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

U.S. *ex rel*. Tullio Emanuele,	)	
	)	
	)	
Plaintiff/Relator,	)	
v.	)	**C.A. No. 10-245 Erie**
	)	
Medicor Associates, *et al*,	)	
	)	
Defendants.	)	
	)	
	)	

OPINION

Conti, Chief District Judge

I. Introduction

Pending before the court are cross-motions for summary judgment filed by Plaintiff/Relator Tullio Emanuele ("Plaintiff") (ECF No. 276) and defendants The Hamot Medical Center of the City of Erie ("Hamot") (ECF No. 286), Medicor Associates, Inc. ("Medicor") (ECF No. 280), and individually named defendants Robert J. Ferraro, M.D. ("Ferraro"), Charles M. Furr, M.D. ("Furr"), Richard W. Petrella, M.D. ("Petrella"), and Timothy C. Trageser, M.D. ("Trageser") (ECF No. 282).[1] In his amended complaint (ECF No. 64), Plaintiff contends that each of the defendants submitted false claims for payment to the United States government based on referrals from Medicor and the physician defendants to Hamot that violated the Stark Act, 42 U.S.C. § 1395nn, and the Anti-Kickback Act, 42 U.S.C. § 1320a-7b. Plaintiff seeks damages pursuant to the False Claims Act, 31 U.S.C. § 3729(a)(1)(A)-(C) (the "FCA"). For the reasons that follow, Plaintiff's motion will be granted in part and

[1] Ferraro, Furr, Petrella and Trageser are referred to collectively as the "physician defendants."

denied in part; Hamot's and Medicor's motions will be denied; and the individual physicians' motion will be granted.

II. Background

From June 2001 through May 2005, Plaintiff was employed as a cardiologist at Medicor, a private practice medical group consisting of several cardiologists and internal medicine physicians. (Am. Compl. (ECF No. 64) ¶¶ 21-23; Hamot's Concise Statement of Material Facts ("Hamot C.S.F.") (ECF No. 288) ¶ 5.) Physician defendants Petrella, Ferraro, Furr, and Trageser are each shareholders of Medicor engaged in the practice of cardiology. (Consolidated Statement of Material Facts ("C.S.M.F.) (ECF No. 328) ¶ 3.)

Hamot is a tertiary care facility, regional referral hub, and Level II Trauma Center located in Erie, Pennsylvania. (Affidavit of Stephen Danch ("Danch Aff.") (ECF No. 289-37) ¶ 4.) Since approximately 1998, Medicor has been the exclusive outside provider of cardiology services to Hamot. (Hamot C.S.F. (ECF No. 288) ¶ 18.) At some point prior to 2004, Hamot and Medicor expanded this relationship into a paired leadership model which became known as the Hamot Heart and Vascular Institute ("HHVI"). (Id. ¶ 20.) Hamot and Medicor cemented this relationship by entering into a series of medical directorship arrangements. (C.S.M.F. (ECF No. 328) ¶ 1.) As of 2005, these agreements included the following:

- Agreement for Medical Supervision and Direction of Clinical Cardiovascular Services ("Clinical Cardiology Agreement");
- Agreement for Medical Supervision and Direction of Rehab/Restorative Cardiovascular Services ("Rehab/Restorative Cardiology Agreement");
- Agreement for Medical Supervision and Direction of Regional Affiliate Hospital Cardiovascular Services ("Regional Affiliate Cardiology Agreement");
- Agreement for Medical Supervision and Direction of Non-Invasive Cardiovascular Lab Services ("Non-Invasive Cardiology Agreement");
- Agreement for Medical Supervision and Direction of Cardiac Catheterization Lab Services ("Cardiac Catheterization Lab Agreement"); and

- Agreement for Medical Supervision and Direction of Electrophysiology Services ("Cardiac Electrophysiology Agreement").

(Id. ¶ 4.)[2] The medical directorship agreements provided for the following payments: $6,250.00/month for Clinical Cardiology Services; $4,166.00/month for Rehab/Restorative Cardiology Services; $5,000.00/month for Regional Affiliate Hospital Services; $6,666.66/month for Non-Invasive Cardiology Services; $6,666.66/month for Cardiac Catheterization Lab Services; and $5,000.00/month for Cardiac Electrophysiology Services. (Id. ¶ 5.)

Each of the directorship agreements detailed specific services and responsibilities that Medicor was to provide for the duration of the agreement. For example, the Cardiac Catheterization Lab Services Agreement outlined the following duties:

1. Facilitate and implement best practices, utilizing outcomes date and established benchmarks;

2. Monitor clinical care and outcomes, discuss and improve clinical outcomes with service staff, and intervene when necessary;

3. Facilitate pre-operational management, care management and post procedure processes;

4. Respond to request for guidance and direction from service line leaders and case management staff;

5. Develop and implement clinical pathways, protocols, guidelines and disease management programs;

6. Assist in the establishment and adherence to budgets; and

7. Assist in the establishment and adherence to service delivery schedules.

(C.S.M.F. (ECF No. 328) ¶ 117.) Dr. Trageser was assigned to provide services pursuant to the Cardiac Catheterization Lab Services Agreement. (Id. ¶ 119.) The Clinical Cardiovascular Services Agreement (assigned to Dr. Kelly Hayes), Cardiac Electrophysiology Agreement (assigned to Dr. Jeffrey Dakas), Non-Invasive Cardiology Services Agreement (assigned to Dr.

[2] Throughout this opinion, these six medical directorships will be referred to as the "original six directorships."

David Strasser), Regional Affiliate Cardiology Agreement (assigned to Dr. Petrella), and Rehab/Restorative Cardiology Agreement (assigned to Dr. Furr) each provided for similar responsibilities and services. (Id. ¶¶ 121, 125, 129, 133, and 137.)

As of 2006, the Regional Affiliate Hospital Services Agreement, Non-Invasive Cardiology Services Agreement, Cardiac Catheterization Lab Services Agreement, and the Cardiac Electrophysiology Services Agreement each contained the following language:

> The terms of this Agreement shall begin on January 1, 2006 (the "Commencement Date") and shall continue through December 31, 2006, at which time this Agreement shall terminate automatically, unless the parties have agreed in writing to an extension of renewal. If this Agreement is terminated as provided herein, the parties hereby agree that they shall not enter into a new agreement or arrangement with each other for the same or similar Services during the first year of the original term of this Agreement.

(C.S.M.F. (ECF No. 328) ¶ 6.) The Rehab/Restorative Cardiology Services Agreement contained substantially identical language:

> The terms of this Agreement shall begin on January 1, 2006 (the "Commencement Date") and shall continue through December 31, 2006, at which time this Agreement shall terminate automatically, unless the parties have agreed in writing to an extension of renewal.

(Id.)

The Clinical Cardiology Services Agreement contained the following language in a 2006 addendum:

> The terms of the Agreement shall be extended to December 31, 2006, at which time the Agreement shall expire, unless terminated sooner as provided for in the Agreement.

(Id. ¶ 7.)

Upon reaching the stated expiration date of December 31, 2006, none of the original six medical directorship agreements were formally extended or renewed. (C.S.M.F. (ECF No. 328) ¶ 9.) Nonetheless, for much of 2007, Hamot and Medicor continued to operate as if the

agreements were still in effect. (Id.) This course of conduct was acknowledged in a memorandum issued by Dr. Joseph McClellan, Senior Vice-President and Medical Director of Hamot Heart Institute, on September 26, 2007:

> Medicor has six medical directorship contracts for, 1) electrophysiology, 2) cardiac catheterization, 3) non-invasive services, 4) clinical cardiovascular services, 5) rehab services, and 6) the Heart Institute diagnostic testing.
>
> It is my understanding that the first 5 of these contracts officially expired on December 31, 2006, however, we have continued to operate under these agreements; the physicians have continued to fulfill the elements of these contracts and payment for these services has continued.
>
> It is our suggestion that contracts be prepared to cover the period from January 1, 2007 until December 31, 2007 under the same terms with the same physicians, at which point they should all expire without any further clauses for automatic renewal. Our expectation is that all payments to the physicians will also cease when these contracts terminate, i.e., upon termination on December 31, 2007, there will no longer be any payment made to the Medicor physicians unless an agreement is reached to renew the contracts with them before that date.

(Id. ¶ 10.)

On November 29, 2007, the parties executed formalized documents, characterized as "addendums," which provided that the terms of each of the five expired medical directorship agreements "shall be extended to December 31, 2007, at which time [the] Agreement shall expire, unless terminated sooner as provided for in the Agreement." (Id. ¶ 16.)[3] Each addendum was backdated to January 1, 2007. (ECF Nos. 279-15, 279-17, 279-18, 279-19, 279-20, 279-21.) A cover letter attached to each addendum stated that, "after December 31, 2007, these Agreements will expire and no further payments will be made on these Agreements unless new Agreements have been completed and fully-executed." (ECF No. 279-36.).

[3] The addendum for the Rehab/Restorative Cardiology Services Agreement only extended that agreement to September 30, 2007. (C.S.M.F. (ECF No. 328) ¶ 17.) That arrangement was subsequently discontinued.

On December 31, 2007, the five remaining medical directorship agreements again reached their stated termination date. (C.S.M.F. (ECF No. 328) ¶ 20.) As in 2007, the parties continued to tender invoices and payments in a manner consistent with their conduct pursuant to the written agreements. (Id.) On December 18, 2008, the parties executed another series of backdated addenda extending the terms of the original contracts "to June 30, 2009," at which point the agreements "[would] expire, unless terminated sooner as provided for in the Agreement." (Id. ¶¶ 21-22.)

The same circumstances presented in 2009. Despite reaching the stated termination date of the governing agreements on June 30, 2009, the parties continued to submit invoices and make payments pursuant to the agreements until March 31, 2010. (Id. ¶¶ 24-25.) At that time, Hamot and Medicor entered into a global Cardiology Outpatient Services Agreement that completely restructured their relationship and eliminated the various medical directorship arrangements between the parties. (Id. ¶ 25.)

In the meantime, Hamot and Medicor had begun to discuss the possibility of entering into arrangements covering two additional service areas: a Women's Heart Health Program and a Chairman for Hamot's Department of Cardiovascular Medicine and Surgery ("CV Chair"). (Hamot C.S.F. (ECF No. 288) ¶ 18; C.S.M.F. (ECF No. 328) ¶¶ 212-13, 256.) Hamot and Medicor had begun working toward implementing a dedicated Women's Heart Program as early as 2007. (C.S.M.F. ¶ 212.) By February 25, 2008, Hamot was considering creating a new medical directorship position for Dr. Kelly Hayes for services performed in conjunction with the Women's Heart Program. (Id. ¶ 215.) Although the record contains a draft "Agreement for Medical Supervision and Direction of the Women's Cardiac Services Program" with a proposed effective date of July 1, 2008 (ECF No. 304-26), this document, prepared at some point after

November 19, 2008, was never signed by the parties. (Id.; C.S.M.F. (ECF No. 328) ¶¶ 220-21; Irwin Depo. (ECF No. 289-22) at 134-35.) Lisa Irwin, Medicor's Rule 30(b)(6) designee, testified that she was "not aware that an agreement was signed but Dr. Kelly Hayes provided that medical directorship's services and still does." (Irwin Depo. (ECF No. 289-22) at 134-35.) Despite the absence of a signed agreement, Hamot made payments to Medicor pursuant to this arrangement through March 31, 2010. (C.S.M.F. (ECF No. 328) ¶ 223.)

Discussions concerning a paid CV Chair position arose in 2008, when Dr. McClellan's departure from Hamot led to Medicor physician Dr. Ferraro assuming the administrative duties of a CV Chair. (Hamot C.S.F. (ECF No. 288) ¶ 35; C.S.M.F. (ECF No. 328) ¶¶ 255-257.) By at least November 19, 2008, Hamot and Medicor had agreed that Dr. Ferraro should be compensated for this work. (C.S.M.F. (ECF No. 328) ¶ 259.) However, no formal arrangement memorializing this agreement exists. (Irwin Depo. (ECF No. 289-22) at 136-37.) Irwin testified that no formal document was ever executed with respect to Dr. Ferraro's payments for the CV Chair position, and Dr. Ferraro testified that he "never really had a formal directorship per se." (Irwin Depo. (ECF No. 289-22) at 136-37; Ferraro Depo. (ECF No. 289-26) at 24.) Nonetheless, Hamot paid for Dr. Ferraro's services as CV Chair until March 31, 2010. (Hamot C.S.F. (ECF No. 288) ¶ 37.)

III. Procedural History

Plaintiff filed a complaint under seal on October 8, 2010, asserting four counts pursuant to §§ 3729 and 3732(a) of the FCA. (ECF No. 1.) A copy of the complaint was served upon the government and, on September 7, 2011, the government elected not to intervene. (ECF No. 10.) Plaintiff opted to proceed with the action on his own.

On November 30, 2012, Plaintiff filed an amended complaint. (ECF No. 64.) Plaintiff's claims in that pleading fell into essentially two categories. First, he alleged that the medical directorship arrangements entered into between Hamot, Medicor, and an entity known as Flagship Cardiac, Vascular, and Thoracic Surgery of Erie ("Flagship") were shams enacted for the purpose of inducing unlawful patient referrals. (Am. Compl. (ECF No. 64) ¶¶ 98-102.) Secondly, he alleged that Doctors Ferraro, Furr, Petrella, Trageser, and Donald Zone ("Zone") "knowingly, systematically, routinely and repeatedly" performed medically unnecessary cardiac and vascular procedures for profit. (Id. ¶¶ 129-148.)

Each defendant moved to dismiss pursuant to Rule 12(b) of the Federal Rules of Civil Procedure. (ECF Nos. 67, 69, 71, 73.) On July 26, 2013, the district judge to whom this action was previously assigned entered a memorandum order dismissing Flagship and Dr. Zone from this action for failure to state a claim. (ECF No. 89.) The motions to dismiss filed by Hamot, Medicor, and the remaining physician defendants were denied. (Id.)

On February 25, 2016, Plaintiff filed a notice withdrawing his claims based on medically unnecessary procedures. (ECF No. 253.)

On July 8, 2016, Medicor (ECF No. 280), Hamot (ECF No. 286), and the physician defendants (ECF No. 282) filed motions for summary judgment pursuant to Federal Rule of Civil Procedure 56. Plaintiff responded to each motion on August 22, 2016. (ECF Nos. 305, 306, 308.) Defendants filed reply briefs in support of their summary judgment motions on September 6, 2016. (ECF Nos. 317, 319.)

On July 8, 2016, Plaintiff filed a cross-motion seeking partial summary judgment with respect to several discrete aspects of his Stark Act claim. (ECF No. 276.) The defendants responded to the motion (ECF Nos. 300, 303), and Plaintiff filed a brief in reply. (ECF No. 313.)

On September 6, 2016, the defendants filed a joint motion to strike (ECF No. 321) the concise statements of material facts submitted by Plaintiff in response to the defendants' motions for summary judgment (ECF Nos. 307, 309.) On September 15, 2016, the defendants filed a similar motion to strike (ECF No. 324) the concise statement of material facts submitted by Plaintiff in support of his own summary judgment motion (ECF No. 314.)[4]

On January 6, 2017, the United States Government sought and received leave to file a Statement of Interest with respect to several issues raised in the parties' summary judgment motions. (ECF No. 339.) On February 7, 2017, the defendants filed a response to the government's position statement. (ECF No. 341.) The government filed a reply on February 17, 2017. (ECF No. 344.)

Each of these matters is now fully briefed and ripe for review.

IV. Standard of Review

Summary judgment may only be granted where the moving party shows that there is no genuine dispute as to any material fact, and that a judgment as a matter of law is warranted. FED. R. CIV. P. 56(a). Pursuant to Federal Rule of Civil Procedure 56, the court must enter summary judgment against a party who fails to make a showing sufficient to establish an element essential to his or her case, and on which he or she will bear the burden of proof at trial. Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). In evaluating the evidence, the court must interpret the facts in the light most favorable to the nonmoving party, drawing all reasonable inferences in his or her favor. Watson v. Abington Twp., 478 F.3d 144, 147 (3d Cir. 2007). The burden is initially on the moving party to demonstrate that the evidence contained in the record does not create a

[4] In their motions to strike, the defendants contend that Plaintiff's responses to the defendants' concise statements of material facts (ECF Nos. 307, 309, 314) contain impermissible legal argument. To the extent that Plaintiff's responses venture into the realm of legal argument, the court will separate and disregard any such statements. See Chamber Rule (3)(F)(c)(i). The defendants' motions to strike will be denied as moot.

genuine issue of material fact. Conoshenti v. Pub. Serv. Elec. & Gas Co., 364 F.3d 135, 140 (3d Cir. 2004). A dispute is "genuine" if the evidence is such that a reasonable trier of fact could render a finding in favor of the nonmoving party. McGreevy v. Stroup, 413 F.3d 359, 363 (3d Cir. 2005). Where the nonmoving party will bear the burden of proof at trial, the moving party may meet its burden by showing that the admissible evidence contained in the record would be insufficient to carry the nonmoving party's burden of proof. Celotex Corp., 477 U.S. at 322. Once the moving party satisfies its burden, the burden shifts to the nonmoving party, who must go beyond his or her pleadings and designate specific facts by the use of affidavits, depositions, admissions or answers to interrogatories showing that there is a genuine issue of material fact for trial. Id. at 324. The nonmoving party cannot defeat a well-supported motion for summary judgment by simply reasserting unsupported factual allegations contained in his or her pleadings. Williams v. Borough of West Chester, 891 F.2d 458, 460 (3d Cir. 1989).

V. Discussion

Plaintiff initiated this action pursuant to the FCA, which imposes liability on any person or entity who "knowingly presents, or causes to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1). In this instance, Plaintiff alleges that the defendants submitted claims to Medicare in violation of the Stark Act and the Anti-Kickback Act. Both the Stark Act and the Anti-Kickback Act prohibit a health care entity from submitting claims to Medicare based upon referrals from physicians who have a "financial relationship" with the health care entity, unless a statutory or regulatory exception or safe harbor applies. 42 U.S.C. §§ 1395nn(a)(1); 1320a-7b(b). "Falsely certifying compliance with the Stark or Anti-Kickback Acts in connection with a claim submitted to a federally funded insurance program is actionable under the FCA." United States

ex rel. Kosenske v. Carlisle HMA, Inc., 554 F.3d 88, 95 (3d Cir. 2009) (citing United States ex rel. Schmidt v. Zimmer, Inc., 386 F.3d 235, 243 (3d Cir. 2004) (other citations omitted)).

Plaintiff seeks partial summary judgment with respect to the following two issues:

(1) A "financial relationship" within the meaning of the Stark Act existed between Hamot and the physician defendants at all times subsequent to December 4, 2007; and

(2) No Stark Law exception applied to that financial relationship for several discrete periods of time between January 1, 2008 and March 31, 2010.

(Plaintiff's Motion for Partial Summary Judgment on Stark Act Issues (ECF No. 276) at 1) ("Plaintiff MSJ").

The defendants, in turn, seek judgment on all claims. The defendants broadly contend that Plaintiff cannot satisfy either the scienter or the materiality elements of his FCA claims. (Defendant UPMC Hamot's Brief in Support of Motion for Summary Judgment[5] ("Hamot Brief in Support") (ECF No. 287) at 5; Brief in Support of Motion for Summary Judgment on Behalf of Individually Named Physician Defendants ("Physician Defendants' Brief in Support") (ECF No. 283) at 2). In addition, the individual physician defendants maintain that Plaintiff failed to adduce any evidence to support individual liability against any of them. (Physician Defendants' Brief in Support (ECF No. 283) at 8-19.) Each of these motions will be addressed in turn.

A. Plaintiff's Partial Motion for Summary Judgment on Stark Act[6] Issues

Section 1395nn(a)(1) of the Stark Act provides, in pertinent part, that:

[5] Medicor's motion for summary judgment simply incorporates the arguments expressed in Hamot's motion.

[6] Although the parties focus their arguments almost entirely upon the Stark Act, the same analysis applies to the defendants' alleged violations of the Anti-Kickback Act. See Kosenske, 554 F.3d at 91 (observing that "the requirements of the Anti-Kickback Act and its implementary regulations are indistinguishable from those of the Stark Act"); United States *ex rel*. Singh v. Bradford Regional Medical Center, 752 F.Supp.2d 602, 616 (W.D. Pa. 2010) (noting that "the requirements of the Anti-Kickback Act and its implementary regulations are for the most part the same as the Stark Act."). Under both legislative acts, a defendant can avoid liability by demonstrating that either a statutory or regulatory exception (or safe harbor) applies. United States *ex rel*. Bartlett v. Ashcroft, 39 F.Supp.3d 656, 679 (W.D. Pa. 2014) ("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.").

> If a physician . . . has a financial relationship with an entity . . ., 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 title, and (B) the entity may not present or cause to be presented a claim under this title 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). 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. Kosenske, 554 F.3d at 94 (citing 42 U.S.C. § 1395nn(a)(2)). The 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." Id. at 95 (citing Jo-Ellyn Sakowitz Klein, *The Stark Laws: Conquering Physician Conflicts of Interest*?, 87 GEO. L.J. 499, 511 (1998)).

The Stark Act also recognizes, however, that financial arrangements between physicians and health care entities may exist for "reasons independent of referrals." Id. Thus, the Stark Act contains a number of statutory exceptions covering a variety of financial arrangements, 42 U.S.C. § 1395nn(b)-(e), and permits the Secretary of the Department of Health and Human Services to promulgate regulations providing additional exceptions. See 42 U.S.C. § 1395nn(b)(4). Once the plaintiff or the government has established a violation of the Stark Act, the defendant bears the burden of establishing that the conduct was protected by an exception. Kosenske, 554 F.3d at 95 (citing United States v. Rogan, 459 F.Supp.2d 692, 717 (N.D. Ill. 2006)).

The parties do not appear to dispute that a financial relationship existed among Hamot, Medicor, and the individual physician defendants. As such, the sole issue presented in Plaintiff's motion is whether the compensation arrangements satisfied one of the Stark Act exceptions

during the relevant time periods. The defendants contend that the following three exceptions are applicable: the fair market value exception, 42 C.F.R. §411.357(l); the personal services arrangements exception, 42 C.F.R. § 411.357(d)(1); and the isolated transaction exception, 42 C.F.R. § 411.357(f).[7] Each exception will be addressed.

1. The Fair Market Value and Personal Service Arrangement Exceptions

With respect to both the fair market value exception and the personal service arrangement exception, Plaintiff's argument at this stage is extremely narrow. For purposes of the instant motion, there is no argument raised about the commercial reasonableness of the arrangements or their fair market value. Instead, Plaintiff seeks summary judgment on the limited basis that the written agreements governing the medical directorship arrangements were occasionally allowed to lapse between January 1, 2008, and March 31, 2010. According to Plaintiff, these lapses violate the statutory and regulatory requirement that any such agreements must be "in writing."

The "fair market value" exception to the Stark Act states that an arrangement for compensation between a physician and an entity does not violate the Act if the arrangement is set forth in an agreement that meets the following conditions:

> (1) **The arrangement is in writing, signed by the parties, and covers only identifiable items or services, all of which are specified in writing**.
>
> (2) **The writing specifies the timeframe for the arrangement**, which can be for any period of time and contain a termination clause, provided that the parties enter into only one arrangement for the same items or services during the course of a year. An arrangement may be renewed any number of times if the terms of the arrangement and the compensation for the same items or services do not change.
>
> (3) **The writing specifies the compensation that will be provided under the arrangement**. The compensation must be set in advance,

[7] Although the defendants argue these exceptions are applicable, they have explicitly declined to seek summary judgment on this basis, noting that "the applicability of Stark exceptions is a highly fact-intensive exercise and not suitable for resolution at summary judgment under the facts of this case." (ECF No. 287 at 21 n. 5.)

> consistent with fair market value, and not determined in a manner that takes into account the volume or value of referrals or other business generated by the referring physician.
>
> (4) The arrangement is commercially reasonable (taking into account the nature and scope of the transaction) and furthers the legitimate business purposes of the parties.
>
> (5) The 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.
>
> (6) The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates a Federal or State law.

42 C.F.R. § 411.357(l) (emphasis added). The "personal services arrangements" exception contains a similar writing requirement:

> (1) **The arrangement is set out in writing, is signed by the parties, and specifies the services covered by the arrangement.**
>
> (2) The arrangements cover all of the services to be furnished by the physician (or an immediate family member of the physician) to the entity.
>
> (3) The aggregate services covered by the arrangements do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangements.
>
> (4) The duration of each arrangement is at least 1 year. To meet this requirement, if an arrangement is terminated with or without cause, the parties may not enter into the same or substantially the same arrangement during the first year of the original arrangement.
>
> (5) The compensation to be paid over the term of each arrangement is set in advance, does not exceed fair market value, and, except in the case of a physician incentive plan (as defined at § 411.351 of this subpart), is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.
>
> (6) The services to be furnished under each arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any Federal or State law.

> (7) A holdover personal service arrangement for up to 6 months following the expiration of an agreement of at least 1 year that met the conditions of paragraph (d) of this section satisfies the requirements of paragraph (d) of this section, provided that the holdover personal service arrangement is on the same terms and conditions as the immediately preceding agreement.

42 C.F.R. § 411.357(d) (emphasis added).[8]

This writing requirement is not a mere technicality. The Stark Act "insist[s] on the transparency and verifiability that comes from an express agreement reduced to writing and signed by the parties which specifies all of the services to be provided by the physician and all of the remuneration to be received for those services." Kosenske, 554 F.3d at 96. In Kosenske, for example, a group of physicians ("BMAA") had entered into a written agreement in 1992 to provide certain anesthesiology services to a local hospital. Id. at 91. Approximately six years later, BMAA began providing pain management services to the hospital at a separate, stand-alone facility. Id. at 93. The district court held that this pain management clinic fell within the personal service arrangements exception to the Stark Act, "tacitly assum[ing] that the [1992] Agreement was applicable to BMAA's service at the Pain Clinic." Id. at 96. The Third Circuit Court of Appeals disagreed:

> In this case, the only written contract in existence between the parties is one that did not, and obviously was not intended to, apply to services at a non-existent facility. It was negotiated in 1992 in a context wholly different from the one that existed six years later after the opening of the Pain Clinic. No pain management services were being provided by BMAA in 1992, and by 1998 it was providing exclusive pain management services for a facility devoted solely to such services. Similarly, with respect to the value to be received by BMAA for those services, in 1992 no free Hospital space, staff or facilities were devoted solely to pain management, and the opening of the Pain Clinic represented a very substantial change.

[8] The Anti-Kickback Act's safe harbor for "Personal services and management contracts" contains a similar writing requirement. See 42 C.F.R. § 1001.952(d)(1) (requiring that any agreement governing payments from a principal to an agent as remuneration for services must be "set out in writing and signed by the parties.").

> In this context, it is apparent that there was no written contract setting forth the relevant arrangement at the Pain Clinic following its opening. Moreover, even if the 1992 Agreement could otherwise be read as reflecting the parties' arrangement at the Pain Clinic, that Agreement said nothing about much of the consideration that BMAA was receiving for its services. The Agreement says nothing whatsoever about the provision of free office space, equipment and staff necessary to the practice of pain management, much less about a stand-alone Pain Clinic.

Id. at 97. Based on the absence of a written agreement, the court of appeals held that BMAA and the hospital had failed to carry their burden of proving that the personal service arrangements exception applied to their activities at the Pain Clinic. Id. at 98; see Singh, 752 F.Supp.2d at 634 (reiterating that many of the Stark Act exceptions require that "the compensation arrangement must be set out in writing, signed by the parties, and specify the services, equipment, or premises covered by the agreement.").

The Center for Medicare and Medicaid Services ("CMS"), the administrative agency primarily responsible for interpreting the Stark Act, has also emphasized that the requirements of the statutory exceptions – including the writing requirement – must each be satisfied at all times. As stated by the CMS, an arrangement cannot satisfy a statutory exception unless it is signed by the parties and set forth in a document or collection of documents that "permit a reasonable person to verify that the arrangement complied with an applicable exception at the time a referral is made." 80 Fed. Reg. 70886, 71316. Compliance with the statutory requirements of the exception must be demonstrated at the time of each physician referral at issue:

> Under the physician self-referral statute, a physician may not refer DHS to an entity, and the entity may not bill Medicare for such referred DHS, if the physician (or an immediate family member) has a financial relationship with the entity, unless an exception applies. For purposes of determining whether a referral for DHS (and the billing of such referred DHS) is protected by an exception, we believe that the most natural reading of the statute is that all of the requirements of the exception must be met at the time the referral is made. Further, we believe that the

> statute does not contemplate that parties have the right to back-date arrangements, return compensation, or otherwise attempt to turn back the clock so as to bring arrangements into compliance retroactively.

73 Fed. Reg. 48434, 48703.

On the other hand, the CMS has acknowledged that an arrangement does not necessarily need to be reduced to "a single 'formal' written contract (that is, a single document that includes all material aspects of the arrangement)" to satisfy the writing requirement:

> In most instances, a single written document memorializing the key facts of an arrangement provides the surest and most straightforward means of establishing compliance with the applicable exception. However, there is no requirement under the physician self-referral law that an arrangement be documented in a single formal contract. Depending on the facts and circumstances of the arrangement and the available documentation, a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties, may satisfy the writing requirement of the leasing exceptions and other exceptions that require that an arrangement be set out in writing.

80 Fed. Reg. 70886, 71314-71315. The agency has provided a non-exhaustive list of "individual documents that a party might consider as part of a collection of documents when determining whether a compensation arrangement complied with the writing requirement of an applicable exception." Id. at 71316. These documents include: "Board meeting minutes or other documents authorizing payments for specified services; written communication between the parties, including hard copy and electronic communication; fee schedules for specified service; check requests or invoices identifying items or services provided, relevant date, and/or rate of compensation; time sheets documenting services performed; call coverage schedules or similar documents providing dates of services to be provided; accounts payable or receivable records documenting the date and rate of payment and the reason of payment; and checks issued for items, services, or rent." Id. Importantly, the CMS has noted that "compliance with the writing

requirement is fact-specific" and "depend[ant] on the facts and circumstances of the arrangement and the available documentation." Id.

With these principles in mind, the original six medical directorship agreements will be addressed. As noted above, the agreements covering each of these medical directorships contained specific dates upon which the agreements were set to expire unless renewed. When those dates passed without the agreements being formally extended, Hamot continued to make payments to Medicor for invoiced services pursuant to the agreements. The agreements were eventually extended through formally executed addenda. The critical question is whether sufficient documentation "evidencing the course of conduct of the parties" exists for the periods of time in between the expiration of the agreements and the execution of the addenda. 80 Fed. Reg. 70886, 71316.

Relying on CMS's suggestion that a "collection of documents . . . may satisfy the written requirement of the leading exceptions" in lieu of a formal contract, the defendants contend that the directorship agreements did not expire because "documents evidencing the continued terms of these agreements existed at all times payments were made." ECF No. 328 ¶ 9. The defendants primarily rely on a series of invoices submitted from Medicor to Hamot, along with corresponding checks from Hamot to Medicor, as evidence that the parties maintained a consistent course of conduct throughout the entire interval in which the written agreements appear to have expired. (C.S.M.F. (ECF No. 328) ¶¶ 161-203.) A review of the invoices, checks, and the written contracts leads to the same conclusion. The original six directorships were initially governed by formal contracts that clearly outlined the "identifiable services" to be provided under the agreement, the "timeframe for the arrangement," and "the "compensation that will be provided under the arrangement." See 42 C.F.R. § 411.357(l); C.S.M.F. (ECF No. 328)

¶¶ 117, 121, 125, 129, 133, and 137. The same requirements were satisfied by the subsequent addenda, each of which referenced a prior medical directorship agreement, stated the parties' intention to extend that agreement for a "period of twelve (12) months," and incorporated the "unchanged" terms of the prior agreement. (ECF Nos. 279-15, 279-17, 279-18, 279-19, 279-20, 279-21.) The checks and invoices exchanged throughout the duration of the agreements – and in between – applied to specific services, covered discrete periods of time, and were commensurate with the rates of compensation specified in the written contracts and addenda. (ECF No. 304-19.) "[C]heck requests [and] invoices identifying items or services provided, relevant date[s], and/or rate of compensation" are explicitly cited by the CMS as examples of individual documents that may be viewed collectively for purposes of satisfying the writing requirement. 80 Fed. Reg. 70886, 71316. When viewed in conjunction with the original written agreements and the subsequent addenda, each of which are formalized documents that meet the statutory standards, a reasonable jury could conclude that the defendants presented the necessary "collection of documents, including contemporaneous documents evidencing the course of conduct between the parties," to "satisfy the writing requirement of the leasing exceptions and other exceptions that require that an arrangement be set out in writing." 80 Fed. Reg. 70886, 71314-71315.

A different conclusion must be reached with respect to the Women's Hearth Health directorship and the CV Chair directorship. The record reflects that the terms and conditions of those directorships were never memorialized in any sort of executed or signed document. Lisa Irwin, Medicor's Rule 30(b)(6) designee, conceded that Medicor was not aware of any signed agreements relating to either of those directorships. (Irwin Depo. (ECF No. 279-48) at 134-37.) Medicor's CEO, Gary Maras ("Maras"), admitted that he was not aware of any such contracts,

despite that he would have ordinarily "participated . . . in their efforts to develop those contracts." (Maras Depo. (ECF No. 279-43) at 208, 228-30.) Stephen Danch ("Danch"), Hamot's CFO, acknowledged that Hamot was unable to produce contracts for either of those directorships. (Danch Depo. (ECF No. 279-47) at 92-94, 96.)

In the absence of a signed contract, the defendants attempt to rely on "contemporaneous documents evidencing the course of conduct of the parties" to satisfy the Stark Act's writing requirement. 80 Fed. Reg. 70886, 71314-71315. The defendants cite a handful of email, memoranda, and an unsigned draft agreement for the proposed Women's Heart Health directorship. (ECF Nos. 304-22, 304-23, 304-24, 304-25, 304-26, 304-27, 304-28.) While these kinds of documents may generally be considered in determining whether the writing requirement is satisfied, it is essential that the documents outline, at an absolute minimum, identifiable services, a timeframe, and a rate of compensation. See 42 C.F.R. § 411.357(l). Those critical terms do not appear in any of the documents cited by the defendants. For example, ECF Number 304-22, an email from Carole Weber to "Medicor Billing," simply states that Medicor would soon begin seeing patients as part of a "new initiative between Hamot and Medicor" called the "Women's Heart Program." (ECF No. 304-22). Aside from noting that Dr. Hayes and Audrey Swonger would perform screening and cardiac risk factor assessments, no other details are provided. Id.

The documents at ECF Numbers 304-23 and 304-25 consist of undated, unsigned memoranda recording some of the goals of the Women's Heart Health clinic. (ECF Nos. 304-23, 304-25.) These goals include: raising awareness of coronary heart disease among women; providing preliminary screening for risk factors; educating patients on risk factor modification; and performing examinations and screenings, as required. Id. While these documents provide

some indication of what kind of service might be provided under the Women's Heart Health arrangement, it is not clear to whom these documents were directed or circulated, and neither document discusses compensation or applicable timeframes. Id.

ECF Numbers 304-24 and 304-27 consist of a letter from Medicor to Hamot dated January 15, 2008, and a response letter dated February 25, 2008. (ECF Nos. 304-24, 304-27.) Each letter contains only a passing reference to the possibility of creating a directorship position for Dr. Hayes with a focus on women's cardiac health. (ECF No. 304-27 at 2; ECF No. 304-24 at 2.)

ECF Number 304-28 consists of an email thread among Maras, Danch, and Hamot CEO Jim Fiorenzo ("Fiorenzo"). Id. The only reference to the Women's Heart Health directorship is the following statement from Fiorenzo: "Womens' Cardiac Services Director . . . K. Hayes …… should be OK to go … implement and get contract together etc." Id.

Finally, ECF Number 304-26 is a draft agreement for the Women's Heart Health program. (ECF No. 304-26.) As discussed above, this draft agreement is unsigned, and there is no evidence that it was ever circulated or finalized. Id.

In short, none of the documents referenced by the defendants "would permit a reasonable person to verify that the [Women's Heart Health] arrangement complied with an applicable exception" at the time that referrals under that compensation arrangement were made. 80 Fed. Reg. 70886, 71316. As noted by Plaintiff, none of the documents are signed by the parties. The CMS has emphasized that the Stark Act requires at least one of the writings considered as part of a collection of documents to bear the signature of the parties:

> [U]nder the proposed rule – which is a clarification of our existing policy – it is the arrangement that must be signed by the parties to satisfy the exception. … To satisfy the signature requirement, a signature is required on a contemporaneous writing documenting the arrangement.

> The contemporaneous signed writing, when considered in the context of the collection of documents and the underlying arrangement, must clearly relate to the other documents in the collection and the arrangement that the party is seeking to protect.
>
> * * * * * * * *
>
> The signature requirement of certain compensation exceptions is statutory, and we believe that the requirement plays a role in preventing fraud and abuse. Among other things, the signature of the parties creates a record of the fact that the parties to an arrangement were aware of and assented to the key terms and conditions of the arrangement. Requiring parties to sign an arrangement encourages parties to monitor and review financial relationships between DHS entities and physicians.
>
> * * * * * * * *
>
> [I]t is not enough that the course of conduct between the parties could support an inference of assent to the terms. Rather, a signature is necessary to provide a written record of the assent of the parties to the arrangement.

Id. at 71316, 71333-71334. The lack of any document bearing a signature vitiates the sufficiency of the "collection of documents" proffered by the defendants in support of the Women's Heart Health arrangement. No reasonable jury could find that the Women's Heart Health arrangement was set forth in writing for purposes of the fair market value and personal service arrangement exceptions to the Stark Act.

The documentation offered in support of the CV Chair position is similarly deficient. The defendants contend that this arrangement is "described in writings to include Hamot's Bylaws, Hamot's Organizations and Functions Manual, meeting minutes, invoices, Hamot's general ledger, and electronic communications." (ECF No. 302 ¶ 261.) Hamot's bylaws, however, do not appear to contain any mention of a compensated directorship position, much less describe its terms. (ECF No. 304-30.) The cited meeting minutes provide evidence that Dr. Ferraro participated in regular departmental meetings, but they do not appear to describe the terms and conditions of any arrangement designating Dr. Ferraro to a CV Chair position. (ECF No. 304-33, 304-34, 304-35.) The only document reflecting any sort of discussion concerning

the compensation and timeframe applicable to the CV Chair arrangement is an email from Fiorenzo to Maras stating that a financial commitment made sense, but describing uncertainty concerning the amount:

> Executive Medical Director . . . Bob? . . . or whoever . . . will need to insure Bob is not named in other Med Director agreements directly as time evaluation and tracking could be conflicted . . . fundamentally OK . . . need to refine hours and commitment . . . worth 100K . . . doubt it . . . worth something . . . yes . . . need to size up and validate.

ECF No. 304-28. This document suggests that several critical terms had yet to be determined, rather than that they had been agreed upon. Finally, none of the cited documents have been signed by the parties "to provide a written record of the assent of the parties to the arrangement." 80 Fed. Reg. 70886, 71334. As with the Women's Heart Health directorship, no reasonable jury could find that the CV Chair arrangement was set forth in writing for purposes of the fair market value and personal service arrangements exceptions to the Stark Act.

2. The Isolated Transaction Exception

The "isolated transaction exception" protects compensation from an entity to a physician pursuant to an arrangement where:

> (1) The amount of remuneration under the isolated transaction is (i) consistent with fair market value of the transaction, and (ii) not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician or other business generated between the parties;
>
> (2) The remuneration is provided under an agreement that would be commercially reasonable even if the physician made no referrals to the entity;
>
> (3) There are no additional transactions between the parties for 6 months after the isolated transaction, except for transactions that are specifically excepted under the other provisions in § 411.357 and except for commercially reasonable post-closing adjustments that do not take into account (directly or indirectly) the volume or value of referrals or other business generated by the referring physician.

42 C.F.R. § 411.357(f).

The defendants invoke this exception with respect to a single payment issued from Hamot to Medicor on December 31, 2008. (C.S.M.F. (ECF No. 328) ¶¶ 227, 230.) This payment was issued in response to several separate invoices from Medicor to Hamot, including: (1) $35,000 for services provided under the Women's Heart Health directorship between July and December, 2008 (ECF No. 304-19 at 12); and (2) $50,000 for services provided under the CV Chair arrangement over that same time period (ECF No. 304-19 at 14). The defendants contend that this payment satisfies the isolated transactions exception to the Stark Act:

> The amount invoiced, and paid, for these services was fair market value and did not take into account the value or volume of referrals. Therefore, the terms for the Women's Cardiac Services Director and CV Chairman arrangements were fixed before the first payment, and only one payment was made before January 1, 2009. Nothing in the Isolated Transactions exception precludes the arrangement from subsequently qualifying for another exception so long as it is not the Isolated Transactions exception.

(ECF No. 300 at 17) (internal citations omitted).

The statute defines an "isolated financial transaction" as a transaction "involving a single payment between two or more persons or entities." 42 C.F.R. § 411.351. By its own terms, the isolated transactions exception generally applies to "[i]solated financial transactions, such as a one-time sale of property or a practice," rather than to discrete payments issued as part of an ongoing financial relationship. See 42 C.F.R. § 411.357(f). Indeed, although caselaw discussing this exception is scarce, it typically arises only in the context of uniquely singular transactions such as the purchase of an entire medical practice. See, e.g., United States *ex rel*. Perales v. St. Margaret's Hosp., 243 F.Supp.2d 843, (C.D. Ill. 2003) (addressing the isolated transactions exception in the context of a hospital's purchase of a physician's medical practice); United States

ex rel. Obert-Hong v. Advocate Health Care, 211 F.Supp.2d 1045, 1049 (N.D. Ill. 2002) ("[The Stark Act] contains an exception for isolated transactions. Purchasing a doctor's practice outright would seem a quintessential example.") (internal citation omitted). To qualify as an isolated transaction, there must also be "no additional transactions between the parties for 6 months after the isolated transaction, except for transactions that are specifically excepted under the other provisions in § 411.357 . . . ." 42 C.F.R. § 411.357(f)(3).

Unlike the singular transactions in Obert-Hong and Perales, the payment at issue here is more accurately characterized as the first installment in a series of payments relating to the Women's Heart Program and the CV Chair position. (C.S.M.F. (ECF No. 328) ¶¶ 224-239, 266-281.) There is no dispute that the parties provided uninterrupted services and payments related to those directorships through March 31, 2010. (C.S.M.F. (ECF No. 328) ¶¶ 222, 264.) As discussed previously, those services and payments do not qualify "under the other provisions in § 411.357," such as the fair market value and personal service arrangements exceptions, because they were not documented in writing. For each of these reasons, no reasonable jury could find that the defendants could satisfy the requirements of the isolated transactions exception.

3. Summary

Based upon the foregoing discussion, Plaintiff's partial motion for summary judgment will be granted in part and denied in part. Plaintiff's motion will be denied with respect to the original six medical directorships. As noted above, there are material issues of disputed fact concerning whether those directorships were adequately described in contemporaneous documents for purposes of the fair market value and personal service arrangements exceptions. See 80 Fed. Reg. 70886, 71316.

On the other hand, the court concludes that the arrangements with respect to the Women's Heart Health directorship and CV Chair position do not satisfy any of the exceptions cited by defendants. Those arrangements were never set forth in a signed writing or collection of writings and do not meet the requirements of the isolated transactions exception. Plaintiff's motion will be granted on the limited ground that those two directorships cannot satisfy a Stark Act exception during the relevant time period.

B. Hamot's and Medicor's Motions for Summary Judgment as to Scienter and Materiality

Section 3729 of the FCA imposes liability on any person who "knowingly presents, or causes to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1). To establish a violation of § 3729(a)(1) of the FCA, a relator (or the government) 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. United States *ex rel*. Wilkins v. United Health Grp., Inc., 659 F.3d 295, 304-05 (3d Cir. 2011); United States *ex rel*. Schmidt v. Zimmer, Inc., 386 F.3d 235, 242 (3d Cir. 2004). The plaintiff/relator must also establish that the alleged misrepresentation to the government was "material to the Government's payment decision in order to be actionable under the False Claims Act." Universal Health Services, Inc. v. U.S. *ex rel*. Escobar, 136 S.Ct. 1989, 2002 (2016). Hamot's motion, which is incorporated into Medicor's summary judgment motion, focuses on the scienter and materiality elements of Plaintiff's claim.

1. Scienter

For purposes of the FCA, the terms "knowing" and "knowingly" mean that "a person, with respect to information . . . (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b). Proof of specific intent to defraud is not required. Id. Thus, "liability is imposed not only for a person with actual knowledge of a false or fraudulent claim and the intent to defraud, but also . . . for a person who acts in deliberate ignorance or reckless disregard of a false or fraudulent claim and who does not intend to defraud." Singh, 752 F.Supp.2d at 642; see United States *ex rel*. Hefner v. Hackensack Univ. Med. Ctr., 495 F.3d 103, 109 (3d Cir. 2007) ("Congress explicitly expressed its intention that the [FCA] not punish honest mistakes or incorrect claims submitted through mere negligence."). Strict enforcement of the scienter requirement "help[s] to ensure that ordinary breaches of contract are not converted into FCA liability." United States v. Sci. Applications Int'l Corp., 626 F.3d 1257, 1270-71 (D.C. Cir. 2010).

The record is replete with testimonial evidence from Medicor and Hamot indicating that their physicians and administrators believed that the medical directorship agreements complied with the Stark Act. Furr, the President of Medicor throughout the relevant time period, testified that "it goes without saying that you have to be compliant with assorted regulations" and that it was his understanding that each of the arrangements between Medicor and Hamot complied with all applicable regulations. ECF No. 309 ¶ 76.[9] Ferraro testified that his duties as Chairman of

[9] Plaintiff repeatedly cites Hill v. City of Scranton, 411 F.3d 118, 129 (3d Cir. 2005), for the proposition that the "self-serving" testimony of interested parties must be disregarded. In Hill, the Third Circuit Court of Appeals suggested that a court should accord no weight to "evidence the jury is not required to believe, including testimony of interested witnesses." Id. at 129 n. 16. The court of appeals, however, subsequently clarified that, "in considering a motion for summary judgment the court should believe uncontradicted testimony unless it is inherently implausible even if the testimony is that of an interested witness." Lauren W. v. DeFlaminis, 480 F.3d 259, 271 (3d Cir. 2007). Lauren W., rather than Hill, provides the standard governing such testimony. See, e.g., Pollock v. City of Phila., Civ. No. 06-4089, 2008 WL 3457043, at *17 (E.D. Pa. Aug. 8, 2008) (noting that Hill was subsequently limited by Lauren W.); see Volek v. Redevelopment Auth. of Fayette, 24 F.Supp.3d 473, 476 (W.D.

the Cardiovascular Department required him to be at work at 5:00 in the morning, leave late at night, and strained his own clinical practice to the point that "pretty much one day a week was taken out of my clinical practice in order to fulfill" the requirements of the position. (Ferraro Depo. (ECF No. 289-26) at 43-44.) Trageser testified that he understood the scope of the duties that he was supposed to perform pursuant to his medical directorship, including managing schedules, training staff and physicians, learning to use new devices, managing procedures and protocols for patients, and managing relationships with vendors, and that these duties typically took anywhere from ten to forty-eight hours per week. (Trageser Depo. (ECF No. 289-35) at 14-15.) Petrella testified that he performed all his duties under his medical directorship agreement at all times between 2002 and 2014. (Petrella Depo. (ECF No. 289-34) at 60.)

By way of affidavit, each individual physician averred that he was aware of the medical director arrangements between Medicor and Hamot and that he believed, at all times, that those arrangements complied with all relevant rules and laws. (Ferraro Aff. (ECF No. 289-38) ¶ 26-27; Furr Aff. (ECF No. 289-39) ¶¶ 33-34; Petrella Aff. (ECF No. 289-41) ¶¶ 26-27; Trageser Aff. (ECF No. 289-42) ¶¶ 25-26.) Each physician maintained regular contact with Hamot's administrative staff and relied on those administrators to ensure that all contracts complied with applicable laws and regulations. (Ferraro Aff. (ECF No. 289-38) ¶ 19, 25; Furr Aff. (ECF No. 289-39) ¶¶ 22, 29-30, 32; Petrella Aff. (ECF No. 289-41) ¶¶ 25; Trageser Aff. (ECF No. 289-42) ¶ 24.) Finally, each physician averred that he performed all his responsibilities pursuant to those contracts without regard for referrals. (Ferraro Aff. (ECF No. 289-38) ¶¶ 17, 23; Furr Aff. (ECF No. 289-39) ¶¶ 19-20, 23; Petrella Aff. (ECF No. 289-41) ¶¶ 23; Trageser Aff. (ECF No. 289-42) ¶¶ 19, 22.)

Pa 2014) ("The Third Circuit instructs district courts to believe uncontradicted testimony unless it is inherently implausible even if the testimony is that of an interested witness.") (internal quotations omitted).

Hamot's Chief Financial Officer, Danch, testified that he believed that each of the arrangements Hamot entered into with Medicor complied with at least one Stark Act exception. Id. ¶ 80. Maras, CEO of Medicor and Vice President of Hamot, testified that he believed that the medical directorship arrangements contained standard language that he understood to comply with all legal requirements, including the Stark Act. (Maras Dep. (ECF No. 289-31) at 117-18.) Hamot CEO Fiorenzo testified that "[all] senior managers were worried about compliance." (Fiorenzo Depo. (ECF No. 289-27) at 35.)

Plaintiff's own testimony supports the notion that the medical directorships were "perfectly legitimate." (Plaintiff Depo. (ECF No. 289-36) at 25, 112.) Plaintiff testified that he consistently performed the services that were required of him pursuant to his own directorship agreement and that he was not aware of anyone else who failed to do so. (Id. at 25, 31-32, 137-138.) He admitted that he never falsified any records related to his performance or allowed false claims to be submitted on his behalf. (Id. at 32-33.)

On the other hand, there is ample evidence in the record to suggest that Hamot and Medicor may have knowingly violated the Stark Act in at least one manner: by submitting claims for payment arising from medical directorships that were not covered by a written agreement. In 2007, Dr. McClellan issued a memorandum stating that each of the original six medical directorship agreements had officially expired, but noting that Medicor physicians had continued providing services (and receiving payments) under those agreements:

> It is my understanding that the first 5 of these contracts officially expired on December 31, 2006, however, we have continued to operate under these agreements; the physicians have continued to fulfill the elements of these contracts and payment for these services has continued.

(C.S.M.F. (ECF No. 328) ¶ 9.) Even if a jury were to conclude that various addenda and other documentation satisfied the writing requirement with respect to those contracts, Dr. McClellan's

memorandum demonstrates that the parties were aware of the possibility that not all their services were being performed pursuant to a current and valid agreement. This awareness is critical because, as discussed above, the parties entered into two additional medical directorship arrangements that were never documented in a signed contract or otherwise adequate collection of documents.

There is no question that Hamot and Medicor were aware of the importance of complying with the Stark Act and its regulations. In 1998, during the exploratory stages of the relationship, Hamot engaged a law firm to address "legal issues involved in the development of a Heart Center." (Plaintiff's Response to Defendants' Joint Concise Statement of Facts ("Pl. R.S.F.") (ECF No. 309) ¶ 17.) The firm responded with an opinion letter cautioning that Medicor physicians "cannot own, or receive payments from, the [Hamot Heart] Institute unless such ownership or payments fits within a Stark exception." (Id. ¶ 18.) The firm rejected a proposed joint venture between Hamot and Medicor because "[t]he Stark Laws generally prohibit physicians from referring Medicare patients for 'designated health services' to an entity that the referring physician owns or receives payment from, unless such payment or ownership fits into one of the permitted exceptions set forth in the Stark statute or the regulations." (Id. ¶ 19.)

In 2004, Hamot engaged another law firm to review several draft medical director agreements. (Id. ¶ 27.) In an email dated December 27, 2004, counsel urged "Hamot and Medicor to have an independent valuation analysis done on the fair market valuation of [their] services." (Id.) The email expressed concern about whether fair value was being provided in the absence of any independent evaluation and noted that "the relationship between Medicor and Hamot is so close-knit that we have concern over what an auditor would say about the arrangement." (Id.)

In 2006, Hamot engaged a Stark Act consultant, John Fenner, to address Hamot's relationships with Medicor "[a]s a result of the federal government's requirements, including Medicare's anti-kickback law, [and] the physician self-referral ("Stark") law." (Id. ¶ 32.) Hamot asked Fenner to review whether the "current physician employment and independent contractor agreements" were in compliance with all regulations pertaining to fair market value, and whether there was "appropriate documentation of physician services on file" to support the compensation provided. (Id.) At least one district court has acknowledged that these kinds of discussions may provide evidence that any subsequent Stark Act violations were committed "knowingly" for purposes of the FCA:

> Relators argue that Defendants acted knowingly within the meaning of the False Claims Act. In support of their argument, Relators argue that the record evidence shows that Defendants and their attorneys were aware from the beginning of their discussions that led to the . . . arrangements that their conduct raised issues under the Stark Act and the Anti-Kickback Act. . . .
>
> This evidence shows that Defendants and their attorneys, while engaged in ongoing lengthy negotiations, were aware that the potential arrangements they were contemplating entering into implicated the Stark Act and the Anti-Kickback Act. . . .
>
> Based on the evidence a fact-finder could believe that when the parties entered into the [agreement], it was apparent, or should have been apparent, to Defendants that BRMC wanted to [enter the arrangement] to obtain Dr. Saleh's and Dr. Vaccaro's referrals . . . On the other hand, a factfinder could also believe that Defendants could not have acted "knowingly" based on the fact that they carefully sought to avoid requiring referrals and attempted to make a business decision based on the fair market value assessment of the arrangements.
>
> Again, the record is not strongly in favor of Defendants as it tends to show that Defendants entered into the [arrangement] fully aware that the arrangement . . . may not be permitted under the Stark Act and the Anti-Kickback Act.

Singh, 752 F.Supp.2d at 642-43.

The same conclusion is appropriate here. Based upon the record as a whole, a reasonable jury could conclude that Hamot and Medicor continued to submit claims for payment despite knowing that the underlying arrangements may not have been properly documented for purposes of Stark Act compliance. It is noteworthy that "issues of knowledge and intent are particularly inappropriate for resolution by summary judgment, since such issues must often be resolved on the basis of inferences drawn from the conduct of the parties." Riehl v. Travelers Ins. Co., 772 F.2d 19, 24 (3d Cir. 1985); see United States *ex rel*. Cantekin v. Univ. of Pittsburgh, 192 F.3d 402, 411 (3d Cir. 1999) ("In applying [the FCA's knowledge] standards to the record before us, we must heed the basic rule that a defendant's state of mind typically should not be decided on summary judgment."); Bartlett, 39 F.Supp.3d at 679 (noting that the scienter requirement in an FCA case is "largely a question of intent, resolution of which is the province of the trier of fact."). Hamot's and Medicor's motions for summary judgment with respect to scienter will be denied.

2. Materiality

To be actionable under the FCA, a misrepresentation must also be "material to the Government's payment decision." Escobar, 136 S.Ct. at 2002. Hamot and Medicor contend that, even if their submissions violated the Stark Act's writing requirements, those violations do not rise to the level of materiality required to support an FCA claim.

The FCA defines "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4); Escobar, 136 S.Ct. at 1996. In Escobar, the United States Supreme Court "clarified how [the] materiality requirement should be enforced" in FCA cases:

> The materiality standard is demanding. The False Claims Act is not "an all-purpose antifraud statute," Allison Engine, 553 U.S., at 672, 128

> S.Ct. 2123 or a vehicle for punishing garden-variety breaches of contract or regulatory violations. A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment. Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance. Materiality, in addition, cannot be found where noncompliance is minor or insubstantial. See United States *ex rel*. Marcus v. Hess, 317 U.S. 537, 543, 63 S.Ct. 379, 87 L.Ed. 443 (1943) (contractors' misrepresentation that they satisfied a non-collusive bidding requirement for federal program contracts violated the False Claims Act because "[t]he government's money would never have been placed in the joint fund for payment to respondents had its agents known the bids were collusive"); see also Junius Constr., 257 N.Y., at 400, 178 N.E., at 674 (an undisclosed fact was material because "[n]o one can say with reason that the plaintiff would have signed this contract if informed of the likelihood" of the undisclosed fact).
>
> In sum, when evaluating materiality under the False Claims Act, the Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive. Likewise, proof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement. Conversely, if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.

Escobar, 136 S.Ct. at 2003-04. A careful reading of the Court's decision reveals a number of factors that warrant consideration in determining materiality: whether compliance with a statute is a condition of payment; whether the violation goes to "the essence of the bargain" or is "minor or insubstantial"; and whether the government consistently pays or refuses to pay claims when it has knowledge of similar violations. Id. at 2003-04. "The language that the Supreme Court used in [Escobar] makes clear that courts are to conduct a holistic approach to determining materiality

in connection with a payment decision, with no one factor being necessarily dispositive." United States *ex rel*. Escobar v. Universal Health Servs., Inc., 842 F.3d 103, 109 (1st Cir. 2016).

Applying the Escobar factors to the instant case, it is clear that the alleged violations at issue here are material. As an initial matter, the Stark Act expressly prohibits Medicare from paying claims that do not satisfy each of its requirements, including every element of any applicable exception. 42 U.S.C. §§1395nn(a)(1), (g)(1). The relevant exceptions expressly require that any financial arrangements that would otherwise violate the Stark Act must be set forth in writing. 42 C.F.R. § 411.357(d), (l). Although "statutory, regulatory, and contractual requirements are not automatically material, even if they are labeled conditions of payment," they nevertheless represent "relevant" evidence in favor of materiality. Id. at 2002-03.

The writing requirement is not "minor or insubstantial." Id. at 2003. The Stark Act "insist[s] on the transparency and verifiability that comes from an express agreement reduced to writing and signed by the parties which specifies all of the services to be provided by the physician and all of the remuneration to be received for those services." Kosenske, 554 F.3d at 96. Compliance with the writing requirement permits a reviewer to analyze the timeframe, rate of compensation, and the identifiable services contemplated in the arrangement to determine whether any portion is based on the volume or value of physician referrals. See 42 C.F.R. § 411.357(l). CMS guidance also requires a signature as a manifestation of the parties' assent to the arrangement, a requirement that "plays a role in preventing fraud and abuse." 80 Fed. Reg. 70886, 71333-71334. These requirements go to the very "essence of the bargain" between the government and health care providers with respect to Stark Act compliance. Escobar, 136 S.Ct. at 2003 n. 5 (quoting Junius Contr. Co. v. Cohen, 178 N.E. 672, 674 (N.Y. 1931)).

There is no evidence in the record to suggest that "the Government consistently refuses to pay claims" based on Stark Act non-compliance (or, conversely, that "the Government pays [those claims] in full despite its actual knowledge that certain requirements were violated"). Id. at 2003-04. Plaintiff, however, has pointed to public records suggesting that health care providers have paid penalties after self-reporting similar violations on at least nine occasions since 2009. (ECF No. 310-12.) In the absence of any evidence to the contrary, this factor weighs slightly in favor of materiality.

On balance, a reasonable jury could find that the materiality requirement of the FCA is satisfied in the instant case. The writing requirements contained in several Stark Act exceptions are important, mandatory, and material to the government's payment decisions. Hamot's and Medicor's motions for summary judgment on this basis will be denied.

C. Physician Defendants' Motion for Summary Judgment

In his amended complaint, Plaintiff's only allegations concerning the individual physician defendants – Petrella, Ferraro, Furr, and Trageser – were that they routinely performed medically unnecessary cardiac procedures to receive payments from Medicare and Medicaid. (Am. Compl. (ECF No. 64) ¶¶ 129, 131.) Plaintiff withdrew those claims. (ECF No. 253.) None of the remaining allegations appear to refer to the physician defendants in any capacity.

To the extent that Plaintiff argues that his remaining claims apply to the individual physicians, Plaintiff must produce evidence to satisfy the scienter requirement *as to each individual defendant*, rather than the group as a collective. See United States *ex rel*. Burlbaw v. Orenduff, 548 F.3d 931, 950 (10th Cir. 2008) (noting that an FCA plaintiff must "produce sufficient evidence that each individual defendant – not the [organization] as an institutional whole – 'knowingly' submitted a false claim."). Plaintiff failed to adduce any such evidence.

Each individual physician provided sworn statements indicating that he believed that the medical directorships complied with all relevant regulations and laws and that he relied on Hamot's administrative staff to ensure compliance. (Ferraro Aff. (ECF No. 289-38) ¶¶ 19, 25-27; Furr Aff. (ECF No. 289-39) ¶¶ 22, 29-34; Petrella Aff. (ECF No. 289-41) ¶¶ 25-27; Trageser Aff. (ECF No. 289-42) ¶¶ 24-26.) There is nothing in the record to suggest that any individual defendant was aware that Hamot and Medicor may have failed to draft written agreements for some of their medical directorships or that the individual defendants were involved in negotiating, drafting, or formulating the terms and conditions of those agreements. As such, the individual physician defendants are entitled to summary judgment with respect to all claims against them.

VI. Summary

For the foregoing reasons, Plaintiff's partial motion for summary judgment will be granted in part and denied in part. Plaintiff's motion will be denied with respect to his contention that the original six medical directorships cannot satisfy the fair market value and personal service arrangements exceptions to the Stark Act because those agreements were not in writing. Plaintiff's motion will be granted with respect to the Women's Heart Health directorship and CV Chair position, neither of which can satisfy a Stark Act exception in the absence of a written agreement.

The motion for summary judgment filed by Hamot and Medicor is denied, as there are material issues of disputed fact concerning both scienter and materiality.

The individual physician defendants' motion for summary judgment is granted. Judgment will be entered in favor of Furr, Trageser, Ferraro and Petrella with respect to all claims against them.

An appropriate order follows.

By the court:

/s/ Joy Flowers Conti
Joy Flowers Conti
Chief United States District Judge

Dated: March 15, 2017