Ambulatory Surgery Center Joint Venture Between Nonprofit Hospital and Surgeons Poses Low Fraud and Abuse Risk, According to Office of the Inspector General

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In an Advisory Opinion (08-08), recently posted by the Office of the Inspector General of the Department of Health & Human Services ("OIG"), the OIG implicitly approved an ambulatory surgery center ("ASC") joint venture owned by a nonprofit hospital and group of surgeons, notwithstanding the fact that the joint venture did not satisfy any applicable anti-kickback safe harbor for ASCs. The advisory opinion arguably represents a shift in the recent trend for the OIG to disfavor such joint ventures and provides guidance for structuring ASC joint ventures among hospitals and physicians.

Proposed Arrangement

A nonprofit hospital corporation owning three hospitals and other healthcare-related facilities ("Hospital"), entered into a joint venture limited liability company ("LLC") with a limited liability company comprised of eighteen orthopedic surgeons ("Partnership"). The LLC is owned seventy percent (70%) by the Partnership and thirty percent (30%) by the Hospital. Both the Hospital and the Partnership made financial contributions to the LLC in proportion to their respective ownership interests for development and operation of the ASC. Moreover, each individual surgeon investor’s ownership interest in the Partnership is proportional to his or her capital investment.

In addition and related to the above, the LLC entered into a written agreement (the “Anesthesia Agreement”) with a Hospital-owned physician practice (the “Practice”) for provision of anesthesiology services at the ASC. The Practice is compensated for anesthesia services by third party payors (including Federal healthcare programs, e.g., Medicare) and by patients in certain instances. One of the Practice’s anesthesiologists will serve, on a part-time basis as the Director of Anesthesiology and Medical Director of the ASC for an annual fixed stipend paid by the LLC.

Relevant Law and Legal Concerns

The anti-kickback statute is implicated by joint ventures between hospitals and physicians who refer to them. The anti-kickback safe harbors which are potentially applicable here are the safe harbor for ambulatory surgery centers jointly owned by physicians and hospitals, and the safe harbor for personal services and management contracts.

The proposed arrangement did not fall squarely within the requirements of the ASC investment safe harbor. As a result, the OIG assessed whether the proposed arrangement...
posed a minimal risk under the anti-kickback statute.

First, the proposed arrangement did not meet the ASC safe harbor requirements because the surgeon investors did not hold their investment interests in the ASC either directly or through a group practice composed of qualifying physicians. Instead, they held their interest through the Partnership. The OIG has expressed concern in the past about intermediate investment entities (such as the Partnership) because they raise concerns that they could be used to redirect revenues to reward referrals or otherwise vitiate the safeguards provided by direct investment, including distribution of profits in proportion to capital investment.

Notwithstanding those concerns, the OIG noted that in this particular case, use of the “pass-through” entity did not substantially increase the risk of fraud or abuse. The reason is that each surgeon investor’s ownership in the Partnership was proportional to his or her capital investment, and the Partnership’s interest in the LLC that owns the ASC is also proportional to its capital investment.

Second, the OIG noted that four of the eighteen surgeon investors did not meet the safe harbor requirement that at least one-third of a physician investor’s income from medical practice in the previous year derives from performing ASC procedures in an ASC setting. According to the OIG, the function of this requirement is to help ensure that the safe harbor applies only to investment income to physicians who are unlikely to use the investment as a vehicle for profiting from their referrals to other physicians using the ASC. Instead, the safe harbor is supposed to apply to physician-investors who are likely to use the ASC regularly as part of their medical practices.

Although the four surgeon investors at issue did not meet the “one-third” test, the OIG concluded that they were unlikely to use the ASC as a means for them to profit from referrals. Part of this conclusion owed to the fact that they were all surgeons that regularly engaged in a genuine surgical practice and derived at least one-third of the medical practice income from procedures requiring a hospital operating room. Moreover, the OIG noted that these surgeon investors were unlikely to refer to the ASC and comprised a relatively small portion of the total surgeon investors in the Partnership, most of whom will use the ASC on a regular basis as part of their medical practice. Importantly, the OIG also noted that this instant arrangement was to be distinguished from potentially riskier arrangements where few investing physician actually use the ASC on a regular basis or where investing physicians are potentially significant referral sources for other investors or the ASC, such as primary care physician investors or cardiologists investing in a cardiac surgery ASC.

Third, the proposed arrangement did not qualify for the safe harbor because the Hospital was in a position to make or influence referrals to the ASC and to the surgeon investors. However, this was mitigated in the eyes of the OIG by several safeguards. For instance, the Hospital represented that it would not encourage any of its affiliated physicians to refer patients to the ASC or to any of the surgeon investors and would not track any such referrals that were made. The Hospital further represented that compensation paid to its affiliated physicians for professional services is commensurate with fair market value and does not take into account the value or volume of any referrals that its affiliated physicians may make to the ASC or its surgeon investors. Further, the Hospital committed to informing its affiliated physicians about these measures each year. As a result of all of the above, the OIG concluded that the Hospital’s ability to direct or influence referrals to the ASC was “significantly constrained”.

Fourth, the Anesthesia Agreement did not
meet all the requirements of the personal services and management safe harbor because it involved part-time services and the scheduled intervals of service, their precise length and exact charge for the intervals was not specified. The OIG did note, however, that all of the services to be provided were set forth in detail, the compensation was fixed and set in advance, was represented to be commensurate with fair market value and did not take into account the volume or value of referrals or other business generated between the parties. Moreover, the parties were to keep accurate and contemporaneous records of the services provided by the Medical Director, and would make those available to the OIG and/or the Secretary of the Department of Health and Human Services upon request. As a result, the OIG concluded that the lack of specificity about the intervals of service did not raise the risk of fraud and abuse under the proposed arrangement.

Take Away

Part of the value of this Opinion is that it is a concrete indication that the OIG may view similar joint ventures as permissible, even if a technical violation of the anti-kickback statute and risk or fraud and abuse may exist, as long as sufficient safe guards such as those discussed above are implemented in a manner that brings the level of risk of fraud and abuse to a sufficiently low level. Apart from the clear importance of the safe guards that were put into place in connection with the proposed arrangement, it was clear that the OIG considered the facts that the surgeon investors who did not meet the “one-third” test were not likely to refer to the ASC and were relatively few in number to be important ones. It is difficult to determine whether, hypothetically, the OIG would have reached the same conclusion had the number of surgeon investors who did not meet the “one-third” test been higher, had they been more likely to refer to the ASC or had some of those investors actually been primary care physicians or cardiologists, as discussed above. Nevertheless, this latest Advisory Opinion reinforces the importance of engaging experienced healthcare legal counsel in the early stages of forming similar joint ventures in order to structure the arrangement in a manner that minimizes or eliminates risk of violating the anti-kickback statute and leading to fraud and abuse.

If you have any questions concerning these developing issues, please do not hesitate to contact any of the following Paul Hastings lawyers:

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