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Health Care Law

Federal Court Finds Pa. Hospital In Violation of Stark Law

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Bradford is a small city (population about 9,000) in western Pennsylvania, near the New York border. It is nestled between New York's Allegheny State Park and the Allegheny National Forest in Pennsylvania. Bradford Regional Medical Center (BRMC), founded in 1887, is a 107-bed nonprofit community hospital located in Bradford. BRMC is part of the Upper Allegheny Health System (UAHS), which also includes Olean General Hospital (OGH) in Olean, N.Y., a 186-bed acute care hospital. UAHS provides care to a service area with more than 160,000 individuals in southwestern New York and northwestern Pennsylvania.

On Nov. 10, 2010, a federal district court judge found BRMC to be in violation of the Stark Law, which governs physician self-referral for Medicare and Medicaid patients. This was a summary judgment motion, and damages have not yet been determined, but they could exceed $20 million. Mandatory penalties imposed by the False Claims Act could total millions more. The court left it to the fact-finder at trial to determine damages, as well as issues of intent under the anti-kickback statute and the False Claims Act. *U.S. ex rel. Singh, et al. v. Bradford Reg'l Med. Ctr., et al.,* Case No. 1:04-cv-186, U.S. District Court for the Western District of Penn., Erie Division.

How did this small community hospital get into such a fix?

It all started when two doctors, (who specialize in internal medicine) formed V&S Medical Associates (V&S). Prior to 2001, these doctors were a significant source of referrals to BRMC, both for inpatient admissions and for outpatient procedures, including diagnostic tests performed on a nuclear imaging camera located at BRMC. In 2001, the doctors considered getting their own nuclear imaging camera and installing it in their office. Learning of the doctors' plans, the hospital compiled information about their referrals, which indicated that these doctors ordered 42.5 percent of the hospital's nuclear studies, and clearly could support their own machine. The hospital met with the doctors on several occasions, and in May 2001, adopted a "policy on physicians with competing financial interests."

In June, 2001, V&S entered into a long-term lease with General Electric (GE) for a nuclear camera. The doctors (both of whom personally guaranteed the lease) placed the camera in their office, where they performed the studies, and thus decreased their nuclear medicine referrals to BRMC. However, their referrals for inpatient admissions and other outpatient procedures did not decrease. The hospital suggested that they may be in violation of the new conflicts policy, and their privileges may be at risk. A lively exchange ensued between the attorneys for the doctors and those for the hospital. Throughout 2002 and into 2003, meetings were held in an attempt to resolve the dispute. The record demonstrates that the attorneys were well aware of Stark and the other federal statutes.

In April 2003, the parties entered into an agreement providing that BRMC would sublease the GE camera, and in October 2003 a formal sublease was signed. V&S agreed to a covenant not to compete with the provision of nuclear cardiology services by BRMC for the term of the sublease. The agreement specifically permitted BRMC to "upgrade" the equipment.

BRMC had a fair market value (FMV) assessment prepared by an accountant, to assure that BRMC was paying fair market value under the sublease. The FMV assessment was never provided to V&S, but took into account the expectation that V&S would refer all their nuclear studies to BRMC, and the profit those referrals were expected

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to generate. A hospital official acknowledged that he expected BRMC would get substantial referrals from the two doctors, as a result of the sublease.

Although the equipment sublease stated that the GE camera would be relocated to the hospital, it remained in the offices of V&S, and BRMC paid an additional sum each month as rent, as well as secretarial and other administrative expenses, pursuant to a "space and services" agreement.

The GE camera was used for only four or five months, through March of 2004. In April 2004, V&S entered into a five-year lease with Philips Medical Capital (Philips) for a Cardio MD nuclear camera. Philips advanced an early termination fee to GE of approximately $200,000, which BRMC guaranteed. The Philips camera was placed in the hospital, and BRMC reimbursed V&S for its payments to Philips under the lease, as well as its payments to Philips relating to the buyout of the GE lease. V&S donated the GE camera to Hamot Medical Center in Erie, Pa. BRMC and V&S did not enter into a second sublease for the Philips camera, under the belief that the 2003 sublease covered the "upgrade" in equipment.

BRMC submitted numerous claims to Medicare for nuclear medicine studies conducted with the cameras.

The Stark Law (42 U.S.C. §1395nn)

The court found that, if the physicians had a financial relationship with BRMC, then they may not make a referral to BRMC for the furnishing of designated health services. In addition, BRMC may not present a claim to Medicare or Medicaid for designated health services furnished pursuant to a prohibited referral. Under the Stark Law, a financial relationship includes a compensation arrangement, defined as "any arrangement involving any remuneration between a physician … and an entity." The court readily concluded that a direct financial relationship existed between BRMC and the doctors for the period of time the sublease was in effect. In addition, the court concluded that FMV must not take into account the volume or value of anticipated or required referrals. See, 42 C.F.R. §411.354(d)(4)(2). Here, the FMV report obtained by BRMC clearly was based, in part, on anticipated referrals from the doctors.

The court further found that no exceptions to the Stark law applied. BRMC and the doctors argued the equipment rental exception and safe harbor (42 C.F.R. §411.357(b)(1) and 42 C.F.R. §1001.952 (c)(1) and (2)) applied. The court found to the contrary, as there was no equipment lease between BRMC and V&S that specified the Philips camera. The court found that the 2003 equipment sublease did not apply, when substantial payments on the new (Philips) equipment were not accounted for in the document, while payments for the old (GE) equipment continued to be made.

Having found a financial relationship and that no exceptions applied, the court then found that BRMC submitted claims to Medicare for designated health services based on referrals from the two doctors. However, the court was unable to conclude that the violations of the Stark Law were done knowingly, so as to implicate the False Claims Act.

The Anti-Kickback Statute (42 U.S.C. §1320a-7b)

The anti-kickback statute makes it unlawful to knowingly and willfully offer, pay, solicit or receive any remuneration for referrals of services covered by a federal health care program. Here, the court focused on whether the payments made by BRMC were knowingly intended to induce or reward referrals. While the court found that the Stark Law was violated because the arrangement "took into account" anticipated referrals, the court stopped short of finding the requisite intent, leaving that to a fact-finder at trial. A fact-finder, said the court, could find from the evidence that the doctors did not knowingly and willfully solicit or receive remuneration for referrals, and that BRMC did not offer or pay remuneration for referrals. However, the court did state that, in light of the record evidence, BRMC and the doctors will "have a difficult challenge to prove to the fact-finder that they did not have the requisite intent." The court identified that the rural nature of BRMC complicates the factual issue. Even though the doctors were not required to refer to BRMC, the fact-finder must consider whether the doctors, as a practical matter, had any real choice. Clearly, the court shifted the burden of proof on this issue to the defendants.

Implications and Lessons To Be Learned

There are several lessons one can take away from this case. First, any fair market value analysis cannot take into account referrals to be generated. Such an analysis should focus solely upon the amount the hospital would pay (or receive) under a similar arrangement with a party *not* in a position to refer patients.

Second, it is possible, particularly in rural areas where the parties' options are limited, that noncompete clauses may be considered the equivalent of a requirement to refer, and therefore improper.

Third, the Bradford case underlines the importance of making certain that *all* arrangements with referring physicians are in writing and signed. The failure to revise the sublease was fatal to the assertion of an available Stark Law exception in this case.

Finally, on the other side of that coin, once a formal agreement is executed, parties must take care to act in accordance with its terms. Any significant changes (such as acquisition of new equipment) may require amendment or a new agreement to satisfy the Stark Law exemption. ■