Salters v. American Family Health Care Inc
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U.S. DISTRICT COURT
N.D. OF ALABAMA

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
NORTHEASTERN DIVISION

UNITED STATES OF AMERICA, *ex rel*. ANITA C. SALTERS,	)	
Plaintiff,	)	
vs.	)	5:10-cv-2843-LSC
AMERICAN FAMILY CARE, INC.,	)	
Defendant.	)	

MEMORANDUM OF OPINION

I. Introduction

Plaintiff/Relator Anita C. Salters ("Salters") filed this action against her former employer American Family Care ("AFC") alleging that AFC violated the False Claims Act ("FCA"), 31 U.S.C. § 3729, by submitting false claims to the Government, and that it engaged in physician referrals in violation of the Stark Law, 42 U.S.C. § 1395nn. She further alleges that she was unlawfully terminated in retaliation for reporting these potential violations to her superiors contrary to the FCA's anti-retaliation provision. 31 U.S.C. § 3730(h). Before the Court is defendant AFC's motion for partial summary judgment on the FCA claims (Doc. 101), which has been

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fully briefed and is ripe for review. For the reasons set out below, AFC's motion is due to be granted in part and denied in part.

II. Background

AFC operates sixty-eight walk-in medical clinics which provide primary, family, and urgent care. Throughout its clinics, AFC employs 165 physicians. Most of AFC's offices are open seven days a week, from 8:00 am to 6:00 pm. However, a few are open for longer hours, and the Huntsville clinic is only open five days a week. All full-time physicians execute a Medicare approved Reassignment of Benefits form, which assigns the physician's right to fees for services performed to AFC.

AFC then submits "claims" or bills to Federal payors—such as Medicare, Medicaid, and Tricare—as a group practice, using Current Procedural Terminology ("CPT") codes to identify services performed and International Certification of Diseases ("ICD") codes to identify diagnoses made. CPT codes "describe medical services such as treatments, tests, and procedures, and are an accepted means of reporting such medical services to [G]overnment and health insurance programs." *U.S. ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 708 n.9 (10th Cir. 2006). ICD codes "describe the diagnosis or medical condition for which medical services are rendered when Medicare claims are

submitted to Medicare carriers." *Id.* at 708 n.8. AFC estimates that it submits thousands of these claims to Federal payors every year, and understands that when claims are submitted to the Federal Government, AFC certifies that it is complying with applicable rules and regulations.

AFC hired Salters as an audit supervisor in January 2007 and promoted her to director of the Claims Processing Center ("CPC") in December 2007. (Salters Dep. at 14, Kerr Dep. at 103.) Her duties as director of the CPC included ensuring that the claims submitted were in compliance with all applicable regulations, collecting all sums due to AFC within a reasonable period of time, and supervising approximately twenty-five other employees in the CPC. (Salters Dep. at 190, Johansen Dep. at 37 & 72, Hawley Dec. ¶ 5.)

a. Locum Tenens Physicians

A *locum tenens* physician fills in when a physician is absent, and bills as if he were the regular physician. Medicare Claims Processing Manual ("MCPM") Ch. 1 § 30.2.11. To supplement its physician employees, AFC uses *locum tenens* physicians, one of which was Dr. Charles Buckmaster ("Dr. Buckmaster"), who worked at AFC clinics between 2006 and 2011, substituting for several different providers at various AFC locations.

b. Ear Popper

The "Ear Popper" is a device that shoots air up through the nostril for the purpose of balancing inner ear pressure with outside pressure. AFC purchased sixteen Ear Poppers for its offices, and billed Federal payors for their usage according to the recommendations of the Ear Popper manufacturer—as is customary in the healthcare industry. (Salters Dep. at 75 & 77.) Salters herself visited the manufacturer's website, found CPT code 69401, and printed the article to show AFC management. (*Id.* at 73-74.) However, she testified that the day after she printed the article, she could no longer find it on the manufacturer's website. (*Id.*)

In 2008, Blue Cross and Blue Shield of Alabama ("BCBS") investigated AFC for billing the Ear Popper under code 69401—ear surgery eustachian tube inflation transnasal without catherization—and concluded that the device was experimental. As a result of this determination, BCBS decided that it would not pay for Ear Popper usage and required AFC to refund previous Ear Popper payments. AFC paid BCBS $28,534.36 in refunds for the Ear Popper bills. However, the Government never questioned, investigated, or requested a refund based on AFC's billing of the Ear Popper under CPT code 69401. Despite a handwritten note on the refund request letter from BCBS that read "check with [Medicare]," AFC never contacted the Government to inquire about the propriety of billing the

Ear Popper under this code, and never refunded any Federal payor for Ear Popper payments received. After refunding BCBS on April 7, 2008, AFC continued to use the Ear Popper, but stopped billing all insurers for Ear Popper usage.

c. Stark Law & Anti-Kickback Statute

Dr. Ronald McCoy ("Dr. McCoy") was an Otolaryngologist (ENT) who had offices in Bessemer and Birmingham. In January of 2000, Dr. McCoy entered into a written contract with AFC to see patients at AFC locations, as well as at his private practices. The contract provided for compensation based on a formula which paid him a percentage of the amount of revenue he generated. However, this formula did not include any collections from Medicare patients. Therefore, his pay did not reflect the volume of Medicare business that he generated. The rate of pay was commercially reasonable and consistent with what other physicians are paid in Alabama for services rendered to a group practice. Further, Dr. McCoy reassigned all the Medicare reimbursements from his work at AFC clinics to AFC.

Dr. McCoy was never an employee of AFC, always performing services as an independent contractor and did not have ownership shares in AFC or the AFC lab. While working at AFC, he often referred patients for testing

at the AFC lab. Generally, these patients were seen at AFC locations first, but AFC admits that on five occasions, Dr. McCoy sent Medicare patients to get blood allergy tests done at the AFC lab without first seeing the patients at an AFC clinic. However, AFC claims that these referrals were done without AFC's knowledge or approval. AFC billed Medicare for these five visits, but Medicare only paid for three of them. Two of these three patients were existing AFC patients at the time the tests were performed, though Dr. McCoy saw them in his private offices. AFC claims that the patient who was not an AFC patient when the blood test was performed did fill out new patient paperwork before the blood draw.

Dr. McCoy also referred a Railroad Medicare patient—Wilma H.—to AFC for blood allergy testing without seeing her at an AFC facility. Medicare reimbursed AFC for this visit. However, prior to the blood draw, Wilma H. saw another AFC physician for dermatitis.

III. Standard of Review

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A material fact is one that "might affect the outcome of the case." *Urquilla-Diaz v. Kaplan Univ.*, 780 F. 3d 1039, 1049 (11th Cir. 2015). A dispute is genuine if "the

record taken as a whole could lead a rational trier of fact to find for the nonmoving party." *Id.* The trial judge should not weigh the evidence, but determine whether there are any genuine issues of fact that should be resolved at trial. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986).

In considering a motion for summary judgment, trial courts must give deference to the non-moving party by "considering all of the evidence and the inferences it may yield in the light most favorable to the nonmoving party." *McGee v. Sentinel Offender Servs., LLC*, 719 F.3d 1236, 1242 (11th Cir. 2013) (citing *Ellis v. England*, 432 F.3d 1321, 1325 (11th Cir. 2005)). In making a motion for summary judgment, "the moving party has the burden of either negating an essential element of the nonmoving party's case or showing that there is no evidence to prove a fact necessary to the nonmoving party's case." *Id.* Although the trial courts must use caution when granting motions for summary judgment, "[s]ummary judgment procedure is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the Federal Rules as a whole." *Celotex Corp. v. Catrett*, 477 U.S. 317, 327 (1986).

IV. Discussion

A. FCA Generally

Salters claims that AFC violated the FCA in a number of different ways: 1) falsely certifying compliance with *locum tenens* regulations 2) failing to reimburse the Government for improper payments for the Ear Popper 3) submitting false claims for the Ear Popper 4) falsely certifying compliance with the Stark Law 5) falsely certifying compliance with the Anti Kickback Statute 6) submitting false claims containing an after-hours billing code 7) submitting false claims during the Global Surgery Period 8) by submitting false claims for level one office visits when patients came in solely for injections and 9) falsely submitting unbundled claims for venipunctures, injection administrations, vaccine administrations, and pulse oximetry.

The FCA allows individuals to file *qui tam* actions and recover damages on behalf of the United States. *U.S.* ex rel. *Clausen v. Lab. Corp. of Am.,* 290 F.3d 1301, 1307 (11th Cir. 2002). These actions may be filed against a person or entity that "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; . . . [or] knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A) & (B). Healthcare providers can be found liable under the FCA for "the submission of a fraudulent claim to the Government," i.e.

for submitting a claim that contains false information. *Urquilla-Diaz*, 780 F.3d at 1045.

B. Use of *Locum Tenens* Physicians

In her complaint, Salters alleges that AFC violated the FCA by allowing new physicians to work in its clinics as *locum tenens* physicians for months while their paperwork was being completed. (Doc. 1 at 23.) The complaint specifically alleges that Dr. Steven Hefter ("Dr. Hefter"), Dr. Eugene Evans ("Dr. Evans"), Dr. Buckmaster, and Dr. Syed Hasan ("Hasan") were regularly used as *locum tenens* physicians in violation of the FCA. (*Id.*) She also claims that "[AFC] is improperly billing for these long term *Locum Tenens* physicians under provider numbers for physicians who were not present in the facility." (*Id.* at 24.) In its motion for summary judgment, AFC argued that claims for Dr. Hasan, Dr. Buckmaster, and Dr. Evans were properly billed.

In her response to AFC's motion for summary judgment, Salters addressed her claims for improper billing based only on Dr. Buckmaster's *locum tenens* work. (Doc. 105 at 17-22.) Salters failed to mention Dr. Hasan, Dr. Hefter, or Dr. Evans in her response to summary judgment, and "grounds alleged in the complaint but not relied upon in summary judgment are deemed abandoned." *Resolution Trust Corp. v. Dunmar*

Corp., 43 F.3d 587, 599 (11th Cir. 1995). Therefore, Salters's claims against AFC for improper billing based on Dr. Hasan's, Dr. Hefter, and Dr. Evans's *locum tenens* work are deemed abandoned.

The only locum tenens claim that remains in this action is Salters's claim based on AFC's billing for Dr. Buckmaster's work. In her opposition to AFC's motion for summary judgment, Salters argues that AFC violated the FCA by falsely certifying compliance with the MCPM's requirements for *locum tenens* doctors. Liability under the FCA can arise from "a 'false certification theory,'" when a provider "falsely certif[ies] . . . that it will comply with [F]ederal law and regulations." *Urquilla-Diaz*, 780 F.3d at 1045. In order to prove FCA liability under a false certification theory, a relator must show "'(1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, causing (4) the [G]overnment to pay out money or forfeit moneys due.'" *Id.* at 1052 (quoting *U.S. ex rel. Hendow v. Univ. of Phx.*, 461 F.3d 1166, 1174 (9th Cir. 2006)). However, "'[m]ere regulatory violations do not give rise to a viable FCA action,'" because "'[i]t is the false certification of compliance which creates liability.'" *Id.* (quoting *Hendow*, 461 F.3d at 1171). The Eleventh Circuit explained that "[l]iability under the [FCA] arises from submission of a fraudulent claim to the [G]overnment, not the disregard

of [G]overnment regulations or failure to maintain proper internal policies." *Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1012 (11th Cir. 2005). A relator must therefore prove that the "false statement" was a pre-requisite and a material cause of the Government's decision to pay the provider's claim. *Id.*

The MCPM contains the following conditions for billing a *locum tenens* physician:

> 1) "[t]he regular physician is unavailable," 2) "[t]he Medicare beneficiary has arranged or seeks to receive the visit services from the regular physician," 3) "[t]he regular physician pays the *locum tenens* for his/her services on a per diem or similar fee-for-time basis," 4) the substitute physician does not provide the visit services to Medicare patients over a continuous period of longer than 60 days," and 5) "[t]he regular physician identifies the services as substitute physician services . . . by entering . . . code modifier Q6 . . . after the procedure code."

MCPM Ch. 1 § 30.2.11. In her response to summary judgment, Salters alleges that AFC violated these requirements by improperly paying Dr. Buckmaster based on productivity and failing to use the required Q6 code modifier when billing Medicare for his work. (Doc. 105 at 20-21.) She does not allege that Dr. Buckmaster worked more than the maximum sixty continuous days.

AFC argues that Salters cannot raise arguments that AFC improperly paid Dr. Buckmaster based on productivity in her response to summary judgment, because she did not raise these arguments in her complaint. The Eleventh Circuit held that "[a] plaintiff may not amend her complaint through argument in a brief opposing summary judgment." *Gilmour v. Gates, McDonald & Co.*, 382 F.3d 1312, 1315 (11th Cir. 2004). Here, Salters attempts to raise new facts and a new theory of liability in her response to summary judgment. However, though Salters was entitled to raise these facts after learning about them in discovery, "the proper procedure for plaintiffs to assert a new claim is to amend the complaint in accordance with Fed.R.Civ.P.15(a)." *Id.* In her complaint, Salters did not mention that AFC improperly paid Dr. Buckmaster based on productivity. She will not be allowed to raise a new theory of liability at this stage of proceedings. *See Merle Wood & Assocs., Inc. v. Trinity Yachts, LLC*, 714 F.3d 1234 (11th Cir. 2013); *GeorgiaCarry.Org, Inc. v. Georgia*, 687 F.3d 1244, 1258 n.27 (11th Cir. 2012).

However, Salters's claims based on the Q6 modifier is not a new claim, because in her complaint, Salters alleges that "[AFC] is improperly billing for these long term *Locum Tenens* physicians under provider numbers for [other] physicians." By allegedly failing to append the Q6 modifier,

Salters was billing for its *locum tenens* providers using the numbers of other physicians, with no designation to show that the claims related to a different doctor. As evidence of this failure to append the Q6 modifier, Salters provided her expert report, which includes a finding that "[o]f the . . . lines reflecting Dr. Buckmaster's direct involvement in providing care, . . . 76% were presented for payment without the Q6 modifier." (Doc. 116 at Ex. O pg. 20.) Though it asserts that it followed the proper billing procedures for *locum tenens* physicians, AFC did not provide evidence that it did append the Q6 modifier. Therefore, viewing the facts in the light most favorable to the non-movant, there is a material issue of fact as to whether AFC properly billed for its *locum tenens* physicians.

However, in order to make out a claim under a false certification theory, Salters must show that AFC's mispayment and misbilling was a material fact in the Government's decision to pay out AFC's claim for work done by Dr. Buckmaster. Proving materiality is a high burden for the relator, because "[a] misrepresentation cannot be deemed material merely because the Government designates compliance with a . . . requirement as a condition of payment." *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, __ U.S. __, 136 S.Ct. 1989, 2003 (2016). A "minor or

insubstantial" violation is also not material, and "it is [not] sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance." *Id.* A plaintiff can prove materiality by providing "evidence that the defendant knows that the Government consistently refuses to pay claims in . . . cases based on noncompliance with the . . . requirement." *Id.* Conversely, "if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated . . . that is strong evidence that the requirements are not material." *Id.* at 2003-04.

As evidence of materiality, Salters provides the opinion of her expert, who states that "[f]ailure to append the modifier Q6 may result in improper payments or allegations of false claims, particularly when a provider fails to comply with all of the provisions associated with proper *locum tenens* arrangements." (Doc. 116 at Ex. O pg. 10.) However, AFC provides a declaration from Susan Garrison, a certified medical coder, which states that "[t]he failure to use a Q6 modifier on a locum tenens claim does not affect the amount Medicare will pay on a claim," and that "[it] is a technical billing error, which is not material to Medicare's decision to pay the claim provided the other *locum tenens* payment rules

are being followed." (Garrison Dec. at ¶ 9.) Viewing the evidence in the light most favorable to the non-movant, Salters has provided sufficient proof of materiality.

Lastly, Salters must show that AFC made these alleged false statements with scienter. In order to show the requisite scienter, Salters must provide evidence that AFC acted with "actual knowledge of the information; . . . deliberate ignorance of the truth or falsity of the information; or . . . reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729 (b)(1)(A). Salters claims that because AFC often scheduled Dr. Buckmaster for "very close to the 60-day limit before taking him off of *locum tenens* duty," AFC must have known that it had to comply with the *locum tenens* rules. (Doc. 105 at 20.) She also provides deposition testimony from AFC president Randy Johansen ("Johansen") that AFC management reviewed the *locum tenens* requirements for each of its insurance providers. (Johansen Dep. at 255.) Therefore, viewing the evidence in light most favorable to the non-movant, there is a material issue of fact as to whether AFC knowingly falsely certified compliance with applicable rules. Summary judgment as to this claim is due to be denied.

C. Billing for Ear Popper

1. Reverse False Claim

In her complaint, Salters also alleges that AFC violated the FCA by not returning money it was paid for "[applying] the surgical code 69401 Eustachian tube inflation, transnasal, without catherization, to bill for using [the Ear Popper] in the office." (Doc. 1 at 22.) Salters contends that after BCBS required AFC to refund BCBS for all Ear Popper payments, AFC should have refunded the Government as well.

Providers can be found liable under the FCA based on a "reverse false claim" theory. This theory allows relators to file suit against a provider who "knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(7), *amended by* Pub. L. No. 111-21, § 4, 123 Stat. 1617, 1621-1625 (2009). The statute was amended on May 20, 2009 by the Fraud Enforcement and Recovery Act ("FERA"). *See* § 4, 123 Stat. at 1625. However, this amendment only applies to "conduct on or after the date of enactment." *See* P. L. No. 1111-2221, § 386, 123 Stat. 1617 (2009). Therefore, the pre-FERA 31 U.S.C. § 3729(a)(7) will apply to conduct before May 20, 2009, and post-FERA 31 U.S.C. § 3729(a)(1)(G) will apply to conduct on or after May 20, 2009.

Liability under the pre-FERA "reverse false claim" theory "results from avoiding the payment of money due to the [G]overnment, as opposed to submitting to the [G]overnment a false claim." *U.S.* ex rel. *Matheny Medco Health Solution, Inc.*, 671 F.3d 1217, 1222 (11th Cir. 2012). The elements of a pre-FERA reverse false claim are

> (1) a false record or statement; (2) the defendant's knowledge of the falsity; (3) that the defendant made, used, or causes to be made or used a false statement or record; (4) for the purpose to conceal, avoid, or decrease an obligation to pay money to the [G]overnment; and (5) the materiality of the misrepresentation.

Id.

Salters contends that AFC's duty to refund the Government arose from the post-FERA FCA. However, AFC correctly notes that this provision only applies to AFC's conduct on or after May 20, 2009. The parties agree that AFC did not bill for the Ear Popper under code 69401 after April 7, 2008.[1] Therefore, because the conduct in question occurred before May 20, 2009, the pre-FERA 31 U.S.C. § 3729(a)(7) applies to all alleged instances of improper billing for the Ear Popper. Salters argues that AFC had an obligation to report overpayments for the Ear Popper to the Government and pay the money back, and AFC counters that it had no such obligation.

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[1] The parties agree that AFC stopped this practice after paying BCBS a refund of $28,534.36 for doing so. According to the record, the date of that payment is April 7, 2008.

The current version of the FCA defines "obligation" as "an established duty . . . arising from an express or implied contract, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from a statute or regulation, or from the *retention of any overpayment*." 31 U.S.C. § 3729 (b)(2)(B)(3) (emphasis added). However, this version of the statute was created by FERA, and is only applicable to "conduct on or after the date of enactment," which was May 20, 2009. P. L. No. 111-21, § 4, 123 Stat. 1617 (2009). The pre-FERA version of the statute contains no definition of obligation. *See* 31 U.S.C. § 3729, *amended by* Pub. L. No. 111-21, § 4, 123 Stat. 1617 (2009).

In *United States v. Pemco Aeroplex, Inc.*, the Eleventh Circuit found an that the defendant's contract with the Government created an "existing [and] legal" pre-FERA obligation. 195 F.3d 1234, 1237 (11th Cir. 1999). While the Eleventh Circuit has not elaborated on the requirements for the finding of this obligation, other circuits have interpreted the "existing [and] legal" language to mean that "the making or using of [a] false record or statement is not sufficient in itself to create an obligation" because "the obligation must arise from some independent legal duty." *U.S. ex rel. Bahrani v. Conagra, Inc.,* 465 F.3d 1189, 1195 (10th Cir. 2006); *see also U.S. ex rel. Bain v. Ga. Gulf Corp.*, 386 F.3d 648, 657 (5th

Cir. 2004), *Am. Textile Mfr. Inst.; Inc. v. The Limited, Inc.*, 190 F.3d 729, 734-37 (6th Cir. 1999); *United States v. Q Int'l Courier, Inc.*, 131 F.3d 770, 772-74 (8th Cir. 1997). Further, the Fifth Circuit stated that

> the reverse false claims act does *not* extend to the potential or contingent obligations to pay the [G]overnment fines or penalties which have not been levied or assessed (and as to which no formal proceedings to do so have been instituted) and which do not arise out of an economic relationship between the [G]overnment and defendant (such as a lease or contract or the like) under which the [G]overnment provides some benefit to the defendant wholly or partially *in exchange* for an agreed or expected payment or transfer of property by (or on behalf of) the defendant to (or for the economic benefit of) the [G]overnment.

Bain, 386 F.3d at 657.

Salters argues that AFC had an "obligation" to refund the Government for overpayments, which arose out of the definition of obligation in the post-FERA 31 U.S.C. § 3729 (b)(2)(B)(3), and 42 C.F.R. § 401.305, which became effective on March 14, 2016. Neither one of these authorities is applicable to pre-2009 conduct. Further, Salters does not provide evidence of any other legal duty AFC may have had to report these overpayments. Salters testified that she researched and found that the manufacturer of the Ear Popper listed 69401 as the proper code for the Ear Popper. (Salters Dep. at 73-4.) She claims that AFC knew or should have known that the code was incorrect because: 1) BCBS determined

that the billing was improper in February 2008; 2) AFC stopped billing all insurers separately for the Ear Popper after the BCBS incident; 3) Irwin or Johansen handwrote a note on the BCBS Ear Popper letter that stated "check w[ith] other states & M[edic]are," 4) and AFC never checked the appropriateness of the billing with the Government. However, none of these arguments establish that the Ear Popper was improperly billed to Medicare. Instead, they establish that the use of the code was improper under BCBS guidelines. Further, Salters does not allege that BCBS and Medicare used the same standards or guidelines for coding and payments.

AFC alleges, and Salters does not dispute, that there was no Federal policy or regulation that prohibited billing for an Ear Popper under the 69401 code. She has provided no evidence that AFC knew of a legal duty to refund Ear Popper overpayments, or that one existed at all. At most, she has alleged that AFC's billing practices could have subjected them to liability, penalties, or fines from Medicare, but potential obligations to pay the Government do not create reverse false claims liability under the pre-FERA 31 U.S.C. § 3729(a)(7). Therefore, summary judgment in AFC's favor is due to be granted as to Salter's claim for reverse false claim liability for Ear Popper billing.

2. False Claim Liability

Salters also argues that the facts support an action for "a direct false claim for payment in violation of 31 U.S.C. § 3729(A), because claiming a surgical code for a hand-held, non-invasive air puffer was knowingly false at the time of submission." (Doc. 105 at 24.) The Court interprets this assertion as intending to claim that AFC violated 31 U.S.C. § 3729(a)(1)(A), which allows a cause of action against a provider who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." To bring a claim under this section, a plaintiff must show "(1) a false or fraudulent claim; (2) which was presented, or caused to be presented, by the defendant to the United States for payment or approval; (3) with the knowledge that the claim was false." *United States v. R&F Props. of Lake Cnty., Inc.*, 433 F.3d 1349, 1355 (11th Cir. 2005).

However, as explained above, Salters has provided no evidence that AFC knew that it was improperly billing for the Ear Popper. Therefore, she cannot make out a claim for "knowingly present[ing] . . . a false or fraudulent claim for payment or approval." Summary judgment in AFC's favor is due to be granted as to Salter's claim for false claim liability for the billing of the Ear Popper.

D. Stark Law

Salters alleges that AFC violated the Stark Law by paying Dr. McCoy for referrals. The parties do not dispute that Dr. McCoy referred patients to the AFC laboratory for blood allergy testing. However, Salters alleges that in exchange for these referrals, AFC agreed to bill for the testing under his provider number, and send him a check for a percentage of the value of these tests. Thus, Salters claims, Dr. McCoy was paid by AFC for services that he was not present for and did not perform—but simply referred patients to receive.

The Stark Law, codified at 42 U.S.C. § 1395nn, prohibits physicians from referring patients to entities with which they have financial relationships, and also forbids entities from presenting a claim for payment "for designated health services furnished pursuant to a [prohibited] referral." 42 U.S.C. § 1395nn(a)(1)(B). The statute lists exceptions that apply in specific circumstances. Further, the Stark Law is enforced through regulations promulgated by the Secretary of Health and Human Services, which describe exemptions to the statute. *See Fresenius Med. Care Holdings, Inc. v. Tucker*, 704 F.3d 935, 937 (11th Cir. 2013). While the Stark law does not provide "its own right of action," Salters alleges that AFC is liable for the alleged Stark Law violation under a FCA false-certification theory. *Ameritox, Ltd. v. Millennium Labs., Inc.*,

803 F.3d 518, 522 (11th Cir. 2015) (quoting *U.S. ex rel. Drakeford v. Tuomey Healthcare Sys., Inc.*, 675 F.3d 394, 395 (4th Cir. 2012)).

AFC argues that the Stark Law applies only to services billed to Medicare, and not to those billed to other Federal programs. However, the Eleventh Circuit has stated that the Stark Law applies to Medicaid and Medicare patients. *Fresenius,* 704 F.3d at 937. Further, "[f]alsely certifying compliance with the Stark or Anti-Kickback Acts in connection with a claim submitted to a *federally funded insurance program* is actionable under the FCA." *U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 243 (3d Cir. 2004) (emphasis added); *see also U.S. ex rel. Keeler v. Eisai, Inc.,* 568 F. App'x 783, 799 (11th Cir. 2014) (citing *Schmidt*, 386 F.3d at 243).

As with all other false-certification claims, the applicability of Stark Law requirements will depend on the entity's certifications, because "[m]erely alleging a violation of the Stark and Anti-kickback statutes does not sufficiently state a claim under the FCA. It is the submission and payment of a false . . . claim and false certification of compliance with the law that creates FCA liability." *U.S. ex rel. Mastej v. Health Mgmt. Assocs., Inc.*, 591 F. App'x 693, 706 (11th Cir. 2014); *see also Urquilla-Diaz*, 780 F.3d at 1045. Therefore, because AFC certified that it complied

with the Stark Law in its submissions to Federal programs, it may be held liable for a violation of the FCA based on those submissions.

AFC alleges that it did not violate the Stark Law because Dr. McCoy received no financial benefit from referring his patients to AFC's labs for testing. AFC points to Dr. McCoy's employment contract, which excluded "all Medicare or Medicaid charges for 'designated health services' within the meaning of [the Stark Law]" from his compensation. (Doc. 102-17.) Salters does not dispute that Dr. McCoy's compensation did not violate the Stark Law as to Medicare patients. However, Salters argues that the compensation did include impermissible payments for Medicaid, TriCare, and Railroad Medicare patients. In support of this contention, Salters provides deposition testimony from Hawley which contains the following exchange:

> Q: When you say [the compensation formula excluded] Medicare, did it also [exclude] Medicaid and TriCare?
> A: No, but I'm not—as I recall, he didn't see Medicaid in our facilities, but I, I don't know what he did on TriCare.
> Q: But the formula did not—
> A: It did not back it out.

(Hawley Dep. at 196.) She also provides billing analyses that shows that Medicare and Railroad Medicare were accounted separately by AFC. (Doc. 106 at Ex. 104 pgs. 11-101.)

Salters further cites to an affidavit from Mark Garst ("Garst"), who is the director of the AFC CPC, which states that one patient, "Wilma H.," was a Railroad Medicare patient who underwent a blood allergy test at AFC based on Dr. McCoy's referral. (Doc. 102-2 at ¶ 15.) Salters alleges that claims submitted to Railroad Medicare include a required certification of compliance with the Stark Law. While AFC claims that the Stark Law applies only to Medicare, it does not dispute that it certified compliance with the law when it submitted its claims under Railroad Medicare.

Instead, AFC claims that it did not submit false claims based on a Stark Law violation because a number of Stark Law exceptions apply. First, AFC alleges that the "fair market compensation" exception applies. 42 C.F.R. § 411.357(l). In order to meet this exception, AFC must show that "[t]he arrangement is in writing, signed by the parties, and covers only identifiable items or services, all of which are specified in writing." *Id.* AFC presents a copy of its contract for Dr. McCoy's services as evidence that the arrangement meets the fair market compensation exception. (Doc. 102-17.)

The contract is in writing and signed by Irwin and another individual, whose name is not indicated. (*Id.* at 9-10.) AFC alleges that the contract

was between AFC and Dr. McCoy's professional corporation. However, the contract contains a blank space where the name of the professional corporation ("P.C.") should be, thus stating that the contract is between "[AFC] and __________ P.C. for the services of Ronald C. McCoy." (*Id.* at 1.) Further, the signature page simply contains an unidentified signature, and leaves the space for the P.C.'s name empty. (*Id.* at 9.) AFC has provided no evidence that the signature on the contract belongs to an individual who has the authority to bind the P.C., and has therefore failed to show that "[t]he arrangement is in a writing[] signed by the parties," as required by 42 C.F.R. § 411.357(l). As AFC has not established that the "fair market compensation" exception applies, summary judgment cannot be granted based on that exception.

AFC also argues that its relationship with Dr. McCoy meets the "personal services arrangement" exception. This exception requires an "arrangement [] set out in writing, [] signed by the parties [that] specifies the services covered by the arrangement." 42 C.F.R. § 411.357(d). As described above, AFC has not shown that the contract is signed by the parties and therefore has not met its burden of showing that the "personal services arrangement" exception applies.

Lastly, AFC claims that it did not violate the Stark Law because Dr. McCoy's referrals qualify for the "[i]n-office ancillary services" exception. 42 C.F.R. § 411.355(b). In order to qualify for this exception, a number of requirements must be met. First, AFC must show that the services "are furnished personally by one of the following individuals: . . . [a]n individual who is supervised by the referring physician, or, if the referring physician is in a group practice, by another physician in the group practice, provided that the supervision complies with all other applicable Medicare payment and coverage rules for the services." *Id.*

AFC argues—and Salters does not dispute—that AFC is a group practice within the meaning of the Stark Law. Therefore, in order to meet the in-office ancillary services exception, AFC must show that a "physician in the group practice" supervised or furnished the testing. However, AFC argues that blood allergy tests are exempted from this requirement, because they are listed in the CPT under the 80000 series. *See* 42 C.F.R. § 410.32(b)(2)(vi) (exempting "[p]athology and laboratory procedures listed in the 80000 series of the [CPT] published by the American Medical Association ['AMA']" from supervision requirements). Further, AFC correctly argues that a doctor's office staff may furnish diagnostic laboratory tests to his patients. *See* 42 C.F.R. § 410.32(d).

AFC claims that it fits the supervision requirement for the "in-office ancillary services" exception because it complies with Medicare's supervision requirements. However, 42 C.F.R. § 411.355(b) does not state that complying with Medicare's supervision requirements is enough to fit the exception. Instead, it describes a specific situation in which an entity would be excepted from the Stark Law's requirements. AFC has not provided any evidence that the blood tests were performed under the supervision of any of AFC's physicians. Therefore, it does not fit the in-office ancillary services exception, and summary judgment cannot be granted on that basis.

For the reasons stated above, AFC's arguments as to its purported violation of the Stark Law in relation to referrals made by Dr. McCoy fail. Therefore, viewing the evidence in the light most favorable to the non-movant, issues of fact remain as to whether AFC violated the FCA by submitting claims in violation of the Stark Law. Summary judgment as to the claims based on violations of the Stark Law is due to be denied.

E. Anti-Kickback Statute

AFC moved for summary judgment on Salter's claims under the Anti-Kickback Statute. Salters does not mention the Anti-Kickback Statute in her memorandum in opposition to AFC's motion for partial summary

judgment.[2] Because "grounds alleged in the complaint but not relied upon in summary judgment are deemed abandoned," Salters's claims against AFC under the Anti-Kickback Statute are deemed abandoned. *Resolution Trust Corp.*, 43 F.3d at 599. Summary judgment in AFC's favor is due to be granted as to Salters's claims under the Anti-Kickback Statute.

F. After-Hours Billing Code

Salters concedes, in her memorandum in opposition to AFC's motion for partial summary judgment, that "there is insufficient evidence of false claims to overcome summary judgment on the after-hours billing claim." (Doc. 105 at 28.) Therefore, summary judgment in AFC's favor is due to be granted as to Salters's claims for improper after hours billing.

G. Global Surgery Period

Salters claims that AFC violated the FCA by improperly billing for visits which should have been included in the Global Surgery Period. Medicare compensates surgical procedures through a Global Surgery Package ("GS Package"). MCPM Ch. 12 at § 40.1. These packages include compensation for various "services related to the surgery when furnished by the

[2] In her recitation of facts, Salters does state that in billing Medicare, providers certify compliance with Stark and Anti-Kickback Statute. However, she does not respond to AFC's arguments that it is not liable under the Anti-Kickback Statute.

physician who performs the surgery" performed during the Global Surgery Period. *Id.* The Medicare Fee Schedule Data Base sets out the appropriate Global Surgery Period for surgical procedures—generally zero, ten, or ninety days after a surgery.[3] *Id.* Therefore, Medicare will not pay, and providers cannot bill, for services that are included in the GS Package. *Id.* at § 40.2. Services improperly billed during the Global Surgery Period are thus "false or fraudulent claim[s]" which can lead to liability under the FCA. *See U.S. ex rel. Sanchez v. Lymphatx, Inc.*, 596 F.3d 1300, 1302 & n. 2 (11th Cir. 2010) (plaintiff asserting false claims based on violation of MCPM); *see also U.S. ex rel. Prather v. Brookdale Senior Living Cmtys., Inc.*, 838 F.3d 750, 780 (6th Cir. 2016) (McKeague, J., concurring in part and dissenting in part) (basing analysis of FCA claim on MCPM guidelines).

Salters provides evidence that AFC submitted claims for services that Dr. Park performed during the Global Surgery Period. First, Salters presents records of visits from patient BJF, who was seen for an excision of a benign or malignant breast tumor with reconstruction on May 21, 2009, which has a ninety-day Global Surgery Period. Dr. Park also billed for an office visit for BJF for the same day as the surgery, and for another office visit on June 4, 2009. The June 4, 2009 visit was for an "open

[3] The MCPM instructs that the Global Surgery Period should also include the day of the surgery and—for major procedures—the day before the surgery.

wound of the breast without mention of complication." Medicare was further billed another office visit for BJF with the same diagnosis on June 18, 2009. Second, Salters provides records of billing for patient MH, who was operated on by Dr. Park on November 16, 2010, for "excision of malignant lesion including margins, trunk, arms or legs excised diameter over 4 cm," which has a Global Surgery Period of ten days. However, on November 22, 2010, AFC billed for an office visit for MH with a diagnosis of "unspecified malignant neoplasm of the skin upper limb, including shoulder," which Salters alleges is the same diagnosis as the date of surgery.

AFC does not dispute that it billed for these visits during the Global Surgery Period. Instead, it claims that Salters should not be allowed to assert these claims because she did not advance them in her complaint. AFC alleges that the only claims in Salters's complaint related to the Global Surgery Period asserted that AFC failed to use the "24" modifier properly. However, Salters's complaint specifically alleges that "Dr. Park routinely charged additional office visits for follow-ups and hospital visits, which were covered by the original surgical charge." (Doc. 1 at 18.) Therefore, Salters's claims for improper billing of visits during the Global Surgery Period are properly before this Court. Further, AFC

provides no evidence that its billing during the Global Surgery Period was proper. Thus, viewing the evidence in the light most favorable to the non-movant, Salters has established that AFC presented false or fraudulent claims under the FCA.

However, false claims only lead to liability under the FCA if they are knowingly presented. 31 U.S.C. § 3729(a)(1)(A). Salters appears to allege that Dr. Park personally submitted these claims with knowledge of their falsity. She also claims that AFC knowingly presented these claims. "Knowingly" is defined in the FCA as meaning that "a person, with respect to the information—(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth of the information." 31 U.S.C. § 3729 (b)(1). There is no requirement of a showing of "specific intent to defraud." *Id.*

In support of her claim, Salters provides evidence that Dr. Park completed his own superbill, and that he was responsible for the accuracy of the claims that he presented for payment. Further, Dr. Park's deposition testimony establishes that he knew that Global Surgery Periods existed but never researched the length of those periods. Thus, Salters concludes, Dr. Park filled out his own superbill while being willfully

ignorant of the proper Global Surgery Periods and their effects on billing. AFC, however, provides Dr. Park's deposition testimony that he was not involved in billing, and did not know about it, and was simply involved in patient care. He stated that he "put down what [his] activity has been with the patient, and it's up to the other departments to determine the billing." (Park Dep. at 42.)

Salters also provides evidence that Dr. Park's wife, Kay Park ("Kay"), who worked at AFC, knew that Salters believed the billing was improper, but instructed other AFC employees to continue this improper practice. This evidence includes emails between Salters and Kay, in which Salters describes her concerns with Global Surgery Periods, and points Kay to a listing of the periods and corresponding surgeries.[4] Salters also advances an email from Diana Hensley ("Hensley"), an AFC employee, which states that "I read an email from Kay stating that per Dr. Irwin, '[w]e are also supposed to charge an office visit on the follow-up visits even if it is within the [Global Surgery Period].'" (Pl. Ex. 6 at AFC 400512.) Further, Johansen's deposition testimony confirms that Irwin's policy was that doctors should bill for their office visits during the Global Surgery Period. However, Johansen testified that Irwin's policy was that doctors should

[4] Salters emailed directions for finding the Global Surgery Periods on March 9, 2009.

bill for all their visits and procedures, and the auditing department should remove the charges for services that were conducted during the Global Surgery Period.

According to Salters's testimony, Kay was also responsible for auditing Dr. Park's claims. AFC disputes this contention, claiming instead that the billing was "handled by [Hensley], and audited by the AFC auditors." (Doc. 111 at 14.) As evidence that Kay did not audit Dr. Park's claims, AFC points to an email chain, which includes an email from Liann Westwood ("Westwood") to Hensley, in which Westwood spoke about her own impending maternity leave, stated that Salters would check Hensley's work while she was on leave, and instructed Hensley to "try to encourage [Dr. Park] to get you [his] hospital charges in a timely manner." (Doc. 111-1 at AFC 502364.) It also includes an email in which Salters directed Westwood on how to fix some mistakes that she was allegedly making. AFC claims that these emails prove that Hensley was in charge of billing for Dr. Park, that Westwood audited the charges, and that Westwood reported to Salters.

Viewing the facts in the light most favorable to the non-movant, Salters has provided evidence that Kay billed for Dr. Park, that she was aware of the Global Surgery Periods, and that false claims were billed for

Dr. Park after Kay became aware of the Global Surgery Periods. While AFC disputes this evidence, the sufficiency of the evidence is a question for the jury, and therefore, summary judgment as to billing during the Global Surgery Periods is due to be denied.

AFC also alleges that it did not misuse the 24 modifier when billing during the Global Surgery Periods. However, in her response to AFC's motion, Salters fails to mention any misuse of the 24 modifier for billing during the Global Surgery Period. Therefore, because "grounds alleged in the complaint but not relied upon in summary judgment are deemed abandoned," Salters's claims against AFC based on the misuse of the 24 modifier during the Global Surgery Period are deemed abandoned. *Resolution Trust Corp.*, 43 F.3d at 599. Summary judgment as to claims based on the misuse of the 24 modifier is due to be granted.

H. Level One Office Visit Billing for Injection Only Patient Encounters

In her complaint, Salters alleges that AFC violated the FCA by "charging a Level 1 office visit, Code 99211, when a patient came in for just a shot or vaccination and saw only a nurse or nurse assistant." (Doc. 1 at 16.) Salters claims that injection only visits should be billed under an injection code, and that AFC overcharged Medicare, Medicaid, Tricare and Champus by misbilling these visits. However, AFC provides evidence

that an injection-only code and a level one office visit code are compensated at "virtually identical" rates. (Doc. 102-2 at ¶ 17.) Therefore, AFC claims, any misbilling that allegedly occurred did not result in overpayments. AFC also alleges that it did not knowingly submit bills containing the wrong code, and cites to apparently conflicting sections in the MCPM to support this assertion.

Salters does not respond to AFC's argument about compensation levels, and also does not provide any evidence that AFC submitted these claims with knowledge of their falsity. Instead, Salters attempts to base this claim on a reverse false claim theory, asserting that AFC had a duty to return overpayments it received as a result of its misbilling. In her Supplemental Evidentiary Submission (Doc. 116), Salters provides an expert report that concludes that AFC received overpayments of $261.29 in relationship to its immunization claims. (Doc. 116 at Ex. 5.) However, none of those overpayments resulted from a billing of Code 99211 and therefore are irrelevant to this claim. Further, because AFC provides evidence that it received no overpayments from its misbilling because the compensation rates were "virtually identical" and Salters does not provide any evidence to the contrary, she cannot make out a claim based

on a reverse false claim theory.[5] Without an overpayment, there cannot be a duty to return an overpayment. *See Matheny Medco,* 671 F.3d at 1222 (setting out the elements for reverse false claim liability). Viewing the evidence in the light most favorable to the non-movant, Salters cannot make out a claim for violation of the FCA based on level one office billing for injection-only office visits. Summary judgment in AFC's favor is due to be granted as to this claim.

I. Unbundling

Salters claims that AFC knowingly submitted unbundled claims—i.e. billed for them separately when they should have been billed together. As evidence of AFC's scienter, she submits her own testimony that she discussed her concerns about unbundling with Irwin, who replied that "this was something he had always done . . . and there was nothing wrong with it and it would continue to be unbundled." (Salters Dep. at 219-20.) She also stated that "Irwin's position . . . was that AFC was going to unbundle and write off what the insurance companies . . . caught," and that AFC had an "unbundling report," which listed "the

[5] Salters does point to deposition testimony from Johansen that states that AFC simultaneously billed for both the office visit and the injection administration code. However, Johansen's testimony was about unbundling of injection codes when a patient was also seen by a doctor, not about injection-only visits. Therefore, his testimony is irrelevant to this claim.

amounts that [were] written off because of bundling or unbundling." (*Id.* at 221-22.)

AFC responds, asserting that Medicare did not provide clear direction about bundled/unbundled services, and therefore, AFC could not have knowingly submitted false claims in this area. Each separate instance of unbundling will be addressed individually below.

1. Venipunctures

A venipuncture involves collecting a blood sample by "inserting into a vein a needle with syringe or vacutainer to draw the specimen." MCPM Ch. 16 § 60.1. In her complaint, Salters alleges that AFC "had a practice of unbundling the lab draw fee and the injection administration codes 36415 and 90772 (2008 and before) and 96372 (2009)" which should have been billed as part of an office visit. (Doc. 1 at 17.) In response, AFC asserts that venipunctures are not bundled services. As evidence for this assertion, AFC claims that MCPM does not mention venipunctures in its section on bundled services. *See* MCPM Ch. 12 § 20.3 (section on bundled services referring to routinely bundled procedures, injection services, GS Packages, intra-operative and/or duplicative procedures, and EKG interpretations).

AFC also argues that the MCPM specifically allows physicians to charge for specimen drawing in some circumstances. MCPM Ch. 16 § 60.1.1. Further, AFC points to testimony from Salters's expert, which states that "as it pertains to unbundling of [venipunctures] . . . we did not find that [Salters's] allegation in that case was legitimate." (Melnykovych Dep. at 79.) Lastly, AFC asserts that through 2013, code 36415 for venipunctures was not listed as a bundled code in the Medicare Newsline published by Cahaba Government Benefit Administrators ("CGBA"). *2013 Bundled Services*, Medicare B Newsline (Cahaba Gov't Benefit Adm'rs, LLC, Birmingham, Ala.), March 2013 at 11-12.

However, Salters provides her deposition testimony—as a medical coder—that if a venipuncture was done during an office visit, and the test was done at an AFC lab, AFC should have only billed for an office visit and not for the blood draw. She also claims that the MCPM, though it does not list venipunctures in the bundled services section, does state that "[s]eparate payment is never made for routinely bundled services and supplies." MCPM Ch. 12 § 20.3.

Further, Salters indicates that though the MCPM allows a specimen collection fee, this only applies when "(1) it is the accepted and prevailing practice among physicians in the locality to make separate

charges for drawing or collecting a specimen, and (2) it is the customary practice of the physician performing such services to bill separate charges for drawing or collecting the specimen." MCPM Ch. 16 § 60.1.1. Salters claims that this language does not apply to blood draws because it is "[c]ommon practice . . . for nurses, not physicians, to perform blood draws." (Doc. 105 at 36.) AFC responds that physicians bill Medicare for medical services performed by their staff, as they are not generally involved in services such as blood draws, vaccine administrations, and injections.

Therefore, while AFC provides evidence that venipunctures were not listed as bundled codes in the Manual or in CGBA's newsletter—which was published after these claims were submitted—Salters cites to language in the Manual which provides that "routinely bundled" claims are not paid for separately. Viewing the evidence in the light most favorable to Salters, there remains a question of fact about whether venipunctures are "routinely bundled" claims. Therefore, the question of whether AFC submitted false claims for unbundled venipunctures will be determined by the jury.

AFC also claims that even if it submitted false claims for unbundled venipunctures, it did not do so knowingly. In support of this assertion, it

provides deposition testimony from Johansen which states that he believed that "submitting a separate charge for a blood draw along with the office visit by the physician is appropriate in all circumstances to Medicare." (Doc. 94-3 at 87-88.) However, Salters's testimony that Irwin intended to submit unbundled claims, apparently without checking their legitimacy, and then simply "write off" the ones that insurance companies did not accept, raises the possibility that AFC billed with "deliberate ignorance of the truth or falsity of the information" or with "reckless disregard of the truth of the information." 31 U.S.C. § 3729(b)(1). Thus, viewing the evidence in the light most favorable to the non-movant, there is a material dispute of fact as to scienter, and summary judgment as to this claim is due to be denied. *See Urquilla-Diaz*, 780 F. 3d at 1061 (holding that existence of scienter is a jury question).

2. Injection Administration

Salters claims that AFC improperly billed Federal payors for an injection administration fee—codes 96372 and 90772—which should have been bundled with the office visit. AFC moved for summary judgment, claiming that it properly billed for injection administrations in conjunction with office visits, and citing the MCPM to support this

contention. In support of her assertion, Salters provides her testimony that Medicare didn't pay for an injection administration and for an office visit separately unless modifier 25 was added. (Salters Dep. at 61-62.) This modifier, according to Salters, is only properly added if an injection was administered for a separate diagnosis than the diagnosis attached to the original office visit. (*Id*. at 178-79.) According to Salters, AFC misused this modifier, and therefore, unbundled injection administrations, billing separate diagnosis codes for what she believes were the same problems. (*Id*. at 178-80.) However, she admits that this contention is based on her opinion and her "reading the [medical] record." (*Id*.)

Salters also asserts that AFC had a policy and trained its employees to routinely bill for office visits that included injection administrations by adding the separate diagnosis modifier. (*Id*. at 177-80.) As evidence of this policy, she provides an email she sent to Valencia McAdory ("McAdory"), a fellow AFC employee, which directs her to "not approve any claims that have the 96372 Admin. Fee without adding the '25' Modifier on the Office Visit." (Pl. Ex. 46.)

The MCPM states that

> CPT code 99211 [office visit] cannot be paid if it is billed with a drug administration service . . . Therefore, when a medically necessary, significant, and separately identifiable

> E/M service (which meets a higher complexity level than CPT code 99211) is performed, in addition to one of these drug administration services, the appropriate E/M CPT codes should be reported with modifier -25 . . . For an E/M service provided on the same day, a different diagnosis is not required.

MCPM Ch. 12 § 30.6.7. This section makes it clear that Medicare will not pay for an office visit coded at 99211 in conjunction with a drug administration service.[6] Instead, it will only pay for an office visit "which meets a higher complexity level than CPT code 99211," billed with modifier 25. However, despite Salters's allegations to the contrary, the MCPM also makes it clear that "[f]or an [office visit] provided on the same day, a different diagnosis is not required."

Salters's claims that AFC required its coders to routinely add a 25 modifier when billing injection codes with an office visit do not amount to a claim of wrongdoing, because the MCPM requires that all claims for office visits which are billed in conjunction with an injection be coded with a 25 modifier. AFC can only be held liable for billing false claims if it fraudulently coded office visits as "meet[ing] a higher complexity level than CPT code 99211," when there was not a "medically necessary, significant, and separately identifiable E/M service."

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[6] The abbreviation "E/M" refers to Evaluation and Management Services, and generally relates to an office visit by a patient. See Dep't of Health & Human Servs., Ctrs. For Medicare & Medicaid Servs., ICN 006764, *Evaluation and Management Services* (2016).

The only evidence Salters provides to show that AFC was improperly billing these office visits is a chart produced by AFC, which purports to show "injection administration . . . when billed with an office visit for Medicare, Medicaid, and Tricare Claims." (Pl. Ex. 27.) This chart only lists one instance of code 99211 billed in conjunction with an injection administration code. In accordance with the MCPM, the chart shows a payment amount of $0 for this visit, presumably because it was misbilled. Further, Salters's expert's report did not find any misbilling for injection administration codes that contained the 25 modifier. (Doc. 116 at Ex. 5 & 6 to Ex. O.) Therefore, viewing the evidence in the light most favorable to the non-movant, Salters did not provide any evidence that AFC presented fraudulent claims which unbundled injection administrations. Summary judgment as to this claim is due to be granted in AFC's favor.

3. Vaccine Administration

Salters alleges that "AFC also unbundled vaccination injections from office visits that should have been billed simply as part of the office visit. The codes for vaccinations are 90471 and 90472." (Doc. 1 at 17.) AFC, however, cites to the MCPM, which states that

> If a physician sees a beneficiary for the sole purpose of administering the influenza virus vaccine, the pneumococcal vaccine, and/or the hepatitis B vaccine, they may not

> routinely bill for an office visit. However, if the beneficiary actually receives other services constituting an "office visit" level of service, the physician may bill for a visit in addition to the vaccines and their administration, and Medicare will pay for the visit in addition to the vaccines and their administration if it is reasonable and medically necessary.

MCPM Ch. 18 §10.2.

Salters provides no evidence that AFC violated this rule. Instead, she presents her expert report, which does not contain proof of any unbundling for codes 90471 and 90472. (Doc. 116 at Ex. 7 & 8 to Ex. O.) Further, the expert testified that she did not find any unbundling related to these codes. (Melnykovych Dep. at 78-84 & 95.) Viewing the evidence in the light most favorable to the non-movant, there is no evidence that AFC presented falsely unbundled claims related to vaccination administrations. Summary judgment as to this claim is due to be granted in AFC's favor.

4. Pulse Oximetry

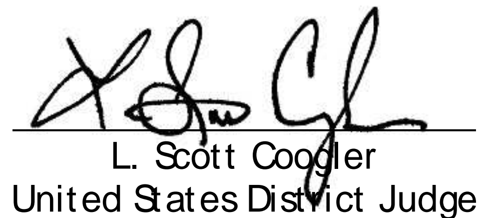
Salters concedes that summary judgment in AFC's favor is due to be granted as to this claim.

J. Conclusion

For the reasons stated above, AFC's motion for partial summary judgment is due to be GRANTED in part and DENIED in part. Summary judgment in AFC's favor is due to be granted as to Salters's claims based

on billing for the Ear Popper, violation of the Anti-Kickback Statute, billing for afterhours claims, billing for injection-only claims, and unbundling of injection administration, vaccine administrations, and pulse oximetry. Summary judgment as to Salters's claims for billing for *locum tenens* physicians, violations of the Stark Law, billing of office visits during the Global Surgery Period, and venipuncture unbundling is due to be denied. A separate order consistent with this opinion will be entered

DONE and **ORDERED** this 18th day of April 2017.



L. Scott Coogler
United States District Judge
186291