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: June 27, 2025

Posted: July 2, 2025

[Address block redacted]

Re: OIG Advisory Opinion No. 25-06 (Favorable)

Dear [redacted]:

The Office of Inspector General ("OIG") is writing in response to your request for an advisory opinion on behalf of [redacted] ("Requestor"), regarding assistance for certain travel, lodging, and associated expenses for qualifying patients receiving the autologous hematopoietic stem-cell based gene therapy [redacted] (the "Product") manufactured by Requestor (the "Arrangement"). Specifically, you have inquired whether the Arrangement constitutes grounds for the imposition of sanctions under: the civil monetary penalty provision at section 1128A(a)(7) of the Social Security Act (the "Act"), as that section relates to the commission of acts described in section 1128B(b) of the Act (the "Federal anti-kickback statute"); the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Act (the "Beneficiary Inducements CMP"); or the exclusion authority at section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute and the Beneficiary Inducements CMP.

Requestor has certified that all of the information provided in the request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties in connection with the Arrangement. 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. This opinion is limited to the relevant facts Requestor presented to us, which we have not independently investigated, and the other publicly available information we reviewed in connection with our assessment of the Arrangement. This opinion is limited to the relevant facts presented to us by Requestor in connection with the Arrangement. If material facts have not been disclosed, have been misrepresented, or change, then this opinion is without force and effect.

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) although the Arrangement would generate—if the requisite

intent were present—prohibited remuneration under the Federal anti-kickback statute, OIG will not impose administrative sanctions on Requestor in connection with the Arrangement under sections 1128A(a)(7) or 1128(b)(7) of the Act, as those sections relate to the commission of acts described in the Federal anti-kickback statute; and (ii) the Arrangement does not generate prohibited remuneration under the Beneficiary Inducements CMP.

This opinion may not be relied on by any person[1] other than Requestor and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. The Product and Treatment Centers

Requestor is a pharmaceutical manufacturer that offers gene therapies for severe genetic diseases. Relevant to the Arrangement, on [redacted], the U.S. Food and Drug Administration (the "FDA") approved the Product for the treatment of children with [redacted] who are: (1) pre-symptomatic late infantile (i.e., age of onset less than or equal to 30 months); (2) pre-symptomatic early juvenile (i.e., age of onset between 30 months and 7 years); and (3) early-symptomatic early juvenile (i.e., age of onset between 30 months and 7 years).[2] These three types of the disease are commonly referred to collectively as early-onset [redacted] (the "Disease").

The Disease affects approximately 1 in 100,000 live births, which is estimated to be fewer than 40 children annually in the United States. The Disease is caused by a mutation in the gene responsible for encoding the enzyme [redacted]. This gene mutation results in toxic [redacted] accumulation in the body, which among other things, damages the myelin sheath that protects the nerve cells in the brain, spinal cord, and peripheral nerves, leading to a loss of motor and cognitive functions and early death. According to Requestor, without treatment, patients with the Disease will not survive. The mean age at death is 4.2 years for patients with late infantile [redacted] and 17.4 years for patients with juvenile (i.e., pre-symptomatic early juvenile and early-symptomatic early juvenile) [redacted].[3] According to Requestor, the current standard of care is supportive care focused on symptomatic relief (e.g., managing muscle spasms, infections, and seizures; pain relief or sedative drugs; feeding support; psychological and social support; genetic advice and planning; and end-of-life care).

The Product—a one-time lentiviral gene therapy—has shown the potential to restore enzymatic function to stop or slow Disease progression. The Product's wholesale acquisition cost is over $4 million. There is no other FDA-approved treatment for the Disease.

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[1] We use "person" herein to include persons, as referenced in the Federal anti-kickback statute and Beneficiary Inducements CMP, as well as individuals and entities, as referenced in the exclusion authority at section 1128(b)(7) of the Act.

[2] [redacted]

[3] Id.

There are multiple treatment stages for patients with the Disease who are treated with the Product:

- Initial Consultation and Care Management. The patient must undergo one or more consultations with a physician at an approved hospital treatment center ("Treatment Center") to determine eligibility for treatment with the Product. When a physician determines that treatment with the Product is medically necessary and the patient's caregiver(s) (because all patients will be under the age of 18) elects to move forward with such treatment, then a physician at the Treatment Center prescribes the Product for the patient and subsequently oversees the patient's entire treatment program. In addition to determining eligibility and overseeing treatment, the treating physician manages the patient's medical care throughout treatment and recovery, in consultation with a Treatment Center's care team. There will be a limited number of Treatment Centers that provide treatment with the Product; consequently, there also will be a limited number of physicians who can administer the Product. Requestor anticipates that Treatment Centers will treat approximately 10 patients with the Disease with the Product per year. This number would increase if state newborn screening programs are updated to include screening for [redacted].

- Blood Transfusions. The patient may undergo red blood cell transfusions prior to the next step of mobilization and apheresis.

- Mobilization and Apheresis. The patient's stem cells are mobilized and collected over the course of approximately 1 week at the Treatment Center.[4] More than one round of mobilization and apheresis may be needed to collect enough cells to manufacture a sufficient dose of the Product.

- Creation of the Product. The Product is made specifically for each patient using the patient's own blood stem cells that are modified.

- Conditioning. Patients undergo chemotherapy-based fully-myeloablative conditioning ("Conditioning") prior to treatment with the Product, which clears existing blood stem cells from the bone marrow so they can be replaced with the modified cells. Conditioning can result in significant acute side effects, including, but not limited to, neutropenia, thrombocytopenia, leukopenia, anemia, and lymphopenia.

- Infusion/Recovery. Patients are infused with the Product. Physicians, in exercising their clinical judgment, may determine that an extended hospital stay after treatment with the Product is necessary so that the patient's health care team can closely monitor the patient's recovery. Physicians, in exercising their clinical judgment, may direct patients to remain in the Treatment Center for 4 to 8 weeks so that the patient's health

[4] Mobilization refers to the process by which hematopoietic stem cells are stimulated out of the bone marrow and into the bloodstream. Apheresis is the procedure that extracts the patient's blood and separates the stem cells from the plasma.

care team can monitor for potential complications.[5] The use of the Product carries a risk of serious potential complications, including: (i) delayed platelet engraftment; (ii) neutrophil engraftment failure; and (iii) hypersensitivity reactions. During the recovery phase of treatment, the patient's health care provider monitors: (i) absolute neutrophil counts to manage infections since neutropenia places patients at high risk for infection; and (ii) hypersensitivity reactions during and after infusion.

Requestor has begun to qualify Treatment Centers; Requestor plans to qualify a total of up to 10 Treatment Centers, based on several objective criteria, including, but not limited to:

- Whether the health care providers at the hospital are highly experienced, recognized clinical experts or well-published key opinion leaders ("KOLs") in the respective specialty for the Disease;
- The experience health care providers at the hospital have with Disease-specific hematopoietic stem cell transplantation and whether they are considered KOLs with respect to such subject matter;
- The number of bone marrow transplants that the hospital conducts annually and its maximum capacity;
- The support the hospital offers for the patient and family in managing travel and local accommodations;
- Whether the hospital has social workers, case workers, and psychosocial support for families;
- The hospital's current practice for accepting out-of-state Medicaid payment;
- Whether the hospital's current freezer configuration can accommodate the Product;
- Whether the hospital has cryo-thawing experience; and
- The ability of hospital personnel to work cross-functionally to manage and treat patients with the Disease.

Requestor certified that a Treatment Center's expected or actual use of the Product does not affect a facility's ability to qualify as or remain a Treatment Center. Furthermore, Requestor does not recommend any particular Treatment Center to patients or providers. Requestor informs health care providers about the Treatment Centers through information on a website and through educational materials shared with health care providers that have been reviewed and approved by Requestor's materials review process.

[5] See UCSF Benioff Children's Hospital, "The Hospital Stay After a Pediatric Bone Marrow Transplant," https://www.ucsfbenioffchildrens.org/education/the-hospital-stay-after-a-pediatric-bone-marrow-transplant; Children's Hospital of Pennsylvania, "Blood and Marrow Transplant Process," https://www.chop.edu/centers-programs/blood-and-marrow-transplant-program/transplant-process; Texas Children's Hospital, "Preparing for Discharge After Stem Cell Transplant," https://www.texaschildrens.org/content/conditions/preparing-for-discharge-after-stem-cell-transplant.

B. The Arrangement

Requestor offers the Arrangement to patients, including Federal health care program enrollees: (i) who are residents of the United States or a U.S. Territory; (ii) whose income is below 600 percent of the Federal Poverty Level ("FPL"); (iii) who meet program distance requirements, as described further below; (iv) who do not receive any assistance for travel, lodging, or associated expenses from their insurer, the Treatment Center, or a third-party charitable organization; and (v) who have an on-label prescription for the Product. Requestor offers the Arrangement to patients during the following phases of treatment: (i) mobilization and apheresis, (ii) conditioning, (iii) infusion, and (iv) recovery. Requestor utilizes a patient support program vendor (the "Vendor") that assesses patient eligibility for the Arrangement and assists in administering the Arrangement. The Arrangement, consisting of the following, is offered to one patient and up to two caregivers:

- Airfare or Ground Transportation. Requestor covers: (i) ground transportation and reimbursement for mileage driven in the caregiver's car (for distances greater than 100 miles or 2 hours of driving time); or (ii) airfare or train fare (for patients who live more than 300 miles away from the closest Treatment Center that is accepting new patients and that accepts the patient's insurance). When airfare is provided, Requestor covers a round-trip flight in economy class for the patient and caregiver(s).

- Lodging. Requestor covers one room at a modest hotel for patients and caregiver(s) living greater than 100 miles or 2 hours driving distance from the closest Treatment Center that is accepting new patients and that accepts the patient's insurance.

- Other Support During Treatment Center Stay. Requestor provides a daily amount up to the current "meals and incidentals" per diem established by the U.S. General Services Administration for the locality in which the Treatment Center is located.[6] To receive this per diem support for meals and incidental expenses, patients and caregivers are required to submit receipts to Requestor (either in writing or electronically), documenting authorized expenses actually incurred by the patient or caregiver(s).

Requestor certified that it does not provide the Arrangement when insurance (e.g., Medicaid or Medicaid managed care),[7] Treatment Center, or third-party charitable assistance is available. If the patient's insurer, Treatment Center, or any charity provides some financial assistance with travel and lodging, Requestor will supplement what the insurer, Treatment Center, or charity does not cover. Requestor certified that it requires caregivers and the Vendor to agree that they will not bill the costs of the Arrangement to any Federal health care program.

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[6] FY 2025 Per Diem Highlights, U.S. Gen. Servs. Admin. (Oct. 2024), https://www.gsa.gov/travel/plan-a-trip/per-diem-rates/fy-2025-per-diem-highlights; see also 41 C.F.R. § 300-3.1.

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

Requestor provides patients and their caregiver(s) with an enrollment form for the caregiver(s) to complete to assist the Vendor with determining a patient's eligibility for the Arrangement. Requestor certified that it requires caregivers to provide information about the patient's household income, health insurance (including Federal health care program participation), diagnosis, and treating physician. The Vendor conducts a detailed benefits investigation to verify whether the patient has any existing insurance coverage for travel and lodging expenses, including coverage from any commercial insurance plan or Federal health care program. The Vendor does not rely on the caregivers' attestation regarding lack of any such coverage.[8] In addition, the Vendor completes an income verification to confirm that the patient's household income is below 600 percent of the FPL.

If the Vendor confirms that the patient is eligible to participate in the Arrangement, then Requestor notifies the patient's caregiver(s) of the patient's eligibility. Requestor provides such assistance for 1 week for each mobilization and apheresis phase (if more than one is necessary to manufacturer the Product) and up to 8 weeks for the conditioning, infusion, and recovery phases; however, if the patient's physician determines that a longer period is required to harvest a sufficient quantity of stem cells to manufacture the Product or that it is medically necessary to monitor the patient for more than 8 weeks after Product administration, then Requestor will provide assistance for the duration deemed medically necessary by the physician. The recovery phase of treatment allows the patient's care team at the Treatment Center to monitor for engraftment of the modified cells and for any other adverse events.

Requestor certified that caregivers are required to provide receipts for all qualified out-of-pocket expenses, including food, parking, gas, taxis, and rideshare services. Requestor requires caregivers to submit receipts within 10 business days of the date the patient (or caregiver(s)) incur(s) a particular expense. Upon receipt, the Vendor reviews the receipts to identify any prohibited purchases and reimburses the caregiver(s) in the amounts authorized by Requestor following its expense verification process.

Requestor does not promote the Arrangement to physicians or caregivers as a reason to prescribe the Product. Requestor's field-based employees provide non-promotional information about the Arrangement (e.g., patient eligibility criteria, terms, and conditions) using materials and messages approved by Requestor's internal review procedures. Requestor may include on its website (for health care providers and for patients) a reference that some patients may be eligible for travel and lodging assistance.

[8] We express no opinion regarding Requestor's use of a benefits investigation to confirm that duplicate support is not provided to patients eligible for the Arrangement. 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.

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.[9] 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.[10] 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.[11] 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 Arrangement. Section 1128A(i)(6)(F) of the Act provides that, for purposes of the Beneficiary

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

[10] Id.

[11] 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).

Inducements CMP, the term "remuneration" does not include "remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs (as defined in section 1128B(f) and designated by the Secretary under regulations)" (the "Promotes Access to Care Exception"). We have interpreted this provision to apply to:

> [i]tems or services that improve a beneficiary's ability to obtain items and services payable by Medicare or Medicaid, and pose a low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs by—(i) [b]eing unlikely to interfere with, or skew, clinical decision making; (ii) [b]eing unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (iii) [n]ot raising patient safety or quality-of-care concerns….[12]

B. Analysis

1. Federal Anti-Kickback Statute

The Arrangement implicates the Federal anti-kickback statute in two ways. First, the assistance for certain travel, lodging, and associated expenses constitutes remuneration to patients—including Federal health care program enrollees—that may induce them to purchase the Product. 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 Arrangement constitutes remuneration to the Treatment Centers and the treating physicians in the form of the opportunity to earn fees related to administering the Product, which may induce Treatment Centers to recommend, and physicians to order, the Product. No safe harbor applies to the streams of remuneration resulting from the Arrangement. However, for the combination of the following reasons, we believe the risk of fraud and abuse presented by the Arrangement is sufficiently low under the Federal anti-kickback statute for OIG to issue a favorable advisory opinion.

First, the Arrangement removes a barrier to accessing medically necessary care that is furnished by Treatment Centers. 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 that is accepting new patients and that accepts the patient's insurance. The Arrangement facilitates access to the Product 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 treatment that may stop or slow Disease progression.

Second, the Arrangement facilitates compliance with the instructions of the health care provider for the patient to remain at a Treatment Center for an extended period of time. Physicians, in exercising their clinical judgment, may determine that an extended hospital stay (i.e., 4 to 8 weeks) after treatment with the Product is necessary so that the patient's health care team can monitor for potential complications, including: (i) delayed platelet engraftment; (ii) neutrophil engraftment failure; and (iii) hypersensitivity reactions.

[12] 42 C.F.R. § 1003.110 (defining "remuneration").

Moreover, while we acknowledge that certain elements of the Arrangement benefit the caregiver(s), it is possible that, without this support, caregivers may not be able to remain with the patients for an extended period of time. Because the patients are all under the age of 18 years, caregiver support is necessary.

Third, the Product is a one-time treatment, such that the Arrangement differs from remuneration provided in connection with problematic seeding arrangements. The Arrangement 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. The Product is a one-time treatment that likely would not lead to additional referrals after treatment with the Product has ended, mitigating the risk that the Arrangement would result in inappropriately increased costs to Federal health care programs in the future.

Finally, the Arrangement includes additional safeguards that mitigate the risk of fraud and abuse. For example, Requestor's certification that it does not authorize the Arrangement for any expenses for which insurance (including Medicaid) or Treatment Center or third-party charitable assistance is available contributes to our conclusion that the Arrangement poses a low risk of fraud and abuse under the Federal anti-kickback statute. Furthermore, Requestor certified that it does not promote the Arrangement to physicians or caregivers as a reason to prescribe the Product.

2. Beneficiary Inducements CMP

Under the Beneficiary Inducements CMP, we must analyze whether Requestor knows or should know that the financial support it provides for travel, lodging, and associated expenses under the Arrangement is likely to influence a beneficiary's selection of a particular provider, practitioner, or supplier for the order or receipt of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program. The facts here implicate the Beneficiary Inducements CMP because Treatment Centers and physicians practicing at Treatment Centers are providers and suppliers that recipients of assistance under the Arrangement could be induced to select.

The Arrangement constitutes remuneration to eligible patients, including State health care program beneficiaries. We conclude that this remuneration likely would influence a beneficiary to select a particular Treatment Center that the beneficiary otherwise may not have selected to receive federally reimbursable items and services. Unless an exception applies, the Arrangement would generate prohibited remuneration under the Beneficiary Inducements CMP.

We conclude that the Arrangement satisfies the Promotes Access to Care Exception to the Beneficiary Inducements CMP. To reach this conclusion, we first must examine whether the remuneration that is offered under the Arrangement improves a beneficiary's ability to obtain items and services payable by Medicare or Medicaid. As noted above, several factors necessary for the safe administration of the Product may create barriers to accessing treatment with the Product. First, there are a limited number of Treatment Centers, as only facilities that meet certain objective criteria may be qualified as Treatment Centers. Second, an extended

inpatient stay (i.e., 4 to 8 weeks) at the Treatment Center may be necessary after infusion with the Product 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, and associated expenses could remove or reduce potential financial and geographic barriers to receiving the Product and thus could improve a beneficiary's ability to obtain items and services payable by Medicare or Medicaid (when the Product is payable by Medicare or Medicaid).

Next, we must examine whether the Arrangement poses a low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs. The Promotes Access to Care Exception to the Beneficiary Inducements CMP states that remuneration poses a low risk of harm if it: (i) is unlikely to interfere with, or skew, clinical decision-making; (ii) is unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (iii) does not raise patient safety or quality-of-care concerns. First, the risk that the Arrangement interferes with, or skews, clinical decision-making is sufficiently low. While the Arrangement may enable a patient to safely access the Product, we believe the health care provider prescribing the Product would base clinical decision-making on the fact that the Product may stop or slow Disease progression. Second, the Arrangement is unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization because the Product is a one-time treatment that may stop or slow Disease progression, and the Arrangement is available only to patients who have an on-label prescription for the Product. Third, the Arrangement does not raise patient safety or quality-of-care concerns, as it is designed to increase patient safety by, for example, facilitating the patient's ability to remain near the Treatment Center so that the patient's health care provider can monitor the patient's recovery. Therefore, we conclude that the Arrangement poses a low risk of harm and satisfies the Promotes Access to Care Exception to the Beneficiary Inducements CMP. The Arrangement thus does not generate prohibited remuneration under the Beneficiary Inducements CMP.

III. CONCLUSION

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) although the Arrangement would generate—if the requisite intent were present—prohibited remuneration under the Federal anti-kickback statute, OIG will not impose administrative sanctions on Requestor in connection with the Arrangement under sections 1128A(a)(7) or 1128(b)(7) of the Act, as those sections relate to the commission of acts described in the Federal anti-kickback statute; and (ii) the Arrangement does not generate prohibited remuneration under the Beneficiary Inducements CMP.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

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

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

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

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

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

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

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

OIG will not proceed against Requestor with respect to any action that is part of the Arrangement taken in good-faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Arrangement in practice comports with the information provided. OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, OIG will not proceed against Requestor with respect to any action that is part of the Arrangement taken in good-faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to OIG.

Sincerely,

/Susan A. Edwards/

Susan A. Edwards
Assistant Inspector General for Legal Affairs