exhibit 3 of her complaint which is captioned, "Local Coverage Determination (LCD) for Noninvasive Ear or Pulse Oximetry for Oxygen Saturation (L29236)." (Compl., Ex. 3, ECF No. 41, 85–86.) She highlights language identifying the overnight procedure as a "separate procedure" and, then, without support, explains that "[s]eparate procedure means the test is performed separately from any other procedure, such as [a spot check]." (Pl.'s Resp. at 14.) First, the exhibit does not support Watt's position. Second, even if it did, Watt fails to provide any facts, as required, that would support, at a minimum, a finding that compliance with this guidance "is a condition for Government payment." *Space Coast*, 94 F. Supp. 3d at 1259.

Watt's reliance on other Medicare guidance is similarly unavailing. First, the Court declines to take notice of the documents Watts refers to—which she has attached to her response brief. For the Court to consider documents beyond the face of the complaint, or attached thereto, the contents must be both undisputed and central to Watt's claim. *Fin. Sec. Assur., Inc. v. Stephens, Inc.*, 500 F.3d 1276, 1284 (11th Cir. 2007). While these documents—another Local Coverage Determination document (Pl.'s Resp., Ex. 4, ECF No. 74-4); and two chapters from the Medicare Claims Processing Manual (Pl.'s Resp., Ex. 5, ECF No. 74-5; Ex. 7, ECF No. 74-7)—may be undisputed, Watt has provided no support, or even argued, that they are central to her claims. *Fin. Sec.*, 500 F.3d at 1284 ("Ordinarily, we do not consider anything beyond the face of the complaint and documents attached thereto when analyzing a motion to dismiss.") Second, even if the Court were to consider them, once again, Watt fails to provide any facts that would support a finding that compliance with the guidance in these documents is a condition for Government payment.

Watt also fails to provide facts or legal authority supporting her bald claim that the "spot check" test, when performed in conjunction with the overnight pulse oximetry test, is redundant and unnecessary. In short, Watt fails to state a claim under the False Claim Act based on VirtuOx's providing or billing for "spot check" services.

C. The complaint fails to allege a false claim based on VirtuOx's selling and marketing a medical device for off-label use.

In her complaint, Watt alleges VirtuOx is marketing and selling a medical device—a capnograph that tests oximetry and carbon dioxide levels—in violation of the Food, Drug, and Cosmetic Act. (Compl. ¶¶ 133–149.) In support of her claim, Watt says the capnograph is only approved by the Food and Drug Administration for use in a hospital environment, under the regular supervision of clinical personnel. (*Id.* ¶ 137.) Despite this limitation, however, she says VirtuOx is marketing and selling the device to durable medical equipment providers, for at-home use, without clinical supervision. (*Id.* ¶¶ 134, 136, 140.) Watt says she does not believe VirtuOx has FDA clearance to use or promote the use of the device in this manner. (*Id.* ¶ 138.) Based on this FDCA violation, Watt argues any claims submitted as a result of VirtuOx's off-label use or promotion of the device are false under the False Claims Act. The Court finds Watt's allegations are insufficient.

In order to be reimbursable, "a device must (1) have FDA approval/ clearance, (2) be reasonable and necessary, and (3) meet any other pertinent regulations." *Dan Abrams Co. LLC v. Medtronic Inc.*, 850 F. App'x 508, 509 (9th Cir. 2021) (cleaned up). The parties do not dispute that the complaint sufficiently alleges the capnograph itself is FDA approved but that the at-home use of the device is off-label. Instead, the crux of Watt's argument is that VirtuOx's use, or marketed use, of the device is not reasonable and necessary simply by virtue of the fact that it is off-label. She provides no legal basis, however, for her conclusion. And, indeed, contrary to her position, "the federal government has recognized that doctors may use medical devices for off-label purposes as long as it is medically necessary and reasonable." *Id.* (citing *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350, (2001), for its recognition that "off[-]label usage of medical devices is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine") (cleaned up). Watt's argument, then, that VirtuOx's use or marketed use of the capnograph is not medically necessary and reasonable because it is off-label, fails. Simply put, "the federal government does not distinguish between on-label and off-label uses in determining whether to pay for medical devices." *Dan Abrams*, 850 F.

App'x at 509; *see also* U.S. Dep't of Health & Hum. Serv. (HHS), *Medicare Benefit Policy Manual*, ch. 14 § 10, available at https://www.cms.gov/RegulationsandGuidance/Guidance/Manuals/Downloads/bp102c14.pdf (noting that Medicare reimburses for "[*d*]*evices* cleared by the FDA through the 510(k) process"—not cleared *uses* of a device) (emphasis added).

The complaint otherwise fails to present any factual allegations that would render VirtuOx's claims, as to the capnographs, either legally or factually false.

D. The complaint fails to allege a false claim based on a kickback scheme.

In her complaint, Watt describes the process involved in measuring a patient's overnight oxygen levels at-home. By way of review, first, a doctor writes a prescription for an overnight pulse oximetry study. (Compl. ¶ 151.) Ordinarily, the doctor faxes that prescription to a durable medical equipment company which then coordinates delivering a pulse oximeter to a patient's home. (*Id.* ¶ 152–53.) Following the overnight measurements, the patient returns the pulse oximeter to the equipment company. (*Id.* ¶ 154.) The equipment company then downloads the data collected and subsequently electronically transmits that data to an independent diagnostic testing facility, like VirtuOx, for analysis. (*Id.* ¶ 155.) The testing facility is paid a fee by Medicare, or other payors, for that analysis. (*Id.* ¶ 157.) If it is determined that a patient qualifies for overnight oxygen therapy, based on the analysis of the data, the equipment company will provide the necessary devices and services for the treatment. (*Id.* ¶ 161.) Under the relevant Medicare guidelines, the equipment company is only reimbursed for the services related to the therapy—not the initial overnight pulse-oximetry study. (*Id.* ¶159–61.) VirtuOx gives various durable medical equipment companies free, or deeply discounted, pulse oximeters. (*Id.* ¶¶ 162, 182, 185.) In exchange, at least one equipment company uses VirtuOx exclusively for interpreting its patients' oximetry data. (*Id.* ¶ 185.) VirtuOx has also offered other equipment companies free pulse oximeters in exchange for those companies' funneling their data-interpretation work to VirtuOx. (*Id.* ¶¶ 182–184.) Reading these allegations in the light most favorable to Watt, the Court concludes Watt has sufficiently established, for the purposes of the Court's analysis at this stage of the litigation, that VirtuOx is, indeed, giving something of value to at least one durable medical equipment company in exchange for that company's agreeing to select VirtuOx to perform its data analysis. That alone, however, is not enough.

In order to establish a violation of the federal Anti-Kickback Statute, a plaintiff must show the defendant offered or provided something of value in

exchange for the referral of any service "for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. §§ 1320a-7(b)(2)(A). Watt maintains that, based on VirtuOx's participation in the kickback scheme, it "is knowingly submitting false claims to Medicare which were tainted by the kickbacks." (Pl.'s Resp. at 18.) Conversely, in urging dismissal of Watt's claim, VirtuOx points out, among other things, that Watt fails to identify any particular false claim that is actually linked to the kickback scheme. The Court agrees.

As set forth above, Watt adequately describes VirtuOx's providing something of value to at least one durable medical equipment company in exchange for that company's referral of diagnostic services to VirtuOx. And, separately, Watt sufficiently alleges that VirtuOx has submitted claims to Medicare for performing that kind of diagnostic service for hundreds of thousands of patients over the relevant years. (*E.g.*, Compl. ¶¶ 115, 119, 167.) Wholly missing, however, are any factual allegations connecting the two. In other words, no matter how favorably to Watt the Court construes the complaint, there is nothing from which the Court could infer that any of VirtuOx's Medicare claims actually arose out of the kickback scheme. Because of this shortcoming, Watt fails to state a claim based the alleged kickback scheme and certainly fails far short of Rule 9(b)'s heightened pleading requirements. *See Clausen*, 290 F.3d at 1311–12 (granting dismissal of False Claims Act case where the plaintiff failed to "provide any factual basis for his conclusory statement[s] . . . that bills were submitted to the Government as a result of [the alleged] schemes) (citing *U.S. ex rel. Butler v. Magellan Health Services, Inc.*, 101 F. Supp. 2d 1365, 1369 (M.D. Fla. 2000) for the proposition that a False Claims Act will be dismissed where a plaintiff "pleading a fraudulent scheme of conduct which may well be prohibited by law" fails to plead "any specific occurrences of a false claim") (cleaned up).

4. Conclusion

While Watt has set forth facts showing that VirtuOx has violated Medicare guidance, as well as offered and provided incentives in exchange for referrals of service, she has failed to nudge her False Claims Act "claims across the line from conceivable to plausible." *Twombly*, 550 U.S. at 570. Because Watt does not dispute VirtuOx's position that Watt's state claims implicate substantively similar requirements as the federal False Claims Act, those claims are dismissed as well. Furthermore, other than conclusory declarations that VirtuOx submitted false claims to the various state payors, Watt supplies no factual allegations that VirtuOx submitted any state claims at all, never mind false state claims, to support her other twenty-nine counts. Those

counts,then, are dismissed, for a failure to state a claim, on that basis as well. Accordingly, the Court **grants** VirtuOx's motion (**ECF No. 53**), thus **dismissing** this case, in its entirety, for a failure to state a claim. Because the case is dismissed on the merits, under Rule 12(b)(6), the dismissal is **with prejudice**. *See Wagner v. Daewoo Heavy Industries Am. Corp.*, 314 F.3d 541, 542 (11th Cir. 2002) ("A district court is not required to grant a plaintiff leave to amend his complaint sua sponte when the plaintiff, who is represented by counsel, never filed a motion to amend nor requested leave to amend before the district court."); *Avena v. Imperial Salon & Spa, Inc.*, 17-14179, 2018 WL 3239707, at *3 (11th Cir. July 3, 2018) ("[W]e've rejected the idea that a party can await a ruling on a motion to dismiss before filing a motion for leave to amend.")

The Court directs the Clerk to **close** this case. Any pending motions are **denied as moot**.

Done and ordered in Miami, Florida on August 31, 2021.

Robert N. Scola, Jr.
United States District Judge