



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 2, 2021

Posted: July 8, 2021

[Name and address redacted]

Re: OIG Advisory Opinion No. 21-08

Dear [Name redacted]:

The Office of Inspector General (“OIG”) is writing in response to your request for an advisory opinion on behalf of [name redacted] (“Requestor”), regarding financial assistance for transportation, lodging, and meals provided by Requestor to certain patients potentially eligible for 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 manufactures [drug redacted] (the “Drug”), a gene therapy approved by the U.S. Food and Drug Administration (“FDA”) for the treatment of individuals who are confirmed to have a rare, inherited retinal disease caused by mutations in [gene redacted] (the “Genetic Disorder”) and who have viable retinal cells. The Drug is a one-time treatment that has the potential to improve vision for a small, objectively identifiable patient population. Currently, there are no pharmacologic treatments available to patients with the Genetic Disorder other than the Drug. To receive treatment with the Drug, a patient first must undergo a genetic test, ordered by the patient’s local ophthalmologist or inherited retinal disorder specialist, to confirm the existence of the Genetic Disorder.² Patients with the Genetic Disorder then must receive an initial evaluation by the physician who would administer the Drug (the “Treating Physician”) at an approved treatment center to determine whether the patients have viable retinal cells.³ Patients with viable retinal cells who elect to undergo treatment receive a surgical injection of the Drug in each eye, as applicable, at least 6 days apart, as required by the Drug’s FDA-approved label, and a post-operative appointment to check the patient’s status. The FDA-approved label requires the Treating Physician to advise patients to rest in a supine position as much as possible for 24 hours following the surgical injection in each eye and to avoid air travel or other travel to high elevations until any air bubbles that formed during the surgical injection dissipate, which may take a week or longer. The label also requires the Treating Physician to verify the dissipation of any air bubbles through ophthalmic

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

² Requestor disclosed that it provides funding for, and facilitates access to, certain genetic tests, offered by independent, third-party laboratories, that involve a panel that evaluates approximately 300 genes for variants associated with inherited retinal diseases. The scope of the Arrangement does not include this conduct, and we express no opinion regarding such conduct.

³ The FDA-approved label requires the Treating Physician to determine whether the patient has viable retinal cells. While the determination related to viable retinal cells requires clinical judgment by the Treating Physician, there are objective clinical bases (e.g., retinal thickness of more than 100 microns, as measured by optical coherence tomography (“OCT”)) on which the Treating Physician may rely.

examination and to monitor patients after each injection for infections, visual disturbances, and retinal abnormalities. Treatment with the Drug is subject to labeled risks and warnings, such as endophthalmitis, permanent decline in visual acuity, retinal abnormalities, increased intraocular pressure, expansion of intraocular air bubbles, and cataracts.

Treating Physicians administer the Drug in the hospital outpatient setting at facilities that request and agree to become a treatment center for the administration of the Drug, meet certain objective criteria established by Requestor in accordance with Requestor's regulatory submissions to the FDA, and complete Requestor's training on the Drug and its administration ("Centers").⁴ Specifically, to become a Center, a facility must: (i) have at least one board-certified, fellowship-trained vitreoretinal surgeon on staff with expertise in managing and treating patients with inherited retinal diseases and at least one other surgeon who can assist with the administration of the Drug; (ii) have at least one retinal or ocular genetic specialist with an active ophthalmology practice on staff or associated with the facility who can provide pre-operative evaluation and diagnostic confirmation and post-operative continuity of care; (iii) have an on-site pharmacy that is capable of storing, handling, and preparing the Drug; (iv) agree to have the pharmacy and surgical staff involved in the preparation and administration of the Drug participate in Requestor's educational program related to the Drug; and (v) have and maintain a full-field light sensitivity threshold machine, used to determine certain outcomes of the Drug.

To date, Requestor has designated only 10 Centers to administer the Drug but is in the process of certifying additional Centers that meet the criteria listed above and that are willing to administer the Drug. According to Requestor, even when it certifies all facilities that currently are both willing and qualified to administer the Drug, only an estimated 13 to 18 facilities will be certified as Centers. Requestor certified that it will not condition a facility's ability to become or remain a Center on the volume or value of Drug treatments at the Center. Requestor also certified that, should a competing product become available, Requestor would not require Centers or Treating Physicians to exclusively prescribe its Drug or otherwise condition a facility's ability to remain a Center on the Center's or any Treating Physician's choice to administer or prescribe the Drug over a competing product, if one becomes available.

B. The Arrangement

Under the Arrangement, Requestor offers certain patients and one caregiver per patient financial assistance for transportation, lodging, and meals associated with: (i) an initial consultation to determine if the patient has viable retinal cells necessary for administration of the Drug; and (ii) administration of the Drug (if the patient has viable retinal cells) and one follow-up appointment. The patients to whom Requestor makes transportation, lodging, and meal assistance available under the Arrangement must live more than 2 hours driving distance or 100 miles from the Center at which the patient will undergo treatment ("Eligible Patients"). If Eligible Patients are Federal

⁴ Requestor disclosed that it has financial relationships with certain Centers and physicians that relate to, for example, intellectual property-related agreements and Requestor-sponsored clinical trials. The scope of the Arrangement does not include these financial relationships, and we express no opinion regarding such financial relationships.

health care program beneficiaries, they also must: (i) declare themselves to Requestor, directly or through a caregiver, unable to obtain the consultation or Drug due to the necessary travel and lodging expenses; and (ii) have a household gross income that is equal to or below 600 percent of the Federal Poverty Level, as verified by Requestor. In addition to the criteria above, if a third party (e.g., an Eligible Patient's insurance or a Center) offers coverage for any travel-related costs for the Eligible Patient or caregiver, Requestor will not cover the cost of the transportation, lodging, or meals for which the third party offers coverage. Requestor certified that it offers the Arrangement to Eligible Patients regardless of their insurance status.

Requestor offers Eligible Patients and caregivers transportation assistance for up to three round trips between the Eligible Patient's home and a Center and local transportation between a hotel and a Center. Specifically, through a third-party vendor, Requestor: (i) provides reimbursement for mileage, tolls, and parking upon presentation of a valid receipt; and (ii) arranges for transportation via air travel, train, bus, or rental car for Eligible Patients and caregivers to and from the closest Center to the patient that accepts the patient's insurance.⁵ The third-party vendor selects the mode(s) of transportation for the Eligible Patient and caregiver that are the most economical and appropriate and purchases all airline, train, or bus tickets at the best available rates on an economy fare at the time of booking or arranges and pays for the most economical rental car.

With regard to lodging, Requestor's third-party vendor arranges for a modest, single, shared hotel room for a length of time determined by the Eligible Patient's Treating Physician to be necessary to complete treatment but subject to the following limitations imposed by Requestor: (i) a maximum of 4 nights to complete preoperative processing and evaluations; (ii) a maximum of 10 nights for a single eye treatment, 19 nights for consecutive eye treatments, or 25 nights for consecutive eye treatments where the Treating Physician requires two weeks of convalescence between procedures without travel; and (iii) a maximum of 3 nights to complete or adhere to postoperative instructions. According to Requestor, the maximum duration of lodging assistance for each stage of treatment is based on the clinical experiences of patients who have received the Drug to date. With respect to meal assistance under the Arrangement, Requestor provides a reasonable per diem amount for food expenses for the Eligible Patient and the caregiver on the days the Eligible Patient is eligible for an overnight hotel stay.

Requestor certified that it has adopted a written policy that specifies the eligibility criteria for the Arrangement and applies that policy uniformly and consistently. Requestor maintains individualized documentation—documenting both an Eligible Patient's eligibility and all transportation, lodging, and meal assistance provided to the Eligible Patient and caregiver—for each Eligible Patient for whom it provides support under the Arrangement. Neither Requestor nor

⁵ If the closest Center to the patient that accepts the Eligible Patient's insurance cannot schedule treatment within 3 months of the Eligible Patient seeking to undergo treatment, then Requestor provides assistance for Eligible Patients to undergo treatment at the closest Center that accepts the Eligible Patient's insurance and that can treat the patient within 3 months. Requestor certified that it is necessary to ensure patient access to the Drug within 3 months of the patient seeking to undergo treatment because a patient could become ineligible for treatment if a patient's condition deteriorates to a point where the patient no longer has viable retinal cells.

the Centers or third-party vendor advertises the Arrangement. In addition, to participate in the Arrangement, the Eligible Patient or the caregiver, acting on the Eligible Patient's behalf, must agree not to request reimbursement from Federal health care programs for costs covered under the Arrangement. Further, Requestor certified that it does not bill or otherwise shift the costs of the Arrangement to Federal health care programs.

II. LEGAL ANALYSIS

A. Law

1. Federal Anti-Kickback Statute

The Federal anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce, or in return for, the referral of an individual to a person for the furnishing of, or arranging for the furnishing of, any item or service reimbursable under a Federal health care program.⁶ The statute's prohibition also extends to remuneration to induce, or in return for, the purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any good, facility, service, or item reimbursable by a Federal health care program.⁷ For purposes of the Federal anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration is to induce referrals for items or services reimbursable by a Federal health care program.⁸ Violation of the statute constitutes a felony punishable by a maximum fine of \$100,000, imprisonment up to 10 years, or both. Conviction also will lead to exclusion from Federal health care programs, including Medicare and Medicaid. When a person commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such person under section 1128A(a)(7) of the Act. The OIG also may initiate administrative proceedings to exclude such person from Federal health care programs under section 1128(b)(7) of the Act.

2. Beneficiary Inducements CMP

The Beneficiary Inducements CMP provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration to a Medicare or State health care program beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier for the order or receipt of any item or service for

⁶ Section 1128B(b) of the Act.

⁷ Id.

⁸ E.g., United States v. Nagelvoort, 856 F.3d 1117 (7th Cir. 2017); United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000); United States v. Davis, 132 F.3d 1092 (5th Cir. 1998); United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir. 1985).

which payment may be made, in whole or in part, by Medicare or a State health care program. The OIG also may initiate administrative proceedings to exclude such person from Federal health care programs. Section 1128A(i)(6) of the Act defines “remuneration” for purposes of the Beneficiary Inducements CMP as including “transfers of items or services for free or for other than fair market value.” Section 1128A(i)(6) of the Act contains an exception to the definition of “remuneration” that may apply in the context of the Arrangement. Section 1128A(i)(6)(F) of the Act provides that, for purposes of the Beneficiary Inducements CMP, the term “remuneration” does not include “remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs” (the “Promotes Access to Care Exception”). We have interpreted this provision to apply to:

[i]tems or services that improve a beneficiary’s ability to obtain items and services payable by Medicare or Medicaid, and pose a low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs by—(i) [b]eing unlikely to interfere with, or skew, clinical decision making; (ii) [b]eing unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (iii) [n]ot raising patient safety or quality-of-care concerns. . . .⁹

B. Analysis

We must analyze whether the Arrangement implicates the Federal anti-kickback statute and whether, under the Beneficiary Inducements CMP, it 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 reimbursable by Medicare or a State health care program. We address these issues in turn, and for the combination of the reasons discussed below, we conclude that the Arrangement poses a sufficiently low risk of fraud and abuse under the Federal anti-kickback statute, and the Arrangement does not constitute grounds for the imposition of sanctions under the Beneficiary Inducements CMP.

1. Federal Anti-Kickback Statute

The Arrangement implicates the Federal anti-kickback statute because the free transportation, lodging, and meals constitute remuneration from Requestor to beneficiaries that may be intended to induce them to purchase the Drug and to receive other federally reimbursable items and services provided by Treating Physicians at Centers. Additionally, because the travel, lodging, and other assistance Requestor offers beneficiaries allows them to travel to, and stay near, a Center that the beneficiaries otherwise may not have selected for treatment, this assistance constitutes remuneration to the Centers and the Treating Physicians, in the form of the opportunity to earn fees related to administering the Drug, that may induce Treating Physicians to order the Drug.

Generally, we are concerned that manufacturers that provide travel, lodging, and meal assistance for patients who are prescribed their drugs could use the assistance to generate business for themselves by steering patients to their drugs over competing drugs, which could be less expensive

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

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 can 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 travel and lodging arrangements 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. Finally, because Requestor sets the eligibility criteria that facilities must meet to qualify as a Center, Requestor theoretically could drive patient volume to Centers that Requestor unilaterally selects in return for an agreement by the Treating Physicians at those Centers to prescribe its Drug exclusively. 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 provides access to the Drug for Federal health care program beneficiaries who lack the financial resources to cover travel and lodging expenses associated with treatment and who, because of their distance from the closest Center that accepts their insurance and that can treat them within 3 months, otherwise may not be able to access the Drug. Patients must undergo treatment at a Center because of objective safety criteria that a facility administering the Drug must meet. Even after certifying all facilities willing and qualified to administer the Drug, Requestor estimates that only 13 to 18 facilities will be certified as Centers, necessitating travel for most patients who want to receive the Drug. Receiving the Drug may involve three round trips between a patient's home and a Center and potentially staying in a hotel near a Center for: (i) a consultation to confirm whether a patient with the Genetic Disorder has viable retinal cells; (ii) an injection in one eye or injections in both eyes, in which case the Treating Physician must administer the injections at least 6 days apart according to the Drug's label; and (iii) a post-operative appointment. The cost of the extensive travel required to undergo administration of the Drug could inhibit Eligible Patients from receiving treatment that has the potential to improve their vision.

Second, the travel and lodging assistance Requestor provides under the Arrangement facilitates the ability of Eligible Patients to undergo treatment consistent with the Drug's label. In particular, the travel and lodging assistance enables Eligible Patients to adhere to the label's requirements that: (i) the Treating Physician determine if the patient has viable retinal cells; (ii) surgical injections take place in each eye, as applicable, at least 6 days apart; and (iii) the Treating Physician monitor the patient after each injection for infections, visual disturbances, and retinal abnormalities. In addition, the FDA-approved label requires the Treating Physician to advise patients to rest in a supine position as much as possible for 24 hours following the surgical injection in each eye and to avoid air travel or other travel to high elevations until any air bubbles that formed during the surgical injection dissipate, which may take a week or longer. The label also requires the Treating Physician to verify the dissipation of any air bubbles through ophthalmic examination. Providing lodging near the Center where an Eligible Patient undergoes treatment facilitates the Eligible Patient's compliance with these instructions.

Third, a facility may become a Center only if it agrees to become a treatment center for the administration of the Drug, completes Requestor's training on the Drug and its administration, and meets the objective safety criteria established by Requestor, including the requirements for the

facility to have certain health care professionals with certain credentials on staff or associated with the facility, as applicable. Therefore, the number of facilities at which Treating Physicians can administer the Drug and the number of Treating Physicians is limited. As explained above, manufacturer actions designed to limit drug distribution networks to particular facilities to reward their physicians create risks under the Federal anti-kickback statute. Here, however, the limited Center network results from the objective safety criteria that Centers must meet. Furthermore, Requestor certified that any facility that meets Requestor's uniform requirements and agrees to become a Center may become a Center and that Requestor will not condition a facility's ability to become or remain a Center on the volume or value of Drug treatments at the Center. Requestor also certified that, should a competing product become available, Requestor would not require Centers or Treating Physicians to exclusively prescribe its Drug or otherwise condition a facility's ability to remain a Center on the Center's or any Treating Physician's choice to administer or prescribe the Drug over a competing product, if one becomes available. These features of the Arrangement limit the likelihood that Requestor uses, or will use, the Arrangement to reward a limited number of Centers and Treating Physicians who prescribe and administer its Drug.

Fourth, because the Drug may be administered only once in accordance with its label, 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 when it would be payable by a Federal health care program. Additionally, because Treating Physicians may prescribe the Drug only to patients with the Genetic Disorder, the genetic tests used to confirm the gene mutations provide an objective, verifiable basis for determining the patient population potentially eligible for the Drug. While the determination of whether patients with the Genetic Disorder have viable retinal cells requires the Treating Physicians to exercise clinical judgment, there are objective clinical bases (e.g., retinal thickness of more than 100 microns, as measured by OCT) on which the Treating Physician may rely. Therefore, the unique nature of the Drug reduces the risk that the Arrangement results in interference with clinical decision making, overutilization, or inappropriate utilization. Further, the Arrangement is available only when the Drug is prescribed in accordance with its label, and neither Requestor nor the Centers or third-party vendor advertises the Arrangement, which reduces the likelihood that the Arrangement serves as a marketing tool to drive patients to the Drug.

Lastly, the Arrangement includes additional safeguards that mitigate the risk of fraud and abuse. For example, if a third party (e.g., an Eligible Patient's insurance or a Center) offers coverage for any travel-related costs for the Eligible Patient or caregiver, Requestor will not cover the cost of the transportation, lodging, or meals for which the third party offers coverage. Further, Requestor provides travel and lodging only to the Center nearest to the Eligible Patient that accepts the Eligible Patient's insurance unless that Center cannot schedule treatment within 3 months of the patient seeking administration of the Drug, in which case Requestor provides assistance for Eligible Patients to undergo treatment at the closest Center that accepts the patient's insurance and can treat the patient within 3 months. Requestor certified that it is necessary to ensure patient access to the Drug within 3 months because a patient could become ineligible for treatment if a patient's condition deteriorates to a point where the patient no longer has viable retinal cells.

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. Because Requestor is a pharmaceutical manufacturer, it is not a "provider, practitioner, or supplier" for purposes of the Beneficiary Inducements CMP; however, an offer of remuneration by a pharmaceutical manufacturer to a beneficiary to influence the beneficiary to select a particular provider, practitioner, or supplier implicates the Beneficiary Inducements CMP.

Under the Arrangement, Requestor assists Eligible Patients and one caregiver per patient with travel, lodging, and meals. These are valuable benefits to Federal health care program beneficiaries that constitute remuneration for purposes of the Beneficiary Inducements CMP from Requestor to beneficiaries participating in the Arrangement. We conclude that this remuneration likely would influence a beneficiary to select a Treating Physician or Center that the beneficiary otherwise may not have selected to receive federally reimbursable items and services. Therefore, the Arrangement implicates the Beneficiary Inducements CMP. Upon making this determination, we next analyze whether an exception applies, and 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 Requestor offers under the Arrangement improves a beneficiary's ability to obtain items and services payable by Medicare or a State health care program. Eligible Patients must have a household gross income that is equal to or below 600 percent of the Federal Poverty Level, as verified by Requestor, and declare themselves to Requestor, directly or through a caregiver, unable to obtain the consultation or Drug due to the necessary travel and lodging expenses. Additionally, Eligible Patients and caregivers cannot receive assistance from Requestor for the cost of any transportation, lodging, or meals for which a third party offers coverage. Therefore, the assistance under the Arrangement does not duplicate other available coverage by a patient's insurer or charitable assistance from a Center or another third party. We believe the travel, lodging, and meals related to administration of the Drug remove or reduce economic barriers to receiving safe treatment and patient monitoring in accordance with the Drug's label.

Next, we must examine whether the remuneration Requestor provides under 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.

In the unique circumstances of the Arrangement, the risk that the remuneration would interfere with, or skew, clinical decision making is sufficiently low because it is designed to increase patient

safety—and avoid serious potential side effects, including endophthalmitis, permanent decline in visual acuity, retinal abnormalities, increased intraocular pressure, expansion of intraocular air bubbles, and cataracts—consistent with requirements in the FDA-approved labeling. Additionally, the Arrangement is unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization because the Drug is a one-time treatment for a small, objectively identifiable patient population. Further, the Arrangement may increase patient safety in connection with the administration of the Drug because it may allow patients, who otherwise could not stay near a Center, to remain near a Center in order to comply with the label’s safety instructions. Therefore, we conclude that the Arrangement presents a low risk of harm and satisfies the Promotes Access to Care Exception to the Beneficiary Inducements CMP.

III. CONCLUSION

Based on the 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,

/Robert K. DeConti/

Robert K. DeConti
Assistant Inspector General for Legal Affairs