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 Summary Judgment (Doc. 277) filed by Defendants Halifax Hospital Medical Center ("Halifax Hospital") and Halifax Staffing, Inc. ("Halifax Staffing"), the response (Doc. 310) filed by the United States (the "Government"), and the reply (Doc. 336) filed by the Defendants.

I. Background

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 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.

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, 42 U.S.C. §1395nn, 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 Law claims involving medical oncologists and neurosurgeons. (Doc. 69, 73). By way of the instant motion, the Defendants seek summary judgment as to all of the Government's claims. The Court has already addressed the legality of the compensation arrangements involving the medical oncologists. (Doc. 396). This order, therefore, will address the compensation arrangements between Halifax Staffing and the three neurosurgeons: Dr. Khanna, Dr. Kuhn, and Dr. Vinas.

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 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,[1] Congress passed amendments to the Social Security Act in 1989 and 1993 – known as "Stark I" and "Stark II," 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)).

[1] 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 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.

> 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.
>
> (D) Radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services.
>
> (E) Radiation therapy services and supplies.
>
> (F) Durable medical equipment and supplies.
>
> (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 require 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).[2] See *also Ragsdale v. Rubbermaid, Inc*., 193 F.3d 1235, 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).

[2]See also *United States ex rel. Williams v. NEC Corp*., 931 F.2d 1493, 1496–98 (11th Cir.1991) (tracing history of Act).

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).[3]

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 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

[3] 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.

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).

III. Analysis

Halifax Hospital[4] paid the neurosurgeons a base salary, plus benefits and a bonus equal to the difference between the base salary and the physicians' collections. In essence, this allowed the

[4] The neurosurgeons were employed by Halifax Staffing. As the neurosurgeons were technically employed by an entity other than the one that submitted the claims to Medicare, there is some dispute as to whether the exception for bona fide employment relationships might apply, or whether the neurosurgeons' agreements would need to satisfy a different exception -- one that involves indirect compensation arrangements. 42 C.F.R. § 411.357(p). However, Halifax Staffing is merely a payroll service provider for Halifax Hospital, with no other business operations. For purposes of this motion, Halifax Hospital will be considered to be the direct employer of the

neurosurgeons to operate their practice with a guaranteed salary and keep 100% of their collections with no overhead expense.

Since the neurosurgeons are referring physicians who made referrals to Halifax Hospital, Defendants rely on the bona fide employee exception to the Stark Act. The Defendants contend that the neurosurgeon agreements satisfy this exception in all respects – *i.e.*, the employment was for identifiable services, the compensation received was consistent with fair market value and did not take referrals into account, and the agreements would have been commercially reasonable even in the absence of any referrals.

The government contends that genuine issues of material fact are in dispute as to most of these factors and the Court agrees. The Government's expert witness on physician compensation has identified a number of issues in regard to whether the compensation received by the neurosurgeons was consistent with fair market value. For example, in a number of years, the neurosurgeons appear to have been paid more than twice as much as neurosurgeons at the 90th percentile of their specialty despite collections from their work falling below (in some instances, well below) that rank. (Doc. 310-3 at 16-17). The Defendants argue that the neurosurgeons were exceptionally productive and their exceptional productivity justified that level of compensation. However, the Government's expert has also raised questions as to whether the neurosurgeons'

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neurosurgeons, and therefore the Court will address the exception for bona fide employment relationships. However, even if the other exception were to apply, the result would be the same.

productivity numbers were improperly inflated by, for example, billing under their name for services performed by nurses and physician assistants. (Doc. 310-3 at 19-27).

The propriety of the neurosurgeons' compensation under the Stark Act is a matter for the jury to decide.

In consideration of the foregoing, it is hereby

ORDERED that the Motion for Summary Judgment (Doc. 277) is **DENIED**.

DONE and **ORDERED** in Chambers, Orlando, Florida on November 18, 2013.

GREGORY A. PRESNELL
UNITED STATES DISTRICT JUDGE

Copies furnished to:

Counsel of Record
Unrepresented Party