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: July 17, 2024

Posted: July 22, 2024

[Address block redacted]

Re: OIG Advisory Opinion No. 24-05 (Favorable in Part and Unfavorable in Part)

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 proposed assistance for certain travel, lodging, meals, and associated expenses (the "Travel Support") and proposed assistance for specified fertility preservation services (the "Fertility Support") for qualifying patients receiving one of two gene therapy treatments manufactured by Requestor (collectively, the Travel Support and the Fertility Support are referred to as the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement, if undertaken, would constitute grounds for the imposition of sanctions under: the civil monetary penalty provision at section 1128A(a)(7) of the Social Security Act (the "Act"), as that section relates to the commission of acts described in section 1128B(b) of the Act (the "Federal anti-kickback statute"); the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Act (the "Beneficiary Inducements CMP"); or the exclusion authority at section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute and the Beneficiary Inducements CMP.

Requestor has certified that all of the information provided in the request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties in connection with the Proposed Arrangement. In issuing this opinion, we have relied on the facts and information Requestor presented to us and, in accordance with 42 C.F.R. § 1008.39(d), other publicly available information. We have not undertaken an independent investigation of the certified facts and information presented to us by Requestor. This opinion is limited to the relevant facts presented to us by Requestor in connection with the Proposed Arrangement. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Relative to the Travel Support, based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, as well as certain publicly available information, we conclude that: (i) although the Travel Support 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 Travel Support 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 Travel Support does not generate prohibited remuneration under the Beneficiary Inducements CMP.

With respect to the Fertility Support, based on the relevant facts certified in your request for an advisory opinion and supplemental submissions and the limited data available regarding, for example, the impact of Fertility Support on access to health care services; costs to Federal health care programs; patient outcomes; competition; and the risk of improper steering, we conclude that the Fertility Support, if undertaken: (i) would generate—if the requisite intent were present—prohibited remuneration under the Federal anti-kickback statute, which would constitute grounds for the imposition of sanctions under sections 1128A(a)(7) and section 1128(b)(7) of the Act; and (ii) would generate prohibited remuneration under the Beneficiary Inducements CMP, which would constitute grounds for the imposition of sanctions under the Beneficiary Inducements CMP and section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Beneficiary Inducements CMP.

As OIG has previously emphasized, an unfavorable advisory opinion does not prohibit the party or parties to whom the advisory opinion is issued from carrying out the arrangement or proposed arrangement that is the subject of the advisory opinion.[1] Importantly, where an unfavorable opinion relates to the application of the Federal anti-kickback statute, it is not a determination by OIG that the arrangement violates the Federal anti-kickback statute. Any such determination would require an assessment of intent, and OIG does not opine on intent as part of the advisory opinion process.

This opinion may not be relied on by any person[2] 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 Drugs

Requestor is a publicly traded biotechnology company that offers gene therapies for severe genetic diseases. Relevant to the Proposed Arrangement:

- For the treatment of [redacted] ("Condition A"), Requestor has obtained approval from the U.S. Food and Drug Administration ("FDA") for the use of [redacted] ("Drug A") as a gene therapy treatment that works by enabling the formation of normal red blood cells, with the goal of achieving transfusion independence in

[1] OIG, Advisory Opinion FAQs, https://oig.hhs.gov/faqs/advisory-opinion-faqs/.

[2] 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.

patients who require regular blood transfusions.[3] Requestor certified that Drug A is a one-time, potentially curative treatment for Condition A.[4]

- For the treatment of [redacted] ("Condition B"), Requestor has obtained FDA approval for [redacted] ("Drug B") as a gene therapy treatment that works to stabilize the disease by preventing [redacted], with the goal of achieving major functional disability-free survival.[5] Requestor certified that Drug B is a one-time treatment which is believed to slow or prevent further progression of the disease.

The list price of each of Drug A and Drug B (individually, each of Drug A and Drug B is referred to as a "Drug," and collectively, Drug A and Drug B are referred to as the "Drugs") is above $2 million. As discussed further below, the use of the Drugs also carries a risk of serious potential side effects. There is one alternative gene therapy treatment to Drug A; there are no alternative gene therapy treatments to Drug B. The only established, curative treatment for Condition A and Condition B is hematopoietic stem cell transplant; however, the availability of stem cell donors is limited. Chemotherapy-based myeloablative conditioning ("Conditioning") is required for hematopoietic stem cell transplant.[6]

To be treated with either Drug, there are multiple stages of treatment:

- Initial Consultation. The patient must undergo an initial consultation with a physician at an approved hospital treatment center ("Treatment Center") to determine eligibility for treatment with either of the Drugs. To the extent a physician determines treatment with one of the Drugs is medically necessary, and the patient (or the patient's caregiver(s)) elects to move forward with such treatment, a physician at the Treatment Center prescribes Drug A or Drug B, as applicable, to the patient. The patient then undergoes mobilization and apheresis (as described below) and, as appropriate, the remaining stages of treatment with the Drug at the Treatment Center.

  A patient may need more than one consultation to determine eligibility for one of the Drugs. The consultation or consultations occur with a treating physician at a Treatment Center, who evaluates a patient's eligibility for gene therapy and subsequently oversees the patient's entire treatment program. The treating physician: (i) determines whether the patient is medically eligible to proceed with the gene therapy administration; (ii) oversees the patient's treatment for administration of the gene therapy; and (iii) manages the patient's medical care throughout treatment and recovery, in consultation with a Treatment Center's care

[3] [Redacted]

[4] [Redacted]

[5] [Redacted]

[6] As discussed further below, Conditioning can result in significant side effects and late-effect complications, including infertility.

team. As described further below, and by virtue of the fact that there will be a limited number of Treatment Centers that provide treatment with the Drugs, there also will be a limited number of physicians who can administer the Drugs.

- Mobilization and Apheresis. The patient's stem cells are mobilized and collected over the course of approximately 1 week at the Treatment Center.

- Creation of the Drugs. The therapies use lentiviral vectors to introduce functional copies of the gene into the patient's stem cells, creating the gene therapy drug product.

- Conditioning. Patients undergo Conditioning, which destroys existing stem cells to accommodate the modified cells. Conditioning can result in significant acute side effects, including severe cytopenia, stomatitis, infection, gastrointestinal complications, end-organ complications, and—particularly relevant to this advisory opinion—late-effect complications, including infertility due to gonadal damage in both males and females.

- Infusion/Hospital Stay. The Drugs' FDA-approved labels ("Drug Labels") indicate that patients are required to stay in the Treatment Center for approximately 3 to 6 weeks after infusion with Drug A, and for up to approximately 2 months after infusion with Drug B. The Drug Labels require the patient to remain in the Treatment Center for this extended period of time so that the patient's health care team can closely monitor the patient's recovery.

The Drugs are available only at a limited number of Treatment Centers that have the expertise to treat the patient's underlying disease and administer gene therapies.[7] Requestor has developed instructions for safely performing apheresis and administering the Drugs and qualifies and trains Treatment Centers consistent with such instructions. According to Requestor, only centers that successfully complete such training may be qualified as Treatment Centers. In selecting Treatment Centers, Requestor applies objective criteria as it assesses a facility's expertise and experience with treating patients with the disease in question, administration of cell and gene therapies, and the performance of hematopoietic stem cell transplants. In particular, Requestor evaluates potential Treatment Centers using the following criteria: (i) the facility's quality controls to manage inventory as well as to prevent contamination and exposure to communicable disease agents; (ii) the procedures in place at the facility for cleaning and sanitation to prevent contamination of products; (iii) access to emergency care for patients; (iv) qualified and trained staff to perform stem cell collection activities and patient care at the facility; (v) policies and procedures for patient screening, testing, stem cell collection, and management of reactions and adverse events; (vi) compliance with applicable FDA regulations, including FDA Good Manufacturing Practice and FDA Good Tissue Practice regulations; and (vii) compliance with applicable standards of the Foundation for the Accreditation of Cellular Therapy. Requestor also

[7] There are 50 Treatment Centers currently available to provide Drug A. There are six Treatment Centers currently available to provide Drug B.

conducts quality and technical assessments to verify that a prospective Treatment Center can meet Requestor's requirements for stem cell collection and infusion of the Drugs.

Requestor certified that a Treatment Center's expected or actual use of the Drugs would not affect the Treatment Center's ability to qualify as, or remain, a Treatment Center, nor would it affect whether Requestor recommends the Treatment Center to any patients or providers. 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.

B. The Proposed Arrangement

Under the Proposed Arrangement, Requestor would provide two categories of support: Travel Support and Fertility Support. The Travel Support and Fertility Support are two independent forms of support that Requestor would offer to all eligible patients under the Proposed Arrangement. Requestor would offer one type of support even if a patient did not meet the eligibility requirements for the other type of support. Requestor certified that it would not require that a treating physician or Treatment Center exclusively use the Drugs in order to be eligible to offer the Travel Support or Fertility Support to patients.

1. Travel Support

Under the Proposed Arrangement, Requestor would offer Travel Support to patients, including Federal health care program enrollees: (i) whose household income is at or below 600 percent of the Federal Poverty Level ("FPL"); (ii) who meet program distance requirements, as described further below; (iii) who state that they have explored and exhausted any assistance for travel, lodging, and associated expenses that may be covered by their insurer or be available through the Treatment Center; and (iv) who either have (a) a consultation appointment to determine gene therapy eligibility, or (b) an on-label prescription for one of the Drugs. The Travel Support would consist of the following for one patient and one caregiver for patients aged 26 and older and one patient and two caregivers for patients under 26 years of age:

- Airfare or Ground Transportation. Requestor would cover round-trip airfare for the consultation, apheresis, and Treatment Center hospital admission for patients and caregivers living more than 300 miles away from the nearest Treatment Center that accepts the patient's insurance. Requestor's airfare-related assistance would be limited to coach/economy seating and up to two luggage pieces per passenger. In addition, Requestor would cover ground transportation costs for patients and caregivers living between 100 miles (or 2 hours driving distance) and 300 miles away from the nearest Treatment Center that accepts the patient's insurance.

- Lodging. Requestor would cover lodging costs incurred during the initial consultation, apheresis, and hospital admission stages of treatment. Requestor would cover one room at a modest hotel for patients and caregivers living more than 100 miles or 2 hours driving distance from the nearest Treatment Center that accepts the patient's insurance.

- Associated Expenses During Treatment Center Stay. Requestor would provide a per diem allowance to patients and caregivers, up to $50 per person, per day, to cover actually incurred costs for meals, parking, and local transportation during the patient's gene therapy treatment, for patients and caregivers living more than 100 miles or 2 hours driving distance from the nearest Treatment Center that accepts the patient's insurance (the "Allowance"). To receive the Allowance, patients or caregivers would be required to submit written receipts to Requestor (or its vendor) documenting expenses actually incurred by the caregivers.

The Travel Support would be implemented and administered by Requestor and a travel agency vendor. Requestor certified that it would not provide Travel Support for any expenses for which insurance, including Medicaid,[8] or Treatment Center support is available.[9] In cases where partial support is available through the patient's insurance, including Medicaid, the Treatment Center, or any other source, Requestor would limit its provision of Travel Support to items not covered by such third-party sources.

Requestor would not advertise the availability of Travel Support beyond providing Treatment Centers, potential referring physicians, and patients with a general overview of the patient support resources that would be available for qualifying patients. Requestor certified that it would not use its offer of Travel Support as a marketing tool to drive product selection, utilization, or referrals.

Requestor certified that providing the Travel Support to caregiver(s)—which is intended to enable the caregiver(s) to remain near the Treatment Center during a patient's treatment with a Drug—may positively impact the patient. According to Requestor, a caregiver's responsibilities with respect to the patient may vary with the patient's age but generally may include the following: oversight and coordination of medical care; appointment scheduling; discharge planning activities; and assisting with activities of daily living. Requestor provided data to illustrate that caregiver support can improve outcomes in patients receiving bone marrow transplants (which Requestor described as a treatment analogous to the Drugs because—like the

[8] 42 U.S.C. § 1396a(a)(4); see also 2021 Consolidated Appropriations Act, Pub. L. No. 116-260, § 209, 134 Stat. 1182, 2986-89 (2020); 42 C.F.R. § 431.53; 42 C.F.R. § 440.170.

[9] Requestor certified that it would perform a benefits investigation to identify available assistance from third-party sources, including State Medicaid programs, to ensure the Travel Support is limited to items not covered by third-party sources. We express no opinion regarding Requestor's proposal to utilize a benefits investigation to confirm that duplicate support would not be provided to patients eligible for Travel Support. In the event Requestor utilizes a benefits investigation to confirm that duplicate 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.

Drugs—bone marrow transplants require Conditioning and extended hospitalization).[10] Requestor certified that having caregivers present and available to patients undergoing treatment with the Drugs improves survival, patient outcomes, or both, based on the core similarities between the treatment experience of a bone marrow transplant and the Drugs.

2. Fertility Support

Under the Proposed Arrangement, Requestor would provide up to $22,500 in Fertility Support to each patient receiving treatment with one of the Drugs to cover some or all costs of specified fertility preservation procedures and storage. Requestor explained that the Fertility Support would assist patients who may otherwise forgo treatment to avoid the risk of infertility associated with the Conditioning required for treatment with either of the Drugs and their inability to afford fertility preservation services. The Fertility Support would be available to patients, including Federal health care program enrollees: (i) with household income at or below 600 percent of the FPL; (ii) who have an on-label prescription for either Drug; and (iii) who confirm that they have exhausted insurance coverage and any support for fertility preservation services that is offered by the Treatment Center or by the treating fertility specialist. Patients would be eligible to receive Fertility Support only one time but could pursue multiple cycles or attempts within the identified cost limit. Requestor stated that, in most states, Medicaid currently does not cover fertility preservation services, which may increase disparities in health equity. According to Requestor, the Fertility Support would be intended to ensure that a patient's treatment options with respect to the Drugs would not be narrowed by virtue of the patient's state of residence, employer, insurance coverage, or financial means.

The Fertility Support would be implemented and administered by Requestor with assistance from a third-party vendor. Requestor would determine if patients qualified for Fertility Support based on the established criteria. Should Requestor determine a patient is eligible, it would first attempt to confirm that no insurance coverage or Treatment Center support options are available, and then it would engage the patient, caregiver(s), or both to confirm that alternative support options have been exhausted. Requestor then would arrange Fertility Support for eligible patients.

Requestor would not advertise the availability of Fertility Support but would provide Treatment Centers, potential referring physicians, and patients with a general overview of the patient support resources that would be available for qualifying patients. Requestor certified that it would not use its offer of Fertility Support as a marketing tool to drive product selection, utilization, or referrals.

[10] Larry W. Foster et al., Survival of Patients who have Undergone Allogeneic Bone Marrow Transplantation: The Relative Importance of In-Hospital Lay Care-Partner Support, J. PSYCHOSOCIAL ONCOLOGY (May 2005).

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.[11] 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.[12] 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.[13] 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 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 Proposed Arrangement. Section 1128A(i)(6)(F) of the Act provides that, for purposes of the Beneficiary Inducements CMP, the

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

[12] Id.

[13] 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).

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 . . . .[14]

B. Analysis

1. Travel Support

a) Federal Anti-Kickback Statute

The Travel Support implicates the Federal anti-kickback statute in two ways. First, the proposed assistance for certain travel, lodging, meals, and associated expenses would constitute remuneration to patients—including Federal health care program enrollees—that may induce them to purchase the Drugs. Second, by enabling patients—including Federal health care program enrollees—and their caregiver(s) to travel to, and stay near, a Treatment Center that the patient may not otherwise have selected for treatment, the Travel Support would constitute remuneration to the Treatment Centers and the treating physicians in the form of the opportunity to earn fees related to administering the Drugs, which may induce Treatment Centers to recommend and physicians to order the Drugs. No safe harbor would apply to the streams of remuneration resulting from the Travel Support.

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

First, the Travel Support removes a barrier to accessing medically necessary care that is furnished by Treatment Centers. 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 Travel Support facilitates access to the Drugs for Federal health care program enrollees by subsidizing travel expenses the patients otherwise would not be able to afford, thereby allowing the patients to receive potentially curative treatment (i.e., Drug A) or treatment that is believed to slow or prevent further progression of the disease (i.e., Drug B).

Second, the Travel Support facilitates compliance with the Drug Labels' instructions for the patient to remain at a Treatment Center for an extended period of time (i.e., 3 to 6 weeks after infusion with Drug A, and for up to approximately 2 months after infusion with Drug B). An

[14] 42 C.F.R. § 1003.110 (defining "remuneration").

extended hospital stay after treatment with the Drugs is necessary so that the patient's health care team can monitor for potential complications, including severe cytopenia, stomatitis, infection, gastrointestinal complications, and end-organ complications. Moreover, while we acknowledge that certain elements of the Travel Support benefit the caregiver(s), it is possible that, without this support, certain caregivers may not be able to remain with the patients for an extended period of time, and Requestor provided information to support its assertion that caregiver support may have a positive impact on patient outcomes such that the Travel Support given to caregiver(s) under the Proposed Arrangement could ultimately benefit the patient.

Third, each of Drug A and Drug B is a one-time treatment, such that the Travel Support offered under the Proposed Arrangement differs from remuneration provided in connection with problematic seeding arrangements. The Travel Support is distinguishable from 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. Each of Drug A and Drug B is a one-time treatment that likely would not lead to additional referrals, mitigating the risk that the Travel Support would result in inappropriately increased costs to Federal health care programs in the future.

Finally, the Travel Support includes additional safeguards that mitigate the risk of fraud and abuse. For example, Requestor's certification that it will not authorize Travel Support for any expenses for which insurance (including Medicaid) or Treatment Center or third-party assistance is available contributes to our conclusion that the Travel Support poses a low risk of fraud and abuse under the Federal anti-kickback statute. Requestor also certified that it does not require either treating physicians or Treatment Centers to prescribe or use its Drugs exclusively. This certification reduces the risk of inappropriate steering or inappropriate utilization of the Drugs. Furthermore, Requestor certified that it will not use its offer of the Travel Support as a marketing tool to drive product selection, utilization, or referrals.

For the combination of reasons set forth above, we would not impose administrative sanctions under the Federal anti-kickback statute on Requestor in connection with the Travel Support.

b) 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 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 that recipients of the Travel Support could be induced to select.

The Travel Support constitutes remuneration to eligible patients, including State health care program beneficiaries. This remuneration, consisting of assistance for certain travel, lodging, meals, and associated expenses, is likely to influence patients to select a Treatment Center and a physician practicing at a Treatment Center over other providers and suppliers that are outside the Proposed Arrangement. 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 that are outside the Proposed Arrangement because, as Requestor certified, the Travel Support offered under the Proposed Arrangement enables the patient to travel to the Treatment Center to obtain the Drugs and enables the caregiver(s) to remain near the Treatment Center during a patient's treatment with the Drugs.

For the foregoing reasons, unless an exception applies, the Travel Support would generate prohibited remuneration under the Beneficiary Inducements CMP.

We conclude that the Travel Support 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 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 Drugs may create barriers to accessing treatment with the Drugs. First, there are a limited number of Treatment Centers, as only facilities that meet certain objective criteria may be qualified as Treatment Centers. Second, consistent with the Drug Labels, an extended inpatient stay at the Treatment Center is required (i.e., approximately 3 to 6 weeks for Drug A, and for up to approximately 2 months for Drug B) after infusion with the Drugs so that the patient's health care team can monitor for side effects. 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 the Drugs, and thus could improve a beneficiary's ability to obtain items and services payable by Medicare or Medicaid (when the Drugs are payable by Medicare or Medicaid).

Next, we must examine whether the Travel Support 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 Travel Support interferes with, or skews, clinical decision-making or raises patient safety or qualify-of-care concerns is sufficiently low. This is because the Travel Support is designed to increase patient safety by assuring adequate patient monitoring, consistent with the Drug Labels, following administration of the Drugs, so that the patient can timely access medical care in the event the patient experiences serious side effects from the Drugs. Second, the Travel Support is unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization because each Drug is a one-time treatment. Third, the Travel Support does not raise patient safety or quality-of-care concerns, as it is designed to increase patient safety by facilitating compliance with the safety protocols set forth on the Drug Labels. Therefore, we conclude that the Travel Support poses a low risk of harm and thus satisfies the Promotes Access to Care Exception to the Beneficiary Inducements CMP. The Travel Support thus does not generate prohibited remuneration under the Beneficiary Inducements CMP.

2. Fertility Support

As we explain in greater detail below, OIG has concluded that it lacks sufficient data to determine that the Proposed Arrangement, as it relates to Fertility Support, is sufficiently low risk to issue a favorable advisory opinion at this time.

We recognize that cell and gene therapies consist of an evolving field that holds significant promise for improving the health of patients, including Federal health care program enrollees. Indeed, we understand that cell and gene therapies, like the Drugs, can transform the lives of individuals living with Condition A and Condition B. The number of cell and gene therapies that are available in the marketplace is rapidly increasing; payors, clinicians, and other stakeholders are adapting to the proliferation of these innovative therapies (e.g., paying for and providing these treatments).[15] These treatments are novel, and much is yet unknown about them and optimal arrangements for ensuring appropriate access to them. This uncertainty makes it difficult to assess the risk of the Fertility Support and offer prospective immunity under our fraud and abuse authorities.

As these transformative therapies become available to patients and the marketplace for them evolves, we expect additional data to become available regarding the ability of Federal health care program enrollees to access these important treatments, as well as data regarding costs, benefits, risks, and outcomes of treatments. Illustratively, we expect additional data related to the provision of fertility services by a pharmaceutical manufacturer at no cost to Medicaid enrollees who receive gene therapy treatments from the Cell and Gene Therapy Access Model developed by the Center for Medicare and Medicaid Innovation ("Innovation Center") at the Centers for Medicare & Medicaid Services ("CMS").[16] As more data become available, we may consider them in future risk assessments regarding arrangements similar to the Fertility Support. Nothing in this opinion forecloses CMS from testing a model that includes fertility services through the Innovation Center, including through the Cell and Gene Therapy Access Model. Safe harbor protection is available for CMS-sponsored model arrangements and CMS-sponsored model patient incentives, as set forth at 42 C.F.R. § 1001.952(ii). Moreover, nothing in this opinion addresses fertility services that are covered by a Federal health care program and nothing in this opinion impacts arrangements for patients who are uninsured or have private insurance.

[15] See, e.g., Medicaid and CHIP Payment and Access Commission, Payment and Coverage of High-Cost Specialty Drugs Report from Technical Advisory Panel (Jan. 2021), https://www.macpac.gov/publication/payment-and-coverage-of-high-cost-specialty-drugs-report-from-technical-advisory-panel/.

[16] CMS, Cell and Gene Therapy (CGT) Access Model, https://www.cms.gov/priorities/innovation/innovation-models/cgt. While sickle cell disease is the initial focus of the model, CMS has indicated that additional cell and gene therapies for other diseases may be included in the model in the future.

a) Federal Anti-Kickback Statute

The Fertility Support would implicate the Federal anti-kickback statute in two ways. First, the Fertility Support would constitute remuneration to patients—including Federal health care program enrollees—that may induce them to purchase the Drugs. In particular, the Fertility Support would cover up to $22,500 in fertility preservation services, including sperm banking and egg freezing. Further, Requestor explained that the Fertility Support would assist patients who would otherwise forgo treatment because of the risk of infertility associated with Drug treatment and their inability to afford fertility services. If a reason a patient would not receive treatment with the Drugs is the patient's inability to pay the costs associated with fertility preservation services, then the Fertility Support would address that inability to pay for these costs and likely would influence the patient's purchasing decision in connection with the Drug. Consequently, the Fertility Support would be designed to remove a financial barrier so that eligible patients would purchase the Drugs. Second, the Fertility Support would constitute remuneration to the Treatment Centers and the treating physicians in the form of the opportunity to earn fees related to treatment with the Drugs (for patients—including Federal health care program enrollees—who otherwise would forgo treatment but for the Fertility Support), which could induce Treatment Centers to recommend the Drugs and physicians to order the Drugs, as opposed to competitor drugs or other clinically appropriate treatments. No safe harbor would apply to the streams of remuneration resulting from the Fertility Support.

As explained in greater detail above, in connection with the Fertility Support, OIG currently lacks data to evaluate the factors OIG considers when assessing the risk of fraud and abuse under the Federal anti-kickback statute (e.g., increased or decreased access to health care services; increased or decreased costs to Federal health care programs; improved or worsened patient outcomes; competitive effects; and the risk of improper steering) and without such data, OIG cannot conclude at this time that the Fertility Support would pose a sufficiently low risk of fraud and abuse under the Federal anti-kickback statute to grant prospective immunity. OIG's conclusion regarding the Fertility Support does not impose any obligations on Requestor. This conclusion also is not a determination by OIG that the Fertility Support would violate the Federal anti-kickback statute; it simply means that, in an exercise of its enforcement discretion, OIG declines to offer prospective immunity—through a favorable advisory opinion—to the Fertility Support offered under the Proposed Arrangement.

b) Beneficiary Inducements CMP

Under the Beneficiary Inducements CMP, we analyze whether Requestor knows or should know that the Fertility Support would be 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 that recipients of the Fertility Support could be induced to select.

Requestor's offer of the Fertility Support valued at up to $22,500 constitutes remuneration to eligible patients, including State health care program beneficiaries. This valuable remuneration is likely to influence patients and 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 that are outside the Proposed Arrangement because, as Requestor certified, the Fertility Support offered under the Proposed Arrangement would assist patients who would otherwise forgo treatment because of the risk of infertility associated with the Drugs and their inability to afford fertility services. For the foregoing reasons, unless an exception applies, the Fertility Support would generate prohibited remuneration under the Beneficiary Inducements CMP.

At this time, we conclude that neither the Promotes Access to Care Exception nor any other exception would be available to protect the Fertility Support. We reach this conclusion because we lack data that would allow us to determine that providing the Fertility Support to eligible patients improves the ability of patients to access the Drugs. It is possible that with time such data may become available and OIG could potentially make the determination that the Fertility Support would constitute "[i]tems or services that improve a beneficiary's ability to obtain items and services payable by Medicare or Medicaid" for the purposes of the Promotes Access to Care Exception. However, due to the lack of available data, we cannot conclude that the Fertility Support would improve the patient's ability to obtain Federally reimbursable items or services for the purposes of this exception.[17]

No other exception to the Beneficiary Inducements CMP applies and the Fertility Support would generate prohibited remuneration under the Beneficiary Inducements CMP. There is no exception that unconditionally protects the offer or provision of remuneration to individuals with financial need. We have long emphasized that "there is no meaningful statutory basis for a broad exemption based on the financial need of a category of patients . . . [and] that categorical financial need is not a sufficient basis for permitting valuable gifts."[18] The financial need requirement here similarly does not resolve the lack of data available to OIG to appropriately assess the fraud and abuse risks of the Fertility Support.

III. CONCLUSION

Relative to the Travel Support, based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, as well as certain publicly available information, we conclude that: (i) although the Travel Support 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 Travel Support 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 Travel Support does not generate prohibited remuneration under the Beneficiary Inducements CMP.

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[17] As with any exception to the Beneficiary Inducements CMP, one element of an exception is not more important than any other element; all must squarely be satisfied to meet the applicable exception.

[18] OIG, Special Advisory Bulletin: Offering Gifts and Other Inducements to Beneficiaries (2002), http://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf.

With respect to the Fertility Support, based on the relevant facts certified in your request for an advisory opinion and supplemental submissions and the limited data available regarding, for example, the impact of Fertility Support on access to health care services; costs to Federal health care programs; patient outcomes; competition; and the risk of improper steering, we conclude that the Fertility Support, if undertaken: (i) would generate—if the requisite intent were present—prohibited remuneration under the Federal anti-kickback statute, which would constitute grounds for the imposition of sanctions under sections 1128A(a)(7) and section 1128(b)(7) of the Act; and (ii) would generate prohibited remuneration under the Beneficiary Inducements CMP, which would constitute grounds for the imposition of sanctions under the Beneficiary Inducements CMP and section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Beneficiary Inducements CMP.

As OIG has previously emphasized, an unfavorable advisory opinion does not prohibit the party or parties to whom the advisory opinion is issued from carrying out the arrangement or proposed arrangement that is the subject of the advisory opinion. Importantly, where an unfavorable opinion relates to the application of the Federal anti-kickback statute, it is not a determination by OIG that the arrangement violates the Federal anti-kickback statute. Any such determination would require an assessment of intent, and OIG does not opine on intent as part of the advisory opinion process.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is limited in scope to the Proposed Arrangement and has no applicability to any other arrangements that may have been disclosed or referenced in your request for an advisory opinion or supplemental submissions.

- This advisory opinion is issued only to Requestor. This advisory opinion has no application to, and cannot be relied upon by, any other person.

- This advisory opinion may not be introduced into evidence by a person other than Requestor to prove that the person did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.

- This advisory opinion applies only to the statutory provisions specifically addressed in the analysis above. We express no opinion herein with respect to the application of any other Federal, State, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Proposed Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act (or that provision's application to the Medicaid program at section 1903(s) of the Act).

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- We express no opinion herein regarding the liability of any person under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008. 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.

With respect to the Travel Support, OIG will not proceed against Requestor with respect to any action that is part of the Travel Support 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 Travel Support in practice comports with the information provided. 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 Travel Support 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