



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 associated with the individual or entity, unless otherwise approved by the requestor.]

Issued: December 28, 2020

Posted: December 31, 2020

[Name and address redacted]

Re: OIG Advisory Opinion No. 20-09

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a program where a pharmaceutical manufacturer provides financial assistance for travel, lodging, and other expenses to certain patients prescribed the manufacturer's drug (the "Arrangement"). Specifically, you have inquired whether the Arrangement constitutes grounds for the imposition of sanctions under the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Social Security Act (the "Act"), or under the exclusion authority at section 1128(b)(7) of the Act or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the Federal anti-kickback statute.

You have certified that all of the information provided in your request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that, although the Arrangement could potentially generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent to induce or reward referrals of Federal health care program business were present, the Office of Inspector General (“OIG”) will not impose administrative sanctions on [name redacted], under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement. In addition, the OIG will not impose administrative sanctions on [name redacted], under section 1128A(a)(5) of the Act in connection with the Arrangement. This opinion is limited to the Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

This opinion may not be relied on by any persons other than [name redacted], the requestor of this opinion, 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 Centers

[Name redacted] (“Requestor”) is a pharmaceutical manufacturer that manufactures [drug redacted] (the “Drug”), a [therapy redacted] (“Therapy”) approved by the U.S. Food and Drug Administration (“FDA”) for the treatment of adult patients with relapsed or refractory [disease redacted] (the “Disease”). The Drug is a personalized medicine made from the patient’s own cells. The Drug is generally administered as a one-time infusion and is a potentially curative treatment.¹ According to Requestor, the Drug differs from other

¹ When hospital outpatient departments furnish the Drug to Medicare beneficiaries, the hospitals may receive payment for the Drug, consistent with how the Centers for Medicare & Medicaid Services (“CMS”) pays for drugs with pass-through payment status under the Medicare Part B Outpatient Prospective Payment System. Hospital outpatient departments also may receive payments for professional services and other items and services related to Drug infusion. When a hospital furnishes the Drug to an inpatient beneficiary, the hospital receives a per-discharge payment rate based on the Medicare Severity Diagnosis Related Group (“MS-DRG”) to which the discharge is assigned. In addition to the MS-DRG payment, a hospital may receive a New Technology Add-On Payment that will vary based on a hospital’s total inpatient covered charges and overall cost-to-charge ratio. Under Medicaid, hospital inpatient and outpatient payment methodologies vary by state and among each state’s Medicaid managed care contractors.

[disease redacted] treatments in that it is individually manufactured for each patient. Manufacturing the Drug involves multiple steps. First, patients undergo leukapheresis in which certain cells are removed from the patient’s body. Second, the cells are shipped to Requestor’s manufacturing facility where the cells are engineered using retroviruses to insert the DNA for the [protein redacted] into the DNA of the patient’s T-cells. Third, the cells are frozen and shipped to the treating facility, where they are infused back into the patient’s bloodstream to treat the Disease. The manufacturing process takes approximately 17 days from leukapheresis to infusion. According to Requestor, Drug treatment requires one visit by a patient to a leukapheresis facility or an inpatient or outpatient facility (“Center”)² and a second visit to a Center where the patient undergoes conditioning chemotherapy, Drug infusion, and post-infusion monitoring.³

The Drug carries a boxed warning of certain life-threatening or fatal reactions including [syndrome redacted] (the “Syndrome”) and certain neurological toxicities. The FDA required Requestor to implement a Risk Evaluation and Mitigation Strategy (“REMS”), which includes elements to assure safe use (“ETASU”) to mitigate the risks of the Syndrome and neurological toxicities associated with the use of the Drug. The Drug’s prescribing information, approved by the FDA, requires Center physicians and other REMS-trained health care staff at a Center or a leukapheresis facility (“Providers”) to monitor patients for signs or symptoms of the Syndrome and neurological toxicities following Drug infusion and to have on-site, immediate access to [drug redacted], which is used to treat severe instances of the Syndrome.⁴ Under the REMS, Providers must instruct patients to stay within two hours of the administering Center for at least four weeks after infusion.

² Centers are certain inpatient and outpatient facilities certified by the Requestor as having the expertise, health care professional teams, and infrastructure to follow the Drug’s prescribing information and safely infuse the Drug.

³ The Requestor certified that the patient may return home after leukapheresis while awaiting the Drug manufacturing process.

⁴ Only REMS-trained health care staff may prescribe the Drug.

According to the Requestor, to be consistent with the REMS⁵ only Centers are permitted to administer the Drug.⁶ Requestor, which unilaterally controls the selection of Centers, certified that Centers must: (i) meet all REMS with ETASU requirements, including accepting responsibility for implementing necessary safety protocols; and (ii) meet all other requirements that it imposes, including having on-site, immediate access to [drug redacted] for purposes of treating the Syndrome. Requestor certified that it does not require either Providers or Centers to prescribe its Drug exclusively and that any inpatient or outpatient facility that meets all REMS with ETASU requirements and Requestor’s criteria, which it uniformly applies, may become a Center.

Leukapheresis services may be performed only at leukapheresis facilities that are either part of, or affiliated with, a Center and that Requestor has evaluated and approved as part of its process for qualifying Centers to perform all stages of Drug treatment. Requestor certified that most of the Centers have a leukapheresis facility, but in a limited number of cases, a third-party medical facility affiliated with a Center will perform that Center’s leukapheresis procedures. Requestor’s process for qualifying Centers ensures that the leukapheresis facility is capable of correctly collecting, storing, packing, and shipping a patient’s cells and that the Drug can be properly matched to each individual patient. Requestor certified that it applies these requirements uniformly.

B. The Arrangement

Under the Arrangement, Requestor assists eligible patients and one caregiver with travel, hotel lodging,⁷ and certain out-of-pocket expenses (e.g., meals) they incur related to obtaining leukapheresis, receiving conditioning chemotherapy, infusing the Drug, and monitoring after Drug infusion. Requestor operates the Arrangement for patients, including Federal health care program beneficiaries, who are prescribed and administered its Drug in accordance with its label. Requestor certified that the remuneration it provides under the Arrangement is designed to ensure patient safety and promote quality-of-care, particularly for indigent and rural patients.

⁵ We also note that, according to the Institute for Clinical and Economic Review (“ICER”), Therapy initially should be administered in manufacturer-accredited centers to ensure the quality and appropriateness of care. See ICER, [cite redacted]. ICER is a nonprofit, independent research organization. See <https://icer-review.org/about/>.

⁶ Currently, Requestor has certified approximately 100 Centers nationwide to administer its Drug.

⁷ Lodging consists of a modest, single, shared hotel room for the patient and his or her caregiver.

Requestor uses a third-party vendor to provide administrative and logistical support for the Arrangement.⁸ Under the Arrangement, Requestor, through its vendor, reimburses eligible patients for mileage-based travel expenses (e.g., fuel costs) and tolls or transportation via bus, rail, rental car, or air travel for a patient and caregiver or arranges for transportation for patients.⁹ Assistance under the Arrangement is available for one round-trip from the patient's and caregiver's place of residence to the Center or leukapheresis facility and one round-trip to the Center for Drug treatment. Travel assistance is limited to the leukapheresis facility and Center closest to the patient's residence and that accepts the patient's insurance, if applicable. Requestor's vendor also arranges for modest hotel lodging for the patient and his or her caregiver to stay near the Center for up to two visits (or one stay near the affiliated third-party medical facility performing leukapheresis and one stay near the Center) related to leukapheresis, Drug treatment, and post-treatment monitoring. Patients may receive up to two nights of lodging to obtain leukapheresis at a leukapheresis facility. Requestor does not authorize lodging under the Arrangement to a patient treated by a Center or leukapheresis facility when Requestor knows, or based on available information should know, that the patient is eligible to receive free lodging from the leukapheresis facility or Center, and such lodging is available for that patient's use.

Requestor, through its vendor, also provides reimbursement for certain out-of-pocket expenses up to \$50 per day per person (e.g., meals and parking or taxi fare between the hotel and the Center). To receive reimbursement for out-of-pocket expenses, patients or caregivers must submit written receipts to Requestor (or its vendor) documenting expenses.

Under the Arrangement, patients may receive lodging and reimbursement for certain out-of-pocket expenses for up to two nights for leukapheresis and from the time of conditioning chemotherapy and Drug infusion until four weeks post-infusion; however, if a patient's physician determines that it is medically necessary to monitor the patient for risks of the Syndrome and neurological toxicities for longer than four weeks, Requestor provides assistance for the duration of monitoring deemed necessary by the physician.

⁸ For example, the vendor created a patient enrollment portal, established a dedicated phone line for a live representative help desk, and currently works with a third-party travel agency to make travel and lodging arrangements for eligible patients. Requestor certified that the vendor is not a referral source for Requestor's products. We have not been asked to opine, nor do we express any opinion, regarding any arrangement between Requestor and the vendor.

⁹ Eligible patients traveling 300 miles or more to the nearest leukapheresis facility and Center may be eligible to receive air transportation.

Eligible patients are patients who: (i) have been prescribed the Drug for an FDA-approved indication; (ii) have a household income that does not exceed 600 percent of the Federal Poverty Level; (iii) live more than two hours driving distance or 100 miles from the nearest leukapheresis facility and Center that accepts the patient's insurance, as applicable; and (iv) lack third-party insurance coverage for the travel and lodging expenses associated with the patient's treatment. Requestor offers the Arrangement to eligible patients regardless of their prescribing Provider or insurance status (i.e., self-insured, uninsured, commercially insured, or federally insured). Requestor certified that it adopted a written policy that specifies the eligibility criteria for the Arrangement and applies that policy uniformly and consistently.

Requestor also certified that it does not advertise the Arrangement. Patients do not learn about, or become eligible for, the Arrangement until they have been diagnosed with the Disease and are prescribed treatment with the Drug. Requestor maintains individualized documentation—documenting both a patient's eligibility and any reimbursement provided to a patient—for each patient to whom it provides support under the Arrangement.

To participate in the Arrangement, the patient must agree not to request reimbursement from Federal health care programs for costs covered under the Arrangement. Requestor certified that it does not bill or otherwise shift the costs of the Arrangement to the Federal health care programs.

II. LEGAL ANALYSIS

A. Law

The Federal anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward, among other things, referrals for, or purchases of, items or services reimbursable by a Federal health care program.¹⁰ The anti-kickback statute specifically prohibits the offer, payment, solicitation, or receipt of any remuneration to induce or reward referrals for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or the purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under Federal health care program.¹¹ Where remuneration is paid purposefully to induce or reward referrals or purchases of items

¹⁰ See section 1128B(b) of the Act.

¹¹ Id.

or services payable by a Federal health care program, the Federal anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible “kickback” transaction. For purposes of the 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 was to obtain money for the referral of services or to induce further referrals.¹² Violation of the statute constitutes a felony punishable by a maximum fine of \$100,000, imprisonment up to ten years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

Section 1128A(a)(5) of the Act (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 (including Medicaid) beneficiary that the benefactor 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 (including Medicaid). The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs.

Section 1128A(i)(6) of the Act defines “remuneration” for purposes of section 1128A(a)(5) of the Act as including “transfers of items or services for free or for other than fair market value.”¹³ Section 1128A(i)(6)(F) of the Act provides that, for purposes of the Beneficiary Inducements CMP, the term “remuneration” does not apply to “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

¹² See, 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).

¹³ See also 42 C.F.R. § 1003.110 (defining “remuneration,” for purposes of the regulations implementing the Beneficiary Inducements CMP, to be consistent with the definition of “remuneration” set forth at section 1128A(i)(6) of the Act).

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.¹⁴

B. Analysis

We must analyze whether the Arrangement implicates the Federal anti-kickback statute, as well as the Beneficiary Inducements CMP. We address these issues in turn, and for the combination of the reasons discussed below, we conclude that we will not impose sanctions on Requestor under the Federal anti-kickback statute or Beneficiary Inducements CMP in connection with the Arrangement.

1. Federal Anti-Kickback Statute

The Arrangement implicates the Federal anti-kickback statute in two ways. First, the free travel, lodging, and other assistance constitute remuneration to beneficiaries that may induce them to purchase Requestor’s Drug. Second, because the travel, lodging, and other assistance Requestor offers to beneficiaries allows them to travel to, and stay near, a Center and Provider that the patient may not otherwise have selected for Drug treatment, this assistance constitutes remuneration to Providers and Centers, in the form of the opportunity to earn fees related to infusing the Drug, that may induce them to order the Drug. The remuneration is inherently tied to the volume of referrals of Requestor’s Drug, and it potentially benefits Providers and Centers by steering federally reimbursable business to them.

Generally, we are concerned that manufacturers that provide travel, lodging, and assistance with other out-of-pocket expenses (e.g., meals) for patients who are prescribed their drugs could use the remuneration to generate business for themselves by steering patients to their drugs over competing drugs, which could be less expensive but equally effective, and that this could result in inappropriate cost increases to the Federal health care programs. Although Requestor certified that it does not shift the Arrangement’s costs to the Federal health care programs, Requestor can increase the Drug’s price to recoup costs related to the

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

Arrangement, and such price increases could lead to increases in Federal health care program costs for the Drug. We also have concerns that arrangements providing financial assistance for travel, lodging, meals and other expenses encourage manufacturers to compete for market share using the free items and services they provide to patients and referral sources. Finally, because Requestor sets the eligibility criteria that facilities must meet to participate in Requestor's network as a Center, Requestor theoretically could drive patient volume to a limited group of Providers that Requestor unilaterally selects in return for an agreement by the Providers to exclusively prescribe its Drug. However, for the combination of the following reasons, we will not impose sanctions under the Federal anti-kickback statute on Requestor in connection with the Arrangement.

First, Requestor certified that the remuneration it provides under the Arrangement is intended to help indigent and rural patients travel, and stay in proximity, to a Center (or affiliated facility performing leukapheresis) for Drug treatment, which includes leukapheresis, conditioning chemotherapy, Drug infusion, and post-treatment monitoring. Indigent patients or rural patients could be disproportionately impacted by significant health risks or even death if they cannot travel, and stay in proximity, to a Center to receive Drug treatment and necessary post-treatment monitoring.

Some Drug-eligible patients are financially needy Medicare or Medicaid beneficiaries. Low-income families eligible for assistance to travel to a Center for treatment may have difficulty affording the travel, lodging, and other related expenses associated with Drug treatment (for both leukapheresis and Drug infusion), which includes expenses associated with staying for at least a month near a Center after treatment. These difficulties are further evidenced by ICER's patient interviews, in which patients indicated that non-medical costs, such as travel and living expenses during treatment, were concerning.¹⁵ Financially needy patients required to travel a significant distance to a Center for treatment who return home following infusion due to the non-medical costs associated with post-infusion monitoring would not receive the benefit of FDA-required safety monitoring. Therefore, to increase access to care that complies with the Drug's REMS with ETASU for financially needy patients and those living in rural areas, we are permitting Requestor, in these limited circumstances, to provide travel, lodging, and certain other assistance to certain beneficiaries taking its Drug.

Second, the modest lodging Requestor provides under the Arrangement following infusion enables physicians to meet the FDA requirements in the Drug's prescribing information and to mitigate patient harm from potentially lethal Drug side effects. The remuneration relates to expenses incurred by an eligible patient to adhere to his or her physician's instructions to

¹⁵ See supra note 5.

receive treatment at a Center and stay within two hours of the Center. These instructions are required by the FDA-approved prescribing information and the REMS with ETASU.¹⁶ Generally, we are concerned when a manufacturer provides significant remuneration to a patient for using the manufacturer's drug. Here, however, the support for Drug infusion allows an eligible patient and his or her caregiver to follow the requirements of the Drug's prescribing information.¹⁷

Third, under the REMS with ETASU imposed by the FDA, only Centers that meet all REMS with ETASU requirements, including accepting responsibility for implementing necessary safety protocols, may administer the Drug; therefore, the number of Centers that can administer the Drug is limited. As explained above, manufacturer actions designed to limit drug distribution networks to particular facilities to reward their physicians may create risks under the Federal anti-kickback statute. Here, however, the limited Center network is necessary for patient safety reasons and to ensure compliance with the Drug's REMS with ETASU. Furthermore, Requestor certified that it does not require Providers to prescribe its Drug exclusively. The Drug's patient safety risks, and Requestor's assurance that any willing facility that meets all REMS with ETASU requirements and Requestor's uniform criteria may participate in the Arrangement, limit the likelihood that Requestor uses the Arrangement to reward a limited number of Providers who prescribe and administer its Drug.

Fourth, the Drug is prescribed only for patients with relapsed or refractory Disease who have undergone two or more lines of systemic therapy, and the Arrangement is available only when the Drug is prescribed and administered in accordance with its label. In other words, the Drug is a treatment of last resort for patients with the Disease. Furthermore, the Drug is a one-time, potentially curative treatment, so the Arrangement does not raise the seeding concerns sometimes present in other arrangements (i.e., the Arrangement is

¹⁶ In concluding that we would not impose sanctions on Requestor in connection with the Arrangement, we relied on the fact that the FDA required a REMS with ETASU to mitigate the Drug's significant safety risks and did not independently undertake extensive investigation, clinical study, testing, or collateral inquiry to evaluate the Drug's safety risks or the patient-safety benefits that the Arrangement may provide. We caution that, in instances where such collateral inquiry may be necessary to reach an informed opinion, OIG would be required to reject a requestor's advisory opinion request. See 42 C.F.R. § 1008.15(b)(3).

¹⁷ The Arrangement does not involve the provision of ambulance transportation, childcare, lost wages, stipends, or other expenses. We caution that the provision of such items or services, depending on the facts and circumstances, may not be low risk under the Federal anti-kickback statute.

distinguishable from providing remuneration in connection with an initial dose of a drug to patients to induce patients to continue purchasing the drug when it would be payable by a Federal health care program). In addition, Requestor does not advertise the Arrangement. These conditions limit the likelihood that the Arrangement serves as a marketing tool to drive patients to Requestor's Drug.

Fifth, to be eligible for the Arrangement, patients must live more than two hours driving distance, or more than 100 miles, from a leukapheresis facility and Center (and must live 300 miles from a leukapheresis facility and Center to receive airfare assistance). Requestor provides travel to the leukapheresis facility and Center nearest to the patient that accepts the patient's insurance, if applicable. Requiring patients to reside a significant distance from a leukapheresis facility and Center mitigates the risk that Requestor uses the Arrangement as a marketing tool for patient referrals.

Requestor also certified that it does not authorize lodging under the Arrangement to patients treated by a leukapheresis facility or Center when Requestor has knowledge, or based on available information should have knowledge, that the patient is eligible to receive free lodging from the leukapheresis facility or Center, and such lodging is available for that patient's use. Therefore, the assistance under the Arrangement should not duplicate other charitable assistance available from a leukapheresis facility or Center.

Sixth, the FDA requires Providers to notify patients of the need to stay in proximity to a Center post-infusion for safety reasons; however, we are not currently aware of any existing authority that would allow the Secretary to pay for these non-medical items and services, such as travel and lodging for outpatients who receive the Drug. Therefore, the support provided by Requestor allows an eligible patient and his or her caregiver to follow the requirements of the Drug's prescribing information.

Lastly, under different facts and circumstances, the provision of remuneration (e.g., travel or lodging) by a manufacturer to a beneficiary to facilitate the collection of patient cells required to manufacture a drug could potentially violate the Federal anti-kickback statute if the remuneration was offered to induce the beneficiary to purchase the manufacturer's drug. However, Requestor certified that due to the unique characteristics of the Drug's manufacturing process and its safety risks, leukapheresis cannot take place at a medical facility unless it is either part of, or affiliated with, a Center and has been evaluated and approved as part of Requestor's process for qualifying Centers to perform all stages of Drug treatment. Requestor's qualification process ensures that the leukapheresis facility is capable of correctly collecting, storing, packing, and shipping a patient's cells and that the Drug can be properly matched to each individual patient. In addition, Requestor certified that it limits reimbursement to obtain leukapheresis under the Arrangement to expenses incurred during a two-night stay.

For all of the above reasons, we would not impose administrative sanctions under the Federal anti-kickback statute on Requestor in connection with the Arrangement.

2. Beneficiary Inducements CMP

We must also analyze whether 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. For purposes of the Beneficiary Inducements CMP, pharmaceutical manufacturers are not "providers, practitioners, or suppliers" unless they also own or operate, directly or indirectly, pharmacies, or other entities that file claims for payment under the Medicare or Medicaid programs.¹⁸ Here, Requestor is a pharmaceutical manufacturer, and it does not own or operate, directly or indirectly, any pharmacy or Provider that administers the Drug. Therefore, Requestor is not a "provider, practitioner, or supplier" for purposes of the Beneficiary Inducements CMP. However, an offer of remuneration by a pharmaceutical manufacturer to a beneficiary to influence the beneficiary to select a particular provider, practitioner, or supplier would implicate the Beneficiary Inducements CMP.

Under the Arrangement, Requestor assists eligible patients and caregivers with travel, lodging, and certain out-of-pocket expenses they incur related to leukapheresis and during and after Drug infusion. These are valuable benefits to Medicare and State health care program beneficiaries. The Arrangement limits travel assistance to the leukapheresis facility and Center closest to the patient's residence and that accepts the patient's insurance, if applicable. Consequently, the beneficiary uses the remuneration offered by Requestor to travel to and stay near a particular Center, leukapheresis facility, or both. Therefore, we conclude that this remuneration is likely to influence a patient to select a particular Provider, leukapheresis facility, or Center that the patient may not otherwise have selected to receive items and services reimbursable by Medicare or a State health care program. Accordingly, we have determined that the Arrangement implicates the Beneficiary Inducements CMP.

Once the Beneficiary Inducements CMP is implicated, we next analyze whether an exception applies. We conclude that the travel, lodging, and out-of-pocket expenses provided to beneficiaries during Drug treatment (including leukapheresis, Drug infusion, and FDA-required patient monitoring), satisfy the Promotes Access to Care Exception. To

¹⁸ OIG, Special Advisory Bulletin, Offering Gifts and Other Inducements to Beneficiaries (Aug. 2002), available at <https://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf>.

reach this conclusion, we first must examine whether the remuneration offered during leukapheresis, Drug infusion, and post-treatment monitoring improves a beneficiary's ability to obtain items and services payable by Medicare or a State health care program. We are not currently aware of any existing authority that would allow the Secretary to pay for these non-medical items and services, such as travel and lodging. Also, Requestor certified that it does not authorize lodging under the Arrangement to patients treated by a Center when Requestor has knowledge or, based on the available information should have knowledge, that the patient is eligible to receive lodging from the leukapheresis facility or Center, and such lodging is available for that patient's use. Therefore, the assistance under the Arrangement should not duplicate other available charitable assistance from a Center or leukapheresis facility. Most importantly, staying near the Center for approximately four weeks following Drug infusion is required by the Drug's REMS with ETASU; therefore, we believe that remuneration provided during Drug treatment removes or reduces economic barriers to receiving safe treatment and patient monitoring required by the Drug's prescribing information and REMS with ETASU.

Next, we must examine whether the remuneration provided during Drug treatment poses a low risk of harm to Medicare and State health care program beneficiaries and the Medicare and State health care programs. The Promotes Access to Care Exception 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. We believe the risk that the remuneration would interfere with, or skew, clinical decision making is sufficiently low here because, as discussed in detail in the Federal anti-kickback statute analysis above, the provision of remuneration during Drug treatment is designed to increase patient safety—and mitigate potentially lethal side effects—in connection with the Drug's REMS with ETASU. In addition, the Drug is unlikely to be overutilized because the Drug is prescribed only for patients with relapsed or refractory Disease who have undergone two or more lines of systemic therapy and is a one-time potentially curative treatment. Lastly, as stated above, the remuneration is designed to ensure patient safety and promote quality-of-care. Therefore, we conclude that the Arrangement presents a low risk of harm and satisfies the Promotes Access to Care Exception to the Beneficiary Inducements CMP.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that, although the Arrangement could potentially generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent to induce or reward referrals of Federal health care program business were present, the OIG will not impose administrative sanctions on [name redacted], under sections 1128(b)(7) or

1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement. In addition, the OIG will not impose administrative sanctions on [name redacted], under section 1128A(a)(5) of the Act in connection with the Arrangement. This opinion is limited to the Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [name redacted], the requestor of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.
- This advisory opinion may not be introduced into evidence by a person or entity other than [name redacted], to prove that the person or entity did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.
- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied 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.
- This advisory opinion is limited in scope to the specific arrangements described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope.
- No opinion is expressed herein regarding the liability of any party 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 [name redacted], 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. 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 [name redacted], 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 the OIG.

Sincerely,

/Robert K. DeConti/

Robert K. DeConti
Assistant Inspector General for Legal Affairs