The Office of Inspector General (OIG) has issued a favorable advisory opinion addressing an investment in an ambulatory surgery center (ASC) made by a health system, certain physicians employed by the same health system, and a management company.

OIG Advisory Opinion No. 21-02 is the first advisory opinion since 2009 to provide guidance on ASC investments and related safe harbors to the Anti-Kickback Statute. This advisory opinion is also notable as it is the first to consider a venture involving
a health system and its own employed physicians — a prospect that has increased as the percentage of system-employed physicians has grown throughout the industry. While the OIG ultimately concluded the proposed arrangement at issue was “low risk” and would not be subject to sanctions, this advisory opinion sends a clear signal to ASC investors that significant safe guards against fraud and abuse are vital for Anti-Kickback Statute compliance, particularly for arrangements which may not satisfy all elements of a safe harbor. Direction from the OIG on ASC investments is rare, and those affiliated with ASCs should pay close attention to this development and the guideposts delineated therein.

Under the proposed arrangement addressed in Advisory Opinion No. 21-02, the health system would own 46 percent of the ASC, a management company would own 8 percent of the ASC, and the remaining ownership interests would be held in their individual capacity by eight physicians (five orthopedic surgeons and three neurosurgeons) employed by the health system. The distributions paid to each ASC investor, in conjunction with their referrals to the ASC for services or items reimbursable under a federal health care program, implicate the Anti-Kickback Statute and trigger the need for the arrangement to fit within a “safe harbor” to the Anti-Kickback Statute in order to avoid potential sanctions. The Anti-Kickback Statute contains a safe harbor applicable specifically to ASCs (ASC Safe Harbor) which permits distributions received by ASC investors as well as referrals made by investors to the ASC. The ASC Safe Harbor contains strict requirements, all of which must be satisfied in order to afford full safe-harbor protection to the arrangement.

The ASC investors who requested this advisory opinion acknowledged they would not satisfy the requirements of the ASC Safe Harbor for two reasons. First, the health system would be in a position to make or influence referrals to the new ASC. This ability to influence referrals is explicitly prohibited by the ASC Safe Harbor. Second, and seemingly more fatal to the proposed arrangement, some of the physician-owners (namely, the three neurosurgeons) would not satisfy the “one-third tests” of the ASC Safe Harbor due to the nature of their practice. The one-third tests require physician investors in ASCs to derive no less than one-third of their medical practice income from the performance of ASC-qualified procedures and, additionally, no less than one-third of procedures performed by each physician investor must be performed at the ASC in which the physician invests.

While the OIG noted the proposed arrangement did not qualify for safe harbor protection and thus may generate prohibited remuneration under the Anti-Kickback Statute, the OIG ultimately concluded that this arrangement was “sufficiently low risk” and did not warrant the imposition of administrative sanctions. Despite this favorable determination by the OIG, ASC investors should be hesitant to stray too far outside of the ASC Safe Harbor requirements; the OIG’s analysis and approval of the arrangement was contingent upon compliance with the remaining elements of the ASC Safe Harbor, as well as extensive safe guards put in place by the ASC investors, some of which are listed below:

- Those physician investors who would not satisfy the one-third tests would still use the ASC on a regular basis as part of their medical practices.
The physician investors would personally perform almost all procedures referred to the ASC.

The physician investors would not be significant sources of cross-referrals to other physician investors in the ASC to generate profit distributions.

Physicians affiliated with the health system would not be incentivized by the health system to make referrals to the ASC. Specifically, the health system would refrain from requiring or encouraging the affiliated physicians to refer patients to the ASC, and the health system would not track referrals made to the ASC by affiliated physicians.

Prior to this advisory opinion, failure to satisfy the one-third tests of the ASC Safe Harbor may have been prohibitive for a physician desiring to invest in an ASC. This advisory opinion suggests there is some flexibility with the one-third tests, so long as investors have other safe guards in place to protect against fraud and abuse.


[2] Under the proposed arrangement, the manager would be in a position to provide services to the ASC and, in fact, would be providing management services to the ASC. While this type of relationship is generally not permitted under the ASC Safe Harbor, the OIG did not address this issue in its advisory opinion.

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National Law Review, Volume XI, Number 132

Source URL: https://www.natlawreview.com/article/new-oig-advisory-opinion-establishes-guideposts-asc-investors-venture-involving