I. FACTUAL BACKGROUND

V&S Medical Associates (the "Practice") was a physician group owned by two internists, Drs. Vaccaro and Saleh (the "Physicians'). The Practice was a significant source of referrals for Bradford Regional Medical Center (the "Hospital"), including referrals for nuclear testing. In 2001, the Practice leased a nuclear camera from GE (the "GE Camera"). The camera was located at the Practice's offices. The Physicians personally guaranteed the lease.

The Hospital threatened the Physicians with loss of medical staff privileges, alleging that the Practice's acquisition of a nuclear camera violated the Hospital's "Policy on Physicians with Competing Financial Interests," which prohibited any physician on the Hospital's medical staff from having an ownership or investment interest in any health care entity or service which significantly competed with the Hospital. In the course of discussions regarding the enforceability of the Policy and possible solutions to the dispute (such as a joint venture "under arrangement" structure), the Hospital and the Practice resolved their differences by entering into a sublease arrangement.

II. THE SUBLEASE ARRANGEMENT

A. Sublease Terms

In October 2003, the Practice and the Hospital executed a written agreement pursuant to which the Hospital subleased the GE Camera from the Practice, and the Physicians agreed not to compete with the Hospital in the provision of nuclear imaging services during the five-year term of the Sublease (which was signed by the Physicians personally). Payments under the Sublease included a pass-through of the monthly amounts due under the Practice's lease for the GE Camera, plus $23,655 per month for "all other rights" under the Sublease, including the non-compete provision. The Sublease stated that the nuclear camera would be moved to the Hospital's premises.

B. Accountant's Report

The Hospital obtained a report prepared by an accountant that concluded the amounts to be paid under the Sublease were "reasonable." In reaching this conclusion, the accountant compared the revenues the Hospital expected to generate with the Sublease in place versus the revenues the Hospital expected to receive without the Sublease in place. The revenue projections were based on the assumption that the Physicians would refer nuclear imaging services to the Hospital once the Sublease went into effect.

C. Initial Use of Equipment (the Actual Arrangement)

The GE Camera was never relocated to the Hospital; instead, it was operated by the Hospital for 5 months at the Practice's office and then ceased being used altogether (because it was not suited to the Hospital's long-term needs). The terms of the actual arrangement were not documented in a formal written contract, but were evidenced in other writings, including a proposal letter from the Practice and an invoice: (i) the Hospital was invoiced and paid the Practice $2,500 per month in space rent, plus additional amounts for secretarial and other

expenses associated with the Hospital's use of the camera at the Practice's offices; (ii) the Practice billed for all tests performed using the GE Camera (in the Hospital's name and tax identification number); and (iii) the Hospital paid the Practice a billing fee equal to 10% of all collections.

D. Replacement Camera

In March 2004, the Practice entered into a five-year lease for a new camera from Philips (the "Philips Camera"). In connection with the new lease, Philips paid off the remaining amounts the Practice owed under the GE lease, the Practice agreed to repay the buy-out fee, and the Hospital guaranteed the Practice's obligation to repay the buy-out fee. The Hospital then reimbursed the Practice for its payments ($200,000) to Philips for the buy-out of the GE Camera. The Philips Camera was placed at the Hospital. The Practice and the Hospital did not execute a formal written lease or agreement reflecting the foregoing terms with respect to the Philips Camera.

III. THE COURT'S STARK LAW ANALYSIS & CONCLUSIONS

A. Sublease Created Indirect Compensation Arrangements Between the Hospital & the Physicians

The plaintiffs alleged that the Sublease effectuated indirect compensation arrangements between the Hospital and each of the Physicians. In response, the Physicians and the Hospital contended that the Sublease did *not* effectuate "indirect compensation arrangements," as defined in 42 C.F.R. §411.354(c)(2), because the aggregate compensation under the Sublease was fixed and did not vary, let alone with the volume or value of patients referred by the Physicians to the Hospital.

The court acknowledged that the compensation under the Sublease was fixed, but found that it was still necessary to consider whether the compensation to the Practice "takes into account" or "otherwise reflects" referrals. Specifically, the court was concerned that the fixed payments took into consideration the value of the Physicians' *anticipated* referrals. The court stated that compensation that takes into account anticipated referrals runs afoul of the Stark Law's definition of "fair market value," which, in relevant part, states that compensation is fair market value only "where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals." 42 C.F.R. §411.351 (definition of "fair market value").

In analyzing whether the compensation under the Sublease "took into account" referrals, the court noted that the accountant's report included a table that showed the expected revenues the Hospital would receive with the Sublease (and its non-compete) in place versus the amounts that the Hospital would pay to the Practice under the Sublease (including for the non-compete). The court stated that this table was "based on the assumption that the physicians would likely refer business to the hospital in the absence of a financial interest in their own facilities or services, although they are not required to do so by virtue of any of the covenants contained in the Agreements or otherwise." The court further found that the accountant's report itself

provided evidence that the payments by the Hospital for the non-compete were based in part on anticipated referrals from the Physicians.

During trial, the Hospital's CEO testified that "the purpose of the non-compete... was to make sure that [the Physicians] didn't have a financial incentive to refer away from the hospital." Further, the Hospital's CEO had given a presentation to the Hospital's Board in which he relied on a written summary that showed expected profit for the Hospital from the Sublease agreement, where the expected profit included a portion of business that would be referred by the Physicians.

In addition, based on affidavits submitted by the Hospital's CEO, the court noted that the amount of the monthly non-compete payments (*i.e.*, $23,655) was equivalent to the Physicians' anticipated monthly profits from operating a nuclear camera, thus confirming that the compensation took into account referrals. The court stated that the only way the proposed amount of business could end up with the Hospital was if the Physicians referred that business to the Hospital, and thus the amount to be paid for the non-compete was arrived at by considering the amount of business the Hospital would receive from the Physicians.

The Hospital and the Physicians argued that, despite this evidence, the compensation under the Sublease met a "bright line rule" created by CMS and therefore did not "take into account" the volume or value of referrals, such that the Sublease did not effectuate indirect compensation arrangements between the Hospital and each of the Physicians. CMS' "bright line rule" is referenced in the preamble to the 2001 Stark II Phase I final regulations:

> A compensation arrangement does not take into account the volume or value of referrals... if the compensation is fixed in advance and will result in fair market value and the compensation does not vary over the term of the arrangement in any manner that takes into account referrals. 66 Fed. Reg. 877-878.

The court analyzed the "bright line rule" and found that it does not actually provide a "bright line" with respect to establishing "fair market value." Further, the court held that the burden of establishing whether fixed compensation is consistent with fair market value rests with the defendants. In this regard, the court concluded that because the accountant's fair market value analysis was based on anticipated referrals from the Physicians to the Hospital, the compensation did not satisfy the Stark definition of "fair market value," but rather, had been "inflated to compensate for the [Physicians'] ability to generate other revenues."

Therefore, the court held that the "bright line rule" was inapplicable and that, because the Hospital "took into account" anticipated referrals from the Physicians when determining the compensation under the Sublease, even though the aggregate compensation was "fixed," the Sublease effectuated indirect compensation arrangements between the Hospital and each of the Physicians.

The court also ruled that the 10% collection fee arrangement between the Hospital and the Practice varied with the volume or value of the Physicians' referrals and therefore also effectuated indirect compensation arrangements between the Hospital and each of the Physicians.

B. Arrangement Also Involved Direct Compensation Between the Hospital & the Physicians

Despite the fact that the parties to the Sublease were the Practice and the Hospital, the court also found that *direct* compensation arrangements existed between the Hospital and the Physicians by virtue of several factors: (a) the Physicians personally signed the Sublease with the Hospital; (b) in connection with the buyout of the GE Lease, the Hospital guaranteed the payments for which the Physicians had personal liability; and (c) the Hospital actually made $200,000 in payments relating to the buyout of the GE Lease. Notably, the court stated that the Hospital relieved the Physicians of a personal liability which is a "substantial benefit" that qualifies as remuneration to the Physicians under the Stark Law.

Further, because the court concluded that the arrangements did not satisfy the Stark Law exception for indirect compensation arrangements (as explained below) prior to the effective date of CMS' regulatory "stand in the shoes" (SITS) provisions, the court concluded that the grandfather clause for pre-SITS arrangements did not apply. Therefore, the court ruled that, as of the effective date of the SITS provisions, there were direct compensation arrangements between the Hospital and each of the Physicians standing in the Practice's shoes.

C. The Arrangements Did Not Satisfy Any Stark Law Exception

The defendants argued that the various compensation arrangements satisfied the Stark Law's exceptions for indirect compensation arrangements and for space and equipment rentals. The court disagreed.

(1) Compensation Was Not Fair Market Value and Was Based on the Volume or Value of Referrals

The court found that the arrangements could not satisfy any of these exceptions because the compensation was determined in a manner that took into account the volume or value of referrals and, thus, was not fair market value (for the same reasons discussed above).

(2) The Arrangements Were Not "Set Out in Writing"

The court also concluded that the arrangements did not satisfy any of these exceptions because the actual arrangements (*e.g.*, for the GE Camera to be operated out of the Practice's offices, and to obtain and use the new Philips Camera) were not "set out in writing." The court rejected the Hospital's and Practice's argument that the proposal letter and initialed invoices constituted a valid written agreement with respect to the space and services provided by the Practice. The court held that the defendants failed to provide sufficient evidence that the parties intended to, and actually did, enter into a formal written agreement. The court stated that the initials on the invoices, at best, proved only that the Hospital approved payments, and further that certain invoices did not match the services described in the proposal letter. The court also found that there was no evidence of a written arrangement with respect to the sublease of the Philips Camera, and that a provision within the GE Lease allowing for upgrade or change of equipment was insufficient, especially because new payments were involved.

IV. FUTURE DETERMINATIONS OF "INTENT" AND DAMAGES

The court stated that, as a matter of law, it could not determine whether the defendants acted with the requisite intent for purposes of determining whether violations of the Anti-Kickback Statute and/or the False Claims Act occurred. However, with respect to the evidence pertaining to the False Claims Act's requisite intent standard, the court stated that "the record evidence is not strongly in favor of Defendants as it tends to show that Defendants entered into the [Sublease] fully aware that the arrangement, which had at its core a non-compete payment roughly equal to the referral business [the Hospital] would gain from the [Physicians] and the business [the Practice] would lose from abandoning its own camera, may not be permitted under the Stark [Law] and Anti-Kickback Act." Because the court made no finding with regard to any issue of "intent," and because of the large volume of claims and the complexity of determining damages, the court deferred ruling on damages until a later date.

V. OBSERVATIONS AND OPEN ISSUES

In light of the Bradford case, hospitals structuring arrangements with referring physicians should consider the following observations and open issues:

(1) Any fair market value analysis obtained in connection with a financial relationship offered to or by physicians should expressly be based on the Stark Law definition of "fair market value." The compensation should be the amount that the hospital would pay (or receive) under a similar arrangement with a party not in a position to generate referrals or other business.

(2) The Bradford ruling raises issues regarding the extent to which valuation reports can be based on assumptions relating to anticipated referrals. In accordance with guidance in the Stark Law's regulatory preambles, in the case of a physician practice acquisition, it may be permissible to consider the value of DHS if such DHS fit into an exception prior to the transaction (*e.g.*, in office ancillary services), and if the transaction is not contingent upon future referrals from the selling physicians. (See 66 Fed. Reg. 877). Some nationally recognized healthcare valuation consultants, however, have indicated that in valuing a practice or service line under the "income approach," valuation principles require that they assess the volume of future services and the revenues associated therewith.

It is not clear whether the Bradford ruling would have been different if the transaction structure had been different (*e.g.*, an acquisition of the physicians' imaging service line, as opposed to a sublease), and/or if the purchase price had been confirmed as being fair market value in a healthcare valuation report based on the Stark Law's definition of "fair market value". Thus, it remains unclear regarding how, if at all, the Bradford ruling will have an impact on practice and service line acquisition transactions. However, given the Bradford ruling, any valuation that considers anticipated referrals may be subject to challenge if scrutinized by the government or a whistleblower.

(3) Non-competes are common in asset acquisition transactions, and there is support in the Stark Law's regulatory preambles that such provisions are acceptable as long is there is

no requirement to make referrals (see 66 Fed. Reg. 787-89; 69 Fed. Reg. 16094). Non-competes are also common in many employment agreements. However, in light of the Bradford ruling, certain issues regarding non-competes remain unclear, and attorneys should carefully consider how to include such provisions within arrangements. In this regard: (i) non-competes in leases may be more problematic than in other arrangements (see also 69 Fed. Reg. 16088); and (ii) it is possible that courts could conclude that non-competes (in *any* transaction) constitute the equivalent of requirements to refer (as the Bradford court stated) and therefore are improper. But see 42 C.F.R. §411.354(d)(4) (certain physician compensation may be conditioned on referrals).

(4) The Bradford case re-emphasizes the importance of ensuring that all arrangements with referring physicians are formally documented in a signed written agreement. Note, however, that although the Bradford court found that a proposal letter and an invoice did not constitute a written agreement sufficient to satisfy a Stark Law exception, other courts in examining similar issues have held that formal, signed contracts may not be required to establish the existence of a "written agreement," so long as there are various writings that memorialize the components of the relationship or document a clearly established course of conduct. See, *e.g.*, *U.S. ex rel. Villafane v. Solinger,* 543 F.Supp. 2d 678 (W.D. Ky. 2008). Further, other courts have stated that state law should be considered when determining if a valid written agreement exists (see, *e.g.*, *U.S. ex rel. Kosenske v. Carlisle HMA, Inc.*, 2007 U.S. Dist. LEXIS 84294 (M.D. Pa. 2007)).

The *Villafane* and *Kosenke* opinions may align better with the Stark Law, which does not define "written agreement" by either statute or regulation, as well as the Stark Law preambles, which at various points indicate that "a writing" may be sufficient to satisfy the "written agreement" element of Stark Law exceptions. See, *e.g.*, 72 Fed. Reg. 51059, 51074 (Sep. 5, 2007) ('fair market value compensation' and 'indirect compensation arrangements' exceptions, respectively). Nevertheless, in light of the Bradford decision (and for other reasons), healthcare providers should strive to formally document in a signed written agreement all financial relationships with referring physicians.

(5) Once a formal written contract is executed, parties should take care to perform consistent with its terms, lest they subject themselves to liability for operating in accordance with an arrangement that is *not* set out in writing. Special care should be given to equipment and staff leasing arrangements in which compensation amounts may change based on modifications to the equipment and staff being provided; in certain circumstances, an amendment or new agreement may be required in order to continue to satisfy a Stark Law exception.

(6) Be wary that personal guarantees executed by physicians may convert to "direct" compensation arrangements those arrangements that may otherwise be considered to effectuate either (i) "indirect compensation arrangements" or (ii) financial relationships that do not satisfy the definition of "indirect compensation arrangements" and thus are outside of the scope of the Stark Law altogether.

(7) Because the government did *not* intervene in this case, it will be interesting to see if the government asserts the same positions as the Bradford relators in future cases involving analogous arrangements and Stark Law issues, and how other courts rule on such issues.

(8) Health law attorneys should also closely follow future determinations (if any) in the Bradford case regarding the "intent" elements under the Anti-Kickback Statute and False Claims Act, as well as the manner in which any damages are calculated.