



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: March 11, 2026

Posted: March 16, 2026

[Address block redacted]

Re: OIG Advisory Opinion No. 26-05 (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”), a medical device company, regarding its proposal to subsidize certain Federal health care program cost-sharing obligations in the context of a clinical trial of a device manufactured by Requestor (the “Proposed Arrangement”). Specifically, you have inquired whether the Proposed Arrangement, if undertaken, would constitute grounds for the imposition of sanctions under: the civil monetary penalty provision at section 1128A(a)(7) of the Social Security Act (the “Act”), as that section relates to the commission of acts described in section 1128B(b) of the Act (the “Federal anti-kickback statute”); the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Act (the “Beneficiary Inducements CMP”); 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 and the Beneficiary Inducements CMP.

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. If material facts have not been disclosed or 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: (i) although the Proposed Arrangement, if undertaken, would generate—if the requisite intent were present—prohibited remuneration under the Federal anti-

kickback statute, OIG would not impose administrative sanctions on Requestor in connection with the Proposed 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; and (ii) although the Proposed Arrangement, if undertaken, would generate prohibited remuneration under the Beneficiary Inducements CMP, OIG would not impose administrative sanctions on Requestor in connection with the Proposed Arrangement under the Beneficiary Inducements CMP or section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Beneficiary Inducements CMP.

This opinion may not be relied on by any person¹ 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

A. The Device

Requestor manufactures and distributes the [redacted] (the “Device”), an implantable device that delivers electrical pulses to baroreceptors located in the wall of the carotid artery. The Device consists of a carotid sinus lead and an implantable pulse generator. The Device is currently approved by the U.S. Food & Drug Administration (“FDA”) for use in heart failure patients who meet certain criteria, including left ventricular ejection fraction of less than or equal to 35 percent. The Device is available for clinical use in the United States under a premarket approval. The Device is intended as a one-time implant, and Requestor does not anticipate that use of the Device would prompt future utilization by patients of any other products manufactured or under development by Requestor, other than battery replacements.

B. The Study

Requestor is the sponsor of a clinical trial designed: (i) to determine the safety and efficacy of the Device in a new population—heart failure patients with a left ventricular ejection fraction higher than 35 percent and up to 50 percent; and (ii) to determine the effect of treatment using the device relative to usual care medical management (the “Study”). The FDA approved the Device through the Category B Investigational Device Exemption (“IDE”) to allow the Device to be used in a clinical trial for an investigational indication. Requestor intends to enroll up to 3,600 potential Study participants who will be asked to participate in a screening appointment. From that group, Requestor expects to randomize up to 2,500 Study-eligible participants. To be eligible to participate in the Study, all participants, including Federal health care program enrollees, must satisfy the enrollment criteria set forth in the Study protocol and execute an informed consent document. The eligible participants will be randomized into a control group and a Device group. Within 45 days of randomization, the Device group will undergo surgery to implant the Device, which will then be activated. Thereafter, both groups will follow the same seven scheduled follow-up visits and assessments over 24 months. The Study will be conducted at up to 200

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

investigational sites² in the United States and Europe, with the majority of the Study participants in the United States.

Requestor certified that the Study will be performed in compliance with all Federal regulations concerning the protection of human subjects found in 45 C.F.R. Part 46, 21 C.F.R. Parts 50 and 56, and all other applicable laws and regulations, and will include, among other things, oversight and monitoring by an Institutional Review Board (“IRB”).

C. Medicare Coverage for Items and Services Furnished in the Study

Medicare may make payment for Category B IDE devices and routine care items and services furnished in an FDA-approved Category B IDE study.³ For Medicare coverage of such items and services, the Centers for Medicare & Medicaid Services (“CMS”) must determine, prior to the submission of the first related claim, that certain Medicare coverage Category B IDE Federal regulatory study criteria are met.⁴ CMS approved Category B IDE coverage for the Study.

D. Overview of the Proposed Arrangement

Under the Proposed Arrangement, Requestor would pay cost-sharing obligations that Medicare enrollees participating in the Study otherwise would owe for Study-related Medicare reimbursable items and services furnished during the Study.⁵ Requestor would pay the cost-sharing amounts directly to the site to which the Study participant otherwise would owe the amount. As a result of these subsidies, Requestor asserted that Medicare enrollees would incur no cost-sharing expenses relating to their participation in the Study. Requestor would not advertise or promote the cost-sharing subsidies to prospective Study participants. Requestor would provide information about the cost-sharing subsidy to potential Study participants during their initial Study consent discussion, and the information would be included in the informed consent documents.

² The investigational sites will be academic medical centers, community health systems and hospitals, and other licensed health care facilities, including private practice physician and cardiology offices, which have the appropriate clinical research infrastructure and resources to perform the associated implant procedures and follow-up assessments.

³ 42 C.F.R. § 405.211(b)–(c).

⁴ *Id.* §§ 405.211(c) and 405.212.

⁵ For Medicare enrollees who have supplemental insurance, such as Medigap, that offers full or partial coverage of cost-sharing obligations, Requestor would subsidize only the remaining cost-sharing obligations, if any, for which a Study participant is personally responsible. For individuals with commercial insurance, Medicaid, or other Federal health care program insurance, Requestor would provide the same types of cost-sharing subsidies that it provides for Medicare beneficiaries.

According to Requestor, the purpose of these cost-sharing subsidies is to reduce financial barriers to enrollment in the Study and attrition of subjects and to facilitate a range of socioeconomic statuses of Study subjects.

With respect to reducing financial barriers, Requestor certified that, absent the Proposed Arrangement, Study participants who are Medicare enrollees likely would incur cost-sharing obligations for billable items and services associated with some of the appointments required as part of the Study.

Requestor asserted that cost-sharing obligations associated with these appointments would be cost prohibitive for many Medicare enrollees who otherwise would participate in the Study and that Requestor's cost-sharing subsidy may be essential to enrolling and retaining enough participants to complete the Study. Additionally, Requestor asserted that the cost-sharing obligations for the items and services provided during the Study could act as a barrier to enrolling and retaining a socioeconomically diverse population of participants.

II. LEGAL ANALYSIS

A. Law

1. Federal Anti-Kickback Statute

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.⁶ 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.⁷ 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.⁸ 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 civil monetary penalties on such person under section 1128A(a)(7) of the Act. OIG also may

⁶ Section 1128B(b) of the Act.

⁷ Id.

⁸ 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).

initiate administrative proceedings to exclude such person from Federal health care programs under section 1128(b)(7) of the Act.

2. Beneficiary Inducements CMP

The Beneficiary Inducements CMP provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration to a Medicare or State health care program beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier for the order or receipt of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program. OIG also may initiate administrative proceedings to exclude such person from Federal health care programs. Section 1128A(i)(6) of the Act defines "remuneration" for purposes of the Beneficiary Inducements CMP as including "transfers of items or services for free or for other than fair market value."

B. Analysis

The Proposed Arrangement would implicate the Federal anti-kickback statute in several ways. With respect to Study participants, Requestor would offer and pay cost-sharing amounts for billable items and services provided to Medicare (and potentially other Federal health care program) enrollees participating in the Study. The Proposed Arrangement would implicate the Federal anti-kickback statute because these subsidies could induce Medicare (and potentially other Federal health care program) enrollees to participate in the Study, during which they would receive health care items and services that are reimbursable by a Federal health care program. Requestor also would provide remuneration to the investigators and sites participating in the Study in two forms: (i) the opportunity to bill Federal health care programs for items and services related to the Study; and (ii) a guaranteed payment of enrollee cost sharing, which, in some circumstances, an investigator or site may not otherwise be able to collect in full.

The Proposed Arrangement would implicate the Beneficiary Inducements CMP because the remuneration would be likely to influence a beneficiary to receive billable items and services from a particular provider, practitioner, or supplier, *i.e.*, the Study investigators and sites.

For a combination of the following reasons, we believe the risk of fraud and abuse presented by the Proposed Arrangement is sufficiently low under the Federal anti-kickback statute for OIG to issue a favorable advisory opinion, and, in an exercise of our discretion, we would not impose sanctions under the Beneficiary Inducements CMP.

First, the Proposed Arrangement appears to be a reasonable means of promoting enrollment and retention of participants in the Study. According to Requestor, the out-of-pocket cost-sharing expenses to participate in the Study would be cost prohibitive for many Medicare enrollees who otherwise would participate in the Study, and Requestor's cost-sharing subsidies may be essential to enrolling enough participants for Requestor to complete the Study. The subsidies also may reduce the likelihood that Study participants would fail to complete the entire course of the Study, which involves a number of clinical visits over a 24-month period.

Second, the Proposed Arrangement would pose a low risk of overutilization or inappropriate utilization of items and services payable by a Federal health care program, and the risk of inappropriate steering is also low. While it is possible that overall utilization of items and services may increase because the cost-sharing subsidies are specifically designed to facilitate enrollment of individuals in the Study and help prevent attrition during the course of the Study, we do not have a reason to believe that such an increase would be inappropriate, nor are we providing any opinion concerning use of the Device outside of its current FDA-approved indication. Further, while individuals may choose to participate in the Study due, in part, to the subsidy, we do not view this potential steering as inappropriate. Importantly, individuals must satisfy the enrollment criteria set forth in the Study protocol and execute an informed consent document, and investigators and sites must comply with the Study protocol and are subject to oversight and monitoring by an IRB. The Proposed Arrangement would include additional guardrails that mitigate the risk of inappropriate steering and inappropriate utilization. In particular, Requestor certified that it would not advertise the availability of cost-sharing subsidies. Potential participants would first learn of the cost-sharing subsidy during their initial Study consent discussion. By that time, they would have already expressed interest in participating and a provider would have confirmed their eligibility for the Study.

Third, the Proposed Arrangement is unlikely to result in improper increased costs to Federal health care programs and is distinguishable from problematic seeding arrangements, such as those in which manufacturers initially offer subsidies to lock in future utilization of a reimbursable item or service. Requestor would provide cost-sharing subsidies relating only to items and services furnished as part of the Study. The Device itself is intended as a one-time treatment, and Requestor does not anticipate that use of the Device would prompt future utilization by Study participants of any other products manufactured or under development by Requestor, other than battery replacements. Accordingly, the Proposed Arrangement would not present the risk exhibited by problematic seeding arrangements.

Finally, CMS approved the Study as a Category B IDE study, meaning certain criteria⁹ are met including: (i) the Study contains appropriate patient protections; (ii) the Study design is methodologically appropriate; and (iii) the anticipated number of enrolled subjects is adequate.

III. CONCLUSION

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) although the Proposed Arrangement, if undertaken, would generate—if the requisite intent were present—prohibited remuneration under the Federal anti-kickback statute, OIG would not impose administrative sanctions on Requestor in connection with the Proposed 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; and (ii) although the Proposed Arrangement, if undertaken, would generate prohibited remuneration under the Beneficiary Inducements CMP, OIG would not impose administrative sanctions on Requestor in connection with the Proposed Arrangement under the Beneficiary Inducements

⁹ 42 C.F.R. § 405.212.

CMP or section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Beneficiary Inducements CMP.

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 will not proceed against Requestor with respect to any action that is part of the Proposed 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 Proposed 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 Proposed 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,

Spencer K. Turnbull
Acting Assistant Inspector General for Legal
Affairs