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: June 17, 2025

Posted: June 20, 2025

[Address block redacted]

Re: OIG Advisory Opinion No. 25-04 (Unfavorable)

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 Requestor's proposal to pay the costs its customers otherwise would incur for a third-party company to screen and monitor Requestor for exclusion from Federal health care programs and to ensure compliance with certain other legal requirements (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement, if undertaken, 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 ("CMP") 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 Proposed 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 Proposed Arrangement.

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement, if undertaken, would generate—if the requisite intent were present—prohibited remuneration under the Federal anti-kickback statute, which would constitute grounds for the imposition of sanctions under sections 1128A(a)(7) and 1128(b)(7) of the Act.

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 is a medical device company, and its customers are hospitals, health systems, and ambulatory surgery centers ("Customers").[2] Under the Proposed Arrangement, some Customers would request or require, as a condition of doing business, that Requestor pay for a third-party company (the "Company") to screen and monitor Requestor for exclusion from Federal health care programs[3] and to ensure compliance with certain other legal requirements.

The Company, which screens and monitors vendors for Federal health care program exclusion on an ongoing basis, would request information from Requestor that would allow the Company to perform initial and continual screenings of Requestor for exclusion from Federal health care programs. The Company also may solicit information from Requestor to ensure Requestor's compliance with other legal requirements, such as compliance with requirements of a particular Medicare Advantage plan.

The Company would charge Requestor an annual subscription fee (the "Fee") for each Customer receiving screening and monitoring reports on Requestor, i.e., the Company would charge Requestor the Fee on a per-Customer basis. Requestor would pay these Fees directly to the Company, and Requestor estimates that it annually would pay approximately $450,000 in Fees. Requestor would pay the Fees on an annual basis during the vendor recredentialing process for existing Customers (and similarly, for new Customers, during the vendor onboarding process). Requestor certified that it would not be a party to any agreements between Customers and the Company and that it has requested information from some Customers regarding their agreements with the Company and that Customers have denied these requests.

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[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.

[2] Customers purchase products and services from Requestor that are used in procedures, some of which may be reimbursable by Federal health care programs.

[3] If a health care provider arranges or contracts (by employment or otherwise) with a person that the provider knows or should know is excluded by OIG, the provider may be subject to CMP liability if the excluded person provides items or services payable, directly or indirectly, by a Federal health care program. Section 1128A(a)(6) of the Act. While there is no statutory or regulatory requirement to check the OIG's List of Excluded Individuals and Entities, OIG has stated that screening employees and contractors each month best minimizes potential overpayment and CMP liability. See Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs, May 2013, https://oig.hhs.gov/exclusions/files/sab-05092013.pdf.

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.[4] 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.[5] 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.[6] 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 CMPs 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.

B. Analysis

The Proposed Arrangement would implicate the Federal anti-kickback statute because Requestor would pay the Company Fees for screening and monitoring Requestor for exclusion from Federal health care programs and to ensure compliance with certain other legal requirements, the costs of which otherwise would be incurred by Customers. Requestor's payment of the Fees could induce Customers to purchase items or services from Requestor that may be reimbursable by a Federal health care program. No safe harbor applies to the Proposed Arrangement, so we analyze the Proposed Arrangement based on the totality of the facts and circumstances.

The Proposed Arrangement, under which Requestor would pay for a valuable service that its referral sources otherwise would cover, presents anti-competitive risks and risks of inappropriate steering. We have longstanding and continuing concerns regarding the provision of free items or services by individuals and entities, including device manufacturers, to referral sources that could lead to the ordering and provision of an item or service payable by Federal health care

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

[5] Id.

[6] 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).

programs. Under the Proposed Arrangement, Requestor would pay the Fee on an annual basis for each Customer and in doing so would relieve Customers of a financial burden they otherwise would bear for exclusion screening and monitoring and screening for compliance with certain other legal requirements. These payments could inappropriately steer Customers to Requestor over Requestor's competitors that are not able or willing to pay the Fees.

We acknowledge that there are myriad ways for parties to structure business arrangements to allocate responsibilities and that there may be different fact patterns that would result in OIG reaching a favorable conclusion in an advisory opinion; however, we are limited to opining on the facts before us, and here—where, among other factors, Requestor would pay Fees to the Company for each individual Customer—there appears to be a risk that the Company would serve as a gatekeeper of referrals between Customers and Requestor (by virtue of Customers potentially conditioning their business on Requestor's payment of such Fees) and that Requestor would pay the Fees in order to access those referrals.

For all of the foregoing reasons, we conclude that the Proposed Arrangement is not sufficiently low risk for OIG to issue a favorable advisory opinion.

III. CONCLUSION

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement, if undertaken, would generate—if the requisite intent were present—prohibited remuneration under the Federal anti-kickback statute, which would constitute grounds for the imposition of sanctions under sections 1128A(a)(7) and 1128(b)(7) of the Act.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is limited in scope to the Proposed 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 Proposed 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 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.

Sincerely,

/Susan A. Edwards/

Susan A. Edwards
Assistant Inspector General for Legal Affairs