

OIG Advisory Opinion No. 21-02 Provides Helpful Insights into Risk Mitigation Factors Regarding Health System-, Physician-, and Management Company-Owned Ambulatory Surgery Centers

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On April 26, 2021, the Department of Health and Human Services Office of Inspector General (“OIG”) issued favorable Advisory Opinion No. 21-02 regarding a proposed investment in an ambulatory surgery center (“ASC”) by a health system, orthopedic surgeon and neurosurgeon employees of the health system, and a management company. This latest Advisory Opinion is notable because it is the first time that the OIG has considered a venture that included a health system and its employees. As employment of physicians has grown, so have the number of potential ventures between employees and their health systems, making this latest Advisory Opinion particularly relevant. OIG guidance on ASCs is also uncommon, and in fact, this is the first ASC Advisory Opinion in over a decade. So, investors should review the OIG’s analysis carefully to understand the numerous elements that the OIG emphasized for mitigating risk. While the OIG concluded that the proposed investment would lead to sanctionable remuneration under the federal Anti-Kickback Statute (“AKS”) if the requisite intent were present, it determined that it would not impose sanctions on the requesting parties because of several integrated safeguards.

A main takeaway from the OIG’s analysis was its conclusion that, with respect to the investments to be made by the health system and physician investors, the proposed investment presents a sufficiently low risk of fraud and abuse under the AKS for the combination of the following reasons.

Physician Investors Who Can’t Meet the 1/3rd Income Test Still Integrate the ASC Into Their Regular Practice; Physician Investors Are Not Significant Source of Cross-Referrals

Since neurosurgeons primarily perform inpatient procedures, one or more of the

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neurosurgeon investors may not comply with the safe harbor requirement that at least one-third of each physician investor's annual income come from the performance of procedures that would be payable by Medicare when performed in an ASC. However, the OIG found it significant that the neurosurgeon investors would integrate use of the proposed ASC into their regular practice. In addition, the physician investors would personally perform almost all of their own referrals to the proposed ASC, rather than referring these procedure to other physicians. The health system estimated that only about 1% of the total number of ASC-qualified procedures done at the ASC would come from a different physician investor's referral.

Risk of Health System's Influence on Referrals Mitigated

The OIG also found that the proposed ASC had sufficient safeguards to mitigate the health system's potential role in making or influencing referrals to the ASC. The health system certified that its affiliated physicians (i.e., employees, independent contractors, and members of the medical staff) would be paid consistent with fair market value and that such compensation would not be related, directly or indirectly, to the volume or value of their respective referrals to the ASC or its physician investors. The health system also certified that it would neither require nor encourage its affiliated physicians to refer patients to the ASC or its physician investors, and it would not track its affiliated physicians' actual referrals.

Reduce Risk of Rewarding Referrals through Structure of Investment Returns and Offers of Ownership

Under the proposed ASC, potential investors' opportunities to invest, and their investment returns, would not be based on anticipated or actual referrals to the ASC. Capital contributions and profit distributions would be based on an individual investor's investment interest in the ASC. Additionally, the ASC and its investors would not be permitted to promise or provide loans for the purpose of another investor gaining an investment interest in the ASC, and investors would be required to invest directly in the ASC (as opposed to through a pass-through entity).

Safeguards on Investors' Other Financial Relationships

The ASC committed that its space or equipment leases would comply with the AKS space and equipment rental safe harbors. Similarly, any services rendered by the health system or the real estate company jointly owned by the investors would comply with the applicable AKS safe harbor for personal services and management contracts and outcomes-based payments. In addition, all ASC patients referred by an ASC investor would be given full written notice of the investor's financial interest in the ASC.

Other Safeguards

The OIG listed several other significant safeguards against fraud and abuse presented by the proposed ASC. First, the ASC and its investors would provide non-discriminatory treatment to patients covered under any federal health care program. Second, the health

system certified that all ancillary services for ASC patients covered under a federal health care program would directly and integrally relate to the ASC's primary procedures. Further, the health system certified that the ASC would not bill any federal health care program separately for ancillary services. Third, the health system certified that it would not include ASC costs on cost reports or claims for payment by a federal health care program (unless such reporting is otherwise required by the program).

With respect to the investments to be made by the management company, the OIG determined that even while the management company may be in a position to directly or indirectly influence referrals and thereby increase its investment returns, the proposed ASC had sufficient safeguards to mitigate that risk. Similar to the health system and physician investors, the management company certified that it would not make or influence referrals to the ASC or its physician investors. Additionally, no physician would have any investment interest in the management company.

For all of these reasons, the OIG concluded that the proposed ASC arrangement presents a sufficiently low risk under the AKS and that the OIG would not impose administrative sanctions against the requesting parties in connection with the ASC.

While Advisory Opinion No. 21-02 may only be relied upon by the requesting parties, it does provide helpful insight into risk mitigation factors when considering other ASC structures. If you have any questions about ASCs, please contact the author or your regular Dorsey attorney.

Summer Associate Laura C.S. Newberry provided substantial assistance researching and drafting this blog post.