



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: February 17, 2023

Posted: February 23, 2023

[Address block redacted]

Re: OIG Advisory Opinion No. 23-01

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 financial assistance for transportation, lodging, and meals provided by Requestor to financially needy pediatric patients and their caregiver(s) in connection with treatment with Requestor’s drug (the “Arrangement”). Specifically, you have inquired whether the Arrangement constitutes grounds for the imposition of sanctions under: the civil monetary penalty provision at section 1128A(a)(7) of the Social Security Act (the “Act”), as that section relates to the commission of acts described in section 1128B(b) of the Act (the “Federal anti-kickback statute”); the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Act (the “Beneficiary Inducements CMP”); or the exclusion authority at section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute and the Beneficiary Inducements CMP.

Requestor has certified that all of the information provided in the request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties in connection with the Arrangement, and we have relied solely on the facts and information Requestor provided. We have not undertaken an independent investigation of the certified facts and information presented to us by Requestor. This opinion is limited to the relevant facts presented to us by Requestor in connection with the Arrangement. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

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

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

I. FACTUAL BACKGROUND

A. The Drug

Requestor developed [redacted] (the “Drug”), which is a regenerative tissue-based therapy that is indicated for immune reconstitution in pediatric patients with [redacted] (the “Condition”). The Condition is an ultra-rare primary immunodeficiency disorder that affects approximately 17 to 24 out of every 4 million children born each year in the United States. The Condition is characterized by the absence of a thymus at birth, which is an organ that plays an essential role in the development of T cells, a type of infection-fighting white blood cell. Newborn screening for severe combined immunodeficiency, a screening that is required nationwide, can identify possible cases of the Condition, which can then be confirmed by further testing.² Requestor certified that patients with the Condition have high health care utilization because their supportive care involves prolonged inpatient hospitalizations, frequent outpatient visits, home health care, significant diagnostic and monitoring testing, both treatment and prophylactic medications, and diagnostic and surgical procedures.³

Requestor certified that the Drug is a one-time, potentially curative treatment and the only treatment option available to rebuild the immune system of a patient diagnosed with the Condition.⁴ To make the Drug, Requestor first obtains donor thymus tissue from donors who are 9 months of age or younger and undergoing cardiac surgery. Next, Requestor aseptically

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 Specifically, the Prescribing Information for the Drug states that “[t]he diagnosis of [the Condition] was based on flow cytometry documenting fewer than 50 naïve T cells/mm³ (CD45RA⁺, CD62L⁺) in the peripheral blood or less than 5% of total T cells being naïve in phenotype in 91/95 patients (range 0-98 naïve T cells/mm³).” Package Insert — [Drug] at 15 (2021), [redacted].

³ Requestor certified that, in the first 3 years of life, the average total economic burden associated with supportive care for patients with the Condition is over \$5.5 million but can be as high as \$11.7 million.

⁴ Requestor anticipates that approximately 70 percent of patients seeking treatment with the Drug will have Medicaid coverage, and approximately 30 percent of patients will have commercial insurance. Requestor certified that it expects broad Medicaid coverage of the Drug through the inpatient hospital services benefit.

processes and cultures the thymus tissue for 12 to 21 days. The Drug is administered via surgical implantation in the thigh muscle of pediatric patients with the Condition.

The Drug can be administered only at [redacted] (the “Treatment Center”)⁵ by a qualified surgeon. The Drug has been investigated at the Treatment Center since 1993, and the Biologics License Application approval letter from the U.S. Food and Drug Administration (“FDA”) approved only a single manufacturing facility, which is located on the campus of the Treatment Center. Because the shelf life of the Drug after manufacturing is only 3 hours, it must be implanted in close proximity to the site of manufacturing.⁶ In preparation for administration of the Drug, patients typically travel to the region where the Treatment Center is located 5 to 11 days before implantation of the Drug for testing, clinical evaluations, and immunosuppressive therapy (as necessary).⁷ Requestor certified that the Treatment Center physicians and the patient’s referring physician determine the number of days that a particular patient should arrive before implantation based on the patient’s individual health condition, the possible need to administer immunosuppressants prior to Drug implantation, needed clinical evaluations, and the timing of the Drug manufacturing process. Absent any complications, patients typically remain inpatients at the Treatment Center for 2 to 7 days after Drug implantation to ensure that there is no wound infection and that proper healing occurs. After discharge, patients return to their communities and their local treatment providers monitor them. According to Requestor, immune reconstitution sufficient to protect from infection is unlikely to develop prior to 6 to 12 months after treatment with the Drug, and patients must continue to take strict precautions to prevent infections until then.

B. The Arrangement

Under the Arrangement, for patients who meet the eligibility criteria described below, Requestor offers assistance in the form of: (i) round-trip medical flights for the patient diagnosed with the Condition and up to two caregivers who accompany the patient on the flights; (ii) ground ambulance travel to and from the airport; (iii) modest lodging in a single hotel room with a private bathroom up to \$150 per night, if charitable housing is not available; and (iv) coverage for out-of-pocket expenses up to \$50 per day for one caregiver (or \$100 per day for two

⁵ Requestor does not own or operate, directly or indirectly, the Treatment Center, any pharmacies, pharmacy benefits management companies, or other entities that file claims for payment under the Medicare or Medicaid programs.

⁶ Specifically, Requestor certified that the FDA recognized that the limited distribution system involves manufacturing a single lot of the Drug and transporting it to the Treatment Center by foot to be implanted within 3 hours of manufacture. Requestor does not have—and would need—FDA approval to transport the Drug to other treatment facilities. Requestor has not asked us to opine on, and we express no opinion regarding, this manufacturing and distribution arrangement.

⁷ For example, the Drug Prescribing Information explains that some patients may require immunosuppressive therapy depending on the disease phenotype and the results of certain pre-procedure testing. Package Insert — [Drug] at 1, 17 (2021), [redacted].

caregivers) to cover ground transportation and meals while staying near the Treatment Center.⁸ Requestor certified that caregiver(s) pay out-of-pocket for their ground transportation and meals and submit receipts for reimbursement, and the hub, as described below, arranges and pays for lodging.

All patients with the Condition are at a high risk of infection, so limited safe travel methods are available; for example, patients with the Condition are unable to travel long distances safely by car or via commercial airlines, but they can travel safely by medical flight. According to Requestor, the medical flights under the Arrangement are considered non-emergency medical flights, are expensive, and often are not covered by insurance. However, Requestor also noted that Medicaid and some commercial insurance plans sometimes cover these types of non-emergency medical flights, and some plans also cover some lodging and other out-of-pocket expenses. Requestor certified that it has evaluated 10 medical flight vendors (and would continue to evaluate others in the future, if potential vendors are identified) to determine whether each vendor: (i) serves pediatric and medically fragile patients; (ii) provides non-charity flights and bills insurance if insurance reimbursement is available; (iii) has a national footprint and can fly patients who live across the United States to and from the Treatment Center; (iv) can fly patients with the Condition and up to two caregivers safely; (v) has flexible scheduling to allow rapid deployment of flights when the Drug becomes available for the patient; and (vi) has planes with isolation options for patients. Requestor certified that, in some cases, a medical flight might not be able to safely accommodate the patient and two caregivers due to the significant amount of medical equipment a particular patient may require and differences among medical flight planes' weight and space limitations. If two caregivers intend to accompany the patient to the Treatment Center and the medical flight can accommodate only one caregiver, either Requestor or the flight vendor pays for alternate transportation for the second caregiver. At present, two vendors meet Requestor's objective criteria and are willing to transport the patients under the Arrangement.

After a patient is diagnosed with the Condition, the patient's health care provider confirms with Requestor that treatment with the Drug would be medically appropriate, which allows the patient to enroll in Requestor's "hub." The hub handles eligibility screening and other administrative functions relating to the Arrangement; for example, the hub evaluates each patient, regardless of insurance status, for eligibility for the assistance offered under the Arrangement by applying the following criteria in a uniform and consistent manner. Specifically, the patient must: (i) have

⁸ Requestor noted that, in the rare event that the Drug manufacturing process is delayed or unsuccessful, the patient has medical complications, or travel is disrupted, any one of which could delay or prevent Drug implantation after the patient has arrived at the Treatment Center, either (i) the time that the patient and caregiver(s) need to be at or near the Treatment Center could be extended by a minimum of 13 days while a new lot is manufactured (assuming donor thymus tissue necessary to manufacture the new lot is available), or (ii) the patient and their caregiver(s) may need to return home and then travel back to the Treatment Center at a later date for implantation. In these circumstances, Requestor pays the new travel-related expenses under the same criteria applied for the initial travel plan, as re-evaluated for the new time of service (e.g., if the patient's insurer covered the first medical flight but denies coverage for a second flight, Requestor would consider the patient to have no insurance for the second medical flight).

been diagnosed with the Condition; (ii) reside in the United States or a Western Hemisphere United States territory within the service area of the medical flight vendors and be more than a 2-hour drive from the Treatment Center;⁹ and (iii) satisfy gross annual household income limits to demonstrate financial need.¹⁰ If the patient meets these eligibility requirements, the hub will arrange and pay for lodging near the Treatment Center and will provide the patient's caregiver(s) with the list of the approved flight vendors that are willing to provide the needed services.

The hub maintains written documentation describing eligibility requirements and procedures for evaluating and fulfilling requests for assistance, and it requires caregiver(s) to provide documentation of financial need. With respect to the medical flights and ground ambulance transportation, in order to receive financial assistance for these services under the Arrangement, patients must have either no insurance coverage or "insufficient" insurance coverage for these services. Requestor considers the coverage to be "insufficient" if: (i) absent Requestor paying for the medical flights and ground ambulance transportation to and from the airport in full, the out-of-pocket costs to the patient for the medical flights and ground ambulance transportation to and from the airport would be equal to or exceed 3 percent of the patient's gross annual household income; or (ii) the flight vendor is unable to seek reimbursement from the patient's state Medicaid program (e.g., the flight vendor does not participate in the state's Medicaid program). In situations where the insurance coverage is deemed "insufficient," Requestor pays the full cost of the transportation;¹¹ the patient's insurance, including Medicaid, is not billed for the service.

⁹ Requestor certified that any patient who lives more than 2 hours away from the Treatment Center and is otherwise eligible for the Arrangement is eligible for, but not required to take, a medical flight. The flight vendor arranges transportation, including both the medical flight and the ground ambulance transportation, to and from the Treatment Center. Decisions about the mode of transportation are made in conjunction with the patient's caregiver(s) and treating physician; Requestor does not control a flight vendor's decision. For example, a flight vendor, caregiver(s), and the treating physician could together choose to use a ground ambulance instead of medical flights for patients who live more than 2 hours from the Treatment Center but close enough that an ambulance might be a more economical option.

¹⁰ Requestor has characterized this advisory opinion request as involving two stages: Stage 1, which has been implemented, and Stage 2, which is proposed. The only difference between Stages 1 and 2 is that there is a single measure of financial eligibility for Stage 1 and differing measures of financial eligibility for Stage 2. In Stage 2, there would be three tiers of financial eligibility based on geographic distance from the Treatment Center to account for the increased cost of the medical flights at varying distances (i.e., families that live the farthest away from the Treatment Center would qualify for assistance with higher gross annual household incomes than families that live closer to the Treatment Center). For purposes of this advisory opinion, we are considering both stages to constitute the Arrangement.

¹¹ Requestor certified that the medical flights and ground ambulance transportation to and from the airport likely would be treated the same: either both or neither would be covered by insurance. However, if, for example, an insurer covered the ambulance transportation to and

If a patient has insurance coverage for the medical flight and ground ambulance transportation, the patient and the patient’s caregiver(s) still may be eligible for the other assistance offered under the Arrangement if the patient does not have insurance coverage that could cover these expenses and, in the case of lodging, no alternative charitable lodging is available. In other words, for any type of assistance that Requestor provides, eligibility is contingent on other sources of funding or coverage being unavailable (or, in the case of medical flights and ground ambulance transportation, coverage being unavailable or insufficient). If a charitable program covers part, but not all, of the lodging, ground transportation, or meals for caregiver(s), Requestor supplements the costs up to the daily limits set forth above.

Requestor certified that it will not shift costs of the Arrangement to Federal health care programs and has priced the Drug independently of the cost of the Arrangement. In addition, Requestor does not advertise the availability of assistance under the Arrangement, and Requestor certified that patients (or their caregiver(s)), flight vendors, and ground transportation vendors must agree not to request reimbursement from Federal health care programs for any costs covered by Requestor.

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.¹² 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.¹³ 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

from the airport but not the flight, then the insurer would be billed for the ambulance transportation unless the coverage was “insufficient” as defined above (i.e., if the patient’s remaining out-of-pocket cost were 3 percent or more of the patient’s gross annual household income, then Requestor would cover the full cost and not bill the insurer).

¹² Section 1128B(b) of the Act.

¹³ Id.

program.¹⁴ Violation of the statute constitutes a felony punishable by a maximum fine of \$100,000, imprisonment up to 10 years, or both. Conviction also will lead to exclusion from Federal health care programs, including Medicare and Medicaid. When a person commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such person under section 1128A(a)(7) of the Act. The OIG also may initiate administrative proceedings to exclude such person from Federal health care programs under section 1128(b)(7) of the Act.

2. Beneficiary Inducements CMP

The Beneficiary Inducements CMP provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration to a Medicare or State health care program beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier for the order or receipt of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program. The OIG also may initiate administrative proceedings to exclude such person from Federal health care programs. Section 1128A(i)(6) of the Act defines "remuneration" for purposes of the Beneficiary Inducements CMP as including "transfers of items or services for free or for other than fair market value."

B. Analysis

We must analyze whether the Arrangement implicates the Federal anti-kickback statute and, if it does, whether the risk of fraud and abuse presented by the Arrangement is sufficiently low under the Federal anti-kickback statute. We also must analyze whether, for purposes of the Beneficiary Inducements CMP, Requestor knows or should know that the remuneration it provides 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 reimbursed by Medicare or a State health care program.

1. Federal Anti-Kickback Statute

The Arrangement implicates the Federal anti-kickback statute in two ways. First, any combination of the free or subsidized transportation, lodging, and meal expenses constitutes remuneration from Requestor to patients, some of whom are Federal health care program beneficiaries, that may induce them to purchase the Drug and to receive other federally reimbursable items and services provided at the Treatment Center. Second, because patients receive assistance that facilitates their travel to and lodging near the Treatment Center, this assistance also could constitute remuneration to the Treatment Center and the treating surgeon in

¹⁴ 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).

the form of the opportunity to earn fees related to administering the Drug. No safe harbor applies to the Arrangement.

Generally, we are concerned that manufacturers that provide travel, lodging, and meal reimbursement amounts for patients who are prescribed their drugs could use such assistance 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 increases in costs to Federal health care programs. Although Requestor certified that it does not shift the Arrangement's costs to Federal health care programs, Requestor could increase the Drug's price to recoup costs related to the Arrangement, and such price increases could lead to increases in Federal health care program costs for the Drug. We also have concerns that arrangements to provide assistance with travel, lodging, and meals encourage manufacturers to compete for market share using the free items and services they provide to patients and referral sources and may create a barrier to entry for potential competitors. 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.

First, the Arrangement facilitates safe access to the Drug for a patient population that cannot travel long distances safely by car or via commercial airlines and that lack the financial resources to travel in a safe manner. The FDA has approved only a single manufacturing site, on the campus of the Treatment Center, for the Drug; because of the short shelf life of the Drug after manufacturing and the current FDA-approval status, it can be administered only at the Treatment Center. Because all patients with the Condition are at a high risk of infection, the safest way for patients to travel to the Treatment Center is via medical flights for air travel or via ambulance for ground transportation. In addition, the patients must stay near, or as an inpatient in, the Treatment Center for a total of 7 to 18 days, including time before and after the administration of the Drug. The out-of-pocket costs associated with the medical flights, ground ambulance transportation, and lodging could either (i) inhibit patients from receiving the Drug, which has the potential to help restore their immune system; or (ii) cause them to take means of transportation that are unsafe given their lack of a functioning immune system.

Second, the Drug is a one-time, potentially curative treatment, and it is the only treatment option available to rebuild the immune system of a patient diagnosed with the Condition. Therefore, the Arrangement is distinguishable from problematic seeding programs where a manufacturer provides remuneration to patients in connection with an initial dose of a drug to induce patients to continue purchasing the drug.

Third, the nature of the Condition and the Drug reduces the risk that the Arrangement would result in interference with clinical decision-making, overutilization, or inappropriate utilization. The Condition is identified through nationally required newborn screening and confirmed by additional laboratory testing, and it affects only 17 to 24 out of every 4 million children born each year in the United States. The Drug is made from thymus tissue that is obtained from donors who are 9 months of age or younger and who are undergoing cardiac surgery, and it then is aseptically processed and cultured for 12 to 21 days to produce the Drug; this is not a mass-produced Drug and does not appear to be subject to risks of inappropriate utilization. It is unlikely that the health care professional diagnosing the patient with the Condition and

prescribing the Drug will receive any financial benefit related to the procedure to implant the Drug because: (i) the Drug is manufactured and administered only in one location; (ii) the Arrangement is available only to patients who reside at least 2 hours away from the Treatment Center; and (iii) the Drug is implanted by a surgeon. Further, because the Condition affects so few children each year, it would be exceedingly rare that a doctor who practices at the Treatment Center would be the physician who diagnoses the patient with the Condition and prescribes the Drug.

Fourth, the Arrangement is unlikely to increase costs inappropriately to Federal health care programs. The Arrangement provides safe transportation and financial assistance with lodging and other costs associated with accessing the Drug. Because it is the only potentially curative treatment option, many (if not most) patients with the Condition might attempt to access the Drug even in the absence of the Arrangement. In addition, patients with the Condition have high health care needs, with an associated average total economic burden of over \$5.5 million—or significantly higher—in the first 3 years of life. Because the Drug is a one-time, potentially curative treatment that may rebuild the immune system of a patient diagnosed with the Condition, it ultimately has the potential to offset some of the costs that these patients might otherwise incur for their supportive care in the first 3 years of life and might continue to incur over time.

Fifth, patients must meet several criteria to be eligible for assistance under the Arrangement, including, for purposes of the medical flights and ground transportation, that the patient has either no insurance coverage or insufficient insurance coverage for those services. In addition, each element of this assistance is available under the Arrangement only if there is no other coverage option; if a patient has insurance coverage or charitable coverage for the medical flight, ground ambulance transportation, lodging, or meals, Requestor does not provide a duplicate benefit. For example, if a patient had insurance coverage for the medical flight but not for lodging, Requestor would assist with the latter but not the former. Similarly, if the patient had no insurance coverage (or insufficient coverage) for the medical flight but obtained charitable housing, Requestor would cover the flight but would not provide funding for lodging.

Finally, we conclude that the remuneration that Requestor provides to patients to facilitate access to the Drug at the Treatment Center, which gives the Treatment Center the opportunity to earn fees related to implanting the Drug, is sufficiently low risk under the Federal anti-kickback statute in the context of the Arrangement. We reach this conclusion for the combination of reasons described above, and particularly because the Drug’s current FDA-approval status requires that all patients prescribed the Drug must obtain it from the Treatment Center, regardless of the Arrangement.

2. Beneficiary Inducements CMP

We also must analyze whether Requestor knows or should know that the remuneration it provides 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. A pharmaceutical manufacturer such as Requestor is not a “provider, practitioner, or supplier” for

purposes of the Beneficiary Inducements CMP unless it also owns or operates, directly or indirectly, pharmacies, pharmacy benefits management companies, or other entities that file claims for payment under the Medicare or Medicaid programs. Because Requestor does not own or operate, directly or indirectly, any pharmacies, pharmacy benefits management companies, or other entities that file claims for payment under the Medicare or Medicaid programs, Requestor is not a provider, practitioner, or supplier for purposes of the Beneficiary Inducements CMP.

Notwithstanding this fact, remuneration offered by a pharmaceutical manufacturer to a beneficiary that the manufacturer knows or should know is likely to influence the beneficiary to select a particular provider, practitioner, or supplier would implicate the Beneficiary Inducements CMP. Because the Treatment Center is a provider, the provision of remuneration under the Arrangement potentially implicates the statute. However, due to: (i) the 3-hour shelf life of the Drug; (ii) the fact that the only FDA-approved manufacturing facility is on the campus of the Treatment Center; and (iii) the fact that Requestor does not have the necessary FDA approval to ship the Drug offsite, the Treatment Center is the only facility where the Drug can be surgically implanted; thus, all patients prescribed the Drug must obtain it at this location, regardless of the Arrangement. Therefore, we conclude it is the limitations related to the manufacturing and distribution of the Drug, rather than the remuneration offered under the Arrangement, that would be likely to influence a patient to select the Treatment Center for items and services for which payment may be made, in whole or in part, by Medicare or a State health care program. As such, the remuneration offered under the Arrangement is not likely to influence a beneficiary to order the Drug from a particular provider, *i.e.*, the Treatment Center.

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 prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present, the OIG will not impose administrative sanctions on Requestor in connection with the 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 constitute grounds for the imposition of sanctions under the Beneficiary Inducements CMP.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is limited in scope to the 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.

The 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. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against Requestor with respect to any action that is part of the 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,

/Susan A. Edwards/

Susan A. Edwards
Chief, Industry Guidance Branch