IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA *ex rel.*; THOMAS BARTLETT; and KIMBERLY GUMMO,	)	**CIVIL ACTION NO. 3:04-57**
	)	**JUDGE KIM R. GIBSON**
Plaintiffs,	)	
v.	)	
DANIEL ASHCROFT; TRI-COUNTY IMAGING ASSOCIATES, INC.; CARLOS A. WEIGERING; RAMESH AGARWAL; URMILA CHOPRA, *as Executrix of the Estate of RAMESH CHOPRA*; and RAJ KANSEL,	)	
Defendants.	)	

MEMORANDUM OPINION

I. Introduction

This *qui tam* action is before the Court on cross motions for summary judgment. Plaintiff-Relators Thomas Bartlett and Kimberly Gummo ("Relators") have alleged that various healthcare providers and related individuals were complicit in a scheme to de-fraud the United States through their submission of false claims and statements under Medicare and other federal healthcare programs. Relators move for partial summary judgment, asking the Court to find as a matter of law that Physician Defendants[1] made prohibited self-referrals, in violation of the Stark Act, and that Defendants[2] knowingly

[1] The term "Physician Defendants" refers to Carlos A. Wiegering, M.D., Ramesh Agarwal, M.D., Raj Kansel, M.D., and Ramesh Chopra, M.D.

[2] The term "Defendants" refers to Physician Defendants, Dan Ashcroft, and Tri-County Imaging Associates, Inc.

caused the submission of false claims to the United States, in violation of the False Claims Act. Defendants also move for summary judgment, asking the Court to find as a matter of law that Relators have no evidence of false claims. For the reasons set forth below, Relators' motion for partial summary judgment will be granted in part and denied in part. Defendants' motion for summary judgment will be denied.

II. Jurisdiction

The Court exercises subject matter jurisdiction under 31 U.S.C. § 3732(a) and 28 U.S.C. § 1331. Venue is appropriate under 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b)(2) because the alleged acts occurred in this judicial district.

III. Background

A. Parties to the action

Plaintiff-Relators Thomas Bartlett and Kimberly Gummo are former employees of Tyrone Hospital. Between April 2000 and October 2003, Bartlett served as the Chief Executive Officer at Tyrone Hospital. (Sec. Am. Compl., ECF No. 77, ¶¶ 139, 157). Between September 2002 and July 2004, Gummo served as the Director of Human Resources at Tyrone Hospital. (*Id.* ¶¶ 161–65). Tyrone Hospital is a not-for-profit organization that provides in-patient and ancillary hospital services to residents of Blair County, Pennsylvania, and to residents of neighboring counties.[3] (*Id.* ¶ 13).

[3] Relators and Tyrone Hospital, Inc., reached a settlement. On July 22, 2010, Tyrone Hospital was terminated as a defendant in this action. (ECF No. 134).

The remaining Defendants in this action include Carlos A. Wiegering, M.D., Ramesh Agarwal, M.D., Raj Kansel, M.D., Ramesh Chopra, M.D., Dan Ashcroft, and Tri-County Imaging Associates, Inc. ("Tri-County"). The Physician Defendants—Wiegering, Agarwal, Kansel, and Chopra—were shareholders in Tri-County. (ECF No. 173 ¶¶ 20–23). Tri-County is a Pennsylvania corporation that identifies as being in the "equipment leasing" business. (Sec. Am. Compl. ¶ 16; ECF No. 173 ¶ 16). Between 1970 and 2002, Defendant Ashcroft served as the Chief Financial Officer at Tyrone Hospital. (Sec. Am. Compl. ¶ 17). Ashcroft was also a shareholder in Tri-County. (*Id.*; ECF No. 173 ¶ 17).

B. Factual allegations

Beginning in 1984, Bernard DiGiacobbe, M.D., now deceased, maintained an exclusive contractual arrangement with Tyrone Hospital to provide radiology services.[4] (ECF No. 173 ¶ 86). According to Relators, Defendant Ashcroft, Dr. DiGiacobbe, and others realized that services for computerized tomography (CT scans)[5] offered "enormous

[4] Dr. DiGiacobbe was terminated as a defendant on June 20, 2012. (ECF No. 229). Defendants have asked the Court to declare this decision a final judgment pursuant to Fed. R. Civ. P. 54(b). (ECF No. 253). Relators oppose this motion. (ECF No. 258). The Court will address this issue in a separate decision. For purposes of this opinion, the Court's Order of June 20, 2012 remains in effect.

[5] The Mayo Clinic describes a CT scan as follows:

> Computerized tomography (CT scan)—also called CT—combines a series of X-ray views taken from many different angles and computer processing to create cross-sectional images of the bones and soft tissues inside your body. The resulting images can be compared to looking down at single slices of bread from a loaf. . . . CT scan images can provide much more information than do plain X-rays.

Mayo Clinic, Tests and Procedures: CT Scan, http://www.mayoclinic.org/tests-procedures/ct-scan/basics/definition/prc-20014610 (last visited June 15, 2014).

profit potential" and thus devised a plan for physicians to invest in a new CT scanning facility to be associated with Tyrone Hospital. (Sec. Am. Compl. ¶ 86–89). To this end, Tri-County was formed in 1987. (*Id.* ¶¶ 87–89).

Tri-County initially issued 25 shares of stock: 23 shares to physicians (including Dr. DiGiacobbe), one share to Defendant Ashcroft, and one share to another non-physician. (*Id.* ¶ 90). The ownership structure changed over time, particularly in 1995, when many of the original investors divested themselves of their shares in Tri-County. Nevertheless, between 1995 and 2002, Physician Defendants and Defendant Ashcroft maintained significant ownership interests in Tri-County. (*Id.* ¶ 102).

Relators claim that, between 1995 and 2002, Defendants participated in a patient referral scheme to generate revenue for Tyrone Hospital and Tri-County. According to Relators, Physician Defendants referred more than 8,000 patients to Tyrone Hospital for inpatient services and other designated health services. (*Id.* ¶ 104). In turn, Tyrone Hospital maintained a business arrangement with Tri-County and Dr. DiGiacobbe, for which Tyrone Hospital paid Tri-County $410 per CT scan. Specifically, Tyrone Hospital paid Dr. DiGiacobbe for each CT scan; these payments were placed in a Tri-County operating account for distribution to the Tri-County shareholders; and Dr. DiGiacobbe received a 15% collection fee. (ECF No. 251 ¶ 4; ECF No. 254 ¶ 4).

Based on this alleged "compensation arrangement" between Tyrone Hospital and Tri-County, and given Defendants' financial interests in Tri-County, Relators assert that Defendants violated federal law by making prohibited self-referrals to Tyrone Hospital.

For purposes of Relators' motion for partial summary judgment, Relators assert that the undisputed evidence shows that Physician Defendants violated the Stark Act and that Defendants caused the submission of false claims to the United States, in violation of the False Claims Act. Defendants also move for summary judgment, asserting that there is no evidence of false claims being submitted. The motions are ripe for disposition.

IV. Standard of Review

Summary judgment should be granted only when "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). Issues of fact are genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Material facts are those affecting the outcome of trial. *Id*. The court's role is "not to weigh the evidence or to determine the truth of the matter, but only to determine whether the evidence of record is such that a reasonable jury could return a verdict for the nonmoving party." *Am. Eagle Outfitters v. Lyle & Scott Ltd.*, 584 F.3d 575, 581 (3d Cir. 2009). "In making this determination, 'a court must view the facts in the light most favorable to the nonmoving party and draw all inferences in that party's favor.'" *Farrell v. Planters Lifesavers Co.*, 206 F.3d 271, 278 (3d Cir. 2000) (quotation omitted).

The moving party must initially demonstrate the absence of any genuine disputes of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Once the moving party meets this burden, the nonmoving party must go beyond the pleadings by using affidavits, depositions, admissions, or answers to interrogatories to show genuine issues of ma-

terial fact for trial. *Id.* at 324. The nonmoving party cannot defeat a well-supported motion for summary judgment by reasserting unsupported factual allegations in the pleadings. *Williams v. Borough of West Chester*, 891 F.2d 458, 460 (3d Cir. 1989).

V. Underlying Law

Before addressing the merits of the parties' respective motions, the Court will briefly summarize the statutes implicated in this case: the Stark Act, the Anti-Kickback Statute, and the False Claims Act. The Court will then evaluate Relators' motion for partial summary judgment and Defendants' motion for summary judgment.

A. The Stark Act

Congress enacted Section 6204 of the Omnibus Reconciliation Act of 1989 ("Stark I")[6] to curtail the increasing costs of healthcare resulting from abusive physician self-referrals. *Am. Lithotripsy Soc. v. Thompson*, 215 F. Supp. 2d 23, 26 (D.D.C. 2002); *U.S. ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88, 95 (3d Cir. 2009) ("The 'oft-stated goal' of the [Stark] Act is 'to curb overutilization of services by physicians who could profit by referring patients to facilities in which they have a financial interest.'").[7] Stark I prohibits physicians from referring Medicare patients to clinical laboratories in which the physician has a financial interest, absent an exception. *See Am. Lithotripsy Soc.*, 215 F. Supp. 2d at 26.

[6] Pub. L. No. 101-239, § 6204, 103 Stat. 2106, 2236 (codified at 42 U.S.C. § 1395nn(a)(2)). The legislation was named after its primary sponsor, Congressman Forney "Pete" Stark.

[7] For further history on the Stark Act, see Greg Radinsky, *Defining A Group Practice: An Analysis of the Stark I Final Rule*, 41 St. Louis U. L.J. 1119, 1121 (1997), and Joan H. Krause, *A Conceptual Model of Health Care Fraud Enforcement*, 12 J.L. & Pol'y 55, 77 (2003).

Congress enacted Section 13562 of the Omnibus Budget Reconciliation Act of 1993 ("Stark II")[8] to expand the reach of Stark I. Specifically, Stark II prohibits physician self-referrals in twelve "designated health services" categories, including clinical laboratory services. *Id.; see also* 42 U.S.C. § 1395nn.

Simply stated, the Stark Act prohibits physicians from making patient referrals for "designated health services," such as inpatient and outpatient hospital services, if the referring physician (or an immediate family member) has a "financial relationship" with the entity providing the services. 42 U.S.C. § 1395nn(a)(1)(A). The Act further proscribes a healthcare entity from presenting or causing to be presented a Medicare claim for services furnished pursuant to a prohibited self-referral. *Id.* § 1395nn(a)(1)(B);[9] *see also U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 239 (3d Cir. 2004).

The Center for Medicare and Medicaid Services (CMS), previously known as the Health Care Financing Administration (HCFA), is the administrative agency primarily responsible for interpreting the Stark Act. 42 U.S.C. §§ 1395nn(b)(4); *see also Council for Urological Interests v. Sebelius*, 946 F. Supp. 2d 91, 95 (D.D.C. 2013). The first set of Stark

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[8] Pub. L. No. 103-66, § 13562, 107 Stat. 312, 596–605 (codified at 42 U.S.C. § 1395nn).

[9] In pertinent part, the Stark Act provides:

> [I]f a physician (or an immediate family member of such physician) has a financial relationship with an entity specified in paragraph (2), then–(A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter, and (B) the entity may not present or cause to be presented a claim under this subchapter or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A).

42 U.S.C. § 1395nn(a)(1).

regulations addressed Stark I and thus applied only to physician self-referrals for clinical laboratory services. 60 Fed. Reg. 41916 (Aug. 14, 1995). CMS then implemented Stark II regulations in three phases. Phase I final regulations were published in 2001, effective January 4, 2002. 66 Fed. Reg. 865 (Jan. 4, 2001). Phase II final regulations were published on March 26, 2004, effective July 26, 2004. 69 Fed. Reg. 16054 (Mar. 26, 2004). CMS published Phase III final regulations in September 2007, without a comment period, thereby bringing the rulemaking cycle to an end. 72 Fed. Reg. 51,012 (Sept. 5, 2007). The Stark regulations are codified at 42 C.F.R. pts. 411 and 424.

1. Definitions under the Act

The Stark Act defines "referral" as "the request or establishment of a plan of care by a physician which includes the provision of [] designated health service[s]." 42 U.S.C. § 1395nn(h)(5)(B). The Stark regulations broadly define "referral" as, among other things, "the request by a physician for, or ordering of, or the certifying or recertifying of the need for, any designated health service for which payment may be made under Medicare." 42 C.F.R. § 411.351.

The Stark Act defines prohibited financial relationships to include any compensation paid directly or indirectly to a referring physician. Specifically, a physician has a "financial relationship" with an entity if the physician has "an ownership or investment interest in the entity," or "a compensation arrangement" with it. 42 U.S.C. § 1395nn(a)(2). A "compensation arrangement" is defined as "any arrangement involving any remuneration between a physician . . . and an entity." 42 U.S.C. § 1395nn(h)(1)(A). The Stark regula-

tions similarly define "compensation arrangement" as "any agreement involving remuneration, *direct or indirect*, between a physician . . . and an entity." 42 C.F.R. § 411.354(c) (emphasis added). "Remuneration" includes "any remuneration, directly or indirectly, overtly or covertly, in cash or in kind." 42 U.S.C. § 1395nn(h)(1)(B).

Relevant here, the Stark regulations elaborate on the definition of a prohibited "indirect compensation arrangement." 42 C.F.R. § 411.354(c)(2).[10] Such an arrangement exists if:

(1) an "unbroken chain" of persons or entities have financial relationships linking the referring physician to the healthcare entity furnishing "designated health services" (the "DHS entity");

(2) the compensation arrangement in the chain closest to the physician receives "aggregate compensation" that "varies with, or otherwise reflects, the volume or value of referrals" generated for the DHS entity; and

(3) the DHS entity has either "actual knowledge of," or acts in "reckless disregard or deliberate ignorance of," the fact that the aggregate compensation varies in this manner.

42 C.F.R. § 411.354(c)(2).

[10] As of 2007, the Stark regulations now include a separate definition of a "direct compensation arrangement." 42 C.F.R. § 411.354(c)(1). That definition is not at issue.

2. Exceptions to liability

Notwithstanding its broad prohibition on self-referrals, a defendant can avoid liability under the Stark Act by establishing that an exception applies. *U.S. ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88, 95 (3d Cir. 2009) ("Once the plaintiff or the government has established proof of each element of a violation under the Act, the burden shifts to the defendant to establish that the conduct was protected by an exception.") (citing *United States v. Rogan*, 459 F. Supp. 2d 692, 716 (N.D. Ill. 2006), *aff'd*, 517 F.3d 449 (7th Cir. 2008)). For instance, the Stark regulations discuss an exception to ordinarily prohibited indirect compensation arrangements. The defendant must show:

> (1) The compensation received by the referring physician . . . is fair market value for services and items actually provided and not determined in any manner that takes into account the value or volume of referrals or other business generated by the referring physician for the [DHS entity].
>
> (2) The compensation arrangement . . . is set out in writing, signed by the parties, and specifies the services covered by the arrangement . . .
>
> (3) The compensation arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

42 C.F.R. § 411.357(p).

Aside from the exception for certain indirect compensation arrangements, the Stark Act includes other important exceptions to liability. *See* 42 U.S.C. §§ 1395nn(c)–(e). The Stark regulations include additional regulatory exceptions and provide further guidance on the application of the statutory exceptions. 42 C.F.R. § 411.357. To the extent a

Stark exception potentially applies here, the Court will reserve further analysis until later in this opinion.

B. The Anti-Kickback Statute

The Anti-Kickback Statute is another law aimed at preventing fraud in the context of federal healthcare programs. The Anti-Kickback Statute makes it unlawful to knowingly and willfully solicit or receive any remuneration for referrals of services covered by federally funded medical services:

> **(1)** whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
>
> > **(A)** in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
> >
> > **(B)** in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b); *see U.S. ex rel. Singh v. Bradford Reg'l Med. Ctr.*, 752 F. Supp. 2d 602, 640 (W.D. Pa. 2010). In addition to criminal penalties, a violation of the Anti-Kickback Statute can lead to "exclusion from participation in federal healthcare programs and, effective August 6, 1997, civil monetary penalties of $50,000 per violation and three times the amount of remuneration paid." *United States v. Rogan*, 459 F. Supp. 2d 692, 714 (N.D. Ill. 2006) (citing 42 U.S.C. § 1320a-7(b)(7) and 42 U.S.C. § 1320a-7a(a)(7)).

As with violations of the Stark Act, a defendant can avoid liability under the Anti-Kickback Statute by demonstrating that either a statutory or regulatory exception applies. *Rogan*, 459 F. Supp. at 716 (citing *United States v. Shaw,* 106 F. Supp. 2d 103, 122 (D. Mass. 2000)). These exceptions, also known as the "safe harbors," are provided by statute and in U.S. Department of Health and Human Services regulations found at 42 C.F.R. § 1001.952. The safe harbors encompass a number of payment practices—including contracts for office space, equipment, and personal services—and each exception has its own requirements. At minimum, the safe harbors generally require a business arrangement to: (1) be made in writing and signed by the parties; (2) cover all of the services or property exchanged between the parties; and (3) provide for payments that are consistent with fair market value in "arms-length transactions." *See generally* 42 C.F.R. § 1001.952(b)–(d).

C. The False Claims Act

The thrust of this *qui tam* action is that Defendants allegedly violated the False Claims Act, 31 U.S.C. §§ 3729–3733 (the "FCA"), by knowingly causing the submission of claims to Medicare in violation of the Stark Act and the Anti-Kickback Statute. "The FCA is a statutory scheme designed to discourage fraud against the United States." *Mann v. Heckler & Koch Def., Inc.*, 630 F.3d 338, 342 (4th Cir. 2010). "Its roots lie in the rampant fraud perpetrated by contractors against the government during the Civil War, and it has served ever since as a safeguard against unscrupulous government contractors." *Id.* (citing *Wilkins v. St. Louis Hous. Auth.*, 314 F.3d 927, 933 (8th Cir. 2002)).

Congress amended the False Claims Act through the Fraud Enforcement and Recovery Act of 2009 ("FERA"), Pub. L. No. 111–21, 123 Stat. 1617 (2009). *See U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 303 (3d Cir. 2011). For purposes of this decision, the pre-FERA version of the FCA applies, which imposes liability on any person or entity who:

> (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;
>
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government.

31 U.S.C. § 3729(a)(1)–(2).[11]

1. Establishing a claim under the FCA

To establish a claim under the FCA, a plaintiff must prove that "(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent." *U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 242 (3d Cir. 2004) (quotation omitted). In this context, "[t]he terms 'knowing' and 'knowingly' mean that a person . . . (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or

[11] The FCA, as amended by the FERA, now imposes liability on 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[.]

31 U.S.C. § 3729(a)(1).

falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information." *Id.* at 241 (quoting 31 U.S.C. § 3729(b)). It is unnecessary to show a specific intent to defraud. *Id.; U.S. ex rel. Hefner v. Hackensack Univ. Med. Ctr.*, 495 F.3d 103, 109 (3d Cir. 2007).

By way of further background, there are two types of false claims under the FCA: "factually false" claims and "legally false" claims. *See, e.g., U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 305 (3d Cir. 2011). "A claim is factually false when the claimant misrepresents what goods or services that it provided to the Government." *Id.* "[A] claim is legally false when the claimant knowingly falsely certifies that it has complied with a statute or regulation the compliance with which is a condition for Government payment." *Id.* A legally false claim is premised on a "certification theory" of liability because it involves "a false representation of compliance with a federal statute or regulation." *Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001) (citations omitted).

2. Establishing a claim under the FCA in this case

Relators rely on a false certification theory, asserting that Defendants submitted claims to Medicare in violation of the Stark Act and the Anti-Kickback Statute. Falsely certifying compliance with either statute constitutes a "false claim" submitted to the federal government for purposes of the FCA. *See, e.g., U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 243 (3d Cir. 2004); *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 902 (5th Cir. 1997); *U.S. ex rel. Kosenske v. Carlisle HMA, Inc.*, CIV.A 1:05-CV-2184, 2010 WL 1390661, at *5 (M.D. Pa. Mar. 31, 2010); *United States v. Rogan*, 459 F. Supp.

2d 692, 717 (N.D. Ill. 2006), *aff'd*, 517 F.3d 449 (7th Cir. 2008); *U.S. ex rel. Pogue v. Diabetes Treatment Centers of Am.*, 565 F. Supp. 2d 153, 159 (D.D.C. 2008).

The relevant task for this Court is to determine whether Defendants violated the Stark Act or the Anti-Kickback Statute. The submission of a Medicare claim in violation of either statute will establish a "legally false" claim under the FCA. The Court must then determine whether Defendants knowingly caused the submission of a false claim to the United States. An affirmative answer to each inquiry will implicate FCA liability. With this background in mind, the Court will now review the parties' respective motions.

VI. Relators' Motion for Partial Summary Judgment

In their motion for partial summary judgment, Relators assert that the undisputed evidence shows the following: (1) there was a "financial relationship" between Physician Defendants and Tyrone Hospital for purposes of the Stark Act; (2) Physician Defendants cannot satisfy an exception under the Stark Act; (3) Tyrone Hospital submitted claims for payments to Medicare pursuant to prohibited self-referrals from Physician Defendants; and (4) Defendants caused the submission of Stark-tainted claims to Medicare by Tyrone Hospital. The Court will discuss each issue in turn.

A. The alleged financial relationship

As discussed above, the Stark Act prohibits a physician from referring patients to a healthcare entity with which the physician has a "financial relationship," provided the referral is for "designated health services" covered by Medicare. 42 U.S.C. § 1395nn(a)(1).

Relators assert that Physician Defendants entered a financial relationship with Tyrone Hospital, thereby triggering the Stark Act's self-referral prohibition.

The summary judgment record shows that, between 1995 and 2002, Physician Defendants were shareholders in Tri-County. (Ans. to Sec. Am. Compl., ECF No. 173, ¶¶ 20–23). During this period, Dr. DiGiacobbe served as the Chairman of the Radiology Department at Tyrone Hospital, maintaining an exclusive contract to provide radiology services. (*Id.* ¶ 18). Dr. DiGiacobbe was also a shareholder in Tri-County. (*Id.*). Between 1995 and 2002, Tri-County provided CT scanning services and leased office space on the property of Tyrone Hospital for that purpose. (ECF No. 246 at 1 ¶ 2).

The parties agree that, between 1995 and 2002, Tyrone Hospital did not have its own CT scan machine. (ECF No. 246-6 at 20, Ashcroft Dep. at 67:17; ECF No. 254 ¶ 3). Although Defendants assert that Tyrone Hospital made no commitments or guarantees that Tri-County would perform CT scans for all Tyrone Hospital patients,[12] Defendant Ashcroft, during his deposition, answered as follows:

> Q. So if somebody was admitted to the hospital, the hospital itself does not have a CAT scan service?
>
> A. That's correct.
>
> Q. So the patient would then be directed to Tri County; is that right?
>
> A. Inpatient you're saying?

[12] Defendants argue that, because there were no guarantees the Tri-County facility would be used for CT scans of all Tyrone Hospital patients, there is a factual dispute as to whether there was a "financial relationship" between Tyrone Hospital and Physician Defendants. (ECF No. 255 at 2). The Court finds this argument irrelevant and unpersuasive.

> Q. Who would make those arrangements at the hospital?
>
> A. The nursing – the girl on the floor. The nurse would. If a physician ordered a CAT scan, then the nurse on the floor would call the CT building [Tri-County], talk with their people, and make arrangements.
>
> Q. Okay. So that patient would then be scheduled for a procedure at Tri County?
>
> A. That's correct.
>
> Q. And for that procedure, Tri County would charge money; is that right?
>
> A. That's correct.
>
> Q. And who would Tri County charge for that service?
>
> A. For an inpatient, the hospital.

(ECF No. 240-6 at 20, Ashcroft Dep. at 67:14–68:16). Based on Defendant Ashcroft's deposition testimony, the undisputed facts establish that Tyrone Hospital arranged for at least *some* of its inpatients to receive CT scans at Tri-County. Tyrone Hospital paid Tri-County for those scans.

In terms of the financial arrangement, the parties further agree that Dr. DiGiacobbe received a flat fee of $410 per scan. (ECF No. 240-6 at 21, Ashcroft Dep. at 72:1–24; ECF No. 254 at 2 ¶ 4). Defendant Ashcroft explained that Dr. DiGiacobbe, not Tri-County, billed Tyrone Hospital for the scans because only physicians can bill for services and later receive reimbursements under the Medicare program. (Ashcroft Dep. at 73:6–11). After Dr. DiGiacobbe billed Tyrone Hospital for scans, (1) the hospital paid Dr. DiGiacobbe, (2) Tri-County representatives deposited the payments in a business account, and (3) Tri-County paid Dr. DiGiacobbe a 15% collection fee:

> A. Maybe we can simplify this. Bill came in, it would be in Dr. DiGiacobbe's name. The hospital would pay the bill and send the check to Doctor DiGiacobbe's office in the CT building. Tri County then took care of the banking. At the end of the month they paid 15 percent of collections to Doctor DiGiacobbe.

(ECF No. 240-6 at 23, Ashcroft Dep. at 80:12–20). Tyrone Hospital would then receive Medicare reimbursements based upon the patient's applicable diagnosis-related group (DRG) code,[13] which included charges for the CT scans. (ECF No. 251 at 2 ¶ 5; ECF No. 254 at 2 ¶ 5). Under this arrangement, Tyrone Hospital paid Tri-County in amounts totaling $108,715 in 2000, and $81,860 in 2001. (ECF No. 251 at 2 ¶ 6; ECF No. 254 at 2 ¶ 6).

After reviewing the undisputed facts in this case, the Court finds that there was a "financial relationship" between Physician Defendants and Tyrone Hospital. *See* 42 U.S.C. § 1395nn(a)(1) (West 1994 & Supp. 1996). A physician has a "financial relationship" with an entity if the physician has a "compensation arrangement" with it. *Id.* § 1395nn(a)(2). During the relevant period—1995 through 2002—the statutory term "compensation arrangement" meant "any arrangement involving any remuneration between a physician" and a healthcare entity that furnished "designated health services." *Id.* § 1395nn(h)(1)(A). "Remuneration" included "any remuneration, *directly or indirectly*, overtly or covertly, in cash or in kind." *Id.* § 1395nn(h)(1)(B).

The Stark II Phase I regulations (published on January 4, 2001, and effective on January 4, 2002) elaborate on what constitutes an "indirect compensation arrangement"

[13] The Government uses DRG codes to calculate how much Medicare pays the hospital for its services. Office of Inspector General, Medicare Hospital Prospective Payment System: How DRG Rates are Calculated and Updated, OEI-09-00-00200 (2001), https://oig.hhs.gov/oei/reports/oei-09-00-00200.pdf.

by using a three-part test: (1) there is an "unbroken chain" of persons or entities having financial relationships linking the referring physician to the entity furnishing "designated health services" (the "DHS entity"); (2) the compensation arrangement in the chain closest to the physician receives "aggregate compensation" that "varies with, or otherwise reflects, the volume or value of referrals" generated for the DHS entity; and (3) the DHS entity has "actual knowledge of," or "acts in reckless disregard or deliberate ignorance of," the fact that the arrangement meets the second criterion. 42 C.F.R. § 411.354(c)(2).

Here, Tyrone Hospital and Physician Defendants entered an indirect compensation arrangement because Physician Defendants were shareholders in Tri-County, and there was an unbroken chain of persons or entities linking Tri-County to Tyrone Hospital. To elaborate on the chain:

(1) Tyrone Hospital paid Dr. DiGiacobbe—both an employee of Tyrone Hospital and a shareholder in Tri-County—for CT scans performed at Tri-County;

(2) Tri-County representatives deposited these payments in a Tri-County business account; and

(3) Tri-County representatives distributed these payments to Tri-County shareholders, which included Physician Defendants.

(ECF No. 251 at 2 ¶ 4; ECF No. 254 at 2 ¶ 4).

Next, the undisputed facts show that the compensation arrangement in the chain closest to Physician Defendants received aggregate compensation that varied with, or otherwise took into account, the volume of referrals to Tyrone Hospital. The proper focus is

the financial arrangement between Tyrone Hospital and Tri-County. 42 C.F.R. § 411.354(c)(2)(ii). Because Tyrone Hospital arranged for some of its inpatients to receive CT scans at Tri-County, the number of patients Physician Defendants referred to Tyrone Hospital would impact the number of scans performed at Tri-County. Thus, the "aggregate compensation" between Tyrone Hospital and Tri-County varied based upon the volume of referrals that Physician Defendants made to Tyrone Hospital.

Finally, the undisputed summary judgment record shows that Tyrone Hospital had actual knowledge that Physician Defendants received aggregate compensation that varied based upon the volume of referrals Physician Defendants made to Tyrone Hospital. Tyrone Hospital had knowledge of the pertinent financial arrangement because it made payments to Dr. DiGiacobbe and Tri-County. Indeed, Defendant Ashcroft—the Chief Financial Officer at Tyrone Hospital—knew of the financial arrangement between Tyrone Hospital and Tri-County; at the same time, Defendant Ashcroft served as a director, officer, and shareholder of Tri-County. (Ans. to Sec. Am. Compl. ¶ 17, ECF No. 173 at 3).

The Court notes that the relevant timeframe in dispute is 1995 through 2002. The three-part definition of an "indirect compensation arrangement" provided in the Stark regulations went into effect on January 4, 2002. The Stark regulations do not apply retroactively. *See* 42 U.S.C. 1395hh(e)(1)(A) (West 2010) ("A substantive change in . . . interpretative rules, statements of policy, or guidelines . . . under [the Stark Act] shall not be applied . . . retroactively . . ."). Although the regulatory definition of an "indirect compensation arrangement" is not technically binding before 2002, the Court nonetheless finds that

it provides instructive guidance on whether Physician Defendants entered into a "compensation arrangement" with Tyrone Hospital for purposes of the Stark Act.[14]

Because a "compensation arrangement" existed between Physician Defendants and Tyrone Hospital, the Stark Act prohibited Physician Defendants from making any patient referrals to Tyrone Hospital for designated health services. To avoid triggering the Stark Act's self-referral prohibition, therefore, Physician Defendants must now establish that their financial relationship with Tyrone Hospital satisfied a Stark exception.

B. Exceptions under the Stark Act

Relators seek summary judgment on the ground that Physician Defendants have not shown that a Stark exception applies in this case. As stated above, it is Defendants' burden to establish the applicability of an exception. *See, e.g.*, *U.S. ex rel. Singh v. Bradford Reg'l Med. Ctr.*, 752 F. Supp. 2d 602, 634 (W.D. Pa. 2010) (citations omitted); *U.S. ex rel. Villafane v. Solinger*, 543 F. Supp. 2d 678, 688 (W.D. Ky. 2008) (stating that the appropriate burden of persuasion is based upon a preponderance of evidence) (citing 2 Kenneth S. Broun, McCormick on Evidence § 339 (6th ed. 2006)).

The Stark Act includes a number of exceptions for compensation arrangements between physicians and DHS entities, including exceptions for office space and medical

[14] At least two district courts have viewed the Stark regulations as persuasive authority in analyzing pre-regulation Stark claims. *See U.S. ex rel. Pogue v. Diabetes Treatment Centers of Am.*, 565 F. Supp. 2d 153, 170 n.7 (D.D.C. 2008) (finding that, in the context of a pre-regulation "indirect compensation arrangement," the Stark regulations "constitute persuasive authority"); *United States v. Rogan*, 459 F. Supp. 2d 692, 712–15 (N.D. Ill. 2006), *aff'd*, 517 F.3d 449 (7th Cir. 2008).

equipment leases, bona fide employment relationships, and physician recruitment agreements, to name a few. 42 U.S.C. §§ 1395nn(b)–(e). By regulation, CMS introduced additional compensation arrangement exceptions, such as the "medical staff incidental benefits" exception and the "indirect compensation arrangement" exception. 42 C.F.R. § 411.357(a)–(w). Each Stark exception includes its own requirements. As a general rule, however, these exceptions require the compensation arrangement to be

(1) set at fair market value and not take into account the volume or value of referrals or business generated;

(2) memorialized in writing, signed by the parties and specifying all the services and compensation provided under the arrangement; and

(3) in compliance with state and federal law, including the Anti-Kickback Statute.

See, e.g., 42 C.F.R. § 411.357(p) (indirect compensation arrangement); *Id.* § 411.357(a)–(b) (rental of office space and equipment); *Id.* § 411.357(d) (personal service arrangements); *Id.* § 411.357(e) (physician recruitment); *see also U.S. ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88, 95 (3d Cir. 2009) (stating that the Stark Act exceptions exclude certain financial arrangements that exist for reasons independent of physician self-referrals).

In opposing Relators' motion for partial summary judgment, Defendants argue that the compensation arrangement at issue was "commercially reasonable." (ECF No. 255 at 3). Defendants further argue that the arrangement was an "arms-length business relationship consistent with the legitimate medical needs of Tyrone Hospital." (*Id.*). But even so, Defendants have not argued that this financial arrangement fit within an estab-

lished Stark exception. In fact, Defendants do not even mention the Stark exceptions. (*See* ECF No. 255). Because Defendants have not argued that an exception applies, the Court will rule in favor of Relators on this issue. *See Siegel Transfer, Inc. v. Carrier Exp., Inc.*, 54 F.3d 1125, 1131 (3d Cir. 1995) (discussing the appropriate standard at summary judgment when the nonmoving party bears the burden of proof at trial).

To the extent a Stark Act exception is potentially relevant here,[15] the Court finds instructive the "indirect compensation arrangement" exception provided in the Stark regulations. As stated previously, this exception requires:

> (1) The compensation received by the referring physician . . . is fair market value for services and items actually provided and not determined in any manner that takes into account the value or volume of referrals or other business generated by the referring physician for the [DHS entity].
>
> (2) The compensation arrangement . . . is set out in writing, signed by the parties, and specifies the services covered by the arrangement . . .
>
> (3) The compensation arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

42 C.F.R. § 411.357(p). Here, Defendants have not come forward with any written agreement, signed by the parties and specifying the precise services and fees covered by the compensation arrangement at issue. In a response to Relators' concise statement of material facts, Defendants briefly mention that "Tri-County had a written service agreement with Dr. DiGiacobbe, and Dr. DiGiacobbe had a written Radiology Agreement with Ty-

[15] The Court reiterates that the Stark II Phase I regulations took effect in January 2002, thus creating the indirect compensation arrangement exception. Defendants cannot technically rely on this exception before 2002 because the Stark regulations do not apply retroactively.

rone Hospital." (ECF No. 254 at 2–3 ¶ 7). Even so, Defendants have not come forward with the agreements themselves, nor would they be useful in establishing a Stark exception unless the *entire* arrangement was set forth in writing. Defendants have not made this argument.

Because Defendants have not argued that their compensation arrangement with Tyrone Hospital fit within a Stark Act exception, the Court finds that, as a matter of law, Physician Defendants were prohibited from making referrals to Tyrone Hospital for designated health services. Between 1995 and 2002, the Stark Act explicitly defined "designated health services" to include inpatient and outpatient hospital services. 42 U.S.C. § 1395nn(h)(6)(K). The next step in the Court's analysis is to determine whether Tyrone Hospital submitted inpatient and outpatient Medicare claims where one of the Physician Defendants was the referring physician.

C. Evidence of referrals and claims

Relators assert that the undisputed evidence shows Tyrone Hospital submitted Medicare reimbursement claims pursuant to referrals from Physician Defendants. To trigger the Stark Act, the claims must be for "designated health services," such as inpatient and outpatient hospital services. On September 9, 2011, the Court entered an Order requiring the U.S. Department of Health and Human Services ("HHS") to produce

> [a] list of inpatient and outpatient Medicare claims submitted by Tyrone Hospital, Provider Number 39-1307, to Highmark Medicare Services, including the amount paid by Medicare on all such claims, on which Bernard H. DiGiacobbe, UPIN B41249, Carlos A. Wiegering, UPIN B34039, Ramesh K. Agarwal, UP IN B37119, Raj G. Kansal, UPIN B37483, or Ramesh K. Chopra is identified as attending physi-

> cian, referring physician, or other physician, for the time period February 23, 1998 to December 31, 2002.

(ECF No. 198 at 1). HHS thereafter produced two spreadsheets identifying thousands of inpatient and outpatient Medicare claims wherein a Physician Defendant was identified as either the "attending" or "other" physician. (*See* ECF No. 252-6, inpatient claims; ECF No. 252-7, outpatient claims; *see also* ECF No. 251 at 3 ¶ 10; ECF No. 254 at 3 ¶ 10).

In opposing Relators' motion for partial summary judgment, Defendants argue that the HHS spreadsheets do not identify the type of service provided or the actual entity providing the service. (ECF No. 255 at 5). According to Defendants, "[w]ithout this information, it cannot be determined whether there were actually any claims submitted arising from CT scans performed at Tri-County." (*Id.*). This argument is without merit. The spreadsheets include inpatient and outpatient Medicare claims, which are "designated health services" under the Stark Act. 42 U.S.C. § 1395nn(h)(6)(K). Moreover, it is immaterial whether the Medicare claims included reimbursements for any CT scans performed at Tri-County. Once Physician Defendants and Tyrone Hospital entered a "financial relationship" within the meaning of the Stark Act, Physician Defendants could not refer patients to Tyrone Hospital for *any* designated health services, including inpatient and outpatient hospital services.

Defendants also argue that the spreadsheets do not show "whether the claim[s] arose from a true patient 'referral' by one of the Defendants, as it is possible that these patients simply presented for treatment on their own initiative." (ECF No. 255 at 5). This argument is unsupported by the record. The term "referral" is defined as "the request or

establishment of a plan of care by a physician which includes the provision of [] designated health service[s]." 42 U.S.C. § 1395nn(h)(5)(B). The Stark regulations, which provide guidance on pre-regulation Stark claims, define "referral" in relevant part as

> (i) . . . the request by a physician for, or ordering of, or the certifying or recertifying of the need for, any designated health service for which payment may be made under Medicare Part B, ... [or]
>
> (ii) . . . a request by a physician that includes the provision of any designated health service for which payment may be made under Medicare, the establishment of a plan of care by a physician that includes the provision of such a designated health service, or the certifying or recertifying of the need for such a designated health service, ...

42 C.F.R. § 411.351.

Between 1995 and 2002, Tyrone Hospital submitted Medicare claims for inpatient and outpatient services on a CMS–1450—Uniform Institutional Provider Bill, also known as the "UB-92 Form." *See, e.g.*, *U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 20 F. Supp. 2d 1017, 1024 (S.D. Tex. 1998); *United States v. Rogan*, 459 F. Supp. 2d 692, 713 (N.D. Ill. 2006), *aff'd*, 517 F.3d 449 n.7 (7th Cir. 2008). As carefully explained by one of our sister courts:

> The fields to be filled out in a Form UB–92 included one labeled "Attending Phys. ID," [Field 82] which was defined in Chapter 25 of the Medicare Claims Processing Manual, Pub. 100–04 (henceforth, "MCPM") as "the clinician primarily responsible for the care of the patient from the beginning of the inpatient episode" for inpatient claims and as "the physician that requested the surgery, therapy, diagnostic tests or other services" for outpatient claims. Form UB–92 also included a field labeled "Other Phys. ID" [Field 83] that was to be filled out whenever a procedure was performed. For inpatient claims, the MCPM specified that this field was to be used to identify the physician performing the principal procedure or, if no principal procedure was performed, to identify the physician who performed the surgical procedure most closely related to the principal diagnosis. For outpatient claims, the field was used to identify the operating physician.

United States v. Halifax Hosp. Med. Ctr., 6:09-CV-1002-ORL-31, 2013 WL 6017329, at *1 (M.D. Fla. Nov. 13, 2013). Some courts have found that, as a matter of law, any physician identified as either the attending or other physician on a UB-92 Form is a "referring" physician for purposes of the Stark Act. *See Rogan*, 459 F. Supp. 2d 692, 713 (N.D. Ill. 2006) ("The 'attending/operating' physician identified in Boxes 82 and 83 of Form UB-92 qualifies as a referring physician as that term is defined by the Stark Statute.");[16] *U.S. ex rel. Singh v. Bradford Reg'l Med. Ctr.*, 752 F. Supp. 2d 602, 639 (W.D. Pa. 2010). At minimum, this form provides strong evidence that the attending or other physician is a "referring" physician under the Act. *See United States v. Halifax Hosp. Med. Ctr.*, 6:09-CV-1002-ORL-31, 2013 WL 6017329, at *10 (M.D. Fla. Nov. 13, 2013).

Here, the two HHS spreadsheets identify inpatient and outpatient Medicare claims wherein a Physician Defendant was either the attending or other physician on a Medicare reimbursement form. Specifically, these spreadsheets contain two columns for "ATTEND" and "OTHER," and identify Physician Defendants in the appropriate column based on

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[16] The *Rogan* Court explained as follows:

> Stark I required providers to submit information with claims that would identify "referring" physicians. Pub. L. 101-239, § 6304(b) (codified at 42 U.S.C. § 1395l (q)). CMS, then HCFA, implemented this provision by requiring hospitals to list the UPIN of the "attending" physician on Form HCFA-1450, which at the time was form UB-82. . . . Providers were instructed to report this information in Boxes 92 and 93 on UB-82. . . . Effective October 1, 1993, CMS instituted UB-92 to replace the UB-82. The information in Boxes 92 and 93 on UB-82 was transferred to Boxes 82 and 83 on UB-92. . . . Obviously, given the broad statutory and regulatory definition of referral, physicians not listed as either the attending or operating physician may also qualify as one of several "referring physicians."

459 F. Supp. 2d 692, 713 n.11 (N.D. Ill. 2006).

their respective physician number. (*See* ECF No. 252-6, inpatient claims; ECF No. 252-7, outpatient claims). These columns correspond to the "Attending Phys. ID" and the "Other Phys. ID" fields on the UB-92 Form.

Similar to the *Halifax* Court of the Middle District of Florida, 6:09-CV-1002-ORL-31, 2013 WL 6017329 at *10, this Court need not determine whether, as a matter of law, every attending or other physician identified on a Medicare reimbursement form is a referring physician under the Stark Act. Instead, the Court finds that the HHS spreadsheets are competent evidence that Tyrone Hospital submitted claims to Medicare pursuant to referrals from Physician Defendants. Moreover, this evidence is uncontested in that Defendants do not dispute the authenticity of these spreadsheets, nor do they claim that the spreadsheets fail to accurately identify the attending or other physicians listed on the actual claims submitted to Medicare. (ECF No. 251 at 3 ¶ 10; ECF No. 254 at 3 ¶ 10).

Because Relators have shown evidence that Tyrone Hospital submitted claims to Medicare pursuant to referrals from Physician Defendants, the Court must now determine whether Defendants have pointed to evidence showing a genuine dispute of material fact for trial. *Williams v. Borough of W. Chester, Pa.*, 891 F.2d 458, 464 (3d Cir. 1989) ("The party moving for summary judgment has the burden of showing that there is no genuine issue of material fact, and once the moving party has sustained this burden, the opposing party must introduce specific evidence showing that there is a genuine issue for trial."). Defendants cannot rely on conclusory statements or allegations unsupported by facts.

Indeed, "conclusory allegations without specific supporting facts have no probative value." *Evers v. Gen. Motors Corp.*, 770 F.2d 984, 986 (11th Cir. 1985).

When viewing the facts in a light most favorable to Defendants, and drawing all reasonable inferences in their favor, the Court finds that Defendants have not introduced any evidence showing a genuine dispute of material fact for trial. Defendants claim that the spreadsheets "do not identify whether a 'referral' took place." (ECF No. 254 at 3 ¶ 10). Aside from this conclusory statement, Defendants do not cite any evidence in the record suggesting that Physician Defendants did not make the actual referrals for the Medicare claims shown on the HHS spreadsheets. Of course, Relators bear the burden of showing referrals—and Defendants need not produce evidence on this point—but summary judgment is warranted when, as in this case, Relators have come forward with uncontested evidence of referrals based upon the Medicare forms. *See United States v. Halifax Hosp. Med. Ctr.*, 6:09-CV-1002-ORL-31, 2013 WL 6017329, at *11 (M.D. Fla. Nov. 13, 2013).

Because Relators have presented undisputed evidence that Physician Defendants made referrals to Tyrone Hospital for designated health services, Relators have established that Physician Defendants violated the Stark Act. 42 U.S.C. § 1395nn(a)(1)(A). Similarly, the HHS spreadsheets establish that Tyrone Hospital submitted claims to Medicare pursuant to prohibited self-referrals, also in violation of the Stark Act. 42 U.S.C. § 1395(a)(1)(B). Finally, because a certificate of compliance with federal healthcare law is a prerequisite to eligibility under the Medicare program, Tyrone Hospital's submission of Stark-tainted claims to Medicare constitute "false claims" for purposes of the FCA. *See,*

e.g., *U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 243 (3d Cir. 2004). The Court will therefore grant summary judgment in favor of Relators on these issues.

D. Alleged violations of the False Claims Act

For purposes of Relators' motion for partial summary judgment, the final issue before the Court is whether Defendants violated the FCA by knowingly causing the submission of false claims to the United States. As stated previously, the pre-FERA version of the FCA applies here, which imposes liability on any person who

> (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; [or]
>
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; . . .

31 U.S.C. § 3729(a). "To establish a *prima facie* claim under 31 U.S.C. § 3729(a)(1), a plaintiff must show that: (1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent." *U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 242 (3d Cir. 2004) (quotations omitted).

As explained by the Supreme Court of the United States, the FCA is quite extensive in its coverage and is intended to "reach any person who *knowingly assisted* in causing the government to pay claims which were grounded in fraud, without regard to whether that person had direct contractual relations with the government." *U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 243 (3d Cir. 2004) (emphasis added) (citing *U.S. ex rel. Marcus v.*

Hess, 317 U.S. 537, 544–45 (1943)). Accordingly, Defendants can be found liable under the FCA even if they did not actually present false claims to the government. *Id.* at 242–44. The crucial issue is whether Defendants knowingly assisted in the presentation of such claims. *Id.*

In the context of the FCA, "the terms 'knowing' and 'knowingly' mean that a person, with respect to information—(1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information . . ." *U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d at 241 (quoting 31 U.S.C. § 3729(b)). Relators need not prove a specific intent to defraud, but negligent or innocent mistakes are not actionable under the FCA. *See U.S. ex rel. Kosenske v. Carlisle HMA, Inc.*, CIV.A 1:05-CV-2184, 2010 WL 1390661, at *7 (M.D. Pa. Mar. 31, 2010) (citations omitted).

Relators assert that Defendants caused the submission of false claims to the United States because they "participated in a scheme resulting in the submission of false claims by the hospital." (ECF No. 250 at 9). In support of this argument, however, Relators do not cite any evidence of Defendants' subjective knowledge or conduct. (ECF Nos. 250, 251, 259). Instead, Relators simply argue that Physician Defendants were responsible for the submission of false claims because they violated the Stark Act and because they benefitted from a financial relationship with Tyrone Hospital. (ECF No. 250 at 9–10).

Unlike the FCA, the self-referral prohibition in the Stark Act is a strict liability offense, with no *scienter* requirement.[17] *See, e.g.*, *U.S. ex rel. Villafane v. Solinger*, 543 F. Supp. 2d 678, 685–86 (W.D. Ky. 2008); 63 Fed. Reg. 1659, 1715 (Jan. 9, 1998) ("[The Stark Act] is triggered by the mere fact that a financial relationship exists; the intention of the referring physician is not taken into consideration."). Because the self-referral prohibition in the Stark Act does not contain the same *scienter* requirement as that of the FCA, a violation of the Stark Act does not necessarily trigger liability under the FCA.

Without any specific evidence that Defendants acted "knowingly" for purposes of the FCA, summary judgment is not warranted on Relators' FCA claims. The Court concludes that a factual dispute remains for trial as to whether Defendants knowingly assisted in causing the submission of false claims to the United States. Accordingly, Relators' motion for partial summary judgment will be denied on this issue.

VII. Defendants' Motion for Summary Judgment

Having fully evaluated Relators' motion for partial summary judgment, the Court will now turn to Defendants' corresponding motion. Defendants argue that summary judgment is appropriate because Relators have no evidence of actual claims being submitted to Medicare. (ECF No. 246 at 26). Assuming the Court found evidence of Medicare claims, Defendants argue that there is no evidence of any "false claims" being submitted

[17] Although the Stark Act is primarily a strict liability statute, certain penalties under the Act are not warranted unless an intent element is shown. For instance, a person who knowingly "presents or causes to be presented" a Stark-tainted Medicare claim can be subject to civil monetary penalties of up to $15,000 for each designated health service included in the claim. 42 U.S.C. § 1395nn(g)(3).

to the government because Defendants did not violate the Stark Act or the Anti-Kickback Statute. (*Id.*). Given the aforementioned discussion on the Stark Act, the Court need only consider whether Defendants are entitled to summary judgment on the alleged violations of Anti-Kickback Statute.

A. Alleged violations of the Anti-Kickback Statute

In their second amended complaint, Relators allege that Defendants violated the Anti-Kickback Statute by receiving remuneration for referrals of services covered by federal healthcare programs. (Sec. Am. Compl. ¶ 85, ECF No. 77 at 21). Relators allege that

(1) Tyrone Hospital leased office space to Tri-County at a below-market rate;

(2) Tyrone Hospital overpaid Tri-County for CT scans performed at Tri-County;

(3) Tyrone Hospital entered an employee-sharing arrangement with Tri-County, in which Tyrone Hospital subsidized a portion of the salaries for radiology technicians working for Tri-County; and

(4) Tyrone Hospital sold radiology supplies to Tri-County at below-market prices.

(*Id.* ¶¶ 91–101). According to Relators, these payments were intended to maximize the profitability of Tri-County and to further induce Physician Defendants to refer Medicare and Medicaid patients to Tyrone Hospital. (*Id.*).

In moving for summary judgment, Defendants argue that they did not violate the Anti-Kickback Statute because the evidence shows that each type of alleged payment was consistent with fair market value. (ECF No. 246 at 16–26). According to Defendants, such evidence proves there were no "kickbacks" because Defendants had "no economic incen-

tives" to make referrals. (*Id.* at 17). In response, Relators argue that there are triable issues of fact as to whether the payments were set at fair market value. Relators further argue that, even assuming Defendants established fair market value for each payment, such evidence would be insufficient to warrant judgment as a matter of law.

B. Legal framework for the Anti-Kickback Statute

The Anti-Kickback Statute forbids any person or entity from knowingly and willfully offering, paying, soliciting, or receiving anything of value ("remuneration") to influence the referral of items or services reimbursable by a federal healthcare program. 42 U.S.C. § 1320a-7b(b); *United States v. LaHue*, 261 F.3d 993, 996 (10th Cir. 2001). In pertinent part, the Act provides:

> (b) Illegal remunerations
>
> (1) whoever knowingly and willfully solicits or receives any remuneration . . . directly or indirectly, overtly or covertly, in cash or in kind—
>
> > (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program . . .
> >
> > * * *
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.
>
> (2) whoever knowingly and willfully offers or pays any remuneration . . . directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
>
> > (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program . . .
> >
> > * * *

> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b). To establish a prima facie case, Relators must show that Defendants (1) knowingly and willfully (2) solicited or received remuneration (3) in return for, or to induce, referrals to a person or entity for services covered by Medicare, Medicaid, or any other federally funded healthcare program.

The statute has been broadly interpreted to cover any arrangement where *one purpose* of the remuneration is to obtain money for the referral of services or to induce future referrals. *See United States v. Greber*, 760 F.2d 68, 72 (3d Cir. 1985) ("If the payments were intended to induce the physician to use Cardio-Med's services, the statute was violated, even if the payments were also intended to compensate for professional services."); *see also United States v. Borrasi*, 639 F.3d 774, 782 (7th Cir. 2011); *United States v. McClatchey*, 217 F.3d 823, 835 (10th Cir. 2000); *United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998); *United States v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989); *United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 33 (1st Cir. 1989).

As with the Stark Act, a number of statutory and regulatory safe harbors protect certain business arrangements that might otherwise violate the Anti–Kickback Statute. *See* 42 U.S.C. § 1320a-7b(b)(3)(A)–(J); 42 C.F.R. § 1001.952. "To receive protection, a business arrangement must fit squarely within a safe harbor; substantial compliance is not enough, although compliance is voluntary and failure to comply is not a per se violation of the statute." *U.S. ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 47 (D. Mass. 2011) (citing OIG Compliance Program for Pharmaceutical Manufacturers, 68 Fed. Reg.

23731, 23734 (May 5, 2003)). These safe harbors are affirmative defenses, and the defendant carries the burden of proof at trial. *See United States v. Rogan*, 459 F. Supp. 2d 692, 716 (N.D. Ill. 2006); *United States v. Job*, 387 F. App'x 445, 455 (5th Cir. 2010) (unpublished); *United States v. Norton*, 17 F. App'x 98, 102 (4th Cir. 2001) (unpublished).

The Court emphasizes that liability under the Anti-Kickback Statute ultimately turns on the intent of the parties and will depend on the facts and circumstances present in each case. *See, e.g.*, Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti–Kickback Provisions, 56 Fed. Reg. 35952, 35955 (July 29, 1991) ("[T]he gravamen of a violation of the statute is 'inducement' and not necessarily the structure of the arrangement," such that "case by case inquiries must necessarily focus on the intent of the parties."); OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4858, 4864 (Jan. 31, 2005) ("Importantly, under the anti-kickback statute, neither a legitimate business purpose for the arrangement, nor a fair market value payment, will legitimize a payment if there is also an illegal purpose (i.e., inducing Federal health care program business))." Indeed, "[t]he reason behind the transaction and the requisite state of mind underlying the criminal act are more significant than form and label." *United States v. Shaw*, 106 F. Supp. 2d 103, 116 (D. Mass. 2000).

C. Discussion on the Anti-Kickback Statute

Defendants devote several pages of their brief in support of summary judgment arguing that there can be no violations of the Anti-Kickback Statute because all of the payments were consistent with fair market value. (ECF No. 247 at 12–17). To support

their view that payments were set at fair market value, Defendants primarily rely on deposition testimony from a former CEO of Tyrone Hospital, Thomas Robinson, and a former Chief Financial Officer at Tyrone Hospital, Defendant Dan Ashcroft. Although such testimony can be a consideration for a jury, it does not support judgment as a matter of law.

First, summary judgment is not warranted because Relators dispute the credibility of the testimony. Relators assert that there is no basis to conclude that the payments were consistent with fair market value "other than [Defendants'] unsupported assertions." (ECF No. 256 at 13). Indeed, it is axiomatic that "[c]redibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge, whether he is ruling on a motion for summary judgment or for a directed verdict." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986).

Second, and of critical importance, Defendants have not argued that the pertinent payments fit within the safe harbors of the Anti-Kickback Statute. Establishing that remuneration is consistent with fair market value is relevant to safe harbor compliance, but such evidence on its own is insufficient to satisfy any of the safe harbors. *See* 42 U.S.C. § 1320a-7b(b)(3)(A)–(J); 42 C.F.R. § 1001.952. In other words, each safe harbor requires more than just a showing that payments were consistent with fair market value. *Id.* The Court reiterates that the failure to comply with a safe harbor is not a per se violation of the Anti-Kickback Statute, but Defendants must prove strict compliance with a safe harbor to avoid liability for an arrangement that might otherwise violate the statute.

Finally, the Court concludes that, when viewing the evidence in a light most favorable to the non-moving party, Relators have raised triable issues of fact regarding the alleged violations of the Anti-Kickback Statute. Defendants received alleged remuneration from Tyrone Hospital in the form of office space rentals, charges for CT scans, radiology technician services, and radiology supplies. Contrary to Defendants' assertion, remuneration need not be in the form of a "kickback"; instead, remuneration can include anything of value—and in any form—which is given in return for, or to induce, a referral for federal healthcare services:

> The text [of the statute] refers to "any remuneration." That includes not only sums for which no actual service was performed but also those amounts for which some professional time was expended. "Remunerates" is defined as "to pay an equivalent for service." Webster Third New International Dictionary (1966). By including such items as kickbacks and bribes, the statute expands "remuneration" to cover situations where no service is performed. That a particular payment was a remuneration (which implies that a service was rendered) rather than a kickback, does not foreclose the possibility that a violation nevertheless could exist.

United States v. Greber, 760 F.2d 68, 71 (3d Cir. 1985). Defendants concede that Tyrone Hospital and Tri-County entered various business relationships, and thus a jury could reasonably infer there was remuneration for purposes of the Anti-Kickback Statute.

The next issue for a jury—and the crux of whether the Anti-Kickback Statute was violated in this case—is whether Defendants had the requisite intent to violate the statute. That is, a trier of fact must determine whether the parties entered business arrangements in exchange for, or to induce, patient referrals to Tyrone Hospital. As explained by HHS:

> Although liability under the anti-kickback statute ultimately turns on a party's intent, it is possible to identify arrangements or practices that may present a significant potential for abuse. For purposes of analyzing an arrangement or practice under the anti-kickback statute, the following two inquiries are useful:

- Does the hospital have any remunerative relationship between itself (or its affiliates or representatives) and persons or entities in a position to generate Federal health care program business for the hospital (or its affiliates) directly or indirectly? Persons or entities in a position to generate Federal health care program business for a hospital include, for example, physicians and other health care professionals, ambulance companies, clinics, hospices, home health agencies, nursing facilities, and other hospitals.

- *With respect to any remunerative relationship so identified, could one purpose of the remuneration be to induce or reward the referral or recommendation of business payable in whole or in part by a Federal health care program?* Importantly, under the anti-kickback statute, neither a legitimate business purpose for the arrangement, nor a fair market value payment, will legitimize a payment if there is also an illegal purpose (i.e., inducing Federal health care program business).

OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4858, 4864 (Jan. 31, 2005) (emphasis added). Here, a reasonable jury could infer that Defendants were in a position to generate federal healthcare business for Tyrone Hospital through patient referrals. A reasonable jury could likewise find that Defendants entered various business arrangements with Tyrone Hospital to receive remuneration from the hospital in exchange for patient referrals. To establish a violation of the Anti-Kickback Statute, Relators must prove that the arrangements were intended, at least in part, to steer federal healthcare business to Tyrone Hospital, and that Defendants "knowingly and willfully" solicited or received remuneration for that purpose.[18]

[18] Interpreting the *mens rea* requirement of the Anti-Kickback Statute has yielded different results. The terms "knowing and willfully" are not defined by statute, and the courts of appeals are divided on the issue. *Compare United States v. McClatchey*, 217 F.3d 823, 829 (10th Cir. 2000) (requiring a specific intent to violate the statute); *and Hanlester Network v. Shalala*, 51 F.3d 1390, 1400 (9th Cir. 1995) (requiring that a defendant know the requirements of the statute and "engage in prohibited conduct with the specific intent to disobey the law"); *with United States v. Starks*, 157 F.3d 833, 838 (11th Cir. 1998) (using a standard set of jury instructions for the term "willfully" and requiring knowledge of unlawful conduct, as opposed to knowledge of violating the specific statute); *and United States v. Jain*, 93 F.3d 436, 440–41 (8th Cir. 1996) (requiring only that a defendant know the

The Court finds that there are disputed issues of fact which preclude summary judgment in favor of Defendants on the alleged violations of the Anti-Kickback Statute. The Court has construed the facts and all reasonable inferences in a light most favorable to Relators, the non-moving parties, and does not comment on the actual merits of Relators' allegations. Indeed, determining whether a business arrangement violates the Anti-Kickback Statute is largely a question of intent, resolution of which is the province of the trier of fact. *See United States v. Dollar Bank Money Mkt. Account No. 1591768456*, 980 F.2d 233, 240 (3d Cir. 1992) (explaining that "a party's mental state is inherently a question of fact which turns on credibility") (citations omitted). Accordingly, Defendants' motion for summary judgment will be denied.[19]

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conduct was wrongful, rather than knowledge that the conduct violated a known legal duty). In *United States v. Greber*, the Third Circuit sustained a jury verdict after explaining that

> [t]he district judge instructed the jury that the government was required to prove that Cardio-Med paid to Dr. Avallone some part of the amount received from Medicare; that defendant caused Cardio-Med to make the payment; *and did so knowingly and willfully* as well as with the intent to induce Dr. Avallone to use Cardio-Med's services for patients covered by Medicare.

760 F.2d 68, 71 (3d Cir. 1985). In light of the *Greber* decision, the Court finds that the law in this Circuit only requires relators (or the government) to prove that a defendant knowingly and willfully received or solicited remuneration where at least one purpose behind the remuneration was to induce referrals for services covered by a federal healthcare program.

[19] In their motion for summary judgment, Defendants also assert that they were not limited to charging the "actual costs" for CT scans because Tri-County and Tyrone Hospital were not "related organizations" for purposes of the Medicare regulations. (ECF No. 247 at 14 n.20). Relators allege that Tyrone Hospital overpaid Tri-County for CT scans because the payments exceeded the "actual cost" and/or fair market value for such services; according to Relators, the payments induced Physician Defendants to make referrals to Tyrone Hospital, in violation of the Anti-Kickback Statute. (Sec. Am. Compl. ¶ 91, ECF No. 77 at 23). The Medicare regulations provide that

> costs applicable to services, facilities, and supplies furnished to the provider by organizations related to the provider by common ownership or control are includa-

VIII. Conclusion

The summary judgment record contains uncontested evidence that Physician Defendants made referrals to Tyrone Hospital for designated health services, thereby violating the Stark Act. As well, there are issues of material fact precluding judgment as a matter of law on the alleged violations of the Anti-Kickback Statute and the False Claims Act. Consequently, the Court will grant in part and deny in part Relators' motion for partial summary judgment, and deny Defendants' motion for summary judgment.

An appropriate order follows.

> ble in the allowable cost of the provider at the cost to the related organization. However, such cost must not exceed the price of comparable services, facilities, or supplies that could be purchased elsewhere.

42 C.F.R. § 413.17(a). "Control exists if an individual or an organization has the power, directly or indirectly, significantly to influence or direct the actions or policies of an organization or institution." *Id.* § 413.17(b)(3). As explained by Judge McVerry, "[t]he term 'control' includes any kind of control, whether or not it is legally enforceable and however it is exercisable or exercised. It is the reality of the control that is decisive, not its form or the mode of its existence." *UPMC St. Margaret Hosp. v. Leavitt*, CIV.A. 06-1237, 2007 WL 4389842, at *7 (W.D. Pa. Dec. 12, 2007), *aff'd sub nom. UPMC St. Margaret Hosp. v. Sebelius*, 349 F. App'x 786 (3d Cir. 2009) (quoting the CMS Provider Reimbursement Manual Ch. 10, § 1004.3 (A.R. 889)). For the reasons explained in this opinion, the Court finds that there are triable issues of fact regarding the Anti-Kickback Statute, even if the costs of the CT scans did not exceed fair market value or the "actual cost" to Tyrone Hospital. To the extent Defendants seek summary judgment on the ground that Tri-County was not limited to seeking actual costs for CT scans, the Court likewise finds that there are disputed issues of material fact. A reasonable jury could infer that Tyrone Hospital and Tri-County were related organizations through common control given that Defendant Ashcroft served as the Chief Financial Officer at Tyrone Hospital and as a director and officer of Tri-County.

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA *ex rel.*; THOMAS BARTLETT; and KIMBERLY GUMMO,	)	CIVIL ACTION NO. 3:04-57
	)	JUDGE KIM R. GIBSON
Plaintiffs,	)	
v.	)	
DANIEL ASHCROFT; TRI-COUNTY IMAGING ASSOCIATES, INC.; CARLOS A. WEIGERING; RAMESH AGARWAL; URMILA CHOPRA, *as Executrix of the Estate of RAMESH CHOPRA*; and RAJ KANSEL,	)	
Defendants.	)	

ORDER

AND NOW, on this 21st day of August, 2014, upon consideration of Relators' motion for partial summary judgment (ECF No. 249) and Defendants' motion for summary judgment (ECF No. 246), and for the reasons explained in the accompanying memorandum opinion of this Court, it is hereby

ORDERED that Relators' motion for partial summary judgment (ECF No. 249) is GRANTED IN PART and DENIED IN PART. The motion is GRANTED as to the following issues:

1. A financial relationship existed between Physician Defendants and Tyrone Hospital such that the Stark Act prohibited Physician Defendants from making patient referrals to Tyrone Hospital for designated health services, including inpatient and outpatient hospital services;

2. Defendants did not establish that their financial relationship with Tyrone Hospital fit within an exception under the Stark Act or its accompanying regulations; and

3. Between February 23, 1998 and December 31, 2002, Tyrone Hospital submitted claims for payment to Medicare pursuant to referrals from Physician Defendants and later received payment from Medicare for such claims. Physician Defendants include Carlos A. Wiegering, M.D., Ramesh Agarwal, M.D., Raj Kansel, M.D., and Ramesh Chopra, M.D.

Relators' motion (ECF No. 249) is otherwise DENIED in all respects. It is further hereby

ORDERED that Defendants' motion for summary judgment (ECF No. 246) is DENIED; and it is finally hereby

ORDERED that a status conference is scheduled for August 28, 2014, at 1:30 p.m., in Courtroom A, Penn Traffic Building, 319 Washington Street, Johnstown, Pennsylvania.

DONE AND ORDERED in Chambers, at Johnstown, Pennsylvania.

BY THE COURT:

KIM R. GIBSON
UNITED STATES DISTRICT JUDGE