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ANESTHESIOLOGISTS SHOULD HEED STARK LAW RULING

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In January, the U.S. Court of Appeals for the Third Circuit rendered a decision in what has become commonly known as the Carlisle case, issuing one of the few interpretations to date of the Stark self-referral statute. The ruling provides highly instructive information for anesthesia groups in their efforts to avoid violating Stark and other antikickback laws, as well as in structuring the relationship between the group and its owner and non-owner physicians.

The Carlisle case dates back to 1992, when Blue Mountain Anesthesia Associates entered into an exclusive contract to provide all anesthesia services at Carlisle Hospital in Carlisle, Pennsylvania. At that time, Blue Mountain did not provide chronic pain management services and the exclusive contract did not obligate them to do so. However, it was contemplated by the hospital and the group that Blue Mountain might provide those services in the future. The 1992 agreement also gave Blue Mountain certain option and first refusal rights to enter into exclusive contracts at future hospital-related facilities. Blue Mountain physicians, including an eventual whistleblower, began providing pain management services at the hospital during the second year of the contract.

In 1998, the hospital opened an outpatient clinic. Blue Mountain relocated its pain practice to the new pain center located in the outpatient clinic. Although Blue Mountain and the hospital neither modified the 1992 exclusive contract nor entered into a new exclusive as to the pain center, Blue Mountain operated the pain center on a de facto exclusive basis.

At the pain center, the hospital provided Blue Mountain with a waiting room, exam rooms and secretarial space, as well as furniture, equipment and staffing, all at no charge.

Blue Mountain physicians, including the whistleblower, consulted with thousands of patients over a period of several years. Many patients were evaluated and prescribed medication, for which consultations Blue Mountain, and not the hospital, billed. Some, but not all, patients were referred for to the clinic for diagnostic testing and for procedures. For those patients, the hospital billed facility fees, including fees billed to Medicare and other federally funded health care programs.

The whistleblower later left Blue Mountain and opened a competing pain management practice. He claimed that the split from the group had its genesis in his demand that the group pay for the space, equipment and services being provided for free by the hospital at the pain clinic. Without fair market consideration, those benefits constituted remuneration for the referral of pain management patients by Blue Mountain to the hospital clinic, in violation of both federal anti-kickback law and Stark. Although hospital executives initially agreed that Blue Mountain was required to pay for the space and equipment, it ultimately abandoned that position.

The whistleblower filed suit under the False Claims Act on the ground that the hospital falsely certified its compliance with federal antikickback law and Stark, a requirement of obtaining payment from a federally funded health care program.

False Claim Finding

The Third Circuit found that Blue Mountain referred federally funded patients to the pain center for diagnostic tests and procedures and that the hospital's provision to the practice of clinic space, equipment and support personnel for those referrals constituted remuneration under the antikickback statute and Stark. As a result, the judges said, the hospital potentially violated the False Claims Act and sent the case back to the trial court to make findings on the other elements of a False Claims Act violation.

In rendering its opinion, the appellate court strictly analyzed Stark's personal services exception. This clause is similar to that of the antikickback statute, both of which require a written agreement between the parties. The only written agreement between Blue Mountain and the hospital was the 1992 exclusive contract. The court found that there was no written agreement with respect to the pain center.

The court found that the 1992 exclusive agreement did not explicitly include the pain center within its scope—there was no pain center at the time—and that it did not apply to a nonexistent facility. The hospital's argument that Medicare considered the outpatient facility to be a part of the hospital for billing under its provider number, and that the pain center therefore was covered by the 1992 exclusive agreement, was rejected as falling outside the scope of issues pertaining to Stark. The court also stated that, even if the 1992 agreement could be read to apply to the pain center, it did not mention the provision of any pain management space, equipment or services, whether at the hospital or at a later free-standing pain clinic. There was no arms-length negotiation over the fair market value of the pain management

space and services provided. Even if there were, the fact of negotiation alone did not establish fair market value.

Practical Lessons

To comply with personal service exceptions to Stark and the federal antikickback statute, written agreements must document the parties' respective obligations and remuneration with a high degree of specificity. If the scope of performance or amount of remuneration changes, so, too must the documentation and the analysis of continued compliance. In the Carlisle case, although Blue Mountain had option and first refusal rights to provide services at other hospital-related facilities, the court found that a written agreement specifically applicable to the pain center was required to qualify under the personal services exception.

Every arrangement involving an exclusive contract in which the level of support or services provided by the hospital, or the scope of services provided by the group, has changed since inception must be audited for strict compliance with Stark and antikickback law.

Arrangements that often go unquestioned due to the lack of an exclusive contract are more vulnerable to attack because they often fail to meet the strict requirements of exceptions to Stark and the federal antikickback statute. Therefore it is essential that those arrangements be audited for compliance. Yet, even exclusive contracts can be attacked indirectly through False Claims Act whistleblower lawsuits. Fair market valuation in respect of hospital-physician arrangements, whether or not reduced to a formal exclusive contract, must be supported by documentation.

Your partner (or employee or subcontractor) may be your downfall. In the Carlisle case, the whistleblower was a physician who was a partner in the group which benefited from the violation of Stark and antikickback law. Although not a panacea, groups must avail themselves of all provisions to dissuade competition that, once contemplated, might lead to indirect attacks, such as allegations under the False Claims Act, appearing more fruitful to a disgruntled former colleague.

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