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 26, 2024

Posted: December 31, 2024

[Address block redacted]

Re: OIG Advisory Opinion No. 24-13 (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 assistance for certain travel, lodging, meals, and associated expenses for qualifying patients receiving a cell therapy product manufactured by Requestor (the "Arrangement"). Specifically, you have inquired whether the Arrangement constitutes 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 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 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 Arrangement would generate—if the requisite intent were present—prohibited remuneration under the Federal anti-kickback statute, OIG will not impose administrative sanctions on Requestor in connection with the 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) the Arrangement does not generate prohibited remuneration under 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

A. The Product and Treatment Centers

Requestor is a pharmaceutical manufacturer that offers [redacted], a one-time, potentially curative tumor-derived autologous T-cell immunotherapy (the "Product") for patients with [redacted] who have tried and failed at least one alternative treatment option. The Product is manufactured from a patient's tumor sample, which is collected at an approved treatment center selected by the patient ("Treatment Center").[2] The tissue-procurement phase of treatment requires the patient to stay at the Treatment Center between 1 and 5 days, depending on whether the procedure occurs in an outpatient or inpatient setting. Once the Product is manufactured, the patient returns to the Treatment Center for the administration phase of treatment, in which the patient receives 7 days of a chemotherapy regimen followed by infusion of the Product. Requestor certified that a patient needs a total of approximately 11 days for the tissue-procurement and administration phases of treatment.

While the Product's U.S. Food and Drug Administration-approved label ("Product Label") recommends that patients stay within 2 hours of the Treatment Center for several weeks for post-treatment monitoring, the patient's treating physician exercises independent medical judgment to determine whether and for how long a patient stays during post-treatment monitoring. Requestor certified that the average treatment journey for a patient using the Product, including the tissue-procurement phase of treatment, administration of the Product, and post-treatment monitoring, takes approximately 1 month but could extend to a second month of monitoring in the treating physician's independent medical judgment.

The Product is available only at a limited number of Treatment Centers that have the expertise to treat the patient's underlying disease and administer the Product.[3] Requestor has developed instructions for safely administering the Product and qualifies and trains Treatment Centers consistent with such instructions. According to Requestor, only facilities that successfully complete such training may be qualified as Treatment Centers. In selecting Treatment Centers, Requestor applies the objective criteria found in the Product Label, including the ability to: (i) conduct tumor tissue procurement; (ii) receive and store third-party cryopreserved Product; and

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[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.

[2] As described further below, to be eligible for the Arrangement, patients' selection of a Treatment Center is subject to certain limitations.

[3] Requestor anticipates establishing a minimum of 60 Treatment Centers by the end of 2024.

(iii) perform T-cell therapy regimen administration inclusive of Product administration. Requestor certified that it approves any willing provider that meets the uniform eligibility criteria as a Treatment Center and that all Treatment Centers may participate in the Arrangement. Requestor also certified that a Treatment Center's expected or actual use of the Product does not affect the Treatment Center's ability to qualify as, or remain, a Treatment Center, nor does it affect whether Requestor recommends the Treatment Center to any patients or physicians. Requestor lists the Treatment Centers on its website, and in instances where a patient requests information about Treatment Centers from Requestor, Requestor provides information only about the Treatment Centers geographically closest to the inquiring patient. While Requestor anticipates that the number of Treatment Centers will grow over time to meet patient need, Requestor does not expect that Treatment Centers will be available in every State.

Requestor offers the Arrangement to patients, including Federal health care program enrollees: (i) who are residents of the United States or a U.S. Territory; (ii) whose income is at or below 600 percent of the Federal Poverty Level; (iii) who meet program distance requirements, as described further below; and (iv) who have an on-label prescription for the Product. Requestor offers the Arrangement to patients during: (i) the tissue-procurement phase of treatment; (ii) administration of the Product; and (iii) post-treatment monitoring for the length of time recommended by the patient's treating physician.

Under the Arrangement, Requestor offers the following to each eligible patient and one caregiver:

- Airfare and Ground Transportation. Requestor covers round-trip airfare with coach/economy seating for patients and caregivers living 300 miles or more from: (i) the nearest Treatment Center to the patient's residence that is available to treat the patient within a reasonable timeframe and that accepts the patient's insurance; or (ii) a Treatment Center with which the patient has already established a treatment relationship, even if it is not the closest Treatment Center to the patient's residence, if the cost of travel and lodging associated with the patient going to that Treatment Center is not materially greater than the cost of travel and lodging with respect to the closest Treatment Center. In addition, Requestor covers ground transportation costs for patients and caregivers living between 100 miles (or the mileage equivalent of 2 hours' driving distance) and 300 miles away from the Treatment Center.

- Lodging. Requestor covers one room at a modest hotel for patients and caregivers living more than 100 miles (or 2 hours' driving distance) from the Treatment Center.

- Other Support During Treatment Center Stay. Requestor provides: (i) up to $50 per person, per day, to cover meals and authorized travel expenses, such as parking and taxi or ride-sharing app rides, during the patient's treatment for patients and caregivers living more than 100 miles (or 2 hours' driving distance) from the Treatment Center. When patients are admitted as inpatients or are staying at a Treatment Center as an outpatient, the Arrangement provides the daily allowance only to the caregivers. To receive this support for meals and authorized expenses, patients and caregivers are required to submit receipts to Requestor documenting authorized expenses actually incurred by the patients or caregivers, as applicable.

Requestor certified that it offers the Arrangement to a caregiver in addition to the patient because patients eligible for the Arrangement—who necessarily must have tried and failed at least one alternative treatment option prior to receiving treatment with the Product—are extremely sick and require caregiver support. Additionally, patients may experience serious adverse events from treatment with the Product, such as prolonged severe cytopenia, severe infections, internal organ hemorrhage, cardiac disorder, renal failure, and respiratory failure. Further, according to Requestor, some Treatment Centers recommend that a caregiver be present to assist the patient in conducting activities of daily living.

The Arrangement is implemented and administered by Requestor and a travel vendor, which arranges for: (i) ground transportation (e.g., rental car or train) or air travel (as applicable); and (ii) lodging. Requestor reimburses patients and caregivers for meals and authorized expenses in the amounts approved by Requestor following its expense verification process.

Requestor certified that, prior to offering the Arrangement to a patient, it determines whether assistance for travel, lodging, meals, or associated expenses is available from any other source, including from the Treatment Center, the patient's insurance, if any, or one or more third-party charities. Requestor further certified that it does not provide the Arrangement to a patient to the extent such other support is available to the patient.[4] In other words, if the Treatment Center, the patient's insurance, a charity, or any other source provides full support, Requestor does not offer the Arrangement, and if one or more of these sources provides only partial support, Requestor limits the Arrangement to support not covered by the third-party sources. Requestor also certified that it requires patients or caregivers to: (i) confirm that they are not eligible for assistance from other sources; and (ii) agree that they will not bill the costs of the Arrangement to any Federal health care program.[5]

Requestor does not advertise the Arrangement beyond providing Treatment Centers, potential referring physicians, and patients with a general overview of the patient support resources that are available for qualifying patients. Requestor certified that it does not use the Arrangement as a marketing tool to drive product selection, utilization, or referrals. Requestor further certified

[4] Requestor certified that it does not solely rely on a representation from the patient to identify whether a patient is eligible to receive support for travel, lodging, meals, and associated expenses from a third-party payor but also performs a benefits investigation to identify available assistance from third-party sources, including State Medicaid programs, to ensure the Arrangement does not provide support that is otherwise available from third-party sources. We express no opinion regarding Requestor's use of a benefits investigation to confirm that alternative support is not provided to patients eligible for the Arrangement. In the event Requestor utilizes a benefits investigation to confirm that alternative support is not provided to patients, such benefits investigation must comply with applicable Federal and State laws, including, without limitation, the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations.

[5] Requestor also requires the travel vendor to agree that it will not bill the costs of the Arrangement to any Federal health care program.

that it does not require either treating physicians or Treatment Centers to prescribe or use the Product exclusively.

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 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

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[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).

than fair market value." Section 1128A(i)(6) of the Act contains an exception to the definition of "remuneration" that may apply in the context of the Arrangement. Section 1128A(i)(6)(F) of the Act provides that, for purposes of the Beneficiary Inducements CMP, the term "remuneration" does not include "remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs (as defined in section 1128B(f) and designated by the Secretary under regulations)" (the "Promotes Access to Care Exception"). We have interpreted this provision to apply to:

> [i]tems or services that improve a beneficiary's ability to obtain items and services payable by Medicare or Medicaid, and pose a low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs by—(i) [b]eing unlikely to interfere with, or skew, clinical decision making; (ii) [b]eing unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (iii) [n]ot raising patient safety or quality-of-care concerns . . . .[9]

B. Analysis

1. Federal Anti-Kickback Statute

The Arrangement implicates the Federal anti-kickback statute in two ways. First, the assistance for certain travel, lodging, meals, and associated expenses constitutes remuneration to eligible patients—including Federal health care program enrollees—that may induce them to purchase the Product. Second, by facilitating eligible patients and their caregivers to travel to, and stay near, a Treatment Center that the patient may not otherwise have selected for treatment, the Arrangement constitutes remuneration to the Treatment Centers and the treating physicians in the form of the opportunity to earn fees related to administering the Product, which may induce Treatment Centers to recommend, and physicians to order, the Product. No safe harbor applies to the streams of remuneration resulting from the Arrangement.

However, for the combination of the following reasons, we believe the risk of fraud and abuse presented by the Arrangement is sufficiently low under the Federal anti-kickback statute for OIG to issue a favorable advisory opinion.

First, the Arrangement removes a barrier to accessing medically necessary care that is furnished by Treatment Centers. In order to receive treatment with the Product, patients need a total of approximately 11 days for the tissue-procurement and administration phases of treatment, which occur at the Treatment Center, and then patients stay at or near the Treatment Center for post-treatment monitoring, to the extent recommended by the patient's treating physician. Because only a limited number of facilities are qualified to become Treatment Centers, some patients may live a significant distance from the closest Treatment Center. The Arrangement facilitates access to the Product for qualifying patients, which may include Federal health care program enrollees, by: (i) subsidizing travel, lodging, meals, and associated expenses the patients and their caregivers otherwise may not be able to afford; (ii) allowing caregivers to remain near the Treatment Center while patients are undergoing treatment; and (iii) allowing patients and

[9] 42 C.F.R. § 1003.110 (defining "remuneration").

caregivers to remain near the Treatment Center during post-treatment monitoring, as recommended by the patient's treating physician. The Arrangement also removes a barrier to caregivers facilitating patients traveling to and from the Treatment Center, as well as caregivers providing support while the patient is undergoing and recovering from treatment because the Arrangement allows for caregiver support for patients who are extremely sick and who have tried and failed at least one alternative treatment option prior to receiving treatment with the Product.

Second, the Product is a one-time, potentially curative treatment, which distinguishes the Arrangement from problematic seeding arrangements that provide free product or other remuneration in connection with an initial dose of a drug to induce patients to continue purchasing the drug when it would be payable by a Federal health care program.

Finally, the Arrangement includes additional safeguards that mitigate the risk of fraud and abuse under the Federal anti-kickback statute. For example, Requestor certified that it does not authorize the Arrangement for any expenses for which assistance for travel, lodging, meals, and associated expenses is available from any other source, including from the Treatment Center, the patient's insurance, if any, or a third-party charity. Because assistance under the Arrangement arises only in circumstances where these categories of assistance are otherwise unavailable from third parties, the likelihood that Requestor would use the Arrangement as a marketing tool to drive patients to the Product is reduced. In addition, Requestor does not advertise the Arrangement beyond providing Treatment Centers, potential referring physicians, and patients with a general overview of the patient support resources that are available for qualifying patients. Requestor also certified that it does not require either treating physicians or Treatment Centers to prescribe or use its Product exclusively. These features of the Arrangement reduce the risk of inappropriate steering or inappropriate utilization of the Product.

2. Beneficiary Inducements CMP

Under the Beneficiary Inducements CMP, we must analyze whether Requestor knows or should know that the financial support it provides for travel, lodging, meals, and associated expenses under the Arrangement is likely to influence a 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 facts here implicate the Beneficiary Inducements CMP because Treatment Centers and physicians practicing at Treatment Centers are providers and suppliers, respectively, that recipients of assistance under the Arrangement could be induced to select.

The assistance for certain travel, lodging, meals, and associated expenses under the Arrangement constitutes remuneration to eligible patients, including Medicare and State health care program enrollees. This remuneration is likely to influence patients to select a Treatment Center and a physician practicing at a Treatment Center over other providers and suppliers. Requestor should know that patients likely would be influenced to select a Treatment Center and a physician practicing at a Treatment Center over other providers and suppliers because, as Requestor certified, the Arrangement facilitates the patient to travel to the Treatment Center to obtain the Product and enables the caregiver to remain near the Treatment Center during a patient's treatment with the Product. For the foregoing reasons, unless an exception applies, the Arrangement would generate prohibited remuneration under the Beneficiary Inducements CMP.

We conclude that the Arrangement satisfies the Promotes Access to Care Exception to the Beneficiary Inducements CMP. To reach this conclusion, we first must examine whether the remuneration that is offered under the Arrangement improves a beneficiary's ability to obtain items and services payable by Medicare or Medicaid. As noted above, several factors necessary for the safe administration of the Product may create barriers to accessing treatment with the Product. First, there is a limited number of Treatment Centers, as only facilities that meet certain objective criteria may be qualified as Treatment Centers. Second, in order to receive treatment with the Product, patients need a total of approximately 11 days for the tissue-procurement and administration phases of treatment, which occur at the Treatment Center, and then patients stay at or near the Treatment Center for post-treatment monitoring, to the extent recommended by the patient's treating physician. For these reasons, it is likely that the support Requestor provides for certain travel, lodging, meals, and associated expenses could remove or reduce potential financial and geographic barriers to receiving treatment with the Product and thus could improve a beneficiary's ability to obtain items and services payable by Medicare or Medicaid (when the Product is payable by Medicare or Medicaid).

Next, we must examine whether the Arrangement poses a low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs. The Promotes Access to Care Exception to the Beneficiary Inducements CMP states that remuneration poses a low risk of harm if it: (i) is unlikely to interfere with, or skew, clinical decision-making; (ii) is unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (iii) does not raise patient safety or quality-of-care concerns. First, the risk that the Arrangement interferes with, or skews, clinical decision-making or raises patient safety or qualify-of-care concerns is sufficiently low because the Arrangement is designed to increase patient safety by facilitating access to treatment with the Product and assuring adequate patient monitoring, consistent with the Product Label and as recommended by the patient's treating physician, following administration of the Product. Second, the Arrangement is unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization because the Product is a one-time, potentially curative treatment. Third, the Arrangement does not raise patient safety or quality-of-care concerns, as it is designed to increase patient safety by facilitating compliance with the requirements for administration of the Product, as set forth in the Product Label. Therefore, we conclude that the Arrangement poses a low risk of harm and thus satisfies the Promotes Access to Care Exception to the Beneficiary Inducements CMP. The Arrangement thus does not generate prohibited remuneration under the Beneficiary Inducements CMP.

III. CONCLUSION

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

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is limited in scope to the 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 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 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 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 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,

/Susan A. Edwards/

Susan A. Edwards
Assistant Inspector General for Legal Affairs