



DEPARTMENT OF HEALTH AND HUMAN SERVICES

## OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



*[We redact certain identifying information and certain potentially privileged, confidential, or proprietary information, unless otherwise approved by the requestor(s).]*

**Issued:** April 20, 2022

**Posted:** April 25, 2022

[Address block redacted]

### **Re: OIG Advisory Opinion No. 22-07**

Dear [redacted]:

The Office of Inspector General (“OIG”) is writing in response to your request for an advisory opinion regarding an arrangement whereby certain physicians have an ownership interest in a medical device company that manufactures products that may be ordered by the physician owners and a physician spouse of one of the physician owners (the “Arrangement”). Specifically, you have inquired whether the Arrangement constitutes grounds for the imposition of sanctions under the exclusion authority at section 1128(b)(7) of the Social Security Act (the “Act”) or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act (the “Federal anti-kickback statute”).

[Redacted] (the “Company”), [redacted] (the “Holding Company”), [redacted] (“Physician A”), [redacted] (“Physician B”), and [redacted] (“Physician C,” and together with the Company, the Holding Company, Physician A, and Physician B, “Requestors”) have certified that all of the information provided in the request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties in connection with the Arrangement, and we have relied solely on the facts and information Requestors provided. We have not undertaken an independent investigation of the certified facts and information presented to us by Requestors. This opinion is limited to the relevant facts presented to us by Requestors in connection with the Arrangement. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that, although the Arrangement would generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present, the OIG will not impose administrative sanctions on Requestors in connection with the Arrangement

under sections 1128A(a)(7) or 1128(b)(7) of the Act, as those sections relate to the commission of acts described in the Federal anti-kickback statute.

This opinion may not be relied on by any person<sup>1</sup> other than Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

## **I. FACTUAL BACKGROUND**

Physician A, Physician B, and Physician C (collectively, the “Physicians”) are orthopedic surgeons and members of [redacted] (the “Medical Group”).<sup>2</sup> Physician A is a hand and upper extremity surgeon and inventor of upper extremity surgical technologies. Physician B is Physician A’s daughter, and Physician C is Physician B’s husband. Physician A formed the Company to develop upper extremity surgical technologies that he has invented into medical devices that the Company sells domestically and internationally. Physician A is the inventor of all of the Company’s intellectual property and the Company’s Chief Scientific Officer and is involved in developing his technologies into products but does not participate in the day-to-day operations of the Company. The Company employs dozens of individuals and is responsible for the full range of operations of a medical device company, including product design, development and testing of products, quality control, the submission of regulatory filings with the U.S. Food and Drug Administration (the “FDA”) and international regulatory bodies, marketing, and inventory management.

The Company granted the majority ownership interest in the Company to Physician A and his spouse, who later contributed their majority ownership interest to two irrevocable trusts—one trust created by Physician A that benefits his spouse and their children, including Physician B, and another trust created by Physician A’s spouse that benefits Physician A and their children, including Physician B (the “Trusts”).<sup>3</sup> The Company certified that it granted the majority ownership interest and preferential voting rights to Physician A and his spouse (and ultimately

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<sup>1</sup> We use “person” herein to include persons, as referenced in the Federal anti-kickback statute, as well as individuals and entities, as referenced in the exclusion authority at section 1128(b)(7) of the Act.

<sup>2</sup> Physician A has an ownership interest in an ambulatory surgery center (the “ASC”) where the Physicians and other Medical Group members perform surgeries in which they may use Company products.

<sup>3</sup> The Holding Company owns 100 percent of the Company, and the Trusts collectively hold the majority ownership interest in the Holding Company. However, for purposes of this advisory opinion, we are treating the Trusts and other owners as holding a direct ownership interest in the Company. Regarding Physician A’s ownership interest in the Company via the Trusts, Physician A certified that both he and his spouse have disclaimed any beneficial interest in the Trusts attributable to the Company, resulting in only Physician A’s children benefitting financially from the Trusts’ holdings in the Company. We do not consider this disclaimer to meaningfully alter Physician A’s or his spouse’s financial interest stemming from the Trusts for purposes of this advisory opinion because of their familial relationship with their children.

the Trusts) in exchange for Physician A assigning ownership of a substantial portfolio of proprietary technology to the Company that the Company has used to develop medical devices and not because of any past or anticipated orders or recommendations from any of the Physicians. The remaining ownership interests in the Company are held by Company managers and employees (or former employees), none of whom are health care practitioners or family members of any of the Physicians, and none of whom have immediate family members who order products from the Company. Physicians A and B are the only physicians with an ownership interest in the Company who order products from the Company, and Physician C is the only immediate family member of an individual with an ownership interest in the Company who orders products from the Company.<sup>4</sup>

The Physicians order Company products, but according to Requestors, those orders, as well as orders by other members of the Medical Group, generate a relatively small percentage of the Company's revenues. For example, orders from the Physicians and their Medical Group partners comprised, respectively, 0.98 percent, 0.36 percent, and 0.45 percent of all gross revenue generated from Company sales in the United States in 2019, 2020, and 2021. The Company certified that, with the exception of the slight increase from 2020 to 2021 noted above, the percentage of the Company's revenue that is generated by the Physicians and their Medical Group partners has been steadily decreasing over the past 7 years and likely will continue to decrease, as the Company's sales have expanded nationally and internationally, with more physicians—who do not have any ownership interest in the Company—ordering the Company's products.

Regarding distributions to Company owners, to date, the Company has not made any profit distributions except annual distributions to cover each owner's income tax obligation deriving from the owner's ownership interest. The Company certified that 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 that any distributions to the Trusts will be reduced by the amount of revenue that is generated by orders from any Physician or other Medical Group member (or if applicable, other non-Medical Group physician performing surgeries at the ASC) that would otherwise be owed to the Trusts (the "Carve-Out Amount"). The Company certified that it does not loan funds or guarantee loans to the Physicians or any other Company owner.

The Physicians certified that they may order Company products for surgeries they personally perform at hospitals and ASCs that permit the use of Company products and may recommend Company products to others, but the Physicians will not otherwise attempt to influence hospitals or ASCs to purchase the Company's products. Additionally, the Physicians certified that they do not, and will not, condition referrals to hospitals or ASCs on the purchase of Company products by, for example: (i) stating or implying they will perform surgeries or refer patients elsewhere if

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<sup>4</sup> The Company certified that it complies with all reporting requirements of the Centers for Medicare & Medicaid Services' Open Payments Program, which is a statutorily required national disclosure program that includes a publicly accessible database of payments that reporting entities, including drug and medical device companies, make to covered recipients, like physicians. We express no opinion regarding any remuneration to any of the Physicians other than as set forth in this opinion.

a hospital or an ASC does not purchase medical devices from the Company; (ii) promising or implying they will move surgeries to a hospital or an ASC if it purchases medical devices from the Company; or (iii) requiring a hospital or an ASC to enter into an exclusive-purchase or minimum-purchase arrangement with the Company. According to Requestors, Company products are not always available or approved at facilities where the Physicians perform surgeries, and the Physicians select products based on each patient's clinical needs.

Additionally, the Company certified that the Trusts' ownership interest is not contingent on any of the Physicians or their Medical Group partners generating business for the Company. More specifically, the Company certified that it has not reserved the right to repurchase the Trusts' ownership interest, and it does not, and will not in the future, have any requirement that the Trusts divest their ownership interest if any of the Physicians cease practicing medicine or ordering from the Company. While the Company certified that it creates daily and monthly sales reports, it neither uses the reports to encourage additional orders from the Physicians or their Medical Group partners nor tracks orders from the Physicians or their Medical Group partners differently than orders from other sources of business (except as necessary to reduce any distributions to the Trusts by the Carve-Out Amount).

The Physicians and other Medical Group members provide certain disclosures to patients related to the Arrangement. Specifically, when the Physicians and their Medical Group partners are able to consult with their patients prior to performing surgery using a Company product (*i.e.*, when patients are first seen at the Medical Group's practice prior to undergoing surgery), they provide written notice of each Physician's ownership interest in the Company or relationship with an immediate family member with an ownership interest in the Company, as applicable. The notice includes the names of alternative medical device companies in which neither the Physicians nor any of their family members have an ownership interest, and patients have the opportunity to instruct the Physicians to use these alternative devices. The Physicians also certified that they have notified all of the hospitals and ASCs at which they currently perform services of their ownership interest in the Company or relationship with an immediate family member with an ownership interest in the Company, as applicable, and would notify any other facilities at which they practice in the future of such interests in the manner and as requested by the facilities. Additionally, when one or more of the Company's products is the subject of an academic presentation, lecture, or peer-reviewed publication by one of the Physicians, the Physician includes a disclosure regarding either the Physician's ownership interest in the Company or relationship with an immediate family member with an ownership interest in the Company, as applicable.

## **II. LEGAL ANALYSIS**

### **A. Law**

The Federal anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce, or in return for, the referral of an individual to a person for the furnishing of, or arranging for the furnishing of, any item or service

reimbursable under a Federal health care program.<sup>5</sup> The statute’s prohibition also extends to remuneration to induce, or in return for, the purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any good, facility, service, or item reimbursable by a Federal health care program.<sup>6</sup> For purposes of the Federal anti-kickback statute, “remuneration” includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration is to induce referrals for items or services reimbursable by a Federal health care program.<sup>7</sup> Violation of the statute constitutes a felony punishable by a maximum fine of \$100,000, imprisonment up to 10 years, or both. Conviction also will lead to exclusion from Federal health care programs, including Medicare and Medicaid. When a person commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such person under section 1128A(a)(7) of the Act. The OIG also may initiate administrative proceedings to exclude such person from Federal health care programs under section 1128(b)(7) of the Act.

Congress has developed several statutory exceptions to the Federal anti-kickback statute.<sup>8</sup> In addition, the U.S. Department of Health and Human Services has promulgated safe harbor regulations that specify certain practices that are not treated as an offense under the Federal anti-kickback statute and do not serve as the basis for an exclusion.<sup>9</sup> However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor. Compliance with a safe harbor is voluntary. Arrangements that do not comply with a safe harbor are evaluated on a case-by-case basis. Because the Arrangement would involve ownership of a non-public entity by interested investors, the small entity investment safe harbor is potentially applicable.<sup>10</sup> This safe harbor protects profit distributions paid on investments in small entities and requires, among other conditions, that no more than 40 percent of the value of the investment interests of each class of investment interests may be held by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity.

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<sup>5</sup> Section 1128B(b) of the Act.

<sup>6</sup> Id.

<sup>7</sup> E.g., United States v. Nagelvoort, 856 F.3d 1117 (7th Cir. 2017); United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000); United States v. Davis, 132 F.3d 1092 (5th Cir. 1998); United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir. 1985).

<sup>8</sup> Section 1128B(b)(3) of the Act.

<sup>9</sup> 42 C.F.R. § 1001.952.

<sup>10</sup> See 42 C.F.R. § 1001.952(a)(2).

## **B. Analysis**

The Arrangement implicates the Federal anti-kickback statute because the Physicians are either beneficiaries of, or the spouse of a beneficiary of, the Trusts, which hold an ownership interest in the Company, and the Physicians order products from the Company that may be reimbursable by Federal health care programs and may recommend the Company's products to others. The Arrangement does not fit in a safe harbor. The Arrangement fails to satisfy the small entity investment safe harbor because the Trusts collectively hold more than 40 percent of the investment interests in the Company, and the Physicians—each of whom is either a beneficiary of the Trusts or a spouse of a beneficiary—are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the Company. Arrangements that implicate the Federal anti-kickback statute and do not have safe harbor protection are evaluated on a case-by-case basis, based on the totality of the facts and circumstances.

The OIG has longstanding concerns regarding physician-owned 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 at hospitals or ASCs.<sup>11</sup> Physician-owned entities are inherently suspect under the Federal anti-kickback statute and are particularly concerning when they exhibit questionable features, such as selecting investors who are in a position to generate substantial business for the entity; requiring investors who cease practicing in the service area to divest their ownership interests; and distributing extraordinary returns on investment compared to the level of risk involved. The physician owners of physician-owned entities also may engage in suspect behavior, such as conditioning their referrals to hospitals or ASCs on the facilities' purchases of the physician-owned entity's devices through coercion or promises by, for example: (i) stating or implying they will perform surgeries or refer patients elsewhere if a hospital or an ASC does not purchase devices from the physician-owned entity; (ii) promising or implying they will move surgeries to a hospital or an ASC if it purchases devices from the physician-owned entity; or (iii) requiring a hospital or an ASC to enter into an exclusive-purchase arrangement with the physician-owned entity. The OIG has warned that physician-owned entities that exhibit these suspect characteristics potentially raise fraud and abuse concerns, such as corruption of medical judgment, overutilization, increased costs to Federal health care programs and beneficiaries, and unfair competition.

The Arrangement does not raise the concerns identified in the 2013 Special Fraud Alert, several of which are discussed in detail below. Importantly, the Arrangement includes certain other safeguards, described below, that further reduce the fraud and abuse risks of the Arrangement. Based on these specific facts and circumstances, we conclude that the Arrangement poses a sufficiently low risk of fraud and abuse under the Federal anti-kickback statute.

First, the Arrangement does not exhibit the suspect characteristics sometimes associated with physician-owned entities related to the legitimacy of the entity as a business from the perspective of the Federal anti-kickback statute. For example, the Company has several characteristics that

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<sup>11</sup> See, e.g., OIG, Special Fraud Alert: Physician-Owned Entities, 78 Fed. Reg. 19,271 (Mar. 29, 2013), [https://oig.hhs.gov/documents/special-fraud-alerts/867/POD\\_Special\\_Fraud\\_Alert.pdf](https://oig.hhs.gov/documents/special-fraud-alerts/867/POD_Special_Fraud_Alert.pdf) (hereinafter the "2013 Special Fraud Alert").

reduce the risk that it serves only as a shell entity. Among other things, the Company develops medical products that it sells domestically and internationally; employs dozens of individuals; and is responsible for the full range of operations of a medical device company, including product design, development and testing of products, quality control, the submission of regulatory filings with the FDA and international regulatory bodies, marketing, and inventory management. Additionally, Physician A's initial ownership interest in the Company, which led to the Trusts' ownership interest, stemmed from Physician A's own inventions. Indeed, the Company's business consists entirely of marketing and selling devices developed from the upper extremity surgical technologies Physician A invented.

Second, the manner in which the Company would make future profit distributions reduces the risk of harms that the Federal anti-kickback statute is designed to prevent (e.g., overutilization or inappropriate utilization, corruption of medical decision-making, increased costs to Federal health care programs, and unfair competition). In particular, the Arrangement meaningfully dilutes the financial incentives the Physicians may have to order the Company's products by reducing any distributions to the Trusts by the Carve-Out Amount. Additionally, the Company does not, and would not, treat the Physicians preferentially compared with non-Physician owners in making any profit distributions. The Company certified that it has not made any profit distributions except annual distributions to cover each owner's income tax obligation deriving from the owner's ownership interest and that, other than reducing any future distributions to the Trusts by the Carve-Out Amount, it will make any future profit distributions to all owners and in direct proportion to each owner's investment interest in the Company.<sup>12</sup>

Third, unlike physician-owned entities where physician owners are the sole, or primary, users of (and sources of business for) the devices sold or manufactured by their physician-owned entities, the Physicians and other Medical Group members generate a very limited amount of business for the Company (less than 1 percent of all gross revenue generated from Company sales in the United States in each of the last 3 years). The Company certified that, with the exception of the slight increase from 2020 to 2021, the percentage of orders by the Medical Group, including the Physicians, has been steadily decreasing over the past 7 years and likely will continue to decrease, as the Company's sales have expanded nationally and internationally, with more physicians—who do not have any ownership interest in the Company—ordering the Company's products. These facts further reduce the risk of fraud and abuse from the Physicians' financial interest in the Company.

Fourth, the Arrangement differs from other physician-owned entity arrangements that select or retain physician investors in suspect ways, such as by retaining the right to repurchase physicians' ownership interests or requiring physician owners to divest their interests if the physicians cease practicing medicine or refer less business to the physician-owned entity. The Company certified that it granted the majority ownership interest and preferential voting rights to

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<sup>12</sup> While the Physicians could increase the Company's overall value by ordering or recommending Company products, we do not believe such increases pose a significant risk in the context of the Arrangement because of the Carve-Out Amount, the low percentage of the Physicians' and other Medical Group members' orders, and other safeguards present in the Arrangement.

Physician A and his spouse (and ultimately the Trusts) in exchange for Physician A assigning ownership of a substantial portfolio of proprietary technology to the Company that the Company has used to develop medical devices and not because of any past or anticipated orders or recommendations from any of the Physicians. The Trusts' ownership interest is not contingent on any of the Physicians or their Medical Group partners generating business for the Company. The Company also certified that it has not reserved the right to repurchase the Trusts' ownership interest, and it does not, and will not in the future, have any requirement that the Trusts divest their ownership interest if any of the Physicians cease practicing medicine or ordering from the Company. Additionally, while the Company certified that it creates daily and monthly sales reports, it neither uses the reports to encourage additional orders from the Physicians or their Medical Group partners nor tracks orders from the Physicians or their Medical Group partners differently than orders from other sources of business (except as necessary to reduce any distributions to the Trusts by the Carve-Out Amount).

Fifth, the Physicians certified that, although they may recommend Company products and order Company products for surgeries they personally perform at hospitals and ASCs that permit the use of Company products, the Physicians will not otherwise attempt to influence hospitals or ASCs to purchase the Company's products. The Physicians also certified that they do not, and will not, condition referrals to hospitals or ASCs on the purchase of Company products by, for example: (i) stating or implying they will perform surgeries or refer patients elsewhere if a hospital or an ASC does not purchase devices from the Company; (ii) promising or implying they will move surgeries to a hospital or an ASC if it purchases devices from the Company; or (iii) requiring a hospital or an ASC to enter into an exclusive-purchase or minimum-purchase arrangement with the Company. More generally, the Physicians certified that, for all procedures, they select products based on each patient's clinical needs.

Lastly, the Physicians and their Medical Group partners are transparent about the Trusts' ownership interest in the Company. While transparency, alone, is not sufficient to decrease the risks associated with a physician-owned entity,<sup>13</sup> in this case, the Physicians' various disclosures to patients, facilities, and the public, in combination with other safeguards present in the Arrangement, further decrease the risk of fraud and abuse from the Arrangement. When the Physicians and their Medical Group partners are able to consult with their patients prior to performing surgery using a Company product (i.e., when patients are first seen at the Medical Group's practice prior to undergoing surgery), they provide written notice of each Physician's ownership interest in the Company or relationship with an immediate family member with an ownership interest in the Company, as applicable. The notice includes the names of alternative medical device companies in which neither the Physicians nor any of their family members have an ownership interest, and patients have the opportunity to instruct the Physicians to use these alternative devices. The Physicians also certified that they have notified all of the hospitals and ASCs at which they currently perform services of their ownership interest in the Company or relationship with an immediate family member with an ownership interest in the Company, as applicable, and would notify any other facilities at which they practice in the future of such

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<sup>13</sup> See 2013 Special Fraud Alert, 78 Fed. Reg. at 19272 ("We do not believe that disclosure to a patient of the physician's financial interest in a [physician-owned entity] is sufficient to address [OIG's] concerns.").



interests in the manner and as requested by the facilities. In addition to the other notices, when one or more of the Company's products is the subject of an academic presentation, lecture, or peer-reviewed publication by one of the Physicians, the Physician includes a disclosure regarding either the Physician's ownership interest in the Company or relationship with an immediate family member with an ownership interest in the Company, as applicable.

### **III. CONCLUSION**

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that, although the Arrangement would generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present, the OIG will not impose administrative sanctions on Requestors in connection with the Arrangement under sections 1128A(a)(7) or 1128(b)(7) of the Act, as those sections relate to the commission of acts described in the Federal anti-kickback statute.

### **IV. LIMITATIONS**

The limitations applicable to this opinion include the following:

- This advisory opinion is limited in scope to the Arrangement and has no applicability to any other arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.
- This advisory opinion is issued only to Requestors. This advisory opinion has no application to, and cannot be relied upon by, any other person.
- This advisory opinion may not be introduced into evidence by a person other than Requestors to prove that the person did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.
- This advisory opinion applies only to the statutory provisions specifically addressed in the analysis above. We express no opinion herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act (or that provision's application to the Medicaid program at section 1903(s) of the Act).
- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.
- We express no opinion herein regarding the liability of any person under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against Requestors with respect to any action that is part of the Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against Requestors with respect to any action that is part of the Arrangement taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/Robert K. DeConti/

Robert K. DeConti  
Assistant Inspector General for Legal Affairs