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, 2022

Posted: March 16, 2022

[Names and addresses redacted]

Re: OIG Advisory Opinion No. 22-05

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 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, 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 [device name redacted], an investigational therapy that uses a patient's own cells for the treatment of ischemic systolic heart failure (the "Therapy"). The Therapy is a bundle of three components: (i) [device name redacted], an investigational device used to process bone marrow cells in preparation for the treatment; (ii) [device name redacted], an investigational device used to inject the bone marrow cells into cardiac tissue; and (iii) a guide catheter that has been cleared by the U.S. Food & Drug Administration ("FDA") to serve as a conduit for access into the chambers of the heart and coronary vasculature.

According to Requestor, the Therapy currently is available for clinical use in the United States only pursuant to an FDA-approved Category B Investigational Device Exemption ("IDE"), which allows an investigational device to be used in a clinical trial. Requestor is the sponsor of one such study: a clinical trial designed to determine the safety and efficacy of the Therapy in patients with ischemic systolic heart failure (the "Study"). Although beneficiaries may continue to receive Medicare-reimbursable follow-up services related to the Therapy, the Therapy itself is intended as a one-time treatment, and Requestor does not anticipate that use of the Therapy would prompt future utilization of the Therapy or any other products manufactured by Requestor.

A. Overview of the Study

Requestor intends to enroll up to 260 subjects in the Study with subjects randomized in a 3:2 ratio into a treatment group and a control group. Subjects in both groups will undergo a bone marrow cell aspiration procedure in an outpatient setting under local anesthesia, and the cells captured during this procedure will be processed using the [device name redacted]. Next, all subjects will undergo a left ventriculography, which involves accessing the subject's heart using a percutaneous catheter. During the ventriculography, for subjects in the treatment group, a cardiologist will deliver the processed bone marrow cells into the subject's heart using the [device name redacted]. For subjects in the control group, the cardiologist will perform the left ventriculography but will not deliver the bone marrow cells or perform any other treatment. In an attempt to preserve blinding of

[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.

subjects, when conducting the ventriculography for control-group subjects, clinicians will follow a pre-defined script and follow actions that mimic the procedures that would be taken if the subject were receiving the processed bone marrow cells.

Study investigators and their staffs will be responsible for recruiting and enrolling Study subjects. 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 document. Requestor will conduct the Study at approximately 40 sites, each of which will consist of an investigator and a surgical site (which will be a cardiac catheterization lab). Requestor will evaluate potential sites using a Study-specific questionnaire that assesses each site for its compatibility with Study requirements and is based on objective criteria such as Institutional Review Board ("IRB") approval timelines, FDA inspection history, past clinical trial experience, conflicts of interest, access to medical records, overall time to activation, staff availability to support the Study, and anticipated enrollment volumes. Investigators also must meet objective criteria to be eligible to conduct the Study. 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 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 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 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

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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.

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

[4] Id. § 405.211(b)-(c).

(iii) the study results are not anticipated to unjustifiably duplicate existing knowledge.[5] When establishing these approval criteria, CMS explained that where Medicare coverage is sought 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 Medicare-reimbursable items and services provided during the Study.[8] Requestor would pay the cost-sharing amounts directly to the institution to which the subject otherwise would owe the amount. As a result of these subsidies, Requestor asserts that Medicare beneficiaries would incur no out-of-pocket expenses relating to their participation in the Study, other than meeting any unmet Part B deductible amounts. Requestor proposes these cost-sharing subsidies to: (i) reduce financial barriers to enrollment in the Study and reduce attrition of subjects during the two-year course of the Study; (ii) facilitate socioeconomic diversity of Study subjects; and (iii) preserve blinding of subjects.

With respect to reducing financial barriers, Requestor certified that, absent the Proposed Arrangement, Study subjects who are Medicare beneficiaries would incur cost-sharing obligations for billable items and services associated with the following appointments in the Study: the initial appointment (when cell aspiration is performed), the treatment visit (when cell implantation occurs), six follow-up visits during the 12 months after the treatment visit, and a 2-year follow-up visit. Requestor asserts that cost-sharing obligations associated with these nine appointments—which could total more than $1,300 per beneficiary—are cost-prohibitive for many Medicare beneficiaries who otherwise would participate in the Study and that Requestor's cost-sharing subsidy is vital to enrolling and retaining a sufficient number of subjects to complete the Study. Additionally, Requestor views the cost-sharing obligations for the items and services provided

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[5] Id. § 405.212.

[6] 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] [Citation 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 subject is personally responsible. For individuals with commercial insurance, Requestor would provide the same cost-sharing subsidies as it provides for 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.

during the Study as a barrier to enrolling and retaining a socioeconomically diverse population of subjects.

Requestor's cost-sharing subsidy also is intended to preserve the Study's blinding procedures. Subjects 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 Study. Requestor asserts that 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 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.[9]

Neither Requestor nor its investigators 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 Requestor asserts 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.[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"

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[9] Although the Proposed Arrangement would not subsidize any unmet Part B deductibles for Study participants, Requestor certified that all participants—in both the treatment and control groups—would receive sufficient Medicare billable procedures on their first Study visit such that any subjects who had not already met their annual Part B deductible would meet the deductible based on services billed during that first visit. As a result, according to Requestor, Study participants would not be able to discern whether they are in the treatment or control group based on assessment of the Part B deductible for services provided as part of the Study.

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

[11] Id.

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.[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, 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

[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).

practitioner, provider, or supplier.

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, 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 appears to be a reasonable means of promoting enrollment, particularly where 40 percent of participating beneficiaries would not have the potential to receive any therapeutic benefit during the Study. According to Requestor, the out-of-pocket costs 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 would be vital to enrolling a sufficient number of subjects 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 subjects by removing a potential financial barrier to participation in the Study. The subsidy also may reduce the likelihood that subjects would fail to complete the entire course of the Study, which involves a total of nine clinical visits over a 2-year period, each of which would—without the subsidy—require beneficiaries to pay cost sharing and each of which Requestor asserted would be necessary for the Study to achieve accurate results.

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 beneficiaries 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, 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 260 subjects, 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, 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 only provide cost-sharing subsidies relating to one course of treatment using the Therapy and related services during the Study. Although beneficiaries may continue to receive Medicare-reimbursable follow-up services related to the Therapy, Requestor would not be in a position to benefit financially from the provision of such items or services. The Therapy is intended as a one-time treatment, and Requestor does not anticipate that use of the Therapy would prompt future utilization of the Therapy or any other products manufactured by Requestor by Study enrollees. Accordingly, the Proposed Arrangement would not present the risk exhibited 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 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, 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