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Buyers Take Note: OIG Opinion Provides Insights on Physician-Owned Entities & Their Technologies

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PART I

On April 20, 2022, the Office of Inspector General ("OIG") of the Department of Health and Human Services ("HHS") issued Advisory Opinion, No. 22-07 ("Opinion 22-07"), an informative opinion regarding arrangements whereby physicians have an ownership interest in a medical device company that manufactures products that the physicians—with ownership interests—or their close family members can order or utilize. In this opinion, the OIG concluded it will not impose administrative sanctions in connection with such arrangement under sections 1128A(a)(7) or 1128(b)(7) of the Social Security Act—as those sections relate to the commission of acts described in the federal anti-kickback statute—even though such an arrangement would create prohibited remuneration under the federal anti-kickback statute if the requisite intent was present.

While Opinion 22-07 is directed at a physician-owned entity, and the particular aspects of that entity, the opinion is instructive for potential purchasers of medical devices from physician-owned entities (e.g., hospitals and ambulatory surgical centers) and acquirers of physician-owned entities or technologies (e.g., medical device manufacturers and private equity firms), who traditionally have had to confront a certain degree of risk that relationships and transactions with physician-owned entities could draw scrutiny.

The Arrangement

Opinion 22-07 involves physicians who are orthopedic surgeons and members of a medical group. The physicians were identified as Physicians A, B, and C. Physician A created a separate company—outside of his practice and participation in the medical group—that invents and sells medical devices using upper extremity surgical technologies. Physician A is also the company's chief scientific officer and the inventor of all of the company's intellectual property. Physician B is Physician A's daughter, and Physician C is Physician B's husband. Physician A and Physician B both have an ownership interest in the company. Physician C is an immediate family member of an individual—Physician B—with an ownership interested in the company (at times, Physician A, B, and C are collectively referred to as the "Physicians"). Although Physician A developed his technologies into the company's medical products, he is not involved in the company's day-to-day operations. The company gave majority ownership interest in the company and preferential voting rights to Physician A and his spouse in exchange for Physician A assigning ownership

of a sizable portfolio of proprietary technology to the company, which it used in its development of medical device. Physician A and his wife subsequently transferred their majority ownership interest to two irrevocable trusts.

Opinion 22-07 discussed various characteristics of the arrangement that led the OIG to reach its conclusion that although the arrangement does implicate the federal anti-kickback statute, it poses a low risk of fraud and abuse. A few of these characteristics are provided below:

- While the Physicians order company products, their revenue accounts for a small percentage of the company's total revenue (e.g., 0.98 percent of the 2019 gross revenue, 0.36 percent of the 2020 total revenue, and 0.45 percent of the 2021 gross revenue).
- The company has not made any profit distributions to its owners except annual distributions to cover each owner's income tax obligation arising from the owners' respective ownership interests, and any future profit distributions to owners will be to all owners and in direct proportion to each owner's investment interest in the company—except for a "carve-out amount," which reduces distributions to the trusts created by the Physicians by the amount of revenue that is generated by orders from any physician or other medical group member.
- While the Physicians can order company products for surgeries they personally perform at hospitals and ambulatory surgical centers ("ASCs") and recommend company products to others, they cannot otherwise influence hospitals or ASCs to order the company's products. The Physicians also certify that they do not condition referrals to hospitals or ASCs on the purchase of company products and that they choose products based on each patient's needs.
- The trusts' ownership interest is not dependent or contingent on any of the Physicians or their medical group partners producing business for the company. More specifically, "the [c]ompany certified that it has not reserved the right to repurchase the [t]rusts' ownership interest, and it does not, and will not in the future, have any requirement that the [t]rusts divest their ownership interest if any of the Physicians cease practicing medicine or ordering from the [c]ompany."
- The Physicians and other medical group members give specified disclosures to patients regarding the arrangement. For example, the Physicians provide written notice to their patients undergoing surgery of their ownership interest in the company before using a company product in a surgery. The written notice also contains names of alternative medical device companies, and patients can inform the Physicians to use the alternative medical devices instead.

Compliance Considerations of the Arrangement

In Opinion 22-07, the OIG emphasized that it has had longstanding concerns regarding physician-owned entities and that they are inherently suspect due to questionable features. According to the OIG, the arrangement in Opinion 22-07 implicates the federal anti-kickback statute since 1) the Physicians are either beneficiaries of, or the spouse of a beneficiary of, the trusts, which hold an ownership interest in the company, 2) the Physicians order products from the company that can be reimbursable by federal health care programs, and 3) the Physicians can recommend the company's products to others. The arrangement did not fall under a safe harbor. It specifically did not fall under the small entity investment safe harbor since the Physicians can generate business (e.g., make or influence referrals to) and more than 40 percent of the company's investment interests are held in the trusts.

Opinion 22-07 noted—however—that the arrangement did not raise concerns identified in the OIG's 2013 Special Fraud Alert Regarding Physician-Owned Entities ("2013 Special Fraud Alert") and included numerous compliance considerations (i.e., safeguards) to reduce fraud and abuse risks. The OIG ultimately concluded—based on **six compliance considerations**—that the arrangement posed sufficiently low risk of fraud and abuse under the federal anti-kickback statute:

1. **Involvement of Physician Owners** – the arrangement does not present suspect characteristics related to the management and oversight of the physician-owned entity (e.g., the legitimacy of the company, the company demonstrates that it is not a shell company as it creates medical products that are sold domestically and internationally, and Physician A's ownership derives from his own medical inventions).

2. **Profit Distribution Structure** – the manner in which the company's future profit distributions reduce the risks of harms associated with the federal anti-kickback statute (e.g., the company lowers distributions per the carve-out amount to the trusts in order to diminish the financial incentives for ordering the company's products and the company does not treat the physician owners preferentially in making any profit distributions).

3. **Percentage of Revenue** – the Physicians and other medical group members' account for a very limited amount of business for the company, and the percentage of orders by the Physicians and other medical group members has been decreasing over the years.

4. **Investor Selection and Characteristics** – the arrangement deviates from other physician-owned arrangements that select or retain physician investors in suspect ways (e.g., the company does not obligate physician owners when they cease practicing medicine to divest their interests nor does the company possess the right to repurchase the Physicians' ownership interests).

5. **Certifications** – the Physicians certified that they will not try to influence hospitals or ASCs to purchase the company's products aside from recommending or ordering the company's products for surgeries they personally perform.

6. **Disclosures** – the Physicians and their medical group partners are clear and candid about their ownership interest in the company (e.g., the Physicians provide written notice to their patients undergoing surgery of their ownership interest in the company before using a company product in a surgery and the Physicians provide written notice that contains names of alternative medical device companies in which none of the physician owners have an ownership interest).

OIG's Prior Guidance in Analyzing Arrangements

This recent advisory opinion mentioned the 2013 Special Fraud Alert—issued on March 26, 2013—and factored the concerns regarding physician-owned distributorships ("PODs") in that guidance to this specific arrangement. The 2013 Special Fraud Alert specifically addressed entities that "derive revenue from selling, or arranging for the sale of, implantable medical devices ordered by their physician-owners for use in procedures the physician-owners perform on their own patients at hospitals or [ASCs]," which are often referred to as PODs. The 2013 Special Fraud Alert recognized **three specific features** in regards to PODs that were inherently suspect and that are reflected in Opinion 22-07:

1. **Investor Selection Based on Ability to Generate Business** – selecting investors because they are in a position to generate substantial business for the entity;

2. **Requiring Investors to Practice Medicine** – requiring investors who cease practicing in the service area to divest their ownership interests; and

3. **Uneven Profit Distribution** – distributing extraordinary returns on investment compared to the level of risk involved.

The 2013 Special Fraud Alert noted that if a POD presents any of these or other questionable features, then OIG would have concerns that the arrangement could result in **four potential harms** generally associated with kickbacks:

1. **Corruption of Medical Judgement** – the arrangement could negatively impact the physician-patient relationship and skew independent medical judgement;

2. **Overutilization** – the arrangement could result in medically unnecessary procedures and an overutilization of the product(s);

3. **Increased Cost to Federal Healthcare Programs** – the arrangement could increase costs to the federal healthcare programs, either due to overutilization or through the self-interested selection of more expensive product(s); and

4. **Unfair Competition** – the arrangement could be anti-competitive and provide an unfair advantage based on commercial considerations, as opposed to other appropriate considerations, such as safety, efficacy, or price.

Conclusion

Opinion 22-07 is helpful in many respects, particularly in light of the fact that that the 2013 Special Fraud Alert was published almost a decade ago. Generally, and in connection with the 2013 Special Fraud Alert, purchasers of medical device products from physician-owned entities have faced a certain degree of risk that such relationships and transactions could draw scrutiny and potentially violate the federal anti-kickback statute. Acquirers of physician-owned entities or physician-owned technologies also face comparable risks.

While such purchasers and acquirers continue to confront a degree of risk when transacting with physician-owned entities, Opinion 22-07 arguably provides some clarity on what type of arrangements may draw OIG scrutiny and could potentially violate the federal anti-kickback statute. Each potential arrangement is fact dependent and requires a careful analysis of the six compliance considerations, three specific features, and four potential harms mentioned in the existing OIG guidance, as well as a thorough review of the purpose and intent behind the potential arrangement.

Part two of this article will focus on how the OIG's guidance on physician-owned entities specifically affects acquirers of physician-owned entities or technologies, such as medical device manufacturers and private equity firms, in the context of today's trends related to mergers, acquisitions, licensing arrangements, and other intellectual property transfers.

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