Published on *The National Law Review* https://natlawreview.com

OIG Issues Favorable Advisory Opinion on Ambulatory Surgery Center Joint Venture

Article By:

Ashley A. Creech

The U.S. Department of Health and Human Services' Office of Inspector General ("OIG") recently issued Advisory Opinion No. 21-02, regarding a joint investment by a health system, a manager, and certain surgeons in an ambulatory surgery center ("ASC") (the "Proposed Arrangement"). According to a national survey, most hospitals and health systems are planning to increase their investments in ASCs and anticipate converting hospital outpatient departments to ASCs. Many hospitals with ASCs operate the ASCs as physician joint ventures. As payors and patients continue to show interest in having outpatient procedures performed in ASCs, there is an expected trend to see an increase in investments and joint ventures in ASCs therefore making the Advisory Opinion particularly noteworthy.

In their request to OIG, the health system and the manager ("Requestors") specifically inquired whether the Proposed Arrangement would constitute grounds for sanctions under the Federal Anti-Kickback statute ("AKS"). Based upon the facts provided in the request for the Advisory Opinion and a supplemental submission, the OIG reached the favorable conclusion that due to the low risk of fraud and abuse, the OIG would not impose sanctions on the health system or the manager in connection with the Proposed Arrangement.

The Proposed Arrangement

Under the Proposed Arrangement, the health system, five orthopedic surgeons, three neurosurgeons employed by the health system, and a manager, would invest in a new ASC. The health system would own 46 percent of the ASC, the surgeons would collectively own 46 percent of the ASC, and the manager would own 8 percent of the ASC. The manager certified that no physician has had, or would have, ownership in the manager that provides management and other services to the ASC. Furthermore, the ASC would operate in a medical facility owned by a real estate company jointly owned by the health system, the surgeons, and the manager. The ASC would enter into space and equipment leases as well as service arrangements with the health system and the real estate company.

OIG's Analysis

Based on the following criteria, the OIG determined that the following safeguards in the Proposed

Arrangement would mitigate the risk and that, as such, the OIG would not impose administrative sanctions in connection with the Proposed Arrangement:

Health System and Physician Investor Interest

(1) Although one or more of the neurosurgeons would fail to meet the Hospital-Physician ASC Safe Harbor Provision requirement that a physician investor derives at least one-third of his or her medical practice income for the previous fiscal year or previous 12-month period from the performance of ASC-qualified procedures, the health system certified that the neurosurgeons would use the ASC on a regular basis as part of their medical practices. Additionally, the health system certified that the surgeons would rarely refer patients to each other.

(2) The Proposed Arrangement would contain certain safeguards to reduce the risk that the health system would make or influence referrals to the ASC or the surgeons. For example, the health system certified that any compensation paid by the health system to affiliated physicians for services furnished would be consistent with fair market value and would not be related, directly or indirectly, to the volume or value of any referrals. In addition, the health system certified that it would refrain from any actions designed to require or encourage affiliated physicians to refer patients to the ASC or the surgeons and would not track referrals made to the ASC.

(3) Certain factors in the Proposed Arrangement reduce the risk that investors who would be referral sources for the ASC would be rewarded for their referrals through (i) the offer of ownership based on past or future referrals; or (ii) profit distributions that would be disproportionate to an investor's ownership in the ASC and would be tied to referrals. For example, neither the ASC nor any investor, would loan funds to or guarantee a loan for any investor to obtain ownership in the ASC. The ASC would not offer ownership to any party based on the previous or expected volume or value of referrals made by any party to the Proposed Arrangement. In addition, capital contributions and profit distributions would be made in proportion to an investor's ownership in the ASC. Further, all ASC investors would invest directly in the ASC (i.e., no investor would hold any ownership through a pass-through entity, which could be used to redirect revenues to reward referrals or otherwise erode the safeguards provided by direct investment).

(4) Certain safeguards within the Proposed Arrangement reduce the risk that the ASC's investors would receive profit distributions for referrals of patients to the ASC. The health system certified that any space or equipment leased by the ASC from the health system or the real estate company would comply with the AKS statute safe harbors for space rental and equipment rental, as applicable, and that any services performed by the health system or the real estate company for the ASC would comply with the safe harbor for personal services and management contracts and outcomes-based payments. In addition, the ASC and its investors would provide written notice to patients referred by ASC investors to the ASC of the referral source's investment interest in the ASC.

(5) The Proposed Arrangement contains other safeguards designed to reduce fraud and abuse risks (e.g., improper billing). The ASC, the health system, surgeons, and the manager would treat patients receiving medical benefits or assistance under any Federal health care program in a nondiscriminatory manner. Further, the health system certified that all ancillary services provided to Federal health care program beneficiaries performed at the ASC would be related directly and integrally to primary procedures performed at the ASC and would not be billed separately to Medicare or any other Federal health care program. The Health System also certified that it would not include on any cost report or any claim for payment from a Federal health care program any costs associated with the ASC unless such costs are required to be included by a Federal health care program.

Manager Investment Interest

The OIG concluded that although the manager might be in a position to directly or indirectly influence referrals to the new ASC, the following safeguards mitigated the risk: (i) the manager would not make or influence referrals, directly or indirectly, to the surgeons or to the ASC; and (ii) no physician had or would have ownership in the manager.

Why This Matters

The AKS is an intent-based statute and provides for criminal penalties for the knowing and willful offer, payment, solicitation, or receipt of remuneration to induce or reward, among other things, the referral of business reimbursable under any of the Federal health care programs, including Medicare and Medicaid.

Health care providers and others may voluntarily seek to comply with statutory and regulatory safe harbors so that they have the assurance that their business practices will not be subject to sanctions under the AKS. To receive protection under a safe harbor, an arrangement must squarely meet each requirement of an applicable safe harbor. However, failure to fit in a safe harbor does not mean that an arrangement violates the AKS. Arrangements that do not fit in a safe harbor are analyzed on a case-by-case basis, including whether the parties had the requisite intent.

While OIG Advisory Opinions are issued only to Requesters and cannot be relied upon by other individuals or health care companies, these Opinions do provide important guidance and insight into to the OIG’s approach to evaluating various scenarios, in this case joint ventures between managers, physicians, and health systems.

National Law Review, Volume XI, Number 144