In two recently released Advisory Opinions, the Office of Inspector General (OIG) offered guidance on arrangements that do not meet the anti-kickback safe harbor requirements for hospital-physician ambulatory surgical center (ASC) joint ventures, approving a joint venture involving a single-specialty medical group while finding that a joint venture involving a multi-specialty group could potentially violate the Anti-Kickback Statute. On January 21, the OIG essentially approved a hospital's acquisition of an ownership interest in an ASC and the parties' participation in related ancillary agreements (Proposed Arrangement I) when the following safeguards existed:

- The hospital certified that it would limit its ability to direct or influence referrals to the ASC, the medical group or the group shareholders;
- The group shareholders who fell outside the ASC safe harbor would not likely be passive referral sources because they derive more than one-third of their income from procedures that qualify as ASC procedures or require a hospital operating room setting;
- Despite the pass-through nature of the group's existing ownership of the ASC (a holding company structure), the return on investment in the ASC for the group and the group shareholders would not reflect referrals, particularly given its certified compliance with the group practice safe harbor (i.e., would be the same as in the case of a direct investment);
- Although term and termination provisions of certain ancillary agreements did not meet safe harbor requirements, the parties certified that protections were in place to ensure that changes to term or fee would not occur more often than annually and/or would be fair market value and unrelated to the volume or value of referrals; and
- The Non-Competition Agreement would not likely violate the federal Anti-Kickback Statute because physicians would be permitted to practice at other ASCs and hospitals.

In contrast, on February 13, the OIG found a potential anti-kickback violation in a proposed ASC joint venture by a hospital and a multi-specialty group practice (Proposed Arrangement II) when many of the ASC's physician-owners would not personally use the ASC (raising risk that the physicians would use their investment as a means to profit from their referrals to other physicians who did use the ASC) and no other safeguards to reduce fraud and abuse risk existed.

"...ASC joint ventures that do not meet safe harbors will be reviewed on a case-by-case basis, and those with sufficient safeguards to minimize fraud and abuse risk are more likely to be approved."

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Impact on Health Care Entities

In these contrasting Advisory Opinions, the OIG reaffirms that ASC joint ventures that do not meet safe harbors will be analyzed on a case-by-case basis. The OIG’s conclusions suggest that arrangements with sufficient safeguards against fraud and abuse will be approved and those lacking such safeguards will not. For example, the OIG found five areas of risk for Proposed Arrangement I, but found these risks mitigated by protections that achieved legitimate business purposes without posing a risk of payments for referrals, including such things as certifications by the hospital that it would refrain from encouraging or tracking referrals and that all physician compensation would be at fair market value and a holding company ASC ownership structure that did not base return on investment on referrals. In contrast, in Proposed Arrangement II, the OIG did not believe that the multispecialty practice structure sufficiently reduced risk, and no other safeguards against fraud and abuse were apparent. As such, entities considering ASC joint ventures should consult counsel regarding their structure to ensure that the joint venture and all participating parties comply with anti-kickback safe harbors and other applicable law and/or that other safeguards serve to minimize fraud and abuse risk.

Importantly, we note that with respect to Proposed Arrangement I, the OIG also permitted ancillary agreements with term and termination provisions that violate the one-year term requirement of applicable safe harbors based on the parties’ certifications that fee renegotiations would not occur more often than annually and would reflect fair market value without taking into account volume or value of referrals. The OIG emphasizes that its opinion was limited to the facts and circumstances of the request and that its original position on term and termination provisions as articulated in the preamble to its 1999 final safe harbor rule still stands. As such, entities should continue to observe existing requirements regarding term and termination provisions in contracts.

Proposed Arrangement I

Proposed Arrangement I involves seven agreements: an Option Agreement, Credit Agreement, Management Services Agreement, Facility Support Agreement, Surgical Center Lease, Group Lease and Non-Competition Agreement.

Option and Credit Agreements: Under these agreements, the hospital will purchase an equity interest in the ASC in exchange for capital contributions and loans. Under Phase I (contingent on receiving a favorable Advisory Opinion), the hospital will purchase a 15 percent ownership interest in exchange for a capital contribution and a line of credit, and the group will guarantee its holding company’s pro rata share of the resulting loan. Under Phase II, the hospital may elect to increase its ownership interest to 40 percent in exchange for another capital contribution and line of credit, and the group will guarantee its holding company’s pro rata share of the resulting loan. Under Phase II, the hospital may elect to increase its ownership interest to 40 percent in exchange for another capital contribution and line of credit, and the group’s holding company will make an additional capital contribution. The parties have certified that all contributions and interest rates on loans are consistent with fair market value.

Management Services Agreement: The Management Services Agreement provides that, for a term of five years, the group will provide financial, accounting and employee benefit services to the ASC for a fixed annual fee, which is subject to renegotiation under certain conditions, but no more often than annually. The parties certified that payments under the agreement are consistent with fair market value and that the agreement meets all of the terms of the personal services and management contracts safe harbor.
Facility Support Agreement: The Facility Support Agreement provides that, for a term of five years, the hospital will provide various services (e.g., quality assurance and utilization management, shared purchasing services, gas services, code coverage services) in return for a fixed annual fee from the ASC, which is subject to renegotiation under certain conditions, but no more often than annually. The parties certified that payments under the agreement are consistent with fair market value and that the agreement meets all of the terms of the personal services and management contracts safe harbor except for the minimum one-year term requirement (because the agreement permits termination for cause and contains fee renegotiation provisions). In addition, the parties certified that if fees are renegotiated prior to the expiration of a year, the new fees will be consistent with fair market value and will not take into account the value or volume of any referrals or other business generated between the parties and renegotiation will not occur more often than annually.

ASC and Group Leases: The ASC and the group each rent space from the hospital and will enter into new 10-year leases under Proposed Arrangement I. The parties certified that the leases will comply with all of the requirements of the space rental safe harbor and that all payments under leases will be consistent with fair market value.

Non-Competition Agreement: The Non-Competition Agreement prohibits the hospital, the group and the group shareholders from developing, managing or investing in ASCs offering orthopedic services, entering into joint marketing arrangements related to orthopedic services with any other hospital and entering into ASC-managed care contracts with hospital competitors. It does not prohibit referrals to or use of other ASCs or restrict the group or the group shareholders from participating in provider networks with other payors.

Other Certifications: The parties certified Proposed Arrangement I meets all of the ASC safe harbor requirements except:

- The requirement that a hospital must not be in a position to make or influence referrals directly or indirectly to any ASC investor;
- The requirement that physician interests must be held directly by the physicians who meet surgeon-owned safe harbor requirements or their group practices; and
- The requirement that any services, equipment or space provided by a hospital to an ASC must comply with a safe harbor.

The hospital also certified with respect to its referral capabilities that:

- It will refrain from encouraging or tracking referrals by hospital-affiliated physicians to the ASC, the group or the group shareholders;
- Physicians employed by the hospital will not refer directly to the ASC, but may refer to the group or the group shareholders;
- Compensation paid to the hospital-affiliated physicians will not be related to the volume or value of referrals or other business generated by such physicians for the ASC, the group or the group shareholders and will be consistent with fair market value; and
The hospital will notify all hospital-affiliated physicians of these policies annually.

**OIG Declines to Impose Sanctions**

The OIG declined to impose either administrative sanctions or civil monetary penalties despite the five areas of risk because:

- **Hospital’s Ability to Influence Referrals Constrained**: The hospital certified that it would limit its ability to direct or influence referrals to the ASC, the group or the group shareholders that own the ASC, by refraining from encouraging or tracking referrals by hospital-affiliated physicians, ensuring compensation paid to hospital-affiliated physicians will be consistent with fair market value and not related to the volume or value of referrals or other business generated by such physicians for the ASC, the group or the group shareholders, and informing hospital-affiliated physicians of these measures annually.

- **Group Shareholders Outside of Safe Harbor, But Not Passive Referral Source**: The group shareholders who do meet the one-third practice income test of the ASC safe harbor are likely to be ASC users rather than passive referral sources for others because they derive more than one-third of their practice income from procedures that either qualify as ASC procedures under the safe harbor or require a hospital operating room setting.

- **Pass-Through Investment Risk Not Tied to Referrals**: The parties certified that the holding company pass-through entity used by the group and the group shareholders to own the ASC is a wholly-owned subsidiary that meets all the requirements of the group practice safe harbor such that the return on investment for the group and the group shareholders would be the same as in the case of a direct investment (i.e., no ability to reward referrals).

- **One-Year Term Requirement Risk Not Related to Referrals**: Although the Management Services Agreement and Facility Support Agreement do not meet that minimum one-year term requirement of the personal services and management contract safe harbor, the OIG found, in the limited context here, that the fee renegotiation and termination for cause provisions were unrelated to referrals, and, in the case of fee negotiation, would not occur more than annually and would be at fair market value and not take into account the volume or value of referrals or other business generated between the parties.¹

- **Non-Competition Restrictions Not a Kickback Risk**: The Non-Competition Agreement permits the group shareholders and hospital-affiliated physicians to use other ASCs and hospitals and thus does not appear objectionable under the federal Anti-Kickback Statute.

Given these safeguards the OIG found a low risk of fraud and abuse and declined to impose sanctions.

**Proposed Arrangement II**

Under Proposed Arrangement II, a hospital⁵ and multi-specialty medical group⁶ formed ASC, a limited liability company, for the purpose of establishing and operating a Medicare-certified ASC. The hospital owns 49 percent and the group owns 51 percent of ASC.⁷ Under the arrangement: (i) each investor’s return on investment will be directly proportional to the amount of capital contributed by the investor, (ii) the ASC will have an open medical staff and (iii) the ASC will be located on land owned by the hospital and leased to the ASC.⁸ The ASC also certified that compensation payable to physicians at the group will not take into account the physician’s referral of patients to the ASC or the volume of surgical procedures performed.
OIG Finds Potential AKB Violation

The OIG interprets the anti-kickback safe harbor for hospital-physician group joint ventures in ASCs narrowly to apply only to physicians who are unlikely to use their investment as a means to profit from their referrals to other physicians using the ASC—specifically, physician-investors must either (i) actually use the ASC on a regular basis as part of their medical practices or (ii) practice the same specialty as other physician-investors, making them unlikely to refer substantial business to “competing” physician-investors when they can earn the fees themselves.

With Proposed Arrangement II, the OIG found that because the group was a multi-specialty practice, the group physicians who do not use the ASC as an extension of their office practices could profit from referrals to the ASC or to their partners who perform procedures at the ASC. Moreover, the OIG found that “the fact that the ownership of the ASC is held indirectly through a group practice whose membership includes both surgeons and other potential referring physicians does not reduce the risk that the venture may be used to reward referrals.” Because Proposed Arrangement II did not meet the safe harbor and no other safeguards existed, the OIG found that it could potentially violate the Anti-Kickback Statute and the parties could potentially be subject to imposition of administrative sanctions and/or civil monetary penalties if the requisite intent was established.

Conclusion

The OIG’s contrasting opinions suggest that ASC joint ventures that do not meet safe harbors will be reviewed on a case-by-case basis, and those with sufficient safeguards to minimize fraud and abuse risk are more likely to be approved.

Endnotes

2 Advisory Opinion No. 03-5, Office of Inspector General, U.S. Department of Health and Human Services, issued February 6, 2003. The OIG does not evaluate intent in the Advisory Opinion process, and, as such, concluded only that Proposed Arrangement II could potentially result in an anti-kickback violation and in imposition of administrative sanctions. No sanctions were imposed here.
4 The OIG emphasized the limited application of this analysis, stating that its position on term and termination provisions set forth in the 1999 final safe harbor regulation (64 Fed Reg. 63526 (November 19, 1999)) remained unchanged, and adding that this Opinion would be without force and effect if the parties renegotiated fees more often than annually or if the agreements were terminated for cause and the parties entered into a new agreement during the original one-year term.
5 The hospital is a non-profit corporation that owns two other hospitals and employs 42 physicians in an array of specialties including family practice, internal medicine, obstetrics/gynecology and pediatrics. The hospital has eight operating suites for inpatient and outpatient surgery, and the group's physicians perform approximately 25 percent of all surgeries performed at hospital.
6 The group consists of 52 shareholders who are each licensed physicians and employees of the group. Each group shareholder owns one share of group stock and receives an equal share of any dividends paid. The group also employs other physicians and health care professionals. Group physicians practice an array of specialties in addition to surgery and orthopedic surgery, including family practice, internal medicine, pediatrics, obstetrics/gynecology and ophthalmology.
7 ASC has two membership classes—Class A voting members (the hospital and the group) and Class B non-voting members (no memberships have been sold, but membership is open to state-licensed physicians eligible for credentialing at the ASC or a state legal entity with a majority of its owners being physicians who are so eligible).
This lease is subject to the space rental safe harbor under the anti-kickback safe harbor.

See 42 CFR 1001.952(p) & (r)(3).

As noted above, the OIG does not opine on intent in the Advisory Opinion process.