



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: May 26, 2022

Posted: June 1, 2022

[Address block redacted]

Re: Notice of Modification of OIG Advisory Opinion 20-02

Dear [redacted]:

The Office of Inspector General (“OIG”) is writing in response to your request on behalf of [redacted] (“Requestor”) to modify OIG Advisory Opinion 20-02 (“AO 20-02”), which we issued to Requestor on January 15, 2020. In AO 20-02, we opined on Requestor’s provision of financial assistance for travel, lodging, and other expenses provided to certain patients prescribed Requestor’s drug in connection with a round trip to an approved treatment center for the administration of the drug (the “Arrangement”). We concluded that the OIG will not impose administrative sanctions on Requestor in connection with the Arrangement under sections 1128(b)(7) or 1128A(a)(7) of the Social Security Act (the “Act”), as those sections relate to the commission of acts described in section 1128B(b) of the Act (the “Federal anti-kickback statute”) or under the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Act (the “Beneficiary Inducements CMP”).

Requestor now seeks to modify AO 20-02 to include Requestor’s provision of financial assistance to eligible patients for travel, lodging, and certain other associated expenses in connection with a round trip to an approved treatment center for a cell-removal process associated with manufacturing Requestor’s drug (the “Modification”). Specifically, Requestor has inquired whether the Arrangement, as modified by the Modification (the “Modified Arrangement”), constitutes grounds for the imposition of sanctions under: the civil monetary penalty provision at section 1128A(a)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute; 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 its request for a modification, 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 Modified Arrangement, and we have relied solely on the facts and information Requestor provided. In

particular, Requestor certified that, apart from the Modification and except as otherwise revised in this notice of modification, the Arrangement continues to operate in accordance with the final set of facts Requestor certified in connection with AO 20-02. 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 Modified 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 a modification of AO 20-02 and all supplemental submissions, and for the reasons set forth in AO 20-02 and herein, we conclude that the Modification does not affect our conclusion in AO 20-02. Accordingly, we conclude that: (i) although the Modified Arrangement would generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present, the OIG will not impose administrative sanctions on Requestor in connection with the Modified 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 Modified Arrangement does not constitute grounds for the imposition of sanctions under the Beneficiary Inducements CMP.

This opinion may not be relied on by any person¹ other than Requestor and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. The Drug and the Leukapheresis Process

Requestor is a pharmaceutical manufacturer that manufactures [redacted] (the “Drug”), a [redacted] therapy currently approved by the U.S. Food and Drug Administration (“FDA”) for two indications: (i) [redacted] (“Disease A”), generally affecting children and young adults; and (ii) [redacted] (“Disease B”), generally affecting adults. The Drug is a personalized medicine made from the patient’s own cells and is intended as a one-time, potentially curative treatment. Because of the patient safety risks associated with the Drug, the FDA required Requestor to implement a Risk Evaluation and Mitigation Strategy (“REMS”), which includes elements to assure safe use (“ETASU”). Only REMS-certified physicians who treat patients with an indication for which the Drug is approved may prescribe and administer the Drug.

Requestor has entered into arrangements with certain inpatient and outpatient facilities (“Centers”)² for the safe infusion of the Drug and the performance of leukapheresis, which is the process of separating a patient’s white blood cells from the patient’s blood sample. Because the

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 Requestor certified that any facility may become a Center if it meets: (i) all REMS with ETASU requirements; and (ii) Requestor’s objective, uniformly applied criteria related to administration of the Drug and the leukapheresis process.

Drug is a personalized [redacted] therapy, leukapheresis is a process that must be performed on each patient for Requestor to manufacture the Drug for that patient. Leukapheresis entails collecting the white blood cells and then processing, testing, labeling, storing, cryopreserving, packaging, and shipping the cells to Requestor. Requestor certified that, because of the Drug's unique manufacturing process and safety risks, leukapheresis must take place only at Centers. In addition to meeting all REMS with ETASU requirements and additional requirements imposed by Requestor in connection with administering the Drug, Centers must: (i) enter into a quality assurance agreement with Requestor that details the requirements for the leukapheresis process; (ii) have been trained by Requestor to undertake the leukapheresis process; and (iii) agree to qualification audits, surveillance audits or technical assessments, and for-cause audits to ensure the leukapheresis process is performed correctly.

After a Center performs leukapheresis, it sends the patient's white blood cells to Requestor so that Requestor may use the patient's cells to individually manufacture the Drug. Once Requestor manufactures the Drug, a Center infuses the Drug in the patient from whom the cells were collected, provided that the patient is healthy enough to receive treatment. According to Requestor, the manufacturing process for the Drug takes a minimum of 22 days from the date on which Requestor receives a patient's cryopreserved cells obtained through the leukapheresis process to the date the Center receives the Drug for administration to the patient. Therefore, Drug treatment requires one patient visit to the Center for leukapheresis and a second visit to the Center for Drug infusion and post-infusion monitoring in accordance with the Drug's REMS with ETASU.

B. The Arrangement

Under the Arrangement, Requestor assists eligible Disease A patients, Disease B patients 18 to 25 years of age, and up to two caregivers per patient with travel, lodging, and certain other out-of-pocket expenses in connection with a patient's Drug infusion and the post-infusion monitoring required by the Drug's prescribing information.³ The Arrangement does not include assistance with patient travel or other expenses associated with the separate leukapheresis process.

Eligible patients are patients who: (i) have been prescribed the Drug for an FDA-approved indication and have a household income that does not exceed 600 percent of the Federal Poverty Level; (ii) live more than 2 hours driving distance or 100 miles from the nearest Center accepting patients; and (iii) have no insurance for non-emergency medical travel. Requestor certified that it created the Arrangement to help eligible patients: (i) with costs they incur to travel, and remain in proximity, to a Center in connection with administration of the Drug; and (ii) meet the FDA requirements set forth in the Drug's prescribing information to ensure patient safety in connection with administration of the Drug.

Under the Arrangement, Requestor provides reimbursement for gas and tolls or arranges for transportation via bus, rail, rental car, or air travel for a patient and caregiver(s) to and from a Center using a third-party travel vendor. Assistance under the Arrangement is available for one

³ For Disease B patients who are 26 and older, Requestor provides the same support for a patient and one caregiver.

round trip from the patient's and each caregiver's place of residence to a Center. Requestor's travel vendor also arranges for a modest, single, shared hotel room located near a Center for the patient and caregiver(s) during Drug treatment and post-treatment monitoring. Requestor also provides reimbursement for certain meal and other travel expenses up to \$50 per day per person (e.g., meals and parking or taxi fare between the hotel and the Center).

Safeguards under the Arrangement include that: (i) Requestor does not advertise the financial assistance available under the Arrangement; (ii) patients do not learn about, or become eligible for, assistance under the Arrangement until they have been diagnosed with an FDA-approved indication and prescribed the Drug; (iii) patients and caregivers must agree not to request reimbursement from any Federal health care program for costs covered under the Arrangement; and (iv) Requestor does not bill for or otherwise shift the costs of the Arrangement to any Federal health care program.

C. The Modified Arrangement

Under the Modified Arrangement, eligible patients may receive financial assistance for one round trip from the patient's and each caregiver's place of residence to a Center for leukapheresis in addition to the round trip to the Center for Drug infusion and post-treatment monitoring.⁴ For each of these two round trips, Requestor arranges for a modest, single shared hotel room located near the Center for the patient and caregiver(s) and reimburses certain meal and other travel expenses up to \$50 per day per person (e.g., meals and parking or taxi fare between the hotel and the Center). Because leukapheresis generally takes 3 days to complete, under the Modified Arrangement, eligible patients may receive up to 2 nights of lodging to obtain leukapheresis at a Center.⁵

Requestor certified that, other than as set forth in this notice of modification, all safeguards and other standards applicable to the Arrangement, as set forth in AO 20-02, apply to the Modification. Requestor further certified that it has undertaken the Modification to help eligible patients: (i) with costs they incur to travel, and remain in proximity, to a Center in connection with the leukapheresis process; and (ii) meet the FDA requirements set forth in the Drug's prescribing information to ensure patient safety in connection with the leukapheresis process.

⁴ Under the Modified Arrangement, Requestor offers assistance for travel for leukapheresis and Drug infusion only to the Center closest to the patient's residence that is accepting patients and that accepts the patient's insurance except in certain circumstances, such as when a patient has been receiving treatment for one of the indications for which the Drug is approved from a physician associated with a Center that is located farther from the patient's home and, for continuity of treatment, the patient desires to continue treatment with the same physician or health care team.

⁵ Requestor does not authorize lodging under the Modified Arrangement when Requestor has knowledge, or based on widely available, public information should know, that the patient is eligible to receive lodging from the Center without charge, and such lodging is available for that patient's use.

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, 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) of the Act contains an exception to the definition of

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).

“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” (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 concerns⁹

B. Analysis

1. Federal Anti-Kickback Statute

The Modification implicates the Federal anti-kickback statute in two ways. First, the free travel, lodging, and meal assistance provided in connection with leukapheresis constitute remuneration to eligible patients who are Federal health care program beneficiaries that may induce them to purchase Requestor’s Drug. Second, because the travel, lodging, and meal assistance Requestor offers to beneficiaries allow them to travel to, and stay near, a Center that they might not otherwise have selected for Drug treatment or leukapheresis, this assistance constitutes remuneration to the Centers and the physicians performing services related to Drug treatment in the form of the opportunity to earn fees related to Drug treatment that may induce the Centers and physicians to order the Drug. This remuneration is inherently tied to the volume of referrals of Requestor’s Drug, and it potentially benefits the Centers and physicians by steering business that is reimbursable by a Federal health care program to them. The provision of remuneration, such as travel, lodging, and meal assistance, by a manufacturer to a beneficiary to facilitate the manufacturing of a drug for that beneficiary could raise significant concerns under the Federal anti-kickback statute, depending on the facts. However, for the combination of reasons set forth below, we conclude that the Modification presents a minimal risk of fraud and abuse under the Federal anti-kickback statute.

The financial assistance Requestor furnishes to eligible patients for leukapheresis is narrowly tailored to remove barriers to undergoing the leukapheresis process, which reduces the risk that the assistance results in inappropriate steering to the Drug. Requestor certified that leukapheresis is a necessary process for manufacturing the Drug for each patient and that, because of the Drug’s unique manufacturing process and safety risks, it must take place only at Centers, which must meet several requirements, including all REMS with ETASU requirements. The remuneration under the Modified Arrangement is subject to numerous limitations, including that it is available only to patients who meet financial eligibility criteria, live a significant distance from a Center, and do not have insurance for non-emergency medical travel. Further, Requestor limits reimbursement to obtain leukapheresis to expenses incurred during a 2-night stay and does

⁹ 42 C.F.R. § 1003.110 (defining “remuneration”).

not authorize lodging when Requestor has knowledge, or based on widely available, public information should have knowledge, that the patient is eligible to receive free lodging without charge from the Center, and such lodging is available for that patient's use. Additionally, Requestor offers assistance for travel for leukapheresis and Drug infusion only to the Center closest to the patient's residence that is accepting patients and that accepts the patient's insurance, except in certain limited circumstances.

In addition, other than as set forth in this notice of modification, all safeguards and other standards applicable to the Arrangement apply to the Modification. For example: (i) Requestor does not advertise the financial assistance available under the Modification; (ii) patients do not learn about, or become eligible for, assistance under the Modification until they have been diagnosed with an FDA-approved indication and prescribed the Drug; (iii) patients and caregivers must agree not to request reimbursement from any Federal health care program for costs covered under the Modification; and (iv) Requestor does not bill or otherwise shift the costs of the Modification to any Federal health care program.

2. Beneficiary Inducements CMP

Under the Modification, Requestor assists eligible patients—some of whom may be Medicare or State health care program beneficiaries—and caregivers with travel, lodging, and certain meal expenses in connection with a round trip to a Center for leukapheresis. Requestor offers such assistance for travel to the Center closest to the patient's residence that is accepting patients and that accepts the patient's insurance, except in certain limited instances. Therefore, we conclude that this remuneration, like the remuneration offered under the Arrangement, implicates the Beneficiary Inducements CMP because it is likely to influence a patient to select a particular physician or Center that the patient may not otherwise have selected to receive items and services reimbursable by Medicare or a State health care program. However, we conclude that, for the same reasons the Arrangement satisfies the Promotes Access to Care Exception, as explained in AO 20-02, the Modified Arrangement also satisfies the Promotes Access to Care Exception.

III. CONCLUSION

Based on the relevant facts certified in your original request for a modification of AO 20-02 and all supplemental submissions, and for the reasons set forth in AO 20-02 and herein, we conclude that the Modification does not affect our conclusion in AO 20-02. Accordingly, we conclude that: (i) although the Modified Arrangement would generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present, the OIG will not impose administrative sanctions on Requestor in connection with the Modified 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 Modified Arrangement does not constitute grounds for the imposition of sanctions 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 Modified 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 Modified 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 Modified 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 Modified 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 Modified 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,

/E. Reynolds Wilson/

E. Reynolds Wilson
Acting Assistant Inspector General for Legal Affairs