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: August 7, 2025

Posted: August 12, 2025

[Address block redacted]

Re: OIG Advisory Opinion No. 25-09 (Favorable)

Dear [redacted]:

The Office of Inspector General ("OIG") is writing in response to your request for an advisory opinion on behalf of [redacted] ("Requestor"), regarding remuneration to physicians with an ownership interest in Requestor (the "Arrangement"). Specifically, you have inquired whether the Arrangement would constitute 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").

Requestor has 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 Requestor provided. We have not undertaken an independent investigation of the certified facts and information presented to us by Requestor. This opinion is limited to the relevant facts presented to us by Requestor in connection with the Arrangement. If material facts have not been disclosed, have been misrepresented, or change, 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 the Arrangement does not generate prohibited remuneration under the Federal anti-kickback statute. Accordingly, OIG will not impose administrative sanctions on Requestor in connection with the Arrangement under section 1128A(a)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute, or the exclusion authority at section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute.

This opinion may not be relied on by any person[1] other than Requestor and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

Requestor develops, manufactures, and sells medical devices relating to emergency stroke treatment. Requestor is owned, in part, by physicians ("Physician Owners"), including the creator of Requestor's medical devices, who may order or purchase Requestor's devices or recommend a hospital order and purchase Requestor's devices. Requestor certified that no more than 40 percent of the value of the investment interests of each class of investment interests is held or has been held in the previous fiscal year or previous 12-month period by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for Requestor, including the Physician Owners. Specifically, Requestor certified that Physician Owners currently comprise approximately 35 percent of Requestor's ownership and that no other owners are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for Requestor.

Additionally, Requestor certified to the following facts:

- The terms on which Requestor has offered or will offer investment interests to Physician Owners who are passive investors, or other passive investors who could recommend Requestor's devices, are and will be the same as, and do not differ from, the terms offered to other passive investors;

- The terms on which an investment interest has been or will be offered by Requestor to an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for Requestor is unrelated to the previous or expected volume of referrals, items or services furnished, or amount of business otherwise generated from that investor to Requestor;

- Requestor has not and will not impose any requirement or suggestion that a passive investor make referrals to, be in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for Requestor as a condition of remaining as an investor;

- Neither Requestor nor any of its investors markets or furnishes Requestor's items or services (or those of another entity as part of a cross-referral agreement) to passive investors differently than to non-investors;

[1] 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.

- No more than 40 percent of Requestor's gross revenue related to the furnishing of health care items and services in the previous fiscal year or previous 12-month period has come from referrals or business otherwise generated from investors;

- Neither Requestor nor any of its investors (or other individuals or entities acting on behalf of Requestor or any investor in Requestor) has loaned or will loan funds to, or guarantee a loan for, a Physician Owner or other investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for Requestor if the Physician Owner or other investor has or will use any part of such loan to obtain their investment interest; and

- To date, Requestor has not made any profit distributions to any Physician Owners, and if it does make such distributions or make any other payments to investors based on their ownership interests in Requestor, then the amount of any payment to an investor by Requestor in return for the investor's investment interest will be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.

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.[2] 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.[3] 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.[4] 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, OIG may initiate administrative proceedings to impose

[2] Section 1128B(b) of the Act.

[3] Id.

[4] 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).

civil monetary penalties on such person under section 1128A(a)(7) of the Act. 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.[5] 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.[6] 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 involves ownership of a non-public entity by interested investors, the small entity investment safe harbor is potentially applicable.[7] This safe harbor protects financial distributions paid on investments in small entities if all of the following eight conditions of the safe harbor are met:

(i) No more than 40 percent of the value of the investment interests of each class of investment interests may be held in the previous fiscal year or previous 12-month period 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;

(ii) The terms on which an investment interest is offered to a passive investor, if any, who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must be no different from the terms offered to other passive investors;

(iii) The terms on which an investment interest is offered to an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must not be related to the previous or expected volume of referrals, items or services furnished, or the amount of business otherwise generated from that investor to the entity;

(iv) There is no requirement that a passive investor, if any, make referrals to, be in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity as a condition for remaining as an investor;

[5] Section 1128B(b)(3) of the Act.

[6] 42 C.F.R. § 1001.952.

[7] See 42 C.F.R. § 1001.952(a)(2).

(v) The entity or any investor must not market or furnish the entity's items or services (or those of another entity as part of a cross-referral agreement) to passive investors differently than to non-investors;

(vi) No more than 40 percent of the entity's gross revenue related to the furnishing of health care items and services in the previous fiscal year or previous 12-month period may come from referrals or business otherwise generated from investors;

(vii) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor in the entity) must not loan funds to or guarantee a loan for an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity if the investor uses any part of such loan to obtain the investment interest; and

(viii) The amount of payment to an investor in return for the investment interest must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.[8]

B. Analysis

The Arrangement implicates the Federal anti-kickback statute because the Physician Owners hold an ownership interest in Requestor that may result in profit distributions, and the Physician Owners may order or purchase Requestor's products and be in a position to recommend the ordering or purchasing of Requestor's products, which products may be reimbursable by Federal health care programs.

OIG has longstanding concerns regarding physician-owned entities that derive revenue from selling, or arranging for the sale of, medical devices ordered by their physician owners for use in procedures the physician owners perform at hospitals.[9] Certain types of physician-owned entities—such as the types of entities described in OIG's 2013 Special Fraud Alert—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.

As described in the 2013 Special Fraud Alert, the physician owners of physician-owned entities also may engage in suspect behavior, such as conditioning their referrals to hospitals on those 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

[8] 42 C.F.R. § 1001.952(a)(2)(i)-(viii).

[9] 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 (hereinafter the "2013 Special Fraud Alert").

hospital does not purchase devices from the physician-owned entity; (ii) promising or implying they will move surgeries to a hospital if it purchases devices from the physician-owned entity; or (iii) requiring a hospital to enter into an exclusive-purchase arrangement with the physician-owned entity. OIG has warned that physician-owned entities that exhibit these—among other—suspect characteristics potentially raise fraud and abuse concerns, such as corruption of medical judgment, overutilization, increased costs to Federal health care programs and enrollees, and unfair competition.

While OIG continues to have concerns about certain physician-owned entities, here, the Arrangement is protected by the small entity investment safe harbor at 42 C.F.R. § 1001.952(a)(2) because each condition is either met or inapplicable based on Requestor's factual certifications. Specifically, Requestor certified that:

- No more than 40 percent of the value of the investment interests of each class of investment interests are held or have been held in the previous fiscal year or previous 12-month period by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for Requestor. Specifically, Requestor certified that Physician Owners currently comprise approximately 35 percent of Requestor's ownership and that no other owners are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for Requestor;

- The terms on which Requestor has offered or will offer investment interests to Physician Owners who are passive investors, or other passive investors who could recommend Requestor's devices, are and will be the same as, and do not and will not differ from, the terms offered to other passive investors;

- The terms on which an investment interest has been or will be offered by Requestor to an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for Requestor is unrelated to the previous or expected volume of referrals, items or services furnished, or amount of business otherwise generated from that investor to Requestor;

- Requestor has not imposed and will not impose any requirement or suggestion that a passive investor make referrals to, be in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for Requestor as a condition of remaining as an investor;

- Neither Requestor nor any of its investors markets or furnishes Requestor's items or services (or those of another entity as part of a cross-referral agreement) to passive investors differently than to non-investors;

- No more than 40 percent of Requestor's gross revenue related to the furnishing of health care items and services in the previous fiscal year or previous 12-month period has come from referrals or business otherwise generated from investors;

- Neither Requestor nor any of its investors (or other individuals or entities acting on behalf of Requestor or any investor in Requestor) has loaned or will loan funds to, or

guarantee a loan for, a Physician Owner or other investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for Requestor if the Physician Owner or other investor has or will use any part of such loan to obtain their investment interest; and

- To date, Requestor has not made any profit distributions to any Physician Owners and certified that, if it does make such distributions or make any other payments to investors based on their ownership interests in Requestor, that the amount of any payment to an investor by Requestor in return for the investor's investment interest will be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.

Therefore, based on Requestor's factual certifications, we conclude that the Arrangement is protected by the small entity investment safe harbor at 42 C.F.R. § 1001.952(a)(2) because each condition of the safe harbor has been met. Our conclusion is based on the specific facts of the Arrangement. Other similar business arrangements involving physician-owned entities that do not meet all conditions of the small entity investment safe harbor could raise fraud and abuse risks under the Federal anti-kickback statute, especially if, due to the physician owners' financial relationship with the company, the physicians: (i) order or purchase—or recommend that a hospital or other provider order or purchase—their devices over competitor devices; or (ii) use their devices over other treatments that may be more clinically appropriate.

III. CONCLUSION

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Arrangement does not generate prohibited remuneration under the Federal anti-kickback statute. Accordingly, OIG will not impose administrative sanctions on Requestor in connection with the Arrangement under section 1128A(a)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute, or the exclusion authority at section 1128(b)(7) of the Act, as that section relates 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 that may have been disclosed or referenced in your request for an advisory opinion or supplemental submissions.

- This advisory opinion is issued only to Requestor. 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 Requestor 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.

OIG will not proceed against Requestor 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. 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, OIG will not proceed against Requestor 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 OIG.

Sincerely,

/Susan A. Edwards/

Susan A. Edwards
Assistant Inspector General for Legal Affairs