UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

USA and ELIN BAKLID-KUNZ,

Plaintiffs,

v. **Case No: 6:09-cv-1002-Orl-31TBS**

HALIFAX HOSPITAL MEDICAL CENTER and HALIFAX STAFFING, INC.,

Defendants.

ORDER

This matter comes before the Court without a hearing on the Motion for Partial Summary Judgment (Doc. 272) filed by the United States of America (henceforth, the "Government"), the response in opposition (Doc. 317) filed by the Defendants, and the reply (Doc. 332) filed by the Government.

I. Background

Halifax Hospital Medical Center ("Halifax Hospital") is a special taxing district that operates a community hospital of the same name in Volusia County, Florida. (Doc. 277 at 9). Halifax Staffing, Inc. ("Halifax Staffing") is an instrumentality of Halifax Hospital. Halifax Staffing employs the individuals who work for Halifax Hospital. Halifax Hospital pays all of the expenses and obligations of Halifax Staffing, including payroll, either directly or by transfer of funds into Halifax Staffing's payroll account.

Halifax Staffing entered into employment agreements with six medical oncologists: Boon Chew, Walter Durkin, Ruby Anne Deveras, Abdul Sorathia, Richard Weiss, and Gregory Favis

(collectively, the "Medical Oncologists"). The employment agreements provided that the Medical Oncologists would receive a salary and bonuses. (Doc. 277 at 11).

The Medical Oncologists treated patients at Halifax Hospital on both an inpatient and outpatient basis and, *inter alia*, ordered or requested outpatient prescription drugs for their patients. Whenever one of the Medical Oncologists personally performed a Medicare-reimbursable procedure, Halifax Hospital would submit two claims for payment to Medicare – one for the physician's services and a second for the facility fee, which would include items such as providing space and equipment, (Doc. 272 at 9, Doc. 317 at 7 n.6).

Until March 1, 2007, the Centers for Medicare & Medicaid Services ("CMS"), the agency within the Department of Health and Human Services that oversees Medicare claims processing, required that claims for these facility fees be submitted using what was known as a "Form UB-92"; after that date, CMS required that such claims be submitted using a "Form UB-04."

Both of these forms included fields that required the identification of what might be thought of as the patient's attending physician and, where applicable, the patient's operating physician, although the titles and descriptions of the pertinent fields varied somewhat between the two forms. The fields to be filled out in a Form UB-92 included one labeled "Attending Phys. ID," 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" 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.

Form UB-04 had a field, labeled "Attending," which the MCPM specified was required to be filled out whenever the "claim/encounter contains any services other than nonscheduled transportation services," that was used to identify "the individual who has overall responsibility for the patient's medical care and treatment reported in this claim/encounter." Another field of Form UB-04, labeled "Operating," had to be filled in whenever a surgical procedure code was listed on the claim; the MCPM stated that the field was to be used to identify "the individual with the primary responsibility for performing the surgical procedure."

For simplicity's sake, the remainder of this opinion will refer to physicians identified in the "Attending Phys. ID" field on Form UB-92 or in the "Attending" field on Form UB-04 as "attending physicians." Similarly, the opinion will refer to physicians identified in the "Other Phys. ID" field on Form UB-92 or in the "Operating" field on Form UB-04 as "operating physicians".

To participate in the Medicare program, Halifax Hospital was required to periodically submit what is known as a Form CMS-855A. In that form, Halifax Hospital certified that it was complying with all applicable Medicare laws, regulations, and program instructions, and that it understood that payment of a Medicare claim was conditioned upon such compliance. Halifax Hospital submitted several of these forms during the time frame at issue in this case.

In fiscal year 2005, the Medical Oncologists became eligible to receive a bonus (henceforth, the "Incentive Bonus") pursuant to the following provision of their employment agreements:

> Compensation [Halifax Staffing] shall pay to Employee as compensation for services the following:

> …
>
> c. Beginning with the fiscal year ending September 30, 2005, an equitable portion of an Incentive Compensation pool which is equal to 15% of the operating margin for the Medical Oncology program as defined by the financial statements produced by the Finance Department on a quarterly basis. The amount of the incentive compensation distributed to the Employee shall be determined by the Medical Oncology Practice Management Group. This compensation shall be paid annually according to the operating margin for the fiscal year.

(Doc. 272-4 at 8-9, 21).[1] Although Halifax Hospital is a nonprofit entity, the operating margin for the Medical Oncology program was in essence what would be recognized in another context as profit – *i.e.*, the program's revenue less its expenses. (Doc. 272-8 at 71). In response to an interrogatory from the Government, the Defendants stated that the operating margin for the Medical Oncology program was made up of "revenue and direct expenses from outpatient medical oncology services" and that "[r]evenue consisted of outpatient medical oncology services, physician services, and related outpatient oncology pharmacy charges." (Doc. 272-4 at 24). The Defendants admit that the revenue at issue included fees for services that were not personally performed by the Medical Oncologists, such as fees for services related to the administration of chemotherapy. (Doc. 317 at 3).

The Incentive Compensation pool was divided between the six Medical Oncologists based on each individual oncologist's personally performed services. Halifax Staffing paid the Incentive Bonuses to the Medical Oncologists for fiscal years 2005-2008. (Doc. 313 at 3). During this time frame, Halifax Hospital submitted thousands of claim forms to Medicare in which one or more of

[1] While the quoted language comes from the employment agreement with Walter Durkin, the bonus provisions in the agreements with the other Medical Oncologists was identical.

the Medical Oncologists was identified as an attending physician or an operating physician. (Doc. 272-10 at 54-55).[2]

The Relator, Elin Baklid-Kunz ("Baklid-Kunz" or the "Relator") filed this *qui tam* action on June 16, 2009, alleging that the Defendants, *inter alia*, violated the Stark Law by billing Medicare for items provided as a result of referrals from physicians with whom the Defendants had improper financial relationships. (Doc. 1). On October 4, 2011, the Government announced that it had elected to intervene as to certain of the Relator's claims, including her Stark Act claim involving the Medical Oncologists. By way of the instant motion, the Government seeks summary judgment as to the alleged Stark Act violation; as well as related claims under the False Claims Act, for unjust enrichment and for payment by mistake; plus a number of affirmative defenses asserted by the Defendants.

II. Legal Standards

A. Summary Judgment

A party is entitled to summary judgment when the party can show that there is no genuine issue as to any material fact. Fed.R.Civ.P. 56(c). Which facts are material depends on the substantive law applicable to the case. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 106 S.Ct. 2505, 2510, 91 L.Ed.2d 202 (1986). The moving party bears the burden of showing that no genuine issue of material fact exists. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323, 106 S.Ct. 2548, 2553, 91 L.Ed.2d 265 (1986). In determining whether the moving party has satisfied its burden, the court considers all inferences drawn from the underlying facts in a light most favorable to the

[2] The claims data referenced by the Government's expert to determine the number of claims submitted extends from the beginning of fiscal year 2005 through February 28, 2009 – i.e., five months after the end of the last fiscal year in which the Medical Oncologists were eligible to receive the Incentive Bonus. As explained *infra*, the Government has now conceded for purposes of this motion that the claims data beyond fiscal year 2008 is not relevant, and has removed such claims from its damages calculation. (Doc. 332 at 8 n.5).

party opposing the motion, and resolves all reasonable doubts against the moving party. *Anderson*, 477 U.S. at 255, 106 S.Ct. at 2513.

When a party moving for summary judgment points out an absence of evidence on a dispositive issue for which the non-moving party bears the burden of proof at trial, the nonmoving party must "go beyond the pleadings and by [his] own affidavits, or by the depositions, answers to interrogatories, and admissions on file, designate specific facts showing that there is a genuine issue for trial." *Celotex Corp.*, 477 U.S. at 324, 106 S.Ct. at 2553. Thereafter, summary judgment is mandated against the nonmoving party who fails to make a showing sufficient to establish a genuine issue of fact for trial. *Id.* The party opposing a motion for summary judgment must rely on more than conclusory statements or allegations unsupported by facts. *Evers v. Gen. Motors Corp.*, 770 F.2d 984, 986 (11th Cir. 1985) ("conclusory allegations without specific supporting facts have no probative value").

The Court must consider all inferences drawn from the underlying facts in a light most favorable to the party opposing the motion, and resolve all reasonable doubts against the moving party. *Anderson*, 477 U.S. at 255, 106 S.Ct. at 2513. The Court is not, however, required to accept all of the non-movant's factual characterizations and legal arguments. *Beal v. Paramount Pictures Corp.*, 20 F.3d 454, 458-59 (11th Cir 1994).

B. The Stark Law

In an effort to contain health care costs and reduce conflicts of interest,[3] Congress passed amendments to the Social Security Act in 1989 and 1993 – known as "Stark I" and "Stark II,"

[3] Stark I and Stark II were passed in the wake of several reports suggesting that physicians with a financial interest in referrals tended to provide excess care. For example, in 1989 the Office of the Inspector General of for the Department of Health and Human Services ("HHS") issued the results of a study that found that "patients of referring physicians who own or invest in independent clinical laboratories received 45% more clinical laboratory services than … Medicare

respectively -- that prohibit physicians from referring their Medicare and Medicaid patients to business entities in which the physicians or their immediate family members have a financial interest. *See* Pub.L. No. 101–239, 103 Stat. 2106 (codified at 42 U.S.C. § 1395nn(a)); Pub.L. No. 103–66, 107 Stat. 312 (codified at 42 U.S.C. § 1395nn(a)).

> The Stark Statute establishes the clear rule that the United States will not pay for items or services ordered by physicians who have improper financial relationships with a hospital. Violation of the Stark Statute may also subject the billing entity to exclusion from participation in federal healthcare programs and various financial penalties. *See* 42 U.S.C. §§ 1395nn(g)(3), 1320a-7a(a).

United States v. Rogan, 459 F.Supp.2d 692, 711 (N.D.Ill. 2006), *aff'd*, 517 F.3d 449 (7th Cir. 2008).

Stark I was in effect between January 1, 1992 and December 31, 1994. It barred physicians from referring Medicare patients to an entity for clinical laboratory services if the physician had a prohibited financial relationship with such entity. 42 U.S.C.A. §1395nn(a)(1)(A) (West 1992). Stark II became effective on January 1, 1995. It expanded the list of prohibited referrals to include the following "designated health services" (henceforth, "DHS"):

> (A) Clinical laboratory services.
>
> (B) Physical therapy services.
>
> (C) Occupational therapy services.
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> (D) Radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services.
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> (E) Radiation therapy services and supplies.
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> (F) Durable medical equipment and supplies.

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patients in general." Steven D. Wales, The Stark Law: Boon or Boondoggle? An Analysis of the Prohibition on Physician Self-Referrals, 27 Law & Psychol. Review 1, 5 (2003). Later studies showed significant increases in referrals by physicians with financial interests (either due to ownership or receipt of bonuses) for such things as X-rays (16%), physical therapy and rehabilitation (39-45%), MRI scans (54%) and CT scans (27%). *Id.* at 6.

> (G) Parenteral and enteral nutrients, equipment, and supplies.
>
> (H) Prosthetics, orthotics, and prosthetic devices and supplies.
>
> (I) Home health services.
>
> (J) Outpatient prescription drugs.
>
> (K) Inpatient and outpatient hospital services.
>
> (L) Outpatient speech-language pathology services.

42 U.S.C. § 1395nn(a)(1), (h)(6).

In pertinent part, the Stark Law provides:

> (a) Prohibition of certain referrals
>
> (1) In general
>
> Except as provided in subsection (b) of this section, if 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). In addition to prohibiting the hospital from submitting claims under these circumstances, the Stark Law also prohibits payment by the Medicare program of such claims: "No payment may be made under this subchapter for a designated health service which is provided in violation of subsection (a)(1) of this section." 42 U.S.C. § 1395nn(g)(1).

The Stark Law broadly defines "financial relationships" to include an ownership or investment interest in an entity or a "compensation arrangement." 42 U.S.C. § 1395nn(a)(1). "Compensation arrangement," in turn, is defined as "any arrangement involving any remuneration between a physician (or an immediate family member of such physician) and an entity." 42

U.S.C. § 1395nn(h)(1)(A). "Remuneration," with certain exceptions not applicable to the instant case, includes "any remuneration, directly or indirectly, overtly or covertly, in cash or in kind." 42 U.S.C. § 1395nn(h)(1)(B).

"Referral," for purposes of the Stark Law, is defined as "the request or establishment of a plan of care by a physician which includes the provision of designated health services." 42 U.S.C. § 1395nn(h)(5)(A). The regulations interpreting the statute also broadly define "referral" as, among other things, "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. A referring physician is defined in the same regulation as "a physician who makes a referral as defined in this section or who directs another person or entity to make a referral or who controls referrals made to another person or entity." *Id*.

If a hospital submits prohibited claims and collects payment, the regulations implementing 42 U.S.C. § 1395nn expressly requires that any entity collecting payment for a healthcare service "performed under a prohibited referral must refund all collected amounts on a timely basis." 42 C.F.R. § 411.353(d).

The Stark Law sets forth several exceptions to its broad prohibition on compensation arrangements between health care entities and referring physicians. To avoid the referral and billing prohibitions in the statute, a hospital's financial relationship with a physician must fall into one of the exceptions. One such exception involves what the Stark Law describes as "bona fide employment relationships." Under this exception, amounts paid by an employer to a physician will not be considered a compensation arrangement for purposes of the Stark Law if

> (A) the employment is for identifiable services,
>
> (B) the amount of remuneration under the employment –
>
> (i) is consistent with the fair market value of the services, and
>
> (ii) is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician,
>
> (C) the remuneration is provided pursuant to an agreement which would be commercially reasonable even if no referrals were made to the employer, and
>
> (D) the employment meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

42 U.S.C. §1395nn(e)(2).

Once the Government has demonstrated proof of each element of a violation of the Stark Statue, the burden shifts to the defendant to establish that his conduct was protected by a safe harbor or exception. The Government need not prove, as an element of its case, that a defendant's conduct does not fit within a safe harbor or exception." *Rogan*, 459 F.Supp.2d at 715.

The Stark Law does not create its own cause of action. *U.S. ex rel. Drakeford v. Tuomey Healthcare Systems, Inc.*, 675 F.3d 394, 396 (4th Cir. 2012) (explaining, in case involving alleged violations of Stark Law, why the United States was seeking relief under the False Claims Act).

C. The False Claims Act

The False Claims Act (henceforth, the "FCA"), 31 U.S.C. § 3729 *et seq*., was enacted in 1863 as a means of combating frauds perpetrated by private contractors during the Civil War. *Vermont Agency of Natural Resources v. United States ex rel. Stevens*, 529 U.S. 765, 781, 120 S.Ct. 1858, 146 L.Ed.2d 836 (2000).[4] See *also Ragsdale v. Rubbermaid, Inc*., 193 F.3d 1235,

[4]See also *United States ex rel. Williams v. NEC Corp*., 931 F.2d 1493, 1496–98 (11th

1237 n. 1 (11th Cir.1999) ("The purpose of the [FCA], then and now, is to encourage private individuals who are aware of fraud being perpetrated against the government to bring such information forward.") (citation omitted); *and see United States ex rel. Williams v. NEC Corp.*, 931 F.2d 1493, 1496–98 (11th Cir.1991) (tracing history of FCA).

The FCA permits private persons (called "relators") to file a form of civil action (known as *qui tam*) against, and recover damages on behalf of the United States from, any person who:

> (1) knowingly presents, or causes to be presented, 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)(1)-(2) (2003).[5]

To prevail under the first of these two sections, a plaintiff must prove three things: (1) a false or fraudulent claim (2) was presented, or caused to be presented, by the defendant to the United States for payment or approval (3) with knowledge that the claim was false. *United States v. R&F Properties of Lake County, Inc.*, 433 F.3d 1349, 1355 (11th Cir. 2005). When a violator of government regulations is ineligible to participate in a government program and that violator persists in presenting claims for payment that the violator knows the government does not owe, that violator is liable, under the False Claims Act, for submission of those claims. *McNutt ex rel. U.S. v. Haleyville Medical Supplies, Inc.*, 423 F.3d 1256, 1259 (11th Cir. 2005) (holding that violation of Anti-Kickback Statute could form basis for qui tam action under FCA). The violation

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Cir.1991) (tracing history of Act).

[5] The FCA was amended in May 2009 and changes were made to 31 U.S.C.§ 3729(a)(2); however, the amended version of 31 U.S.C.§ 3729(a)(2) only applies to claims for payment (such as Medicare claims) pending on or after June 7, 2008. *Hopper v. Solvay Pharmaceuticals, Inc.*, 588 F.3d 1318, 1327 n.3 (11th Cir. 2009). The Government does not allege that any of the Medicare claims at issue here were pending on or after that date, and therefore the previous version of 31 U.S.C.§3729(a)(2) applies here.

of the regulations and the corresponding submission of claims for which payment is known by the claimant not to be owed make the claims false under Section 31 U.S.C. § 3729(a)(1). *Id. See also U.S. ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1311 (11th Cir. 2002) (stating that, in health care context, FCA liability does not arise from provider's disregard of Government regulations or failure to maintain proper internal policies unless those acts allow provider to knowingly ask Government to pay amounts it does not owe.)

Falsely certifying compliance with the Stark Law in connection with a claim submitted to a federally funded insurance program is actionable under 31 U.S.C. §3729(a)(2). *U.S. ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88, 94 (3d DCA 2009) (citing cases). To establish a claim under 31 U.S.C. §3729(a)(2), a plaintiff must demonstrate that

> (1) a "claim" was presented to the government by the defendant, or the defendant "caused" a third party to submit the "claim," (2) the claim was "false or fraudulent," (3) the defendant presented the claim knowing it was "false or fraudulent," and (4) the defendant made or used a false statement which the defendant knew to be false, and which was causally connected to the false claim.

U.S. ex rel. Aakhus v. Dyncorp, Inc., 136 F.3d 676, 682-83 (10th Cir. 1998) (citing cases).

For purposes of the FCA, the terms "knowing" and "knowingly" mean that the person either had actual knowledge of the information, acted in deliberate ignorance of the truth or falsity of the information, or acted in reckless disregard of the truth or falsity of the information. 31 U.S.C. §3729(b)(1)(A). However, proof of intent to defraud need not be shown. 31 U.S.C. §3729(b)(1)(B). The Government must prove all essential elements of an FCA claim, including damages, by a preponderance of the evidence. 31 U.S.C. § 3731(d).

D. Payment by Mistake and Unjust Enrichment

In addition to its FCA claim based on the alleged Stark Law violations, the Government has asserted common law claims for payment by mistake and unjust enrichment. *See, e.g., United*

States v. Rockwell Intern. Corp., 795 F.Supp. 1131 (N.D.Ga. 1992) (Government suit under the FCA, and for relief in equity for unjust enrichment, payment under mistake of fact, and breach of contract). Because these common-law claims involve rights of the United States under a nationwide federal program, federal common law governs. *United States v. Kimbell Foods, Inc.*, 440 U.S. 715, 726, 99 S.Ct. 1448, 59 L.Ed.2d 711 (1979); *Clearfield Trust Co. v. United States*, 318 U.S. 363, 366-67, 318 U.S. 744, 63 S.Ct. 573, 87 L.Ed. 838 (1943).

The Government by appropriate action can recover funds which its agents have wrongfully, erroneously, or illegally paid. No statute is necessary to authorize the United States to sue in such a case. The right to sue is independent of statute. *United States v. Wurts*, 303 U.S. 414, 415, 58 S.Ct. 637, 638, 82 L.Ed. 932 (1938). To prevail on a claim of payment by mistake, the Government must show that it made payments "under an erroneous belief which was material to the decision to pay." *United States v. Mead*, 426 F.2d 118, 124 (9th Cir. 1970).

To prevail on an unjust enrichment theory, the Government must show that (1) the government had a reasonable expectation of payment; (2) the defendant should reasonably have expected to pay, or (3) "society's reasonable expectations of person and property would be defeated by nonpayment." *Rogan*, 459 F. Supp. at 728 (citing *Provident Life & Accident Ins. Co. v. Waller*, 906 F.2d 985, 993-94 (4th Cir. 1990)). Where disbursement of public funds is concerned, the Government is not obligated to show that the recipient was unjustly enriched or that the balance of equities otherwise lies in its favor. *Mt. Vernon Co-op Bank v. Gleason*, 367 F.2d 289, 291 (1st Cir. 1996).

III. Analysis

A. Stark Law Compliance

The Government contends that during the period when the Medical Oncologists were eligible to receive the Incentive Bonus, the Defendants violated the Stark Law by submitting Medicare claims resulting from referrals made by the Medical Oncologists for designated health services. The Defendants dispute this contention on two grounds. The Defendants argue that the compensation arrangement with the Medical Oncologists fit within the Stark Law exception for bona fide employment relationships and therefore referrals by the Medical Oncologists were not prohibited by the Stark Law.[6] The Defendants also argue that the Government has failed to produce any evidence that the Medical Oncologists actually made referrals of DHS during the pertinent time frame.

1. Bona Fide Employment Relationship

It is undisputed that the Medical Oncologists had a financial relationship with Halifax Hospital. Because of this, the burden shifts to Halifax Hospital to show that the compensation arrangement with the Medical Oncologists fit within one of the Stark Law's exceptions. *Rogan*, 459 F.Supp.2d at 715 (N.D.Ill. 2006). Halifax contends that the Medical Oncologists'

[6] Because the Medical Oncologists were employed by Halifax Staffing rather than Halifax Hospital (which submitted the Medicare claims), there is some dispute as to whether the exception for bona fide employment relationships could apply. In the alternative, the Defendants have pled that what is known as the "Indirect Compensation Exception", *see* 42 C.F.R. § 411.357(p), would apply to the compensation agreements with the Medical Oncologists. (Doc. 317 at 10). There are some distinctions between the two, but to qualify for either exception, the compensation received by the physician cannot take into account the value or volume of referrals. 42 C.F.R. §411.357(c), (p). The Government takes no position as to which of the two exceptions should be assessed, and the parties agree that the disputed issue is the same under either exception. For purposes of summary judgment the Court will adopt the position espoused by the Defendants, Doc. 317 at 10, that the exception for bona fide employment relationships is the exception that might apply.

compensation arrangement satisfied the exception for bona fide employment relationships, which requires a showing that:

> (A) the employment is for identifiable services,
>
> (B) the amount of remuneration under the employment –
>
> (i) is consistent with the fair market value of the services, and
>
> (ii) is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician,
>
> (C) the remuneration is provided pursuant to an agreement which would be commercially reasonable even if no referrals were made to the employer, and
>
> (D) the employment meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

42 U.S.C. §1395nn(e)(2).

The Government contends that the requirements of this exception were not satisfied because the Incentive Bonus, and therefore the Medical Oncologists' remuneration, varied based on referrals for designated health services. More particularly, the Government points out that the pool from which the Incentive Bonus was drawn was equal to 15 percent of the operating margin of the Medical Oncology program, and the program's revenue included fees for designated health services such as outpatient prescription drugs and outpatient services not personally performed by the Medical Oncologists.[7] (Doc. 272 at 9). Thus, revenue from referrals made by the Medical Oncologists would flow into the Incentive Bonus pool, and additional referrals would be expected

[7] Referrals for services that are personally performed by the physician at issue are not prohibited by the Stark Law. 42 U.S.C. § 1395nn(b)(1).

to increase the size of the pool. All other things being equal, this would in turn increase the size of the Incentive Bonus received by the referring Medical Oncologist.[8]

Halifax points out that the requirement in the bona fide employment exception that the remuneration not be "determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician," 42 U.S.C. § 1395nn(e)(2)(B)(ii), is itself subject to an exception. The final sentence of 42 U.S.C. § 1395(e)(2) provides that "[s]ubparagraph (B)(ii) shall not prohibit the payment of remuneration in the form of a productivity bonus based on services performed personally by the physician (or an immediate family member of such physician)". The Incentive Bonus, the Defendants argue, was just such a bonus, because "it is undisputed the bonus pool was divided up based on [each] oncologist's personally performed services." (Doc. 317 at 11) (emphasis in original).

This is not enough to bring the Incentive Bonus within the bona fide employment exception. The Incentive Bonus was not a "bonus based on services personally performed" by the Medical Oncologists, as the exception requires. 42 U.S.C. § 1395(e)(2). Rather, as described by the Defendants themselves, this was a bonus that was divided up based on services personally performed by the Medical Oncologists.[9] The bonus itself was based on factors in addition to personally performed services -- including revenue from referrals made by the Medical Oncologists for DHS. The fact that each oncologist could increase his or her share of the bonus

[8] As described in a February 2009 memo from attorneys retained by Halifax Hospital to assess whether the Incentive Bonus complied with the Stark Law, "the bonus money available in the incentive pool (15% of the operating margin of the medical oncology program) itself would vary with the volume and value of each Oncologist's referrals to the District's hospital and other cancer care facilities." (Doc. 313-5 at 6-7).

[9] In the memo referred to in the previous footnote, the authors described the bonus as being determined "based solely on each Oncologist's relative personal clinical production for the fiscal year as measured by charges (converted to Medicare rates), and thus this percentage, or relative allocation, did not directly or indirectly take into account the volume or value of any Oncologist's referrals." (Doc. 313-5 at 6).

pool by personally performing more services cannot alter the fact that the size of the pool (and thus the size of each oncologist's bonus) could be increased by making more referrals.

During the time period when the Incentive Bonus was being paid, the compensation arrangement between Halifax Staffing and the Medical Oncologists did not satisfy the requirements for the bona fide employment exception. As a result, the Medical Oncologists were prohibited from making referrals to Halifax Hospital for DHS, and Halifax Hospital was prohibited from submitting Medicare claims for services furnished pursuant to such referrals. 42 U.S.C. § 1395nn(a)(1).

2. Evidence of Referrals and Claims

To prove that the Medical Oncologists made such referrals and that Halifax Hospital made claims for services furnished pursuant to such referrals, the Government relies on the UB-92 and UB-04 forms submitted by Halifax Hospital. To that end, the Government retained a database expert, Ian Dew ("Dew"), to review Medicare claims data for claims submitted by Halifax Hospital and "various other entities". (Doc. 272-10 at 53). Dew compiled a database of claims with service end dates from October 1, 2004 through February 28, 2009 in which one of the Medical Oncologists was identified as an attending or operating physician on a Form UB-92 or a Form UB-04. (Doc. 272-10 at 53-54). Dew determined that Halifax Hospital submitted 1,496 such claims for inpatient hospital services and 24,097 such claims for outpatient hospital services with end dates between October 1, 2004 and February 28, 2009. (Doc. 272-10 at 53-54). Dew further determined that these inpatient hospital services claims resulted in $11,457,981 in Medicare reimbursements, and these outpatient hospital services claims resulted in $19,393,003 in Medicare reimbursements. Dew also determined that certain third parties had submitted 19,849 claims with these same end dates where one of the Medical Oncologists had been identified as a

referring physician, resulting in reimbursements of $3,417,683. (Doc. 272-10 at 54). In all, the claims identified by Dew resulted in reimbursements of $34,268,667.

The Defendants do not take issue with Dew's calculations; their own expert, using the same parameters, reached essentially identical results. (Doc. 305-1 at 13). Instead, the Defendants argue, *inter alia*, that Dew's numbers are not relevant because the fact that one of the Medical Oncologists is identified as the attending or "other" physician on a Form UB-92 or as attending or operating provider on a Form UB-04 is not evidence that that physician made the referral for which the claim was submitted, the prerequisite for a violation of the Stark Law. The Defendants contend that the only way to determine the identity of the physician who made the referral is to review the patient's medical records, not a claim form.

It is true that the instructions for filling out Form UB-92 or Form UB-04 do not explicitly require the identification of the physician who made the referral, which the Stark Law defines as "the request or establishment of a plan of care … which includes the provision of designated health services." 42 U.S.C. § 1395nn(h)(5)(A). To accept the Defendant's argument that these claims forms are of no evidentiary value, one would have to assume that in a typical case, both attending physicians and operating physicians are completely disconnected from any "request or establishment of a plan of care … which includes the provision of designated health services."[10] The Defendants have pointed to no authority suggesting that the physicians identified on Medicare claims forms as filling such roles are no more likely than any other physician to have made the referral at issue, and this Court's own research has not uncovered any. On the other hand, at least

[10] Federal Rule of Evidence 401 defines evidence as relevant if it "has any tendency to make a fact more or less probable than it would be without the evidence [and] the fact is of consequence in determining the action."

some courts have concluded that physicians identified as attending or operating physicians on Medicare claims forms are referring physicians as a matter of law:

> The "attending/operating" physician identified in Boxes 82 and 83 of Form UB-92[11] qualifies as a referring physician as that term is defined by the Stark [Law]. … These manual provisions were adopted to implement Congress's requirement that the identification number of referring physicians be reported with claims made to Medicare. Hospital Manual, Transmittal No. 637, May 1, 1992.

Rogan, 459 F. Supp. 2d at 714. *See also* 42 U.S.C. § 1395*l*(q) (providing that "[e]ach request for payment, or bill submitted, for an item or service furnished by an entity for which payment may be made under this part and for which the entity knows or has reason to believe there has been a referral by a referring physician (within the meaning of section 1395nn of this title) shall include the name and unique physician identification number for the referring physician."). And other courts have concluded that where a physician personally performs a service, the resulting facility fee is a referral as a matter of law for Stark Act purposes.[12] *Tuomey Healthcare Systems, Inc.*, 675 F.3d at 407. Thus, where one of the Medical Oncologists is identified as the operating physician on a Form UB-92 or a Form UB-04, that oncologist made a referral as to the facility fee resulting from his or her personally performed services.

Although it is not necessary for purposes of this motion to hold that every attending or operating physician identified on a Medicare claim form is a referring physician as a matter of law, such an identification would appear to be relevant to that determination. This conclusion is reinforced by the fact that the Defendants have not presented any evidence to the contrary. Although they do not bear the burden of proof on this issue, and thus have no obligation to

[11] Box 82 and Box 83 are the fields labeled "Attending Phys. ID" and "Other Phys. ID," respectively, on Form UB-92.

[12] As noted above, the Defendants have admitted that where one of the Medical Oncologists performed a Medicare-reimbursable procedure, it would submit one claim for the oncologist's services and a second for the facility fee. (Doc. 317 at 7 n.8).

produce evidence on this point, it would certainly behoove them to provide, for example, medical records for particular patients showing that someone other than one of the Medical Oncologists made the referral underlying a particular claim, or testimony from any of the Medical Oncologists to that same end. However, they have not done so.

Thus the Court concludes that the claims forms relied on by the Government are evidence of referrals for DHS made by the Medical Oncologists during the time period the Incentive Bonus was in effect, thereby violating the Stark Law. 42 U.S.C. § 1395nn(a)(1). By the same token, the claims forms are evidence that Halifax Hospital submitted claims to Medicare for the DHS furnished pursuant to such referrals, also in violation of the Stark Law. 42 U.S.C. § 1395nn(a)(2). The Defendants have not presented any evidence to the contrary. As the Government's evidence on this point is undisputed, the Government has established that Halifax Hospital violated the Stark Law.

3. Damages

Although the Government has established that a violation of the Stark Act occurred, a genuine issue of material fact remains as to the extent of the violation. Originally, the Government argued that it was entitled to recover $34,268,667 in Medicare claims that were improperly submitted and paid in violation of the Stark Law due to the Medical Oncologists' financial relationship with Halifax Hospital. (Doc. 272-10 at 54-55). The Defendants raised numerous objections to this figure. Among other things, the Defendants argued that the claims forms relied on by the Government's expert captured services (such as evaluation and management services) that did not qualify as DHS. (Doc. 317 at 28). The Defendants also argued that the Government's total included claims billed on a third type of form – a "Form 1500" – that is only used to bill for personally performed professional services, "the majority of which are not

considered DHS." (Doc. 317 at 28). In addition, the Defendants argued that the Government's expert improperly included claims data for part of fiscal year 2009, although the Incentive Bonus (and thus any potential Stark Law violation) terminated at the end of fiscal year 2008. (Doc. 317 at 3 n.3).

In its reply to the Defendants' response, the Government reduced its expected recovery from $34,268,667 to $27,102,793. (Doc. 332 at 9). In so doing, the Government stated that it was accepting, for purposes of the motion, the Defendants' arguments "on the non-institutional (Form 1500) and fiscal year 2009 claims" and asserted that those claims "were not included in the damages number reflected in this brief." (Doc. 332 at 8 n. 5). However, the Government did not include any calculation, so the Court is unable to verify this figure. Moreover, the Government did not address the Defendants' other arguments about the original figure; instead, the Government listed those arguments and then listed other documents where those arguments had supposedly been answered:

> The United States fully addressed Halifax's arguments on the identification of the referring physician on the claims forms, the lack of any need for a review of the underlying medical records, and the relevance of transfer and emergency department patients in its Motion for Partial Summary Judgment at 17-19; Opposition to Halifax's Motion for Summary Judgment at 8-13; Motion to Exclude Donald Moran (Dkt. No. 305) at 4; and Opposition to Halifax' Motion to Exclude Ian Dew (Dkt. No. 320) at 3-4, 7-9.

(Doc. 332 at 4). Despite diligent effort, the Court is unable to determine which of these arguments are allegedly addressed in which of the listed documents and therefore cannot determine which party ought to prevail in regard to them. In addition, the Defendants make at least one argument – that one of the Medical Oncologists did not receive a bonus in fiscal year 2005 and therefore could not have violated the Stark Act that year (Doc. 317 at 3) – that, so far as the Court can discern, the Government does not even claim to have addressed anywhere. For all of these reasons, summary

judgment as to the extent of the Stark Law violation involving the Medical Oncologists will be denied.

B. False Claims Act, payment by mistake, unjust enrichment

This remaining issue of material fact as to the extent of the Stark Law violation (damages) precludes summary judgment in the Government's favor on any of the three theories it now advances – the False Claims Act, payment by mistake of fact, or unjust enrichment. Moreover, insofar as the False Claims Act is concerned, the Court finds that a genuine issue of material fact remains as to whether the Defendants acted knowingly.

C. Affirmative Defenses

The Defendants have asserted the following affirmative defenses: failure to state a claim; estoppel; waiver; good faith; limitations on damages; fraud with particularity; public disclosure; and exceptions to the Stark Law. (Doc. 112 at 12-13). By way of the instant motion, the Government attacks the first through third and fifth through seventh affirmative defenses.[13] In response, the Defendants rely on the arguments raised in their response (Doc. 314) to the motion for summary judgment filed by the Relator, which also attacks these affirmative defenses.

Several of the defenses asserted by the Defendants are not available as a matter of law. Failure to state a claim upon which relief may be granted (first affirmative defense) and failure to plead fraud with particularity (sixth affirmative defense) are failures of pleading, not affirmative defenses. The Defendants do not even dispute the Government's argument that the equitable defenses of estoppel (second affirmative defense) and waiver (third affirmative defense) are not available against the United States.[14] And public disclosure (seventh affirmative defense) is a bar

[13] In their answer, the Defendants also "reserve[d] the right to assert" additional affirmative defenses. (Doc. 112 at 13). However, they have not done so.

[14] In their response to the Relator's motion for summary judgment, the Defendants dispute

to an FCA claim brought by a Relator, but not to an FCA claim asserted by the United States. 31 U.S.C. § 3730(e)(4) (exempting action brought by Attorney General from public disclosure bar).[15]

The Defendants' fifth affirmative defense, titled "Limitations on Damages," consists of a single sentence: "The United States is precluded from recovering treble damages and civil penalties under applicable provisions of law." (Doc. 112 at 12). Although the Defendants are certainly entitled to contest the amount of damages, it is not clear that this is an affirmative defense. Nonetheless, given that the Court has deferred resolution of the issue of damages (due to the unresolved issue of material fact as to the amount of Stark Act violations), consideration of this purported affirmative defense at this point would be premature.

As their fourth affirmative defense, the Defendants contend that they acted in good faith. However, the Defendants did not raise it in opposition to this motion or make any effort to support it, and the Court is unaware of any authority that would do so. Finally, although the Government did not specifically attack the eighth affirmative defense (titled "Exceptions to the Stark Law") as such, the issue raised by that defense has been resolved. Specifically, Defendants' argument that the Medical Oncologists' compensation agreement fits within the bona fide employment exception or the indirect compensation exception was addressed and rejected *supra*.

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the Relator's argument that these defenses are inapplicable to the Relator's claims. However, they do not address the Government's argument, which has a different basis than the Relator's argument.

[15] Again, the Defendants dispute only the Relator's argument on this point, not the Government's.

IV. Conclusion

In consideration of the foregoing, it is hereby

ORDERED that the Motion for Partial Summary Judgment (Doc. 272) is **GRANTED IN PART AND DENIED IN PART,** as set forth above.

DONE and **ORDERED** in Orlando, Florida on November 13, 2013.

GREGORY A. PRESNELL
UNITED STATES DISTRICT JUDGE

Copies furnished to:

Counsel of Record
Unrepresented Parties