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:** December 21, 2023

**Posted:** December 27, 2023

[Address block redacted]

**Re: OIG Advisory Opinion No. 23-11 (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 the proposed subsidization of certain Medicare cost-sharing obligations in the context of a clinical trial (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, 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 prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present, 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 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 manufactures [redacted] (the "System"), a medical device-based therapy that is designed to modulate the strength of cardiac muscle contraction in patients experiencing heart failure. The System consists of a rechargeable implantable pulse generator, a charger device, a programmer, and implantable therapy-delivery leads manufactured by a third party. The System is currently approved by the U.S. Food & Drug Administration ("FDA") for use in heart failure patients who meet certain criteria, including a left ventricular ejection fraction ranging from 25 percent to 45 percent. Requestor is the sponsor of a clinical trial designed to determine the safety and efficacy of the System in a different population: heart failure patients with a higher ejection fraction of between 40 percent and 60 percent (the "Study"). For this population, the System currently is available for clinical use in the United States only pursuant to a Category B Investigational Device Exemption ("IDE") approved by the FDA, which allows a device to be used in a clinical trial for an investigational indication.

Although patients, including Medicare and other Federal health care program beneficiaries, may continue to receive reimbursable follow-up services related to the System, the System itself is intended as a one-time treatment, and Requestor does not anticipate that use of the System would prompt future utilization by Study participants of any other products manufactured or under development by Requestor.

### A. Overview of the Study

Requestor intends to enroll up to 1,500 participants in the Study with participants randomized in a 2:1 ratio into a treatment group and a control group. All Study participants will receive the System's pulse generator and associated leads. Specifically, for all Study participants, a physician will implant the System via a surgical procedure in an operating room or cardiac catheterization lab. For individuals in the treatment group, the System will be activated immediately. For individuals in the control group, the System will be inactive for the initial 18-month Study period.

[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.

Study investigators and their staff members will be responsible for recruiting and enrolling Study participants. To be eligible to participate in the Study, all participants, including Federal health care program beneficiaries, must satisfy the enrollment criteria set forth in the Study protocol and execute an informed consent document. Once enrolled in the Study, participants will remain in the Study through completion of the required follow-up period unless they withdraw consent or Requestor terminates the Study for any reason. Each participant's participation is expected to last for an initial period of approximately 18 months, and participants will be asked to participate in follow-up visits every 6 months thereafter until the FDA makes a determination regarding the System (e.g., approval of an expanded indication). Eighteen months after the implantation procedure, the unblinded trial phase will begin, and the System will be activated for participants in the control group. At that time, control group participants will also have the option to have the therapy activated (if the participant still satisfies all of the Study's original medical inclusion criteria).

Requestor will conduct the Study at up to 150 sites in the United States and up to 75 sites abroad. Requestor will evaluate potential sites using a Study-specific questionnaire that assesses each site for its compatibility with Study requirements based on objective criteria such as FDA enforcement history, past clinical trial experience, conflicts of interest, access to medical records, and staff availability to support the Study. Requestor will enter into written agreements with each site and each investigator, setting forth the parties' respective responsibilities and compensation terms. Requestor certified that the compensation paid to sites and investigators will be fair market value for necessary Study-related services.[2] Investigators and sites must comply with requirements set forth in the Study protocol.

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").

### B. Medicare Coverage for the Study

If certain criteria are met, Medicare pays for Category B IDE devices and routine care items and services furnished in a clinical study involving an FDA-approved Category B IDE device.[3] The Centers for Medicare & Medicaid Services ("CMS") must specifically approve a Category B IDE study for it to be eligible for coverage.[4] To be approved for Medicare coverage, a study must meet a number of criteria, including, for example, that: (i) the principal purpose of the

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[2] We have not been asked to opine on, and express no opinion regarding, the proposed compensation arrangements between Requestor and the investigators and sites outside of the Proposed Arrangement. We are precluded by statute from opining on whether fair market value shall be, or was, paid for goods, services, or property. Section 1128D(b)(3)(A) of the Act. For purposes of this advisory opinion, we rely on Requestor's certification of fair market value.

[3] 42 C.F.R. Part 405 Subpart B.

[4] Id. § 405.211(b)–(c).

study is to test whether the device improves health outcomes of appropriately selected patients; (ii) the rationale for the study is well supported by available scientific and medical information, or it is intended to clarify or establish the health outcomes of interventions already in common clinical use; and (iii) the study results are not anticipated to unjustifiably duplicate existing knowledge.[5] When establishing these approval criteria for Medicare coverage, CMS explained that these criteria help to ensure that the study design is appropriate to answer questions of importance to the Medicare program and its beneficiaries and to reduce the risk of harm to individuals.[6] CMS approved the Study as a Category B IDE study for which, as described above, Medicare pays for the Category B IDE device and routine care items and services furnished in the study.[7]

### C. The Proposed Arrangement

Under the Proposed Arrangement, Requestor would pay cost-sharing obligations that Medicare beneficiaries participating in the Study otherwise would owe for Study-related Medicare-reimbursable items and services provided during the Study, up to a maximum of $2,000 per Study participant.[8] Requestor would pay the cost-sharing amounts directly to the site and investigator to which the participant otherwise would owe the amount. As a result of these subsidies, Requestor asserts that Medicare beneficiaries would incur no cost-sharing expenses relating to their participation in the Study, unless their out-of-pocket cost-sharing obligations relating to the Study exceed $2,000.[9]

According to Requestor, the purpose of the Proposed Arrangement is to: (i) reduce financial barriers to enrollment and prevent attrition from the Study due to financial reasons; (ii) facilitate socioeconomic diversity of the Study population; and (iii) preserve blinding of participants. With respect to reducing financial barriers, Requestor certified that, absent the Proposed Arrangement, Study participants who are Medicare beneficiaries likely would incur cost-sharing

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[5] Id. § 405.212.

[6] CMS, Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014, 78 Fed. Reg. 74,230, 74,431 (Dec. 10, 2013).

[7] [Redacted].

[8] For Medicare beneficiaries 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, Requestor would provide the same cost-sharing subsidies as it provides Medicare beneficiaries. Requestor certified that, to the extent the Study is covered by Medicaid or other Federal health care programs, Requestor would provide the same types of cost-sharing subsidies that it provides for Medicare beneficiaries.

[9] Requestor anticipates that most Medicare beneficiaries' cost-sharing obligations incurred during participation in the Study would not exceed this limit.

obligations for billable items and services associated with some of the appointments required as part of the Study. Such appointments would include the initial screening appointment, surgical implantation of the System, seven follow-up appointments over the next 18 months, and possible follow-up appointments every 6 months until the FDA makes a determination regarding the System. Requestor asserts that cost-sharing obligations associated with these appointments would be cost prohibitive for many Medicare beneficiaries who otherwise would participate in the Study and that Requestor's cost-sharing subsidy may be essential to enrolling and retaining a sufficient number of participants to complete the Study. Additionally, Requestor views the cost-sharing obligations for the items and services provided during the Study as a barrier to enrolling and retaining a socioeconomically diverse population of participants.

Requestor's cost-sharing subsidy also is intended to preserve the Study's blinding procedures. Participants normally would be billed cost sharing for Medicare-billable items and services furnished as part of the Study. Requestor certified that it does not wish for providers to collect cost-sharing amounts from control-group beneficiaries because they do not have the potential to receive any therapeutic benefit during the initial 18-month period of the Study. Requestor maintains that failing to charge cost sharing to participants in the control group while charging cost sharing to participants in the treatment group could alert the former that they are in the control group, which could un-blind the Study. By subsidizing cost-sharing obligations for participants in both the control and treatment groups, the Proposed Arrangement would avoid cost sharing as a potential signal to participants regarding their assignment in the Study.

Neither Requestor nor its investigators would advertise the availability of cost-sharing subsidies to prospective participants. Information about the subsidies would be included in the informed consent documents provided to each participant, which Requestor asserts is the point at which most participants would learn of them.

## 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.[10] 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.[11] 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.

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

[11] Id.

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.[12] 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 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." Section 1128A(i)(6)(A) of the Act provides that, for purposes of the Beneficiary Inducements CMP, the term "remuneration" does not apply to the waiver of coinsurance and deductible amounts by a person if: (i) the waiver is not offered as part of any advertisement or solicitation; (ii) the person does not routinely waive coinsurance or deductible amounts; and (iii) the person waives the coinsurance and deductible amounts after determining in good faith that the individual is in financial need or fails to collect coinsurance or deductible amounts after making reasonable collection efforts.

**B. Analysis**

Under the Proposed Arrangement, Requestor would offer and pay cost-sharing amounts for billable items and services provided to Medicare (and potentially other Federal health care program) beneficiaries 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) beneficiaries to participate in the Study, during which they would receive health care items and services that are reimbursable by a Federal health care program. Although Requestor would not advertise the availability of cost-sharing subsidies, investigators nevertheless would inform participants of the subsidies as part of the informed consent process. The Proposed Arrangement would implicate the Beneficiary Inducements CMP because the remuneration would be likely to influence a beneficiary to receive Medicare-billable items and services from a particular provider, practitioner, or supplier.

[12] 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).

Under the Proposed Arrangement, 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 beneficiary cost sharing (at least up to the $2,000 limit), which, in some circumstances, an investigator or site may not be able to collect in full. Both forms of remuneration to investigators and sites would implicate the Federal anti-kickback statute.

The Proposed Arrangement would not fall squarely within any exception to the definition of "remuneration" for purposes of the Beneficiary Inducements CMP or any safe harbor to the Federal anti-kickback statute. For example, the Proposed Arrangement would not meet the exception to the Beneficiary Inducements CMP at section 1128A(i)(6)(A) of the Act for waivers of beneficiary cost-sharing obligations because, among other reasons, the exception applies only to a "waiver" of cost-sharing obligations. Insofar as Requestor would pay investigators and sites the cost-sharing amounts they otherwise would have collected from beneficiaries (pursuant to Medicare programmatic requirements), the remuneration is a subsidy paid on behalf of the beneficiary by a third party, not a waiver of cost-sharing obligations by the provider. Nevertheless, for 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 in the Study, particularly where patients participating in the control group would not have the potential to receive any therapeutic benefit during the first 18 months of the Study. According to Requestor, the out-of-pocket cost-sharing expenses to participate in the Study would be cost prohibitive for many Medicare beneficiaries who otherwise would participate in the Study, and Requestor's cost-sharing subsidy may be essential to enrolling a sufficient number of participants to complete the Study. In addition, the cost-sharing subsidies that would be offered under the Proposed Arrangement appear to be a reasonable means to facilitate enrollment of a socioeconomically diverse set of participants by removing a potential financial barrier to participation in the Study. The subsidy also may reduce the likelihood that participants would fail to complete the entire course of the Study, which involves a number of clinical visits over an 18-month period plus potential follow-up visits every 6 months thereafter.

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. 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, it is possible that overall utilization of items and services may increase, but there is nothing to suggest that such an increase would be inappropriate. Indeed, the Proposed Arrangement would include various guardrails that mitigate the risk of inappropriate utilization or improper increased costs to Federal health care programs. In particular, Requestor certified that it would not advertise the availability of cost-sharing subsidies. In addition, individuals must satisfy the enrollment criteria set forth in the Study protocol and execute an informed consent document to be eligible to participate in the Study. Further, investigators and sites must comply with the Study protocol and are subject to oversight and monitoring by an IRB. Finally, Study enrollment is capped at 1,500 participants, further

reducing the risk that the Proposed Arrangement would result in overutilization or an inappropriate increase in costs to Federal health care programs.

In addition, CMS approved the Study as a Category B IDE study, meaning CMS evaluated the Study and determined that it meets criteria to ensure appropriate patient protections and that the study design is appropriate to answer questions of importance to the Medicare program and its beneficiaries. Given this determination by CMS, in combination with the other facts set forth above, it appears unlikely that the Proposed Arrangement would result in overutilization or inappropriate utilization of Federal health care program items and services.

Finally, the Proposed Arrangement 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 System itself is intended as a one-time treatment, and Requestor does not anticipate that use of the System would prompt future utilization by Study participants of any other products manufactured or under development by Requestor. Accordingly, the Proposed Arrangement would not present the risk exhibited by problematic seeding arrangements.

## 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 prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present, 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.

## 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,

*/s/ Susan A. Edwards*

Susan A. Edwards
Assistant Inspector General for Legal Affairs