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: November 16, 2021

Posted: November 19, 2021

[Name and address redacted]

Re: OIG Advisory Opinion No. 21-17

Dear [Name redacted]:

The Office of Inspector General ("OIG") is writing in response to your request for an advisory opinion on behalf of [Name 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 you 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, the 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

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, the 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 the [device name redacted] (the "Device"), an implantable medical device approved by the U.S. Food and Drug Administration (the "FDA") for two indications: (i) use as an adjunctive therapy in reducing the frequency of seizures in patients with partial onset seizures that are refractory to antiepileptic medications; and (ii) use as an adjunctive long-term treatment of chronic or recurrent depression for patients who are experiencing a major depressive episode and have not had an adequate response to four or more adequate antidepressant treatments (treatment-resistant depression, or the "Disease"). The Device uses vagus nerve stimulation ("VNS"), which involves targeted modulation of brain activity through the delivery of pulsed electrical signals to the vagus nerve by a neurostimulator electrode array and pulse generator implanted under the skin. The FDA approved the Device for treatment of epilepsy in 1997 and for treatment of the Disease in 2005.

Requestor is the sponsor of a clinical trial designed to determine whether the Device achieves superior reduction in baseline depressive symptom severity in patients with the Disease as compared to subjects in a placebo control group (the "Study").

A. Overview of the Study

Requestor intends to enroll up to 1,000 subjects in the Study, with subjects randomized equally into a treatment group and a control group. Subjects in both groups will be implanted with the Device. For 12 months, subjects in the treatment group will receive VNS therapy using the Device, while subjects in the control group will not receive any stimulation from the Device. After the 12-month endpoint of the randomized, controlled portion of the Study (or earlier, if the Study achieves positive interim success criteria), the Study will transition into an unblinded phase to collect data relating to the Device over time. At that time, control group subjects may elect to "activate" their implanted Device and begin receiving VNS therapy.

Requestor will recruit subjects to participate in the Study via investigators (i.e., the physicians who conduct the Study) and by contracting with third-party vendors to identify eligible patients. To be eligible to participate in the Study, all subjects, including Federal health care program beneficiaries, must satisfy the enrollment criteria set forth in the Study protocol and execute an informed consent

[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.

document. Requestor will enter into written agreements with each site, setting forth the parties' respective responsibilities and compensation terms. Requestor has represented that the compensation paid to sites and investigators will be fair market value for necessary Study-related services.[2]

Requestor will enroll up to 100 sites, each of which must be a specialty psychiatry clinic with significant experience treating subjects with the Disease. Each specialty psychiatry clinic will partner with an investigator, the investigator's group practice or clinic, and a surgical site (either an ambulatory surgery center or a hospital outpatient department) for implantation of the Device. Sites also must have sufficient time and personnel to carry out the Study and must have access to a sufficient number of prospective subjects who meet the eligibility criteria for the Study. Per the Study protocol, an investigator must be a specialist in the field of psychiatry who: (i) has been appropriately trained in mental health care; (ii) has considerable experience in treating depression; and (iii) is affiliated with a specialty psychiatric clinic. Any health care professional who meets these and other eligibility criteria and is willing to follow the Study protocol may participate in the study as an investigator, subject to the Study's overall enrollment target.

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

In February 2019, the Centers for Medicare & Medicaid Services ("CMS") issued a National Coverage Determination ("NCD") and accompanying Decision Memorandum (the "Decision Memo") announcing that Medicare would cover VNS therapy for the Disease through Coverage with Evidence Development ("CED") for Medicare beneficiaries enrolled as subjects in clinical trials that meet certain criteria established by CMS and set forth in the Decision Memo.[3] The CED paradigm allows CMS to offer Medicare coverage for otherwise non-covered items and services on the condition that they are provided to Medicare beneficiaries enrolled in an approved clinical study or when additional clinical data are collected to assess the appropriateness of an item or service for

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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. 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. If the compensation is not fair market value, this opinion is without force and effect.

[3] Medicare National Coverage Determination Manual ch. 1, § 160.18 - Vagus Nerve Stimulation (VNS), available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part2.pdf; Decision Memo for Vagus Nerve Stimulation (VNS) for Treatment Resistant Depression (TRD) (CAG-00313R2) (Feb. 15, 2019), available at https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=292.

use with a particular beneficiary.[4] Coverage in the context of ongoing clinical research protocols or with additional data collection can expedite earlier beneficiary access to innovative technology while ensuring that systematic patient safeguards are in place to reduce the risks inherent to new technologies or to new applications of older technologies.[5]

The NCD authorizes Medicare coverage for VNS therapy in a CMS-approved, double-blind, randomized, placebo-controlled trial with a follow-up duration of at least 1 year. The NCD also permits study sponsors to offer to activate the implanted VNS device at the end of the randomized portion of the trial for subjects in the control group, which allows control group subjects to receive VNS therapy after the initial 1-year Study period.

CMS approved the Study under CED pursuant to the NCD.[6] Requestor certified that Medicare will cover the cost of the Device as well as the implantation procedure, treatment of any complications from the implantation procedure, routine pre-operative and follow-up care, and clinician visits during the course of the Study for subjects in both the treatment and control groups.

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 Medicare-reimbursable items and services provided during the randomized, controlled portion of the Study.[7] Requestor would pay the cost-sharing amounts directly to the person or entity to whom the subject otherwise would owe the amount. As a result of these subsidies, Medicare beneficiaries would incur no out-of-pocket expenses relating to their participation in the randomized, controlled phase of the Study. Requestor proposes these cost-sharing subsidies to: (i) reduce financial barriers to enrollment in the Study; and (ii) preserve blinding of subjects.

With respect to reducing financial barriers, Requestor certified that Study subjects who are Medicare beneficiaries would incur cost-sharing obligations associated with the following billable items and services: a pre-operative physical or consultation; evaluation for surgical clearance; the implantation surgery and cost of the Device; anesthesia services; any required follow-up visits; and

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[4] Section 1862(a)(1)(E) of the Act permits Medicare coverage for items and services furnished in certain clinical research studies; in general, CED has been used when evidence is not sufficient for coverage under section 1862(a)(1)(A) of the Act.

[5] See generally CMS, Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development (Nov. 20, 2014), available at https://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27.

[6] [Citation redacted].

[7] Requestor would not provide financial assistance to Medicare beneficiaries who have supplemental insurance, such as Medigap, that covers their cost-sharing obligations. Requestor would, however, pay all non-covered costs for non-Medicare-eligible subjects whose commercial insurance does not cover the full costs of the Study, including any cost sharing, if applicable. Requestor also would pay all costs associated with the Study for any subjects who are uninsured.

any re-implant or explant[8] that occurs during participation in the Study. Requestor asserts that these financial obligations—which would total more than $1,000 per beneficiary and potentially up to almost $5,000 per beneficiary, depending on the site of service—are cost-prohibitive for many Medicare beneficiaries who otherwise would participate in the Study and that Requestor would be unable to enroll a sufficient number of subjects to complete the Study without subsidizing beneficiary cost-sharing obligations. Although enrollment in the Study will not be limited to Medicare beneficiaries, Requestor anticipates that the majority of subjects will be Medicare beneficiaries.

Requestor's proposed cost-sharing subsidy also is intended to preserve the Study's blinding procedures. Subjects normally would be billed cost sharing for Medicare-billable services as part of the Study. Requestor certified that it does not wish to collect cost-sharing amounts from control-group beneficiaries because they do not have the potential to receive any therapeutic benefit during the Study's initial 12 months. Failing to charge cost sharing to subjects in the control group while charging cost sharing to subjects in the treatment group could alert the former group that they are in the control group, which could un-blind the Study. By subsidizing cost-sharing obligations for subjects in both the control and treatment groups, the Proposed Arrangement would avoid cost sharing as a potential signal to subjects regarding their status in the Study.

Neither Requestor nor its investigators nor its third-party recruitment partners would advertise the availability of cost-sharing subsidies to prospective subjects. Information about the subsidies would be included in the informed consent documents provided to each subject, which is the point at which most subjects 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.[9] 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.[10] 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.

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[8] Requestor certified that it expects re-implant or explant to be required in no more than 5 percent of Study participants.

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

[10] 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.[11] 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.

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. The 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 beneficiaries participating as subjects in the Study. The Proposed Arrangement would implicate the Federal anti-kickback statute because these subsidies could induce Medicare 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 subjects 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 practitioner, provider, or supplier.

The Proposed Arrangement 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,

[11] 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).

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, the remuneration is a subsidy paid on behalf of the beneficiary by a third party, not a waiver of cost-sharing amounts by the provider obligated under Medicare programmatic requirements to collect cost sharing from the beneficiary. Nevertheless, for the combination of reasons set forth below, we conclude that the Proposed Arrangement would present a minimal risk of fraud and abuse under the Federal anti-kickback statute and, in an exercise of our discretion, we would not impose sanctions under the Beneficiary Inducements CMP.

First, the Proposed Arrangement is part of a clinical study that has been developed in consultation with, and approved by, CMS. Subsidizing the cost-sharing obligations for beneficiaries participating in the Study appears to be a reasonable means of promoting enrollment, particularly where half of the participating beneficiaries would not have the potential to receive any therapeutic benefit during the Study's initial 12 months. According to Requestor, the out-of-pocket cost to participate in the Study would be cost-prohibitive for many Medicare beneficiaries who otherwise would participate in the Study, and Requestor would be unable to enroll a sufficient number of subjects to complete the Study without subsidizing beneficiary cost-sharing obligations.

Second, the Proposed Arrangement would pose a low risk of overutilization or inappropriate utilization of Federal health care program items and services. Because the cost-sharing subsidies are specifically designed to facilitate enrollment of Medicare beneficiaries in 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, beneficiaries 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 must comply with the Study protocol and are subject to oversight and monitoring by an IRB. Finally, Study enrollment is capped at 1,000 subjects, further reducing the risk that the Proposed Arrangement would result in overutilization or an inappropriate increase in costs to Federal health care programs.

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. Except in the rare event of a re-implant or explant, Requestor would provide cost-sharing subsidies relating only to one implant of the Device and related services during the 12-month randomized, controlled portion of the Study. Although beneficiaries may continue to receive Medicare-reimbursable follow-up services related to the Device, Requestor would not be in a position to benefit financially from the longer-term use of the Device. Accordingly, the Proposed Arrangement would not present the risks posed by problematic seeding

arrangements.

For the combination of reasons described above, we conclude that the Proposed Arrangement would present a minimal risk of fraud and abuse under the Federal anti-kickback statute. For the same reasons, in an exercise of our discretion, we would not impose sanctions under the Beneficiary Inducements CMP in connection with the Proposed Arrangement.

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, the 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 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, the 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.

The 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. 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 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 the OIG.

Sincerely,

/Robert K. DeConti/

Robert K. DeConti
Assistant Inspector General for Legal Affairs