

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
AT LOUISVILLE

CIVIL ACTION NO. 3:03-CV-519-H

UNITED STATES OF AMERICA, et al.

PLAINTIFFS

V.

ROBERT E. SOLINGER, et al.

DEFENDANTS

MEMORANDUM OPINION

Plaintiff Villafane, et al., bring this *qui tam* action under the Federal Claims Act, 31 U.S.C. § 3729, against various Defendants based upon alleged violations of the Fraud and Abuse, Anti-kickback, and prohibited referral provisions of 42 U.S.C. § 1320a-7b(b), 42 U.S.C. § 1395m, and 42 C.F.R. § 411.353. Additionally, Villafane asserts a number of federal and state antitrust violations as well as common law claims.

Defendants have moved for judgment on the pleadings or summary judgment pursuant to Federal Rules of Civil Procedure 9(b), 12(b)(1) & (6), 12(c) and 56(b) on all of Plaintiff's claims. The Court has carefully reviewed the memoranda submitted by the parties and has had the benefit of hearing their arguments and their answers to questions at a conference in chambers. The Court will consider each claim in turn.¹

I.

¹ The Court will address many of Plaintiff's state common law claims in a later memorandum.

Plaintiff Villafane is a pediatric cardiologist. From 1985 through 2005, he was employed as an Associate Professor of Pediatrics at the University of Louisville School of Medicine (the “Medical School”). Defendants Solinger, Elbl, and Rees (collectively, “the Physician Defendants”) are each pediatric cardiologists and professors at the Medical School.² Pediatric Cardiology Associates, P.S.C., (“PCA”) is the practice group of the Physician Defendants as well as several other pediatric cardiologists employed by the Medical School. Villafane was a member of PCA from 1986 to 1990. In 1990, Villafane formed his own practice group, Children’s Heart Specialists, P.S.C. (“CHS”), and of which he is the sole member. After forming his own group, Villafane remained on the Medical School faculty through 2005.

Defendant Larry Cook is a neonatologist, a professor at the Medical School, and the President of the University of Louisville Research Fund (“the Research Fund”). He is one of several members of Neonatal Associates, P.S.C., (“NNA”), through which he conducts his medical practice. Cook is also the chief of staff of Defendant Norton Hospitals, Inc., d/b/a Kosair Children’s Hospital (“Kosair”) and a member of its governance and executive committees. Kosair is Kentucky’s only full-service pediatric hospital.

The Research Fund collects funds from Medical School faculty through the Professional Practice Plan (the “PPP”). All Medical School full-time faculty members must participate in the PPP, which collects a portion of their professional income. According to the complaint, the Research Fund then distributes funds to the University of Louisville Research Foundation, Inc. (the “Research Foundation”). While a member of the Medical School faculty, Villafane contributed portions of his practice income to the Research Fund as the PPP required. Over the

² Solinger is Villafane’s immediate supervisor, and Elbl and Rees are also Villafane’s superiors.

years, Kosair has made substantial payments to the Research Foundation, which allocates the funds among certain faculty salaries for specialists who work for PCA and other private practices. From the years 1998 to 2000, those payments totaled approximately \$1.7 million each year. Villafane is not a recipient of any of those monies. Kosair submitted claims to the U.S. government and its agencies, including Medicare, for various reimbursements of those payments. Kosair did not disclose its relationships with the various doctors in its Medicare Hospital Cost Report. The failure to disclose the payments forms the basis of Villafane's FCA claim.

In the spring of 1990 Villafane became a shareholder of PCA. However, Villafane was not offered shareholder status in PCA's affiliated entity, CVS³, to which, Villafane alleges, portions of the PCA revenues were diverted. Villafane left PCA before the end of the year and proceeded to establish CHS. Immediately thereafter, the PPP was amended to bar recognition of new faculty practice groups and to prevent any departmental entity from contracting with a new practice group unless certain conditions were met.

In 1991, Villafane sued PCA and the Physician Defendants after learning he had been excluded from Kosair's on-call schedule. The suit was settled in 1994, resulting in a mutually agreeable schedule. In November 2000, Villafane learned that Kosair had implemented its on-call rotation schedule to direct patients from outside Louisville to Elbl, Rees, Solinger, and PCA. According to Kosair, it did this because Villafane did not have offices in some of the surrounding areas.

In early 2000, the Division of Pediatric Cardiology (the "Division") of the Medical School began searching for a new chief. In particular, they were seeking candidates with a

³ Complaint fails to define CVS.

subspecialty in electrophysiology. Although Villafane was the Division's Director of Electrophysiology and the only member of the Division who was an electrophysiologist, he was excluded from the search committee. Ultimately the Medical School hired a PCA employee to be chief of the division. In 2002, PCA also hired an electrophysiologist, who also received appointment as Director of Electrophysiology in the Division and as Director for Arrhythmia Service at Kosair.

In March 2000, Kosair completed and closed a review of several Villafane cardiac catheterization laboratory ("cath lab") complications. Only a month later, Dr. Elbl sent a letter to the Kosair Medical Director concerning cardiac cath lab complications in Villafane's lab from 1994 through 1999. In December of 2000, certain PCA members made formal complaints about the quality of Villafane's catheterizations. In January 2001, Kosair informed Villafane that it would not seek review of his cath lab procedures. Shortly afterwards, Kosair's Governance and Medical Executive Committees re-credentialed Villafane staff privileges.

In April, one of Villafane's patients died in the cath lab while undergoing diagnostic procedures. In May, while the patient's death was undergoing a "root cause analysis", Villafane's legal counsel advised Kosair of concerns about its financial relationships with PCA and NNA. Following this communication, Kosair undertook a peer review of Villafane, which resulted in the revocation of Villafane's privileges and his being banned from the premises of all Norton facilities beginning in October 2001. In February 2002, a Kosair hearing panel reviewed Villafane's privileges, and recommended that the majority of Villafane's privileges be reinstated. Nevertheless, the Kosair Governing Board declined to reinstate any of Villafane's privileges. During this same time period, Villafane hired a pediatric cardiologist in his private practice,

whom Cook declined to recommend her for a Medical School clinical appointment. As a consequence, she was denied staff privileges at University Hospital. Kosair formally terminated Villafane on May 7, 2002. In the spring of 2003, Villafane pre-applied for Kosair privileges. Kosair declined to reinstate his privileges and noted his “lack of remorse” over the incidents that led to his dismissal. During this time, Villafane remained on the paid Medical School faculty.

Villafane originally filed his verified complaint on August 29, 2003. As provided under the *qui tam* statute, the file was sealed while the government investigated the claims to determine whether it would intervene as a party. *See* 31 U.S.C. 3730(b) (2006). Numerous extensions of the time for intervention followed. Almost two years later, on June 22, 2005, the government notified the Court and Villafane that it declined to intervene as a party plaintiff pursuant to 31 U.S.C. § 3730(b)(4)(B). In August, 2005, Villafane obtained and substituted new counsel. Between December 2005 and March 2006 all of Defendants either filed answers or motions to dismiss. By July 14, 2006, all parties had filed numerous responses and replies to the various motions. On October 5, 2006, the Court and the parties discussed the pending issues for over two hours.

This Court reviews a motion for judgment on the pleadings under the same standard as review under Rule 12(b)(6); the Court must “construe the complaint in the light most favorable to the plaintiff, accept all of the complaint's factual allegations as true, and determine whether the plaintiff undoubtedly can prove no set of facts in support of the claims that would entitle relief.” *Grindstaff v. Green*, 133 F.3d 416, 421 (6th Cir.1998). Where a defendant challenges subject matter jurisdiction under Rule 12(b)(1), the plaintiff “bears the burden of establishing jurisdiction.” *United States ex rel. Jones v. Horizon Healthcare Corp.*, 160 F.3d 326, 329 (6th

Cir. 1998); *United States ex rel. McKenzie v. BellSouth Telecomms., Inc.*, 123 F.3d 935 (6th Cir. 1997).⁴

II.

Count I of the complaint asserts a *qui tam* action under the False Claims Act (“FCA”), 31 U.S.C. §§ 3729-3733 (2006). Defendants first raised a jurisdictional defense to the FCA claims.

The FCA creates liability for any person who “(1) knowingly presents, or causes to be presented, to [the Government] . . . a false or fraudulent claim for payment or approval; (2) knowingly makes, uses or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; [or] (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid.” 31 U.S.C. § 3729(a) (2006). *Qui tam* provisions of the FCA serve the two-fold purpose of encouraging whistleblowers to act as private attorneys-general in bringing suits for the common good, while simultaneously seeking to discourage opportunistic plaintiffs from bringing parasitic lawsuits whereby would-be relators merely feed off a previous disclosure of fraud. *Walburn v. Lockheed Martin Corp.*, 431 F.3d 966, 970 (6th Cir. 2005).

To further these purposes, the FCA contains a so-called public disclosure bar that restricts the subject matter jurisdiction of the courts in *qui tam* actions. It is upon this concept that Defendants’ first defense rests. The public disclosure bar provides as follows:

No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought

⁴ The various statutes of limitations are not at issue here because in 2002 Villafane executed agreements with Kosair, NNA, PCA, the Research Foundation, and the Research Fund to toll those limitations on their respective claims.

by the Attorney General or the person bringing the action is an original source of the information.

31 U.S.C. § 3730(e)(4)(A). “Because federal courts are courts of limited jurisdiction, the plaintiff must establish subject matter jurisdiction.” *Walburn*, 431 F.3d at 970 (citing *McKenzie*, 123 F.3d at 938).⁵ The jurisdictional bar applies where (1) there has been a public disclosure; (2) of the allegations or transactions that form the basis of the relator’s complaint; and (3) the action is ‘based upon’ the publicly disclosed allegations or transactions. If the answer is ‘no’ to any of these questions, the inquiry ends, and the *qui tam* may proceed.” *Jones*, 160 F.3d at 330. If each of the three elements are satisfied, however, then the relator must qualify as an “original source” under § 3730(e)(4)(B). *Id.* Only if so, may the suit proceed. *Id.*

Defendants argue that Villafane’s FCA claim is precluded by public disclosure on three separate occasions (1) when information was obtained through Kentucky Open Records Act (“ORA”) requests to the University, (2) when Villafane made allegations in response to the National Practitioner Data Bank (“NPDP”) that were disclosed to the Commonwealth of Kentucky Board of Medical Licensure (the “Kentucky Medical Board”) in connection with its proceedings to restrict his medical license, and (3) when that same information was included in tolling agreements with various defendants. The Court must review each instance to determine whether it constitutes a public disclosure.

⁵ Some courts consider §§ 3730(e)(4)(A) & (B) to be matters of substantive law rather than a “jurisdictional bar”. *See United States ex rel. Yannacopolous v. General Dynamics*, 315 F.Supp.2d 939, 946-947 (N.D. Ill. 2004). As such, dismissal of a claim due to the public disclosure bar would be considered under Rule 12(b)(6) rather than Rule 12(b)(1). *See id.* The difference is significant because under a Rule 12(b)(6) analysis, the Court construes the complaint “in the light most favorable to the plaintiff.” *Grindstaff*, 133 F.3d at 421. Under a Rule 12(b)(1) analysis, however, plaintiff bears the burden of proving jurisdiction. *Jones*, 160 F.3d at 329. The Sixth Circuit analyzes the public disclosure bar using a Rule 12(b)(1) analysis. *See id.*

A.

In the Sixth Circuit, the disclosure of information in response to a Freedom of Information Act (“FOIA”) request does not necessarily trigger the public disclosure bar; rather, a court must examine each element of § 3730(e)(4)(A) before making such a determination. *See United States ex rel. Burns v. A.D. Roe Co.*, 186 F.3d 717, 722-725 (6th Cir. 1999).⁶ This Court interprets *Burns* as recognizing that although the FOIA requests may have satisfied the public disclosure element of § 3730(e)(4)(A), the information received must also satisfy the remaining statutory elements. *See Id.* In other words, it must also be shown to be an “allegation or transaction” disclosed in one of the statutorily enumerated sources, i.e., “in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media.” *Id.* at 726. Here, the information Villafane obtained almost certainly constitutes a public disclosure of allegations or transactions, but it is unclear whether the source of the information is contained in the statutorily enumerated list of sources.

The survival of the claim hinges on whether the information obtained from the Kentucky ORA request constitutes an “administrative report” or “administrative investigation” for purposes of the public disclosure bar. This is crucial because the list of sources set out in the statute is exhaustive, and if the information is not from one of these sources, then the statute did not mean to exclude claims on that basis. *Burns*, 186 F.3d at 725 (citing *United States ex rel. Dunleavy v. County of Delaware*, 123 F.3d 734, 744 (3d Cir. 1997)). At least one circuit has

⁶ Although no court has considered the issue, the Court believes that Kentucky ORA requests are analogous to FOIA requests and should be treated the same for purposes of the public disclosure bar.

held that virtually any information obtained via such a request is considered an administrative report or investigation for purposes of the statute. *See United States ex rel. Mistick PBT v. Housing Auth.*, 186 F.3d 376, 383 (3d Cir.1999). This is so because the information results from an agency's search for the requested documents and constitutes an official and formal statement concerning those results. *See id.*

This Court finds more persuasive a recent Ninth Circuit opinion, which held that whether a FOIA request invokes the jurisdictional bar depends on the nature of the documents obtained. *See, e.g., United States ex rel. Haight v. Catholic Healthcare West*, 445 F.3d 1147, 1153 (9th Cir. 2006). In *Haight*, the court recognized that because “responding to a FOIA request requires little more than duplication, labeling any response to a FOIA request a ‘report’ or ‘investigation’ would ignore the way in which each of the enumerated sources [in § 3730(e)(4)(A)] involves a governmental work product.” *Id.* Thus, the court concluded, if a document obtained via FOIA does not *itself* qualify as an enumerated source, its disclosure in response to the FOIA request does not make it so. *See id.* at 1156.

Here, Defendants do not possess sufficient information to determine whether the information Villafane received in the Kentucky ORA requests qualifies as a source enumerated in § 3730(e)(4)(A).⁷ In other words, the public disclosure bar will apply if the information Villafane received was part of “a criminal, civil, or administrative hearing in a congressional,

⁷ The fact that Defendant obtained information via a Kentucky ORA request rather than a FOIA request may be significant in that some courts have interpreted the word “administrative” in § 3730(e)(4)(A) to refer only to reports produced by federal sources. *See Burns*, 186 F.3d at 725 (citing *Dunleavy*, 123 F.3d at 745). The Eleventh Circuit has gone even further, holding that the report must be issued by an administrative agency, not merely by an employee of the agency. *See United States ex rel. Williams v. NEC Corp.*, 931 F.2d 1493. Taken together, this would mean reports and investigations performed under the Kentucky ORA would not trigger the public disclosure bar unless the underlying information included reports or investigations performed by federal administrative agencies.

administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media.”

The Court will provide Defendants with an early opportunity to discover sufficient information about the nature of Villafane’s Kentucky ORA request.

B.

Defendants next argue that public disclosure occurred when Villafane made allegations in response to the NPDP in the Kentucky Medical Board proceedings to restrict his medical license. The Board’s orders state, in relevant part:

The Board received a report from the National Practitioner Data Bank, which . . . contained the following narrative, . . . Dr. Villafane responded on January 4, 2002, as follows: . . . The suspension of his privileges at Kosair Children’s Hospital occurred in retaliation against Dr. Villafane *after he complained about funding improprieties occurring at the hospital*. . . He further responded on May 8, 2002, as follows: . . . The review was instigated by his competitors. . . The action finally taken by the Board . . . was in retaliation for *Dr. Villafane having complained (before peer review was initiated) about antitrust violations and funding improprieties occurring at Kosair Children’s Hospital*. . . [emphasis in Plaintiff’s response]⁸

The information disclosed in a Kentucky Board of Medical Licensure administrative proceeding is among the kind of statutorily enumerated public sources of disclosure. 31 U.S.C. § 3730(e)(4)(A). However, the issue is whether these prior statements of “funding improprieties” constitute a public disclosure of “allegations or transactions” under § 3730(e)(4)(A).

As the Sixth Circuit explained in *United States ex rel. Gilligan v. Medtronic, Inc.*, 403 F.3d 386 (6th Cir. 2005), there are two ways that prior public disclosure of fraud can occur:

⁸ The Board’s Agreed Order of Indefinite Restriction and its Agreed Order, both of which contain the potentially publicly disclosed statements, were signed December 18, 2003, and November 30th, 2004, respectively, after this suit had been filed. Thus, the orders cannot serve as public disclosures upon which the suit is based. However, the statements themselves were made prior to the filing of this suit and could potentially be considered public disclosures.

First, if information about both a false state of facts and the true state of facts has been disclosed, we should find that there has been adequate public disclosure because fraud is implied. (citation omitted). Second, if there has been a public allegation of fraud, the Court should also find public disclosure.

Id. at 389 (citing *Dingle v. Bioport Corp.*, 388 F.3d 209, 212 (6th Cir.2004)). In this case, it is the second form of public disclosure that is alleged.

Villafane's passing reference to "funding improprieties" falls short of a public disclosure of allegations of fraud. The purpose behind the public disclosure bar is to prevent parasitic lawsuits based on information of which the government is already aware. Although the Sixth Circuit does not require a "specific disclosure of fraud" to find public disclosure of allegations, the disclosure must be "sufficient to put the government on notice as to the possibility of fraud." *See Dingle v. Bioport Corp.*, 388 F.3d 209, 214-215 (6th Cir. 2004). Villafane's statement concerning "funding improprieties", which states neither the type of impropriety or how they could be found, can hardly be said to put the government on notice of the Medicaid or Medicare fraud alleged in this suit.

Though Defendants argue that the allegation of funding improprieties is sufficient, none of the cases they cite involve allegations of such a vague and indirect nature. In *Dingle*, the prior allegations triggering the public disclosure bar had been made in congressional testimony stating that a defendant's vaccine may not be the same one approved by the Food and Drug Administration ("FDA") due to modifications. *United States ex rel. Dingle v. Bioport Corp.*, 388 F.3d 209, 214 (6th Cir. 2004). In *Gilligan*, the prior allegations had been made by plaintiffs in prior lawsuits in which they specifically alleged that the FDA had engaged in fraudulent conduct while manufacturing leads. *United States ex rel. Gilligan v. Medtronic, Inc.*, 403 F.3d 386, 390 (6th Cir. 2005). In *Jones*, the prior allegations were made when the relator alleged in a

complaint that false forms had been deliberately prepared or allowed to remain in a false version, presumably to be submitted to the government. *United States ex rel. Jones v. Horizon Healthcare Corp.*, 160 F.3d 326, 331-332 (6th Cir. 1999).

The Court concludes that the passing references to “funding improprieties” do not constitute a public disclosure under the FCA and that, therefore, the claim is not precluded on those grounds.

C.

Defendants’ last argument is that even if the records requests alone do not satisfy the public disclosure requirement, they were subsequently made public in the tolling agreements with various defendants. However, agreements, no matter how public, are not among the list of sources enumerated in § 3730(e)(4)(A) that trigger the public disclosure bar. Since the statutory list is exhaustive, public disclosure in a source not listed in the statute will not bar the claim. *See Dunleavy*, 123 F.3d at 744. For the time being, the Court finds no public disclosure. Therefore, the Court need not make a determination as to whether Villafane is an “original source” in order for him to bring a *qui tam* action. *See Jones*, 160 F.3d at 330.⁹ Based on the current status of the action, Villafane’s *qui tam* action is not precluded by the public disclosure bar.

III.

In the event that their broad jurisdictional attack should fail, various Defendants raise

⁹ If the court were to decide that the statement to the Kentucky Medical Board about “funding improprieties” constitutes a public disclosure, Villafane would fail the original source test. An original source is “an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government *before* filing an action under this section which is based on the information.” § 31 U.S.C. 3730(e)(4)(B). Additionally, “the individual must have provided the government with the information *prior to any public disclosure.*” *Walburn*, 431 F.3d at 974 (emphasis in the original). Thus, if the statements about “funding improprieties” were deemed a public disclosure, Villafane would not have provided the information to the government until after the public disclosure, since he contacted an Assistant U.S. Attorney two weeks after the statements were received by the Kentucky Medical Board.

pleading issues: (1) that the FCA allegations fail to comply with Rule 9(b) of the Federal Rules of Civil Procedure (“Rule 9(b)”) which requires the circumstances surrounding all allegations of fraud to be stated with particularity and (2) that the Research Fund and the Research Foundation may be immune from suits brought under the FCA. Fed. R. Civ. P. 9(b).

A.

Villafane alleges that Kosair’s cost certifications to Medicaid and Medicare were fraudulent because they failed to disclose the presence of financial relationships and payments with certain physicians.¹⁰ Although neither the Stark nor Anti-kickback statutes provide for a right of private enforcement, *see West Allis Mem’l Hosp., Inc. v. Bowen*, 852 F.2d 251 (7th Cir. 1988), Courts have permitted plaintiffs to bring FCA claims based on similar alleged false cost certifications that violate the Stark and Anti-kickback statutes. *See, e.g., United States ex rel. Pogue v. American Healthcorp, Inc.*, 914 F. Supp. 1507 (M.D. Tenn. 1996); *United States ex rel. Goodstein*, 2001 U.S. Dist. LEXIS 2917 (E.D. Mich. 2001); *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 20 F. Supp. 2d 1017 (S.D. Tex. 1998).

The Stark law commonly referred to as "Stark II," prohibits physicians from referring patients to an entity for the furnishing of certain designated health services if the physician has a financial relationship (through ownership/investment or compensation arrangement) with the entity, unless the relationship meets an enumerated exception. 42 U.S.C. § 1395nn (2006). Plaintiff also bases his FCA claim on 42 U.S.C. § 1320a-7b (2006), commonly referred to as the “Anti-kick-back statute”, which prohibits financial relationships between hospitals and physicians that involve payments made knowingly and willingly for or to induce referrals.

¹⁰ Villafane does not allege any fraud with regard to the services provided by either Kosair or any physician on Medicaid or Medicare reimbursements.

The Sixth Circuit requires a plaintiff, at a minimum, to “allege the time, place, and content of the alleged misrepresentation on which he or she relied; the fraudulent scheme; the fraudulent intent of the defendant; and the injury resulting from the fraud”. *U.S. ex rel. Bledsoe v. Community Health Systems, Inc.*, 342 F.3d 634, 644 (6th Cir. 2003) (quoting *Coffey v. Foamex, L.P.*, 2 F.3d 157, 162 (6th Cir. 1993)). “The purpose of Rule 9(b) is to provide the defendant with fair notice so as to allow him to prepare an informed pleading responsive to the specific allegations of fraud.” *Resource Title Agency, Inc., et al. v. Morreale Real Estate Services, Inc., et al.*, 314 F.Supp.2d 763, 775 (N.D. Ohio 2004) (citing *Advocacy Organization for Patients and Providers v. Auto Club Ins. Ass'n*, 176 F.3d 315, 322 (6th Cir.1999)). Claims brought under the FCA are subject to the particularity requirement of Rule 9(b). *See Bledsoe*, 342 F.3d at 642.

Villafane identifies the entities which allegedly committed the fraudulent activity; describes how the fraudulent activity was committed (by signing fraudulent cost report certifications); describes why the certifications were fraudulent (because Kosair had a financial relationship with physicians who referred it Medicaid/Medicare patients); describes the time period when the fraudulent activities took place (the years when the cost reports were falsely certified) and identifies the years the named physicians made improper referrals to Kosair. Identifying which referring physician made which improper referral and the dates of such referrals is pivotal to the Stark and Anti-kickback laws allegations. However, that level of detail is unnecessary to alert Defendants to the nature of the fraud. Plaintiff admittedly does not have access to information concerning the number of improper referrals, which is in exclusive possession of the Defendants. Plaintiff need not establish in the pleadings intent and knowledge

for the alleged fraudulent activities. Whether the conduct was performed “knowingly and willfully” is a question of fact not properly decided on the pleadings. Under Rule 9(b), intent and knowledge may be averred generally by the Plaintiff. Fed. Rule Civ. P. 9(b).

The Court concludes that the FCA portion of the complaint does satisfy those minimum requirements of Rule 9(b).

B.

Both the Research Fund and Research Foundation enjoy immunity from suits brought under the FCA. The FCA subjects to liability “any person” responsible for presenting fraudulent claims to the government. 31 U.S.C. § 3729(a) (2006). The sovereign is not a “person” for purposes of the statute. *Vermont Agency of Natural Resources v. U.S. ex rel Stevens*, 529 U.S. 765, 780-781 (2000). Furthermore, the University of Louisville is a Kentucky state agency to which sovereign immunity applies. *Martin v. University of Louisville*, 541 F.2d 1171, 1174-75 (6th Cir.1976).

The Court finds that both the Research Fund and Research Foundation are part of the university. The Research Fund was created explicitly “for the purpose of benefitting and furthering the academic endeavors of the University of Louisville School of Medicine, including in such purpose the provision of financial support for the Medical School’s teaching, research, and service programs and financial support for the personnel and equipment necessary for such purposes,” while the Research Foundation serves as the umbrella organization for managing research grants and other sponsored programs at the University. It also acts as fiduciary and billing agent for various clinical activities at the University’s Health Sciences Center. Both the Fund and Foundation are entirely governed and run by University personnel; the members of

their Board of Directors are the Chairs of the School of Medicine’s clinical departments and the University of Louisville Board of Trustees, respectively. Both the Research Foundation and Fund operate from University offices and their registered agent is the university counsel.

Therefore, as part of the University, neither the Research Fund nor the Research Foundation may be subject to liability under the FCA.

IV.

Defendants’ broadest substantive defense to the FCA claim is that all of the financial dealings among the Medical School, Kosair and the individual faculty members are part of a permissible arrangement to fund research, teaching and clinical services within the academic context. Indeed, Defendants point out that the Health Care Financing Administration (“HCFA”) has recently clarified the original intent of the Stark law by finalizing regulations that essentially establish a safe harbor for such conduct. The safe harbor provisions are now known as the Academic Medical Center (“AMC”) exception to the Stark law. *See* 42 C.F.R. § 411.355(e) (2006).

A.

Kosair argues that its financial relationships with all of the other defendants fall under the AMC exception to the Stark law.¹¹ Defendants contend, however, that the AMC exception was

¹¹ Because whether Defendants’ financial relationship qualifies for the AMC exception is so pivotal, the following issues will be considered only after a determination of whether the AMC exception applies:

Defendant Kosair argues that the Stark law does not apply to the type of “indirect” relationship that exists between the Hospital and defendant faculty physicians. Under the Stark statute, prohibited financial relationships include indirect compensation arrangements when the referring physician receives aggregate compensation “that varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing designated health services...” 42 C.F.R. § 411.354(c)(2) (2006). Although it has not been shown that the payments vary with referral value or volume, Villafane alleges that the amount paid by Kosair to the referring physicians is well above the fair market value of any teaching services provided, and this difference may “otherwise reflect” the volume or value of referrals. Further discovery could illuminate the nature of this difference.

not effective until after the alleged Stark violations had occurred and should not apply retroactively. *See* 66 Fed. Reg. 99 (January 4, 2001) (setting forth the Final Rule with comment period on 42 C.F.R. Parts 411 and 424). The Court believes that Plaintiff has framed the issue incorrectly. Since the AMC exception is contained in the Code of Federal Regulations, it does not arise from a change to the statute itself. As such, it should not be interpreted as though Congress has changed its mind and amended the existing statute. That has not occurred. Rather, the regulation serves as an administrative interpretation of the meaning Congress intended when creating the statute.

The question for the Court is whether the agency's interpretation is based on a permissible construction of the statute. *See Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-843 (1984). The legislative history indicates that HCFA, authors of the regulation, believed that the faculty practice plan reference in the statute "demonstrates congressional intent to address the circumstances of physicians practicing in academic medical settings." *Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships*, 66 Fed. Reg. 856, 916 (Jan. 4, 2001) (codified at 42 C.F.R. pts. 411 and 424). From the statutory language and this legislative history, it appears that Congress intended to protect such arrangements and believed that existing exceptions were sufficient for that purpose. Later, they realized that a regulatory clarification would be helpful to achieve that purpose. *See id.*¹² Therefore, the Court must conclude that the regulations defining the scope of

¹² Had the statute itself been changed, the Court would determine whether it applies retroactively using a two-step test. The Court would first determine "whether Congress has expressly prescribed the statute's proper reach." *Landgraf v. USI Film Products*, 511 U.S. 244, 280 (1994). If no such express command by Congress exists concerning the AMC exception, the court must then "determine whether the new statute would have retroactive effect, i.e., whether it would impair rights a party possessed when he acted, increase a party's liability for past conduct, or impose new duties with respect to transactions already completed," in which case the court will apply the

the AMC exception to the Stark law constitute a reasonable and permissible construction of the statute.

B.

Even though the AMC exception does apply, this Court has insufficient information to determine whether the relationship between the university meets the exception. The burden is on Defendants, who have all the relevant information, to prove that the relationship between Kosair and the Medical School meets the requirements for the exception found in 42 C.F.R. § 411.355(e).

Defendants will satisfy the requirements for the Academic Medical Center exception if they can show that the referring physicians are bona fide employees of the Medical School, a faculty practice plan, or Kosair, on a full-time or substantial part-time basis, are licensed to practice medicine in Kentucky, and have a bona fide faculty appointment at the Medical School. 42 C.F.R. § 411.355(e) (2006). The physicians must also provide either substantial academic services or substantial clinical teaching services for which they receive compensation.¹³ *Id.* The total compensation paid by all academic medical center components to the referring physicians must be set in advance and, in the aggregate, must not exceed the fair market value for the services provided, and must not be determined in a manner that takes into account the volume or value of any referrals or other business generated by the referring physician within the academic

traditional presumption against retroactive legislation. *Id.* In this case, applying the AMC exception retroactively does not impair Defendants' rights or increase their liability or duties. Rather, if found to apply to Defendants, it would shield them from liability that Congress never intended to create. Thus, the AMC exception should apply retroactively to financial relationships in existence prior to the effective date of the regulation.

¹³ Parties should use a reasonable and consistent method for calculating a physician's academic services and clinical teaching services. A physician will be deemed to meet this requirement if he or she spends at least 20 percent of his or her professional time or 8 hours per week providing academic services or clinical teaching services, though physicians who spend less than this amount are not necessarily disqualified.

medical center. *Id.* Furthermore, all transfers of money between Kosair and the other Defendants must directly or indirectly support the missions of teaching, indigent care, research, or community service, and their relationship must be set forth in written agreement(s) adopted by the governing bodies of each component. *Id.* All money paid to the referring physicians for research must be used solely to support bona fide research or teaching and must be consistent with the terms and conditions of the grant. 42 C.F.R. § 411.355(e). The referring physicians' compensation arrangements must not violate the anti-kickback statute, or any Federal or State law or regulation governing billing or claims submission. *Id.* Defendants must also show that a majority of the physicians on the medical staff at Kosair consists of physicians who are faculty members at the Medical School and a majority of all hospital admissions are made by physicians who are faculty members at the Medical School. *Id.*

Defendants may well be able to show that the relationship between Kosair and the other Defendants satisfies these requirements for the AMC exception, so the Court will provide Defendants an early opportunity to do so.

C.

Whether Defendants qualify for the AMC exception to the Stark law is legally independent of whether or not they violate the Anti-kickback statute. Nevertheless, one of the requirements for the AMC exception is that the financial arrangement does not violate the Anti-kickback statute. 42 C.F.R. § 411.355(e)(1)(iv) (2006). The Anti-kickback statute provides in relevant part:

Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person

(A) to refer an individual to a person for the furnishing or

arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

42 U.S.C.A. § 1320a-7b(b)(2) (2006). Although as a matter of law the AMC exception does not apply to the Anti-kickback statute, as a practical matter satisfaction of the former will indicate there has been no violation of the latter. Payments made between the components of an AMC necessarily “support the missions of teaching, indigent care, research, or community service” and may not exceed the fair market value of the academic and clinical teaching services provided. *See* 42 C.F.R. § 411.355(e) (2006). As such, they are not made “to induce” referrals and thus cannot be characterized as kickbacks that would violate § 1320a-7b.

V.

Plaintiff brings numerous antitrust claims against Kosair and the other Defendants under Sections 1 and 2 of the Sherman Act and corresponding Kentucky statutes. Before considering these claims on the merits, the Court must determine whether or not Plaintiff has standing to bring suit under the antitrust laws. Upon investigation, the Court finds numerous reasons to question Plaintiff’s standing to bring such claims.

While the United States may sue anyone violating the federal antitrust laws, a private plaintiff must demonstrate standing. *See, e.g., Cargill, Inc. v. Monfort of Colo.*, 479 U.S. 104, 110 (1986). The Sixth Circuit has noted the importance of making this threshold determination in antitrust suits:

Antitrust standing to sue is at the center of all antitrust law and policy. It is not a mere technicality. It is the glue that cements each suit with the purposes of the antitrust laws, and prevents abuses of those laws. The requirement of antitrust standing ensures that antitrust litigants use the laws to prevent anticompetitive action and makes certain that they will not be able to recover under the antitrust laws when the action challenged would tend to promote competition in the economic sense. Antitrust laws reflect considered policies regulating economic matters. The antitrust standing requirement makes certain that the laws are used only to deal with the economic problems whose solutions these policies were intended to effect.

HyPoint Tech., Inc. v. Hewlett-Packard Co., 949 F.2d 874, 877 (6th Cir. 1991). To establish antitrust standing, “[p]laintiffs must prove antitrust injury, which is to say that they have suffered an injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants’ acts unlawful.” *Valley Prods. Co., Inc. v. Landmark, A Div. of Hospitality Franchise Sys., Inc.*, 128 F.3d 398, 402 (6th Cir. 1997) (quoting *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977)). The reason for this heightened standard is that the relevant antitrust laws were enacted for “the protection of competition not competitors.” *Brunswick Corp.*, 429 U.S. at 488 (quoting *Brown Shoe Co. v. United States*, 370 U.S. 294 (1962)). An injury to an economic actor does not necessarily mean there has been an injury to the market. The standing requirement prevents litigants from recovering under the antitrust laws when the action challenged would “tend to promote competition in the economic sense.” *HyPoint Tech., Inc.*, 949 F.2d at 877.

In determining whether a plaintiff has standing, courts look to a number of factors, including:

(1) the causal connection between the antitrust violation and harm to the plaintiff and whether that harm was intended to be caused; (2) the nature of the plaintiff’s alleged injury including the status of the plaintiff as consumer or competitor in the relevant market; (3) the directness or indirectness of the injury, and the related inquiry of whether the damages are speculative; (4) the potential for duplicative recovery or complex apportionment of damages; and (5) the existence of more direct victims of

the alleged antitrust violation.

NicSand, Inc. v. 3M Co., 457 F.3d 534, 549 (6th Cir. 2006) (citing *Southaven Land Co., Inc. v. Malone & Hyde, Inc.*, 715 F.2d 1079, 1085 (6th Cir. 1983)). This list is not exhaustive, and no single factor is determinative. *See id.* (citing *Indeck Energy Servs., Inc. v. Consumers Energy Co.*, 250 F.3d 972, 976 (6th Cir. 2000)).

In this case, Plaintiff's antitrust claims are based on a variety of legal theories. The bulk of his allegations are brought under Section 1 of the Sherman Act, which prohibits conspiracies in restraint of trade. *See* 15 U.S.C. § 1 (2006). Plaintiff alleges that Defendants attempted to exclude Villafane and CHS from the market for pediatric services by terminating Villafane's privileges at Kosair, and such action coupled with other efforts to exclude Villafane constitute a group boycott and a conspiracy to eliminate a competitor by unfair business conduct. He further alleges that contracts among the Defendants are exclusive dealing arrangements in furtherance of an illegal monopoly, and he characterizes Kosair as an essential facility from which Villafane may not be excluded. He charges the Research Fund, Cook, and the Physician Defendants with use of the PPP as an anti-competitive device. Plaintiff also alleges that Defendants conspired to deny Villafane the ability to recruit other physicians, which effected an output restriction on CHS.¹⁴ Plaintiff also brings claims under Section 2 of the Sherman Act, which prohibits monopolies. *See* 15 U.S.C. § 2 (2006). Plaintiff alleges that Defendants have conspired, attempted, or actually monopolized the Louisville market for pediatric services.

For each of these claims, Plaintiff also asserts the Kentucky state law equivalent under

¹⁴ Interestingly, Plaintiff has equated the university's refusal to hire employees of Villafane with price fixing, which typically occurs when two or more competitors selling the same product agree to sell at some price that will guarantee profit windfalls.

the Little Sherman Act, *see Consumer Protection Act*, Ky. Rev. Stat. Ann. § 367.175 (2006), and brings two additional state law claims of unfair competition and unlawful conspiracy in excluding Villafane from the Louisville marketplace and in conspiring to drive him out of business. *See* Ky. Rev. Stat. Ann. § 367.170 (2006).

A careful analysis of Plaintiff's antitrust allegations reveals significant factual, conceptual and legal difficulties. Specifically, Plaintiff has failed to show any legally cognizable antitrust injury. Plaintiff has alleged no facts that tend to show that Defendants actions actually harmed the market for pediatric cardiac services by increasing price or reducing the quality of service. Plaintiff's personal injury is obvious: his privileges at Kosair were revoked following a peer review, resulting in his inability to practice at Kosair. Plaintiff contends that the peer review action was only the final move by Defendants in a string of actions designed to eliminate him from the pediatric cardiology market. Prior to the revocation of his privileges, he contends, Defendants had consistently attempted to exclude him from the marketplace by manipulating his on-call schedule and failing to grant CHS employees positions at the university. Assuming the facts alleged in the complaint are true, the injury to Villafane is clear. Without a suitable on-call rotation he would not be able to obtain as many patients as other doctors, and without the blessings of the university, his new employees would not be granted privileges at Kosair. Ultimately his practice was destroyed, he contends, when the peer review resulted in the revocation of his own privileges at Kosair.

The peer review action cannot support an antitrust claim. Injury to Villafane alone, without a showing that it is the type of injury that the Sherman Act is designed to prevent, is not sufficient to sustain an antitrust action. *Care Heating & Cooling, Inc. v. A.M. Standard Inc.*, 427

F.3d 1008, 1014-15 (6th Cir. 2005). Even if not protected by HCQIA immunity, a decision by a hospital to terminate a single doctor's privileges simply does not result in the type of injury to competition that the antitrust laws were designed to prevent. The Sixth Circuit has been reasonably aggressive in using the antitrust injury doctrine to bar recovery where the asserted injury, although linked to an alleged violation of the antitrust laws, flows directly from conduct that is not itself an antitrust violation. *Valley Products Co., Inc. v. Landmark, a Div. of Hospitality Franchise Systems, Inc., et al.*, 128 F.3d 398, 403 (6th Cir. 1997). The *Valley Products* court affirmed the district court's ruling that "because Valley's and Savannah's injuries do not result from a decrease in competition in the marketplace, but rather from the termination of their respective contracts, the court finds that there is no antitrust showing in the plaintiffs' original complaints." *Id.* at 404 (quoting *Valley Products Co., Inc. v. Landmark*, 877 F.Supp. 1087 (W.D.Tenn.1994)). Similarly, termination of Villafane's privileges at Kosair cannot be the basis for antitrust standing.

Nor does the alleged manipulation of the on-call rotation schedule amount to an antitrust injury. The on-call rotation is a primary source of new business for physicians. As unscheduled patients arrive in the hospital they are assigned to the on-call physician, who will often remain as their physician for subsequent procedures. Failure to obtain a favorable on-call rotation schedule can be very damaging to a given physician's practice, but it is not an antitrust injury. There are other available methods for resolving disputes among doctors concerning their on-call schedules, such as the mediation process that was used in 1994, and failure of this process does not show an injury of the type the antitrust laws were designed to prevent. A shift in patients from one competitor to another simply does not reduce output, or establish harm to market wide

competition. *See Expert Masonry, Inc. v. Boone County, Ky.*, 440 F.3d 336, 346-47 (6th Cir. 2006).

The fact that the university refused to grant clinical appointments to Villafane's recent hires does not create antitrust injury either. Villafane cannot hope to compel the university to hire his employees simply because he wants to grow his business, CHS, to compete with PCA. The university's refusal to hire Villafane's picks, at a time when Villafane's catherization laboratory procedures were under investigation, does not constitute injury to consumers or the market.

Some circuits have enunciated a further requirement that a plaintiff be an efficient enforcer of the antitrust laws in order to enforce them. *See, e.g., Todorov v. DCH Healthcare Auth.*, 921 F.2d 1438, 1450-52 (11th Cir. 1991); *see also Daniel v. Am. Bd. of Emergency Med.*, 428 F.3d 408 (2nd Cir. 2006). Even if it could be shown that Defendants actions are injurious to the market for pediatric services, Villafane is not an efficient enforcer of the antitrust laws. Rather, he is a competitor seeking a share of the profits. The Second Circuit recently dismissed a similar case for lack of antitrust standing. *See Daniel*, 428 F.3d at 408. In *Daniel*, plaintiffs alleged that their inability to obtain certification from the American Board of Emergency Medicine prevented them from obtaining the same supra-competitive profits as the defendant conspirators, who were able to obtain certification. The Second Circuit affirmed the dismissal of the complaint on the basis of lack of antitrust standing, noting that "there is no antitrust right to join a cartel." *Id.* at 24. Here, Villafane's personal injury is that he was not permitted to "join the cartel", if it can be called that at all, allegedly created by PCA through its relationship with Kosair.

Villafane’s vague and conclusory allegations of antitrust law violations fail to identify any legally cognizable antitrust injury. It is true that when the proof of antitrust violations is largely in the hands of the conspirators, “dismissals prior to giving the plaintiff ample opportunity for discovery should be granted very sparingly.” *Hospital Bldg. Co. v. Trustees of Rex Hospital*, 425 U.S. 738, 746-747 (1976). However, knowledge of one’s own injuries and a conceptual knowledge of injury to the marketplace should be known and alleged in the complaint. Moreover, additional discovery will add little more to Plaintiff’s status as an efficient enforcer. Thus, Plaintiff has no standing to sue under his antitrust claims.

Plaintiffs also asserted a variety of other common law and state law claims which Defendants have urged this Court to dismiss. The Court will issue a further Memorandum Opinion on these issues at a later time. The Court will enter an order consistent with this Memorandum Opinion.

cc: Counsel of Record