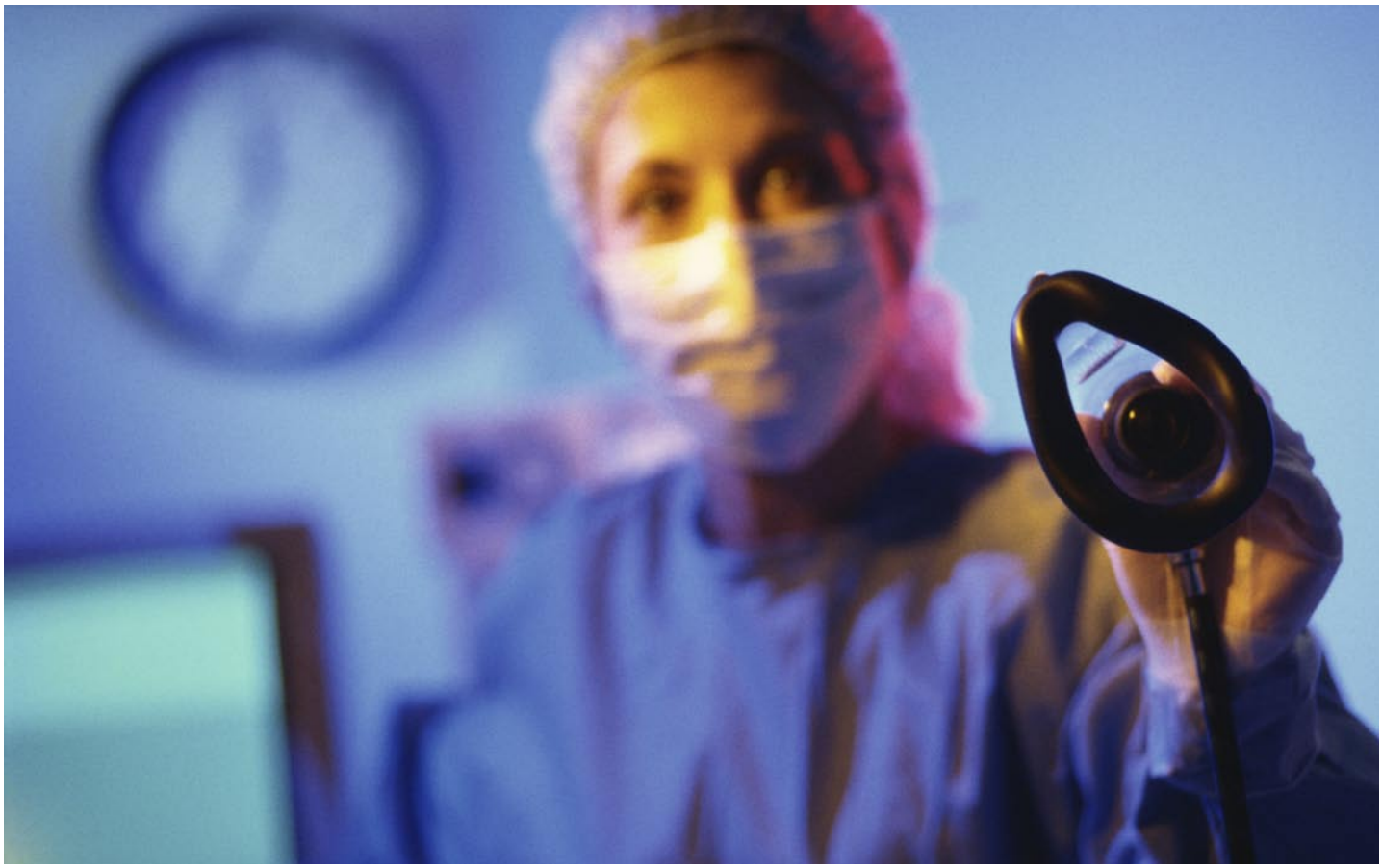
KOSENSKE:
PHYSICIAN-HOSPITAL ARRANGEMENT QUESTIONED UNDER STARK



BC Legal On January 21, 2009, a three-judge panel of the Third Circuit Court of Appeals reversed a summary judgment granted in favor of defendants Carlisle HMA, Inc. and Health Management Associates finding that the defendants failed to establish that a relationship between a hospital and its exclusive anesthesiology providers satisfied the requirements of the personal service exception to the federal Stark Law and the safe harbor to the federal Anti-Kickback Statute applicable to personal services and management contracts.

Background.

Carlisle Hospital and Health Systems ("CHHS") engaged Blue Mountain Anesthesia Associates, P.C. ("BMAA"), a group of four anesthesiologists, to be the exclusive provider of anesthesiology services at a hospital operated by CHHS in Carlisle, Pennsylvania (the "Hospital"). Pursuant to the Anesthesiology Services Agreement executed by the parties in 1992, BMAA agreed to provide 24/7 anesthesiology coverage at the Hospital on an exclusive basis. The Hospital agreed to provide BMAA, at no charge, with the space, equipment, supplies and the services of certain personnel necessary to provide the services.

Several years later, in 1998, the Hospital built a new freestanding outpatient ambulatory surgical facility and pain clinic (the "Clinic") located approximately three miles from the Hospital. From the opening of the Clinic, BMAA provided pain management services to patients there, and the Hospital similarly provided BMAA with the use of certain personnel, space and equipment at no charge. Consistent with the billing arrangement for anesthesia services, BMAA billed Medicare for the professional pain management services performed by its physicians at the Clinic, and the Hospital billed for the facility/technical component of the pain management services. In 2001, HMA purchased the Hospital and the Clinic from CHHS, and HMA and BMAA continued to operate under the terms of the existing Agreement.

The parties did not enter into a new or separate agreement with respect to BMAA's provision of pain management services at the Clinic.

The Plaintiff is in this case was a former anesthesiologist with BMAA. He filed a qui tam action against Carlisle HMA, Inc. and Health Management Associates under the federal False Claims Act alleging that the defendants submitted outpatient hospital claims to Medicare that were falsely certified as being compliant with the Stark Law and the Anti-Kickback Statute. The District Court had found that the relationship between BMAA and the HMA implicated the Stark Law; but that summary judgment in favor of the defendants was appropriate because they were able to establish that the arrangement qualified for the personal service exception to the Stark Law. The Third Circuit Court of Appeals reversed this opinion, concluding that the arrangement did not meet the requirements of the personal service exception. For the purposes of its opinion, the Third Circuit analyzed the arrangement solely under the Stark Law and corresponding regulations, opining that the requirements of the Anti-Kickback Statute and its corresponding safe harbor regulations were indistinguishable from those of Stark as applied to the facts of Kosenske.

The Stark Law.

The Stark Law prohibits a physician or immediate family member from making a referral to an entity with which he or the family member has a financial relationship, including a compensation arrangement, for the furnishing of a "designated health service" for which payment may be made under Medicare or Medicaid. (42 U.S.C. § 1395nn) Designated health services include, among others, inpatient and outpatient hospital services. Penalties for violation of Stark include civil money penalties for each tainted referral and for each claim submitted pursuant to a tainted referral, potential false-claims liability, and exclusion from participation in Medicare. Where a physician has a compensation relationship with a provider or supplier of designated health services covered by the Medicare program, the physician's referrals to that entity will be deemed to violate the Stark Law unless the relationship fits within one of several regulatory exceptions, such as the personal service exception.

The Stark Personal Service Exception.

Pursuant to this Stark exception, referrals by a physician to an entity in which the physician has a financial relationship will not violate the Stark law where the arrangement between the referring physician and the entity meets the following requirements:

1. The arrangement is set out in writing, is signed by the parties, and specifies the services covered by the arrangement.

2. The arrangement covers all of the services to be furnished by the physician (or an immediate family member of the physician) to the entity;

3. The aggregate services contracted for, do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement;

4. The term of the arrangement is for at least 1 year;

5. The compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties;

6. The services to be furnished under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law;

7. A holdover personal service arrangement for up to six months following the expiration of an agreement that meets the requirements in numbers 1-6 above, provided that such arrangement is on the same terms and conditions as the immediately preceding

agreement. (42 C.F.R. § 411.357(d))

The Ruling.

As an initial matter, the Third Circuit found that the provision of space, personnel and equipment by the Hospital to BMAA at no charge constituted remuneration in kind from HMA to BMAA, thereby creating a financial relationship between the parties sufficient to implicate the Stark Law.

The Third Circuit then concluded that the arrangement failed to satisfy the personal service exception to the Stark Law and, accordingly, summary judgment was wrongly awarded to the defendants by the District Court.

According to the opinion, when the parties entered into the original 1992 Anesthesiology Services Agreement, no pain management services were being provided by BMAA at the Hospital, although the Agreement contemplated that such services might be provided at a future date. When the Clinic opened in 1998, the parties failed to enter into a new agreement with respect to BMAA's services there, nor did they amend the original 1992 Agreement to address this increase in coverage and responsibility.

According to the Third Circuit, the District Court had assumed that the 1992 Anesthesiology Services Agreement was applicable to BMAA's pain management services at the Clinic and, therefore, the defendants had satisfied the first prong of the personal service exception that the arrangement be set out in writing. The Third Circuit disagreed with this assumption, finding that the only written contract in existence between the parties did not, and was not intended to, apply to services at a facility not yet in existence. Consequently, it determined that there was no written contract governing the parties' relationship as required by the Stark personal service exception.

Further, even assuming that the 1992 agreement could be construed to encompass pain management services at the Clinic, the Third Circuit found that the agreement failed to satisfy the compensation prong of the personal service exception, which requires that the compensation that will be paid over the term of the agreement be set in advance, because the agreement failed to describe the free staff, space and equipment being provided to BMAA at the Clinic.

Lastly, the Third Circuit held that the defendants failed to establish that the arrangement was consistent with fair market value because, in the Court's opinion, the 1992 negotiations could not possibly reflect the value of services provided under materially different circumstances six years later.

In the course of the opinion, the Court interestingly noted that the Department of Health and Human Services has recognized with traditional hospital-based practices such as anesthesiology, there is often little concern under the Stark Law because the physicians are generally not in a position to refer patients to the hospital; in fact, it is typically the other way around. In such instance, the concern is primarily remuneration flowing from the anesthesiologists to the hospital. The Court stated that in the context of pain management services, however, a physician in an outpatient facility is in a position to generate substantial business for a hospital. The concern with such arrangements, according to the Court, is remuneration from the hospital to the physicians in order to induce referrals from the physicians to the hospital facility.

Lessons to Learn from Kosenske.

Kosenske represents a "stark" reminder (pun intended) of the critical importance of making sure that all arrangements between hospitals and physicians are properly documented and updated as necessary.

Specifically, both hospitals and physicians should learn the following lessons from the Kosenske case:

1. If there is any sort of financial relationship between a hospital and a physician(s), the terms of the arrangement should be reflected in a signed agreement;
2. The arrangement should be structured so that it complies with an applicable Stark exception; and
3. The written agreement should be reviewed frequently, and updated as necessary, to make sure that the arrangement remains in compliance with the applicable Stark exception, including the requirement that any compensation, whether in cash or in kind, be consistent with fair market value.

If you would like assistance with the review of the hospital/physician arrangements affecting your organization or practice, please contact Victoria Heller Johnson, Esq. at (610) 458-4980 or by email at vjohnson@foxrothschild.com.

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