

A MULTI-SPECIALTY ASC IS THE SUBJECT OF LATEST OIG ADVISORY OPINION

FRED M. LARA, CFA, ASA, CVA

On April 29, 2021, the Office of Inspector General (the "OIG") posted Advisory Opinion No. 21-02, which addressed a request from a health system and management company (the "Requestors") for review of a proposed investment, along with certain physician surgeon owners, in an ambulatory surgery center (the "Proposed Arrangement"). While the OIG ultimately indicated that it would not impose administrative sanctions on the Requestors under the applicable sections of the Federal anti-kickback statute, its determination hinged on certain key facts and stipulations made by the Requestors. This article summarizes Advisory Opinion 21-02 and highlights certain key safeguards of the Proposed Arrangement that were noted by the OIG.

FACTS OF THE PROPOSED ARRANGEMENT



Ownership

- Health System 46%
- Physician Investors (collectively) 46%
 - ► 5 orthopedic surgeons
 - ▶ 3 neurosurgeons
 - Individually will own between 4-8%
- Management Company 8%

Per the <u>2021 ASC Valuation and Benchmarking Survey</u>, orthopedics is the #1 specialty ranked in terms of case type desirability and neurosurgery is ranked #4. (per Q26 of the Benchmarking Survey)

Real Estate

Newly constructed medical facility owned by a Real Estate Company that is a joint venture comprised of the same parties.

SAFEGUARDS NOTED IN ADVISORY OPINION 21-02

In the Analysis section of Advisory Opinion 21-02, the OIG concludes that each of the investors *may be* (manager), or would be (physician investors and health system) in a position to (directly or indirectly) influence referrals of items or services reimbursable by a Federal health care program to the new ASC. The OIG ultimately indicated that it would not impose administrative sanctions on the Requestors under the applicable sections of the Federal anti-kickback statute. This determination hinged on certain key facts and stipulations made by the Requestors.



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We have summarized certain of the reference "safeguards" from the opinion in the left hand column of the table, below. One way to gain additional perspective on the commentary provided by the OIG, in addition to identifying the key safeguards, is to consider the opposite of the fact patterns cited in the safeguard – as shown in the right hand column of the table below. We present the information in the right hand column of the table noting that the OIG generally warns that Advisory Opinions are specific to the facts presented and cannot be assumed to indicate position or action on a different set of facts.

SAFEGUARD NOTED IN ADVISORY OPINION 21-02

Manager will not have physician ownership

Although neurosurgeons would fail to meet the 1/3 safe harbor regarding medical practice income, Physician Investors will use the new ASC on a regular basis as part of their practices

Physician investors will rarely refer patients to each other for ASC-Qualified Procedures, with estimated volume to be fewer than 1% of aggregate annual volume at the new ASC.

The health system will not track referrals made to the new ASC by physicians who are its employees, independent contractors, or medical staff members ("Affiliated Physicians").

Affiliated Physicians' compensation, including any Physician Investor employment compensation, would be consistent with FMV and would not be related directly or indirectly to the volume or value of referrals Affiliated Physicians may make to the new ASC or its physician investors.

Neither the new ASC nor any of the investors would loan, or guarantee a loan of, funds to any other investor.

Capital contributions and profit distributions are to be made in proportion to ownership.

All New ASC investors would invest directly in the New ASC.

All ancillary services provided to Federal health care program beneficiaries at the new ASC will relate directly and integrally to primary procedures performed at the new ASC and not be billed separately to any Federal health care program.

OPPOSITE FACT PATTERN OF SAFEGUARD

An ASC management company has physician ownership

Physician investors in an ASC who do not meet the 1/3 Safe Harbor have possible procedures to perform at the ASC but elect to rarely, if ever, use the ASC.

Physician investors who rarely, if ever, use an ASC cross refer a significant amount procedure volume to other physician investors who perform those cases at the ASC.

A health system tracks referrals made to an ASC in which it has an investment.

Physician employees of a health system have a compensation plan that earmarks incentive compensation tied directly to procedure volume at the health system's ASC.

A physician invests in an ASC without providing upfront capital through proceeds of a loan made, or guaranteed by, a health system.

Physicians are never required to make capital contributions as they are solely made by manager or health system.

Profit distributions are based on referred case volume.

Physician investors own shares through a separate entity which adjusts profit distributions in a manner that is disproportionate to ownership.

Ancillary services provided at an ASC do not relate to the procedures performed therein.

KEY TAKEAWAYS

As the ambulatory surgery center industry is not a frequent subject addressed by the OIG, Advisory Opinion 21-02 is worth particular attention. This Advisory Opinion highlights the litany of related transactions or activities surrounding a joint venture investment in an ASC that might impact overall physician investment outcomes, and therefore, have regulatory implications. Though the Requestors have prudently and proactively addressed these surrounding transactions with safeguards that mitigate potential regulatory risk that might arise in the Proposed Arrangement, industry participants should consider with care whether any of their own surrounding transactions (individually or collectively) serve to undermine the spirit of the regulatory framework under which physician investments in ASC's are permitted.

