UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

UNITED STATES OF AMERICA, *ex rel., et al.*, Plaintiffs/Relators, v. CENTER FOR DIAGNOSTIC IMAGING, INC., *et al.*, Defendants.	Case No. C05-0058RSL ORDER GRANTING IN PART AND DENYING IN PART CDI DEFENDANTS' MOTION TO DISMISS; GRANTING LEAVE TO AMEND

I. INTRODUCTION

This matter comes before the Court on a motion filed by two of the three defendants in this *qui tam* action, Center for Diagnostic Imaging, Inc. ("CDI") and Medical Scanning Consultants P.A. (collectively, "defendants"), to dismiss Counts I, II, and III of the plaintiffs/relators' third amended complaint (the "TAC"). A motion to dismiss filed by the third defendant, Onex Corporation, is addressed in a separate order. The Court previously granted CDI's motion to compel arbitration of Count IV, Relator West's employment-related claim.

Defendants contend that the plaintiffs/relators have not alleged their fraud

allegations with sufficient particularity or met their pleading requirements pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6). At defendants' request, the Court heard oral argument in this matter on March 29, 2011. For the reasons set forth below, defendants' motion is granted in part and denied in part, and the Court grants plaintiffs leave to amend.

II. ANALYSIS

A. Background Facts.

The following facts are taken from the TAC. Relator Patricia West was formerly employed by CDI as Vice President of Operations and Business Development for the state of Washington. Until her termination in May 2005, she was responsible for the management of operations, marketing, and business development for CDI's Washington diagnostic centers. Relator Alexander Serra is a radiologist and founding partner of Sound Medical Imaging, which provides radiology services to CDI's out-patient imagining centers in the Puget Sound area.

CDI is a national radiology and imaging company headquartered in Minnesota that operates 54 diagnostic imaging centers in ten states across the country, including Seattle, Washington. Among other things, its imaging services include magnetic resonance imaging ("MRI"), computed tomography ("CT"), x-ray, and ultrasound procedures. Defendant Medical Scanning Consultants Physicians Association ("MSCPA") is an association of radiologists who perform professional services for CDI patients, including interpreting MRI and CT scans. In nearly all of CDI's diagnostic centers, the reading radiologists belong to MSCPA, with the exception of the radiologists in Washington, Wisconsin, and Duluth, Minnesota. TAC at ¶ 45.

According to plaintiffs, CDI "has developed a basic business model for

expansion." TAC at ¶ 115. The company identifies a radiologist[1] "in a geographic market that it is interested in for the purpose of opening a new diagnostic center." Id. at ¶ 115. The targeted radiologist then joins MSCPA or the physicians form their own independent professional associations. As described more fully below, CDI allegedly enters into an arrangement with the physicians group whereby CDI funnels significant sums of money to the group in exchange for the referral of patients.

In January 2005, plaintiffs filed suit under seal in this Court. The case remained under seal for several years while the government investigated plaintiffs' claims. In the interim, plaintiffs have amended their complaint three times, although this motion is the first time the Court has addressed the sufficiency of the complaint. The third amended complaint, which is the operative pleading, contains four claims: (1) Count I alleges that CDI violated the Anti-Kickback Statute (the "AKS"), 42 U.S.C. § 1320a-7b(b) by entering into certain lease and joint venture arrangements with physician groups and funneling money to them in exchange for referrals of government insured patients and by providing free and discounted services to physicians to induce referrals; (2) Count II alleges that CDI violated the Stark Act, 42 U.S.C. § 1395nn by inducing referrals from physicians through improper financing relationships; (3) Count III alleges that CDI violated the False Claims Act, ("FCA"), 31 U.S.C. § 3729-3733 by failing to obtain written orders prior to providing services, offering free and discounted services, and charging more for epidurographies than the billing rules permit; (4) Count IV alleges West's employment-related claim. Plaintiffs bring the first three claims in a *qui tam* capacity. The government and CDI have entered into a settlement agreement to settle the

[1] Radiologists are medical doctors who are specially trained to interpret imaging exams to aid a treating physician in patient assessment and diagnosis.

claim that CDI up-charged for epidurographies. The government declined to intervene regarding the other claims.

B. Legal Standards.

Defendants have filed a 12(b)(6) motion for failure to state a claim upon which relief can be granted. The complaint should be liberally construed in favor of the plaintiff and its factual allegations taken as true. See, e.g., Oscar v. Univ. Students Co-Operative Ass'n, 965 F.2d 783, 785 (9th Cir. 1992). The Supreme Court has explained that "when allegations in a complaint, however true, could not raise a claim of entitlement to relief, this basic deficiency should be exposed at the point of minimum expenditure of time and money by the parties and the court." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 558 (2007) (internal citation and quotation omitted). Plaintiffs must show a "plausible entitlement to relief," which requires more than labels and conclusions. Id. at 555 (explaining that a "formulaic recitation of the elements of a cause of action will not do."); Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949 (2009) ("To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim for relief that is plausible on its face.").

Conclusory allegations of fraud are insufficient. Bly-Magee v. California, 236 F.3d 1014, 1019 (9th Cir. 2001). Instead, to comply with Rule 9(b), allegations of fraud must state the who, what, when, where and how of misconduct. Vess v. Ciba-Geigly Corp., 317 F.3d 1097, 1106 (9th Cir. 2003). That standard also applies in FCA cases. See, e.g., Bly-Magee, 236 F.3d at 1019 (citing Wang v. FMC Corp., 975 F.2d 1412, 1419 (9th Cir. 1992) (explaining that insiders should have knowledge of the alleged wrongdoing and be able to comply with Rule 9(b)); Frazier v. Iasis Healthcare Corp., 2010 U.S. App. LEXIS 16894 at *2-3 (9th Cir. Aug. 12, 2010). The allegations "must be

specific enough to give defendants notice of the particular misconduct which is alleged to constitute the fraud charged so that they can defend against the charge and not just deny that they have done anything wrong." Bly-Magee, 236 F.3d at 1019. A FCA plaintiff "is not required to plead representative examples of false claims submitted to the Government to support every allegation, but he must plead with sufficient particularity to lead to a strong inference that false claims were actually submitted." Frazier, 2010 U.S. App. LEXIS 16894 at *2-3 (citing Ebeid v. Lungwitz, 616 F.3d 993, 998 (9th Cir. 2010)).

C. False Claims Act and Anti-Kickback Statute Claims.

The federal False Claims Act, 31 U.S.C. § 3729, provides, in relevant part:

> (a) Liability for certain acts.
> (1) In general. Subject to paragraph (2), any person who--
> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
> (C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);
> . . . .
> (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government, is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains because of the act of that person.

Plaintiffs contend that defendants violated the FCA by up-coding, by submitting claims for procedures that were not medically necessary because they were not supported by a written order from a physician, and by offering free and discounted services as inducements for referrals.

The AKS makes it a crime to knowingly and willfully offer, pay, solicit or receive any remuneration to induce a person: (1) to refer an individual to a person for the

furnishing of any item or service covered under a federal health care program; or (2) to purchase, lease, order, arrange for or recommend any good, facility, service, or item covered under a federal health care program. 42 U.S.C. § 1320a-7b(b)(1) & (2). When analyzing alleged violations of the Anti-Kickback statute, a key distinction is that the law "does not criminalize referrals for services paid for by Medicare or Medicaid – it criminalizes knowing and willful acceptance of remuneration in return for such referrals." Klaczak v. Consol. Med. Transp., 458 F. Supp.2d 622, 678 (N.D. Ill. 2006). The AKS covers arrangements if even one purpose of remuneration was to obtain referrals or induce further referrals of Medicare patients. United States v. Kats, 871 F.2d 105, 108 (9th Cir. 1989). Plaintiffs contend that defendants violated the AKS by funneling millions of dollars to physicians in exchange for referring government insured patients to CDI and by providing free and/or low cost services as inducements for referrals.

1. Arrangements with Physicians Groups.

a. The Nature of the Arrangements.

Plaintiffs contend that CDI violated the False Claims Act and federal and state[2] anti-kickback statutes by entering into certain arrangements with referring physicians groups to direct millions of dollars to those groups to induce them to refer patients to CDI. TAC at ¶ 358. The TAC alleges that beginning in 2001, CDI entered into lease and joint venture arrangements with physicians and physician practices to "funnel illegal kickbacks to physicians groups across the country to induce Medicare and Medicaid referrals." Id. at ¶¶ 185, 187. Plaintiffs contend that CDI has used three types of lease

[2] Plaintiffs contend that defendants violated the anti-kickback statutes of Washington, Indiana, Wisconsin, Florida, Illinois, Kansas, and Ohio. The parties' memoranda do not separately address the state law anti-kickback laws. As the parties did, the Court will analyze those claims consistently with the federal claim.

and joint venture arrangements: (1) facility leasing (or "Per Click") arrangements, (2) "in-office" scanner arrangements, and (3) equipment joint venture arrangements. Id. at ¶ 188. Relator West claims that a CDI Vice President expressly instructed CDI executives on how to aggressively market the lease and joint venture arrangements to physician groups. Under all three arrangements, physicians groups were incentivized to refer patients to CDI; the more referrals they made, the greater the financial rewards. Id. at ¶¶ 235-36.

Under the facility leasing arrangement, CDI establishes an imaging center geographically near a physicians group and provides all of the capital, office space, equipment and personnel, and provides all diagnostic imaging services, including using a radiologist to interpret the results. The physicians group refers patients to the CDI imaging center and bills insurers for the technical component of the services even though it did not perform the diagnostic services or incur the costs of operating the center. TAC at ¶ 201. In turn, the physicians group pays CDI a "leasing" fee on a per service or per-click fee basis. "For each technical component fee that the physicians group collects, it pays a portion of that fee back to CDI." Id. at ¶ 202. The physicians group retains the difference between the reimbursement it received and the "per click" fee it pays CDI. Id. at ¶ 203, Ex. A. Although the per click fee is not paid for government insured patients, CDI required that physicians groups refer their Medicare and Medicaid patients to CDI in order to be eligible for the facility leasing arrangement. Id. at ¶ 205. CDI entered into these arrangements with small and medium sized physicians groups in Kansas, Minnesota, Wisconsin, Illinois, Indiana, Missouri, and Florida. Id. at ¶ 196.

Plaintiffs also contend that CDI used a variant of the facility leasing arrangement, what they refer to as the "In-Office Scanner" arrangements, to induce additional referrals from large physicians groups in Minnesota, Wisconsin, Illinois, Kansas, Indiana,

Missouri, and Florida. TAC at ¶ 211. Under the arrangement, CDI forms an LLC partnership with a large physicians group, provides a scanner in their officers, provides office equipment and supplies, personnel, and site build-out, and offers to "loan" the physicians group all, or substantially all, of the physicians group's portion of the capital investment. CDI then recoups the loan by deducting periodic payments on the amounts from the ownership dividends paid to the physicians group as a co-owner of the LLC. Id. at ¶¶ 214-216. The physicians group refers its Medicare and privately insured patients to the center, CDI performs the imaging services, and submits claims for reimbursement. When the reimbursement is received, CDI retains a portion for its imaging services and sends the remainder to the LLC, which in turn pays its profits as dividends to the physicians group and CDI. Id. at ¶ 220. Under that arrangement, the physician group "earns substantial money for doing nothing more than referring its Medicare and non-Medicare patients" to the CDI center. Id. at ¶ 221, Ex. B.

Plaintiffs also contend that CDI entered into illegal Equipment Joint Venture Arrangements ("EJVA") with physicians groups in Minnesota, Wisconsin, Illinois, Kansas, Indiana, Missouri, and Florida. TAC at ¶ 225. Under that model, CDI and the physicians group establish and co-own a joint venture that would purchase and maintain diagnostic equipment with what CDI described in a presentation as a "minimal capital outlay" from the physicians group. Id. at ¶ 227. As with the in-office scanner arrangement, CDI offers to "loan" the physicians group all, or substantially all, of the physicians group's portion of the capital investment, then recoups the loan by deducting periodic payments on the amounts from the ownership dividends paid to the physicians group. CDI executes a rental agreement with the joint venture for use of the diagnostic equipment, paying per scan (or "per click") for use of the equipment. Under the

arrangement, "the 'per-click' fee flows in the opposite direction of the per-click fee in the facility lease arrangement, *i.e.*, CDI pays the per-click fee to the EJVA, which is a thinly-veiled per-click referral fee." Id. at ¶ 228. The physicians group refers its Medicare and non-Medicare patients to CDI, which performs diagnostic imaging and makes claims for reimbursement to the government or to the applicable private insurance. CDI pays the joint venture the per-click fee for each privately insured scan it performs, then the fee is divided among the owners of the joint venture: CDI and the physicians group. As a result of the arrangement, the physicians group that referred the patients earns a fee for the referral. Although plaintiffs acknowledge that the per-click fee is not paid for the referral of government-insured patients, they contend that the referral fee for privately insured patients is deliberately lucrative enough to compensate physicians groups for all referrals. Absent the referrals of both types of patients, the EJVA model would not work. Id. at ¶ 231. Plaintiffs contend that CDI provided Relator West received a detailed spreadsheet that included CDI's estimate that its proposed EJVA "CDI Seattle Everett" would result in net income of nearly $100,000 to the physician group in the EJVA's first year. Id. at ¶ 232.

b. Allegations Against CDI.

Plaintiffs concede that the agreements, on their face, exclude government insured patients. TAC at ¶¶ 185, 204, 231. Despite those statements, plaintiffs contend that CDI violated the law by requiring physicians to refer Medicare patients. Id. at ¶¶ 205, 231. Plaintiffs describe the arrangements in detail.[3] In addition, plaintiffs allege that CDI's

[3] Plaintiffs also allege that CDI's 2003 marketing presentation to Orthopedics International demonstrated that Medicare referrals were sent to CDI under the arrangements. TAC ¶ 206. Defendants have filed a copy of that presentation and it does not support plaintiffs' position.

former Chief Development Officer informed Relator West in the Spring of 2004 that physicians were required to agree to refer all of their Medicare patients to CDI as a condition of the facility leasing arrangement. Id. at ¶¶ 207-08. Plaintiffs also allege that CDI provided Relator West "with Excel spreadsheets containing financial calculators utilized by CDI to demonstrate to physicians groups the amount of kickbacks they would receive if they participated in one of CDI's three lease and joint venture arrangements." Id. at ¶ 192. Plaintiffs contend that CDI used those calculators to induce physicians to enter into the arrangements. Although those allegations are terse, they are sufficient to state a claim that CDI designed and used the arrangements to induce referrals from physicians groups in violation of the AKS.

CDI argues that plaintiffs have failed to offer sufficient details about the arrangements, including specifically identifying the participating physician groups, their location, the dates or amounts billed, the identity of the patients involved, the dates the contracts were entered into, or the dates of the allegedly improper actions. Although plaintiffs do not identify the participating physicians groups by name, the TAC essentially alleges that all of the groups that participated in the lease arrangements were offered and/or received kickbacks. That argument, though broad and subject to Rule 11, sufficiently identifies the participants to allow CDI to respond. CDI argues that plaintiffs have failed to plead the specifics of the agreements, but the "courts have not held that proof of an agreement to refer program-related business is a prerequisite to establishing a violation" of the AKS. Hanlester Network v. Shalala, 51 F.3d 1390, 1396 (9th Cir. 1995). In *Hanlester Network*, the court found that the AKS was violated when a Hanlester representative made representations to limited partners to induce referrals, including telling them that they would be pressured to leave the partnership if they did not refer

business. Id. at 1399. Plaintiffs' allegations in this case are similar.

Because of the nature of plaintiffs' claims, this case is similar to *Singh v. Bradford Reg'l Med. Ctr.*, 2006 U.S. Dist. LEXIS 65268 (W.D. Pa. Sept. 13. 2006), in which the court rejected defendant's argument that plaintiff had to plead patient-specific false claims in alleging Stark Act and AKS violations. The court noted that it could not see "how requiring Relators to provide a single claim example would put Defendants in a better position to answer and defend against the claims where . . . falsity of the instant claims does not turn on anything unique to any individual claim or that would be revealed from an examination of any claim [because] the claims are false because of the improper financial arrangements," which "does not rely on any specific claim." Id. at *19-20. Similarly, in this case, plaintiffs' claims hinge on the allegedly improper financial relationships, which have been sufficiently alleged, combined with the statement of a high level CDI representative about the purpose of the arrangements. Furthermore, the AKS prohibits willfully *offering* remuneration to induce the referral of program-related business, so proof of payment is not required. Therefore, for purposes of this motion, plaintiffs have sufficiently alleged the improper scheme and that CDI offered remuneration in exchange for the referral of program-related business.

Plaintiffs also allege that CDI acted knowingly. CDI is aware of the law, cognizant of its own arrangements detailed above, and knew that paying physician groups to refer their government insured patients was unlawful. TAC at ¶ 235. Plaintiffs contend that CDI continued to push for and use their illegal arrangements, even though the Office of the Inspector General ("OIG") issued a Special Advisory Bulletin, a Special Fraud Alert, and an Advisory Opinion warning about the potential illegality of similar joint venture agreements. Id. at ¶¶ 237-244. Plaintiffs's allegations regarding wilfullness are also

supported by the alleged statement to Relator West from CDI's former Chief Development Officer and the documents reflecting financial calculations CDI used to demonstrate the amount of potential kickbacks to physicians. Id. at ¶¶ 192, 207-08. Accordingly, the allegations regarding wilfullness are sufficient.

c. Allegations Against MSCPA.

Because most of the allegations in the TAC refer to "defendants" collectively even though some of the allegations make little sense against MSCPA, it is unclear exactly what claims are being asserted against MSCPA. It appears that the TAC alleges that defendant MSCPA is liable for FCA violations under the lease arrangements because its physicians were performing and receiving payment for the diagnostic testing services that were illegally referred to CDI. TAC at ¶¶ 46-50. The allegations against MSCPA are scant. Plaintiffs contend that MSCPA "routinely assigns to CDI the right to submit claims" to the government for payment, and, "upon information and belief, MSCPA is a "knowing and voluntary participant in CDI's scheme to submit false claims toe the United States." Id. at ¶¶ 47, 50. Plaintiffs do not identify a single false claim submitted by MSCPA. Although that deficiency is not fatal to the claim, plaintiffs also fail to allege any other details, including where the claims were submitted, when, by whom, or any facts to support plaintiffs' "belief" that MSCPA was a knowing participant in the scheme to submit false claims. A plaintiff relying on "information and belief" must state the factual basis for the belief, but plaintiffs have failed to do so. See, e.g., Neubronner v. Milken, 6 F.3d 666, 672 (9th Cir. 1993). Accordingly, defendants' claims against MSCPA are dismissed as insufficient.

2. Add-on Tests, Free or Discounted Services as Inducements.

Plaintiffs also contend that CDI provided remuneration in the form of free or

discounted services to induce referrals in violation of federal and state anti-kickback laws and the FCA. Plaintiffs allege that CDI, based on its own internal protocols, automatically added free or discounted MRAs (Magnetic Resonance Angiography) without a written order from physicians to MRI exams ordered. TAC at ¶ 292. Relator West contends that she raised the issue with CDI Chief Accounting Officer Don Jacobsen. Jacobsen allegedly subsequently stated that performing the add-on procedures was "potentially medically unnecessary" and outside the scope of the work ordered. Id. at ¶¶ 297-98. The alleged failure to obtain proper written orders may support a FCA claim as discussed below but plaintiffs have not shown how it supports the alleged AKS violation. Rather, the AKS claim turns on whether CDI provided the free and discounted services as inducements for referral of government insured patients.

a. The Alleged Nationwide Scheme.

Plaintiffs contend that the free or reduced fee "add-on" services were improper inducements for two reasons: (1) the conduct encourages the over-utilization of MRI tests because "it is likely" that physicians "may" order more MRIs than are medically necessary in order to obtain the free MRAs, and (2) "since the free MRA test results are given to the 'referring doctor' who is treating the patient, the doctor is receiving a benefit from the free services and indirect remuneration in exchange for sending his MRI and other diagnostic imaging tests to CDI." TAC at ¶ 308. The first theory is too speculative to state a claim. Furthermore, both theories are undermined by the fact that plaintiffs do not allege that the referring physicians were even aware that CDI was not charging for the MRAs. In fact, the TAC alleges that CDI bills third party payors, not the physicians. Id. at ¶¶ 200, 220. Without such knowledge, there is no inducement for referrals. Therefore, the allegations are insufficient to state a claim.

Even if the allegations satisfied Rule 12(b)(6), the are insufficient under Rule 9(b). Defendants contend that plaintiffs' allegations are too vague and fail to include specifics. Plaintiffs allege that during a meeting in June 2004, a CDI physician at an unnamed location informed Relator West and his staff that he performed free MRAs on his MRI patients "as an 'added' service for his referring physicians, to get more business." Id. at ¶ 306. That statement is insufficient because it fails to include the physician's location, to state that he performed the free tests to obtain government insured referrals, or to identify any other physicians who referred to CDI as a result or the details of any such referrals. Nor can plaintiffs extrapolate a broader scheme from that lone statement. Plaintiffs, as self described "high level insiders," should be able to provide specifics to support their claims. Plaintiffs' Opposition at p. 1; Bly-Magee,236 F.3d at 1019; Lee v. SmithKline Beecham, Inc., 245 F.3d 1048, 1052 (9th Cir. 2001). Therefore, plaintiffs have failed to sufficiently allege their claim of a nationwide scheme to induce referrals by providing free or discounted services.

b. Free Services at Mountlake Terrace Facility.

Plaintiffs allege that CDI's internal audit at its Mountlake Terrace Facility from 2003-2004 revealed a substantial percentage of MRAs performed for free or for a reduced charge. TAC at ¶¶ 304-05. Medicare beneficiaries were not provided the discounted rate, which might mean that the safe harbor is inapplicable. Id. at ¶ 305; 42 C.F.R. § 1001.952(h)(3)(iii). Plaintiffs contend that Exhibit E to the TAC is a list of 26 patients who received free MRAs at CDI's Mountlake Terrace facility. Although patient names have been redacted, the list includes the date of service, medical record number, and referring physician. However, as with the allegations about a nationwide scheme, plaintiffs fail to allege that the physicians who referred to the Mountlake Terrace facility

knew that they were receiving free services.

The TAC also alleges that CDI physicians at the Mountlake Terrace facility "performed two x-rays on patients as an 'added service' to referring physicians from Sound Urological for no charge" to induce referrals of governmental insured and privately insured patients. TAC at ¶ 311. Plaintiffs allege that CDI specifically marketed the free services to Sound Urological, which then consequently referred patients to CDI. Although those allegations come closer to satisfying plaintiffs' pleading requirements than their other allegations, they still fail to allege the "who" (patient names) and the "when" (when the free services were allegedly offered and/or performed. Without that information, CDI will be unable to defendant against the claim. Therefore, plaintiffs' allegations fail to satisfy Rule 9(b).[4]

c. Discounted Services.

Although plaintiffs contend that defendants offered discounts to induce referrals, they have failed to allege that the discounted services were offered for less than fair market value, which is "the gauge of value when assessing the remuneration element of the offense." Klaczak, 458 F. Supp. 2d 622, 678-79 (N.D. Ill. 2006). Nor have they alleged that the discounted prices were not commercially reasonable. See Department of Health & Human Services, OIG Advisory Opinions 99-2 (Feb. 26, 1999). Without alleging the fair market value of those services, plaintiffs have failed to plausibly allege that the "discounted" services constituted remuneration.

In addition to failing to sufficiently allege an AKS violation in connection with the

[4] The TAC alleges that in addition to the two free x-rays, CDI offered other discounts to Sound Urological. TAC at ¶ 311. Without providing any specifics, however, that allegations fails to state a claim or to meet the requirements of Rule 9(b).

discounted services, plaintiffs' allegations fail to allege a violation of the False Claims Act. The FCA allegations in that regard are untethered to any specific statutory or regulatory provision. Although the TAC alleges that the discounts violated Medicare's "most favored nation" pricing, plaintiffs appear to have abandoned that argument and their response makes no reference to it. In fact, if the MRAs were provided for free, then by definition CDI did not bill for them and no false claims were submitted. Therefore, the Court dismisses plaintiffs' FCA claim based on the provision of free and/or discounted procedures.

3. Failure to Obtain Written Orders.

Plaintiffs contend that CDI intentionally submitted thousands of false claims to Medicare for radiological exams without obtaining a written order from the treating physician in violation of the False Claims Act and the Medicare regulations. TAC at ¶¶ 261, 265; id. at ¶271 (citing 42 C.F.R. § 410.33(d)). The crux of plaintiffs' claims is that all procedures performed in an Independent Diagnostic Testing Facility ("IDTF") must be specifically ordered in writing by the physician treating the beneficiary *before* the procedure is performed. TAC at ¶ 262; see also TAC at ¶ 275 (stating that Relator West discovered the absence "of *an appropriate* written order *on the date of service*" in some federal beneficiary patient files audited at the Mountlake Terrace Facility) (emphasis in TAC); id. at ¶¶ 276-77 (same regarding Minnesota facilities). Otherwise, plaintiffs claim, the IDTF submits a false claim when it seeks reimbursement.

As an initial problem, plaintiffs conceded during oral argument that West reviewed physical files only at the Mountlake Terrace facility. For the other CDI facilities, the allegations are based on West's review of whether orders were scanned into electronic files. TAC at ¶¶ 285-91. However, the absence of scanned orders does not necessarily

mean that the files lacked appropriate documentation.

Defendants also contend that they were not required to obtain a written order prior to performing any procedures. Medicare and other federal health care programs require as a condition of coverage that services rendered must be reasonable and medically necessary. 42 U.S.C. § 1395y(a)(1)(A). Medicare also requires that all diagnostic tests "must be ordered by the physician who furnishes a consultation or treats a beneficiary for a specific medical problem . . . ." 42 C.F.R. § 410.32(a). "Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary." Id. 42 C.F.R. § 410.33(d) states that all procedures performed by an IDTF "must be specifically ordered in writing by the physician who is treating the beneficiary." However, none of the sources plaintiffs cite states that an IDTF's subsequent claim for reimbursement is false if the IDTF does not obtain a written order prior to performing the service. In fact, the case on which plaintiffs rely suggests otherwise. In *KGV Easy Leasing Corp. v. Leavitt*, 2011 WL 491010 (9th Cir. Feb. 14, 2011), the Ninth Circuit considered the written order requirement. The court noted that 42 C.F.R. § 410.33(d) "mandates both that (1) the beneficiary's treating physician order the tests; and (2) the results are used 'in the management of the beneficiary's specific medical problem.'" Id. at * 1. Instead of stating that a prior written order was required, the court noted that KGV "never presented evidence that supplemented the information contained on its [unsigned] order forms or otherwise established medical necessity, such as medical records or signed declarations from the physicians named on the forms." Id. at * 1. That discussion demonstrates that an IDTF can fulfill its obligations with documentation created after the procedure has been performed as long as medical necessity is supported when the claim is submitted for reimbursement. Therefore, plaintiffs' claim based on the failure to obtain a prior written

order fails.

Even if the regulation requires a prior written order, as defendants note, "[v]iolations of law, rules or regulations alone do not create a cause of action" under the FCA. U.S. ex. rel. Hopper v. Anton, 91 F.3d 1261, 1266 (9th Cir. 1996). Rather, "some request for payment containing falsities made with scienter (i.e., with knowledge of the falsity and with intent to deceive) must exist." Id. at 1265. The TAC relies on the absence of written orders prior to performing the procedures without alleging that CDI failed to obtain appropriate documentation prior to submitting claims. Accordingly, the TAC fails to state a claim under Rule 12(b)(6).

D. The Stark Act.

The Stark Act, also referred to as the Physician Self-Referral Law, prohibits two things if a physician or member of his or her immediate family has a direct or indirect "financial arrangement with an entity:" (1) the physician "may not make a referral to the entity of certain designated health services" covered by the Medicare program; and (2) the entity "may not present or cause to be presented" a claim to Medicare for any such services following any such referral. 42 U.S.C. § 1385nn(a)(1)(A) & (B).

Plaintiffs contend that CDI's facility lease arrangements violate the Stark Act because CDI had financial relationships with the physicians groups that participated in CDI's facility leasing arrangements, CDI was an "entity" for purposes of the Stark Act because it performed and billed the diagnostic imaging services for the government insured patients who were referred by the physicians participating in CDI's lease arrangements, the referrals were for "Designated Health Services" as defined by Stark Act regulations, and CDI presented claims to Medicare for designated health services referred from physician groups involved in CDI's lease arrangements. TAC at ¶¶ 251, 366-368;

see also 66 Fed. Reg. 856 (defining "entity" during the relevant time for purposes of the referral prohibition "as the business organization, or other association that actually furnishes, or provides for the furnishing of, a service to a Medicare or Medicaid patient and bills for that service"). Plaintiffs confirmed during oral argument that their Stark Act claims relates only to the facility lease arrangements.

Defendants argue that CDI was not an "entity" because the physicians groups billed and received payments from Medicare. In fact, the TAC explicitly alleges that regarding the facility leasing agreements, the physicians groups billed and received reimbursements. (id. at ¶¶ 200-203). Accordingly, plaintiffs have failed to allege that CDI was an "entity" for purposes of the facility leasing arrangements, and their Stark Act claim is dismissed.

E. Leave to Amend.

As set forth above, the Court dismisses plaintiffs' (1) AKS and FCA claims based on defendants' alleged provision of free and discounted services to induce referrals, (2) plaintiffs' claim against MSCPA, (3) plaintiffs' FCA claim based on the failure to obtain prior written orders, and (4) plaintiffs' Stark Act claim. In their response to the motion to dismiss, plaintiffs requested leave to amend if the Court is inclined to dismiss any of their claims. Leave to amend should be granted "when justice so requires." See, e.g., Owens v. Kaiser Found. Health Plan, 244 F.3d 708, 712 (9th Cir. 2001). Although this is plaintiffs' third amended complaint, this motion is the first time the sufficiency of the complaint has been adjudicated. Defendants will not suffer prejudice if leave to amend is granted. Plaintiffs will be granted leave to amend to augment their allegations.

However, plaintiffs will not be granted leave to amend their allegations that defendants violated the Stark Act by engaging in the facility leasing arrangements. The TAC specifically alleges that under those arrangement, the physicians groups bill the

government and receive reimbursement. Therefore, defendants are not an "entity" for purposes of the Stark Act and that claim fails as a matter of law.

III. CONCLUSION

Accordingly, CDI's motion to dismiss (Dkt. # 85) is GRANTED IN PART AND DENIED IN PART. The motion is denied with respect to plaintiffs' claims that CDI violated the AKS and FCA through the leasing arrangements. The Court dismisses plaintiffs' (1) AKS and FCA claims based on defendants' alleged provision of free and discounted services to induce referrals, (2) plaintiffs' claim against MSCPA, (3) plaintiffs' FCA claim based on the failure to obtain prior written orders, and (4) plaintiffs' Stark Act claim. Plaintiffs are granted leave to amend the dismissed claims except for the claim that defendants violated the Stark Act through their facility leasing arrangements; that claim is dismissed without leave to amend.

DATED this 4th day of April, 2011.

Robert S. Lasnik
United States District Judge