

**UNITED STATES DISTRICT COURT  
MIDDLE DISTRICT OF FLORIDA  
TAMPA DIVISION**

**UNITED STATES OF AMERICA *ex rel.*  
SAMUEL L. ARMFIELD, III, and  
PATRICIA ARMFIELD,**

**Plaintiffs,**

**vs.**

**Case No. 8:07-cv-2374-T-27TBM**

**JAMES P. GILLS, *et al.*,**

**Defendants.**

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**ORDER**

**BEFORE THE COURT** is Relators' Motion for Summary Judgment on Defendants' Ninth Defense (Dkt. 386) and Defendants' response in opposition (Dkt. 403). Based on the undisputed facts, Relators have not demonstrated entitlement to judgment as a matter of law with respect to whether the financial arrangement between Dr. Deverick and Defendants comply with the safe harbor provisions of the Anti-Kickback Act. Accordingly, the motion is due to be denied.

**Introduction**

In Count IV of their Fourth Amended Complaint, Relators allege that the financial arrangement between Dr. Stephanie A. Deverick and Defendants, specifically the space and equipment leases and personal services contract, violated the federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b)(1)(A) ("**Anti-Kickback Act**"). Specifically, Relators allege that the payments made by Dr. Deverick pursuant to those agreements were intended, at least in part, to induce referrals of patients to her in violation of the Anti-Kickback Act. *See* Joint Pretrial Stipulation (Dkt. 412), p. 6.

In their Ninth Affirmative Defense, Defendants contend that each of the agreements falls within the safe harbor protections of the Anti-Kickback Act. Specifically, Defendants allege:

To the extent that it is deemed an affirmative defense, Defendants have no liability under Count IV of the Fourth Amended Complaint because the payments at issue in Count IV satisfy the standards set forth in 42 C.F.R. § 1001.952 (“Exceptions”) and, thus, are not prohibited “remuneration” within the meaning of 42 U.S.C. § 1320a-7b(b). Defendants reserve and do not waive their position that this is not an affirmative defense and that it is Relators’ burden to prove as part of their affirmative case that defendants have not complied with the Exceptions.

Amended Answer to Relators’ Fourth Amended Complaint (Dkt. 375), p. 30.<sup>1</sup> The issue on summary judgment is whether the undisputed facts demonstrate, as Relators contend, that the contracts failed to comply with the regulatory requirements of the safe harbor provisions.

#### **Undisputed Facts**

Dr. James P. Gills, Jr. (“**Dr. Gills**”), a physician specializing in ophthalmologic surgery, founded Defendant St. Luke’s Cataract and Laser Institute (the “**Institute**”) and Defendant St. Luke’s Surgical Center (the “**Surgical Center**”). Joint Pretrial Statement (Dkt. 412), ¶¶ 9.2, 9.5. The Institute is a Florida corporation doing business in Tarpon Springs. *Id.* The Surgical Center is a Florida corporation operating an ambulatory surgical center (“**ASC**”) in Tarpon Springs. *Id.* at ¶ 9.3. The Institute and the Surgical Center are located in the same building. *Id.* at ¶ 9.6.

Dr. Deverick is a physician providing preoperative examinations at the complex owned by Defendants to patients referred to her by Dr. Gills and other physicians at the Institute and/or the Surgical Center. *Id.* at ¶ 9.37. Dr. Deverick leased space, equipment, and personal services from

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<sup>1</sup> Defendants acknowledge in the Joint Pretrial Stipulation that “[t]he burden is on the party seeking protection under any safe harbor to demonstrate strict compliance with each and every element of such safe harbor.” Joint Pretrial Stipulation (Dkt. 412), ¶ 10.34.

Defendants to conduct her medical practice pursuant to written agreements.<sup>2</sup> As described by Defendants, the agreements between Dr. Deverick and Defendants essentially provided Dr. Deverick a “‘turnkey’ practice setting, with the office space, equipment, and administrative and personnel support she needed to provide preoperative consultations to St. Luke’s patients on St. Luke’s premises.” Defendants’ Response Memorandum (Dkt. 403), p. 3.

The business relationship between Dr. Deverick and Defendants was outlined in an Agreement for Lease of Space (“**Space Lease Agreement**”), a Medical and Office Equipment Lease Agreement (“**Equipment Lease Agreement**”), and a Personal Services Agreement (“**Services Agreement**”), each originally dated October 14, 1998 (collectively, the “**Rental Agreements**”). *Id.* at ¶ 9.38.<sup>3</sup> Copies of the Rental Agreements are attached as Exhibit 20 to the Fourth Amended Complaint and filed under seal at Dkt. S-13.

The Rental Agreements described in general terms the space, equipment, and services covered by the agreements. While the Rental Agreements provided for a “total contract value” and aggregate monthly payment, the total payment was allocated between the three agreements in a document attached to the Rental Agreements as Exhibit A, entitled: “Deverick Contract Calculations Based on Guidance from Safe Harbor Proposals.” Exhibit A allocated a portion of the aggregate rent to the Space Lease Agreement based on Dr. Deverick’s use of 1,021.66 square feet of the Surgery Center. The exhibit also identified and allocated portions of the aggregate payment amount to

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<sup>2</sup> “Under the arrangement, Dr. Deverick leased certain office space, equipment, and personnel in the surgery center, for the purpose of performing pre-operative consultations on patients undergoing procedures at the surgery center.” Joint Pretrial Stipulation (Dkt. 412), p. 6.

<sup>3</sup> The Rental Agreements were subsequent to agreements dated April 1, 1990, and December 29, 1987. *Id.* at ¶ 9.39.

certain “equipment” and “other services” that would be furnished by Defendants under the Rental Agreements.

Between 2001 and 2004, Dr. Deverick’s payments to Defendants remained constant and consistent with the terms of the Rental Agreements originally negotiated in 1998. Joint Pretrial Statement (Dkt. 412), ¶ 9.41. In 2005, Dr. Deverick and Defendants negotiated an amendment to the Rental Agreements, increasing the amount paid by Dr. Deverick by approximately 12%. The payment reflecting the increase in lease payments was documented in a Memorandum of Understanding, effective March 1, 2005. *Id.* The Memorandum of Understanding allocated the aggregate payment between “Premises Rent, “Equipment Rent,” and “Personal and Other Services.”

Dr. Deverick and Defendants entered into a second Memorandum of Understanding dated September 1, 2006, and a third Memorandum of Understanding, dated July 1, 2008, both of which reduced the payments due under the Rental Agreements. *Id.* at ¶¶ 9.42, 9.43, 9.44. These Memoranda of Understanding also allocated the aggregate payment between “Premises Rent, “Equipment Rent,” and “Personal and Other Services.”

### **Summary Judgment Standard**

Summary judgment is proper if, following discovery, the pleadings, depositions, answers to interrogatories, affidavits and admissions on file show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); Fed. R. Civ. P. 56(c). “An issue of fact is ‘material’ if, under the applicable substantive law, it might affect the outcome of the case.” *Hickson Corp. v. N. Crossarm Co.*, 357 F.3d 1256, 1259-60 (11th Cir. 2004). “An issue of fact is ‘genuine’ if the record taken as a whole could lead a rational trier of fact to find for the nonmoving party.” *Id.* at 1260. All the

evidence and factual inferences reasonably drawn from the evidence must be viewed in the light most favorable to the nonmoving party. *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 157 (1970); *Jackson v. BellSouth Telecomms.*, 372 F.3d 1250, 1280 (11th Cir. 2004).

### **Discussion**

The Anti-Kickback Statute prohibits any person from knowingly or willfully paying or receiving any remuneration in cash or in kind for referrals for any services under Medicare/Medicaid programs. The Department of Health and Human Services (“HHS”) has promulgated regulations establishing a safe harbor for certain arrangements between healthcare providers which remove them from the scope of the Anti-Kickback Act. *See* 42 U.S.C. § 1320a-7b(b)(3)(E). These safe harbor provisions include:

(b) **Space rental.** As used in [the Anti-Kickback] Act, “remuneration” does not include any payment made by a lessee to a lessor for the use of premises, as long as all of the following six standards are met--

- (1) The lease agreement is set out in writing and signed by the parties.
- (2) The lease covers all of the premises leased between the parties for the term of the lease and specifies the premises covered by the lease.
- (3) If the lease is intended to provide the lessee with access to the premises for periodic intervals of time, rather than on a full-time basis for the term of the lease, the lease specifies exactly the schedule of such intervals, their precise length, and the exact rent for such intervals.
- (4) The term of the lease is for not less than one year.
- (5) The aggregate rental charge is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated

between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.

(6) The aggregate space rented does not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the rental. Note that for purposes of paragraph (b) of this section, the term fair market value means the value of the rental property for general commercial purposes, but shall not be adjusted to reflect the additional value that one party (either the prospective lessee or lessor) would attribute to the property as a result of its proximity or convenience to sources of referrals or business otherwise generated for which payment may be made in whole or in part under Medicare, Medicaid and all other Federal health care programs.

(c) **Equipment rental.** As used in [the Anti-Kickback] Act, “remuneration” does not include any payment made by a lessee of equipment to the lessor of the equipment for the use of the equipment, as long as all of the following six standards are met--

(1) The lease agreement is set out in writing and signed by the parties.

(2) The lease covers all of the equipment leased between the parties for the term of the lease and specifies the equipment covered by the lease.

(3) If the lease is intended to provide the lessee with use of the equipment for periodic intervals of time, rather than on a full-time basis for the term of the lease, the lease specifies exactly the schedule of such intervals, their precise length, and the exact rent for such interval.

(4) The term of the lease is for not less than one year.

(5) The aggregate rental charge is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or all other Federal health care programs.

(6) The aggregate equipment rental does not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the rental. Note that for purposes of paragraph (c) of this section, the term fair market value means that the value of the equipment when obtained from a manufacturer or professional distributor, but shall not be adjusted to reflect the additional value one party (either the prospective lessee or lessor) would attribute to the equipment as a result of its proximity or convenience to sources of referrals or business otherwise generated for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.

**(d) Personal services and management contracts.** As used in [the Anti-Kickback] Act, “remuneration” does not include any payment made by a principal to an agent as compensation for the services of the agent, as long as all of the following seven standards are met--

(1) The agency agreement is set out in writing and signed by the parties.

(2) The agency agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent.

(3) If the agency agreement is intended to provide for the services of the agent on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals.

(4) The term of the agreement is for not less than one year.

(5) The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.

(6) The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.

(7) The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

For purposes of paragraph (d) of this section, an agent of a principal is any person, other than a bona fide employee of the principal, who has an agreement to perform services for, or on behalf of, the principal.

42 C.F.R. § 1001.952 (2007). In adopting the safe harbor provisions, HHS explained that “[i]f a person participates in an arrangement that fully complies with a given [safe harbor] provision, he or she will be assured of not being prosecuted criminally or civilly for the arrangement that is the subject of that provision.” *Background to Safe Harbor Provisions*, 56 Fed. Reg. 35952, 35954 (July 29, 1991).

Where, as here, a single payment is made for multiple purposes (*i.e.*, payment of rent and compensation for services), each separate aspect of the payment must comply with the respective safe harbor provision. *See Background to Safe Harbor Provisions*, 56 Fed. Reg. 35952, 35957 (July 29, 1991).<sup>4</sup> In this regard, each of the applicable safe harbor provisions require that the compensation arrangement be in writing, signed by the parties, and specify the services, equipment,

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<sup>4</sup> In comments accompanying the adoption of the safe harbor provisions, HSS stated:

A person engaged in a ‘multi-purpose’ payment practice who seeks protection will need to document separately his or her compliance with the safe harbor applicable to each purpose being served by the payment practice. Compliance with one provision (for one of the purposes of the payment practice) would not insulate the entire payment practice from criminal prosecution or exclusion, where another purpose of the payment practice is implemented in a manner which violates the statute.

*Background to Safe Harbor Provisions*, 56 Fed. Reg. 35952, 35957 (July 29, 1991).



or premises covered by the agreement. *See* 42 C.F.R. § 1001.952(b); *United States ex rel. Singh, M.D. v. Bradford Regional Medical Center*, 752 F.Supp.2d 602, 635 (W.D. Pa. 2010). The burden is on the party seeking protection under a safe harbor provision to demonstrate strict compliance with each and every element of the safe harbor. *See, e.g., United States ex rel. Westmoreland v. Amgen, Inc.*, 812 F.Supp.2d 39, 47 (D. Mass. 2011); *see also United States ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88, 91 (3d Cir. 2009) (applying personal service contract exception under Stark Act, which court stated was “substantially identical” to corresponding Anti-Kickback Act safe harbor); *see also* Joint Pretrial Stipulation (Dkt. 412), ¶ 10.34.

Here, it is undisputed that the agreements were in writing, signed by the parties, were for a period of not less than a year, the payments were set in advance without regard to referrals, and were negotiated in an arm’s length transaction. The only record evidence concerning fair market value is Defendants’ evidence that the rent and equipment payments were calculated based on fair market value and that the aggregate payments made by Dr. Deverick were consistent with fair market value.

The focus therefore is on whether the agreements met the safe harbor provisions requiring that the space, equipment and personal services to be provided by Defendants be specified in the writing. Relators contend that the Rental Agreements fail to specify the premises, equipment, and services. The Court disagrees.

First, it is noted that Relators have no difficulty describing the financial arrangement between Defendants and Dr. Deverick, or the office space, equipment and services covered by the Rental Agreements. *See* Relators’ Motion for Summary Judgment (Dkt. 386), pp. 4-5. Nor do relators have any difficulty understanding the allocation of the aggregate rent. *Id.* Rather, Relators essentially

contend that the safe harbor provisions require greater specificity than what is set out in the agreements. Relators cite no persuasive authority, however, supporting their contentions.

With respect to the space rental, Relators contend that the lease agreement “does not purport to identify any particular space being rented,” and that the agreement “does not give any clue as to how the rental amount is calculated.” *Id.* at pp. 7-8. They contend that “without knowing what premises are being rented at any given time, it is impossible to perform a fair market value analysis.” *Id.* at p. 9.

Contrary to Relators’ contention, the Space Lease Agreement does not fail to “specify the premises covered by the lease.” *See* 42 C.F.R. § 1001.952. Indeed, it provides that the “Space” being leased by Dr. Deverick is “sufficient Space for the rendering of medical services and administration of Deverick P.A. located at 43309 U.S. Highway 19 North, Tarpon Springs, Florida.” The agreement defines “Space” as the “exclusive use of private office space sufficient for physician and officer manager; exclusive use of an examination area to perform preoperative clearances on Surgery Center patients; exclusive use of an area for the storage of medical records of Deverick P.A.; and non-exclusive use of common areas including, but not limited to hallways, waiting areas, rest rooms and kitchen facilities.” Space Lease Agreement, ¶ 6.1. Further, Exhibit “A” to the lease specifies the aggregate contract value, monthly payments, and “1021.66 SQ Feet @ \$ 20.00” as the premises rented.

Relators’ contention that 42 C.F.R. § 1001.952(b)(2) requires greater specificity is unpersuasive. Nothing in the regulation requires any more than what is contained in the Space Lease Agreement, and Relators cite no authority requiring any greater specificity. Had the agreement

merely provided that Dr. Deverick would be renting “sufficient Space for the rendering of medical services and administration of Deverick P.A.,” Relators’ argument would be more persuasive.

It is undisputed that the actual space occupied by Dr. Deverick changed over time because of construction at the Surgery Center or personnel turnover.<sup>5</sup> And it is undisputed that her lease rate was adjusted on an annual basis as reflected in each Memorandum of Understanding executed by the parties in March, 2006, September, 2006 and July, 2008. Contrary to Relators’ contention, however, the record demonstrates the reasons why her rent was adjusted. *See, e.g.*, Defendants’ Motion for Summary Judgment (Dkt. 387), pp. 17-18.

Relators overlook that each Memorandum of Understanding is expressly designated as an “Amendment” to the original Rental Agreements and each Amendment provided that “[a]ll other terms of the Agreements remain in full force and effect.” Contrary to Relators’ argument, the safe harbor regulations do not require an explanation of the reasoning behind annual rent adjustments. It follows that Defendants are correct that “the safe harbor regulations do not require an explanation in the contract of the rationale behind rental payments, amounts, or charges.” Relators’ contentions to the contrary are unpersuasive, unsupported by legal support, and certainly do not support their request for judgment as a matter of law.

With respect to the Equipment Lease Agreement, the lease similarly complies on its face with the safe harbor requirement that the equipment covered by the lease be specified. Relators acknowledge that the Equipment Lease specifies the items of equipment leased by Dr. Deverick and the annual rent for that equipment. *See* Relators’ Motion for Summary Judgment (Dkt. 386), p. 17.

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<sup>5</sup> The premises occupied by Dr. Deverick changed over time and varied between “rather large” and “very small” areas at the Surgical Center. Deverick Dep. (Dkt. 386-1), pp. 58-59, 190-91. For example, Dr. Deverick acknowledged that at the time of the March 2005 Amendment (increasing the rental amount) her practice’s “office space was decreased in size pretty remarkably at that time ... . We were like in a little closet, one small area.” *Id.* at 184.

Indeed, the definition of “Medical & Office Equipment” identifies office furnishings, equipment, and medical equipment covered by the lease. *See* Equipment Lease, p. 2 (defining “Medical & Office Equipment” as “including but not limited to” certain furniture, supplies, and equipment “as mutually agreed upon by the parties as appropriate for the assessment and diagnosis of disease”).

Relators contend that “Defendants have offered no evidence that this amount reflected fair market value for the particular items of equipment rented.” *See* Relators’ Motion for Summary Judgment (Dkt. 386), p. 17. However, the record contains Mr. Yates’ explanation of his calculation of fair market value of the equipment covered by the original lease, which was done without regard to referrals. *See, e.g.*, Declaration of David Yates (Dkt. 387-39), ¶¶ 21. Moreover, Exhibit A to the Rental Agreement lists the items of medical equipment covered by the Equipment Lease, as well as the calculation of market value, useful life of each item, and the fair market value of each item. Simply put, Defendants’ contentions do not demonstrate entitlement to judgment as a matter of law.

The Services Agreement likewise complies with the requirement that it specify the services provided. Although it recites that Defendants will provide “sufficient Non-Medical Personnel for reasonable administrative support of Deverick P.A. ... on a non-exclusive basis for use by Deverick P.A. during normal business hours at its medical practice located at 43309 U.S. Highway 19 North ... ,” the agreement specifies that “Non-Medical Personnel means support staff, including but not limited to receptionists, medical records staff, clerical support staff, nurses and others necessary to assist Deverick P.A. in its provision of medical services.” Personal Services Agreement, ¶ 6.1. By describing the “Non-Medical Personnel,” the agreement specifies what services are to be provided by Defendants. Nothing in the safe harbor provision requires any greater specificity, contrary to Relators’ unsupported contentions.

Finally, the Services Agreement provides that Defendants and Dr. Deverick may employ on a part time basis “certain physician assistants, nurse practitioners or certified nurse anesthetists.” Significantly, the agreement provides that the party employing those “Physician Extenders” is “solely” responsible paying them. In other words, those employees are made available to Dr. Deverick but she has the sole responsibility for paying them for services rendered.

Relators contend that “Dr. Deverick does not have full-time use of “Non-Medical Personnel and Physician Extenders,” and therefore 42 U.S.C. § 1001.952(d)(3) requires that the agreement “specif[y] exactly the schedule of such intervals, their precise length, and the exact charge for such intervals.” Relators’ Motion for Summary Judgment (Dkt. 386), p. 11. That contention is misplaced. With respect to “Non-Medical Personnel,” the agreement specifies that the Surgery Center shall provide those personnel “during normal business hours.” On its face, therefore, section 1001.952(d)(3) is inapplicable to “Non-Medical Personnel.” With respect to the part-time “Physician Extenders,” Dr. Deverick was solely responsible for paying those “Physician Extenders” rendering services to her. Accordingly, section 1001.952(d)(3) is not implicated.

To the extent Relators challenge whether Dr. Deverick’s annual payments for the use of these “Non-medical Personnel” and “Physician Extenders” bear any resemblance to fair market value, Defendants have submitted the opinion of Daryl Johnson, their valuation expert. Relators have submitted no contrary evidence. This necessarily precludes summary judgment in favor of Relators on this contention.

Finally, Relators seemingly contend, without fully developing their argument, that the inclusion of patient transportation expenses and “Other Services Provided” in Exhibit A to the Agreements removes the agreements from safe harbor protection. Relators reason that the

transportation payments and other services are not covered by the lease and services agreements and therefore the agreements fall outside the safe harbor provisions. These arguments do not support summary judgment in Relators' favor.

Exhibit A is implicitly, if not expressly, incorporated into each of the Rental Agreements. Accordingly, the services described in Exhibit A necessarily are covered by the Personal Services agreement as "reasonable administrative support," specifically "clerical support staff, billing support staff, data processing support staff, transportation staff, nurses and others necessary to assist Deverick P.A. in its provision of medical services." Likewise, the inclusion of "transportation staff" necessarily implies the provision of transportation services for which Deverick P.A. agreed to pay. And again, Defendants have presented Mr. Yate's explanation of his calculation of fair market value, including the cost of the van. Relators offer no contrary evidence.

### **Conclusion**

Relators have not demonstrated that they are entitled to summary judgment as a matter of law based on the undisputed evidence. As the HHS Office of Inspector General noted in the Special Fraud Alert cited by Defendants, "[s]pecific equipment used should be identified and documented and payment limited to the prorated portion of its use. Similarly, any services provided should be documented and payment should be limited to the time actually spent performing such services." *Special Fraud Alert, Rental of Space in Physician Offices by Persons or Entities to Which Physicians Refer*, Office of Inspector General, Department of Health and Human Services, 2000 WL 35747422 (Feb. 2000). The Rental Agreements between Defendants and Deverick P.A. facially comply with this alert, to the extent that it constitutes a persuasive interpretation of the safe harbor requirements at issue.

The safe harbor provisions are intended to offer the transparency and verifiability “that comes from an express agreement reduced to writing and signed by the parties which specifies all of the services to be provided by the physician and all of the remuneration to be received for those services.” *Kosenske*, 554 F.3d at 97-98. The Rental Agreements in this case provide that transparency and verifiability.<sup>6</sup> Accordingly, Relators’ Motion for Summary Judgment on Defendants’ Ninth Defense (Dkt. 386) is **DENIED**.

This order only addresses whether Relators are entitled to judgment as a matter of law on Defendants’ Ninth Defense. Disputed factual issues regarding the business arrangement between Defendants and Dr. Deverick must be resolved to the jury.

**DONE AND ORDERED** this 29<sup>th</sup> day of October, 2012.

  
**JAMES D. WHITTEMORE**  
United States District Judge

Copies to: Counsel of Record

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<sup>6</sup> Even if the agreements were not sufficiently specific to satisfy the safe harbor provisions, that does not mean that the arrangement between Dr. Deverick and Defendants violated the Anti-Kickback Act. *See Background Relating to Adoption Final Rule Clarifying Safe Harbor Provisions Under the Anti-Kickback Statute*, 64 Fed. Reg. 63518, 63519 (Nov. 19, 1999); *see also Westmoreland*, 812 F.Supp.2d at 47; *Feldstein v. Nash Cmty. Health Svcs.*, 51 F.Supp.2d 673, 687 (E.D.N.C. 1999) (“[T]he failure to fall within a[n Anti-Kickback] safe harbor does not necessarily mean that the conduct/relationship is prohibited by the ... statute.”).