



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



[We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestor.]

Issued: January 15, 2020

Posted: January 21, 2020

[Name and address redacted]

Re: OIG Advisory Opinion No. 20-02

Dear [Name redacted]:

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

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

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

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

This opinion may not be relied on by any persons other than [name redacted], the requestor of this opinion, and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. The Drug

[Name redacted] (“Requestor”) is a pharmaceutical manufacturer that manufactures [drug redacted] (the “Drug”), a [therapy redacted] (“Therapy”) approved by the U.S. Food and Drug Administration (“FDA”) for two indications: (i) refractory or recurrent [disease redacted] (“Disease A”),¹ generally affecting children and young adults; and (ii) relapsed or refractory [disease redacted] (“Disease B”),² generally affecting adults. The Drug is a personalized medicine made from the patient’s own cells and is a one-time, potentially curative treatment.³

¹ Requestor estimates that, for Disease A, approximately 40 percent of Drug-eligible patients are potentially Medicare or Medicaid beneficiaries.

² Requestor estimates that, for Disease B, approximately 60 percent of Drug-eligible patients are potentially Medicare or Medicaid beneficiaries.

³ When hospital outpatient departments infuse Medicare beneficiaries with the Drug, the hospital outpatient departments may receive payment for the Drug, consistent with how the Centers for Medicare & Medicaid Services (“CMS”) pays for drugs with pass-through payment status under the Medicare Part B Outpatient Prospective Payment System when the drugs are furnished in hospital outpatient departments. Hospital outpatient departments also

The Drug carries a black box warning of certain life-threatening or fatal reactions including [syndrome redacted] (the “Syndrome”) and certain neurological toxicities. The Drug’s prescribing information, approved by the FDA, requires physicians to monitor patients for signs or symptoms of the Syndrome two to three times during the first week following Drug infusion and to instruct patients to remain within proximity of the administering facility (i.e., close enough to return to the treatment facility to receive required patient monitoring) for at least four weeks after infusion. The FDA also requires Requestor to implement a Risk Evaluation and Mitigation Strategy (“REMS”), which includes elements to assure safe use (“ETASU”) to mitigate the risks of the Syndrome and neurological toxicities associated with the use of the Drug. Only REMS-certified physicians who treat Disease A or Disease B patients may prescribe and administer the Drug. This means that only certain physicians, who accept the responsibility for implementing necessary safety protocols, may prescribe and administer the Drug.

Consistent with the REMS,⁴ Requestor has entered into arrangements with certain inpatient and outpatient facilities (“Centers”) to safely infuse its Drug.⁵ In addition to infusing the Drug, the Centers perform leukapheresis services⁶ and collect, process, package, and ship the patient’s white blood cells to Requestor so that Requestor may use the patient’s cells to individually manufacture the Drug. Requestor, which unilaterally controls the selection of

may receive payments for professional services and other items and services related to Drug infusion. When inpatient hospitals infuse the Drug, the hospitals receive a per-discharge payment rate based on the Medicare Severity Diagnosis Related Group (“MS-DRG”) to which the discharge is assigned. In addition to the MS-DRG payment, hospitals may receive a New Technology Add-On Payment (“NTAP”) that will vary based on a hospital’s total inpatient covered charges and overall cost-to-charge ratio. Under Medicaid, hospital inpatient and outpatient payment methodologies vary by state and among each state’s managed Medicaid contractors.

⁴ We also note that, according to the Institute for Clinical and Economic Review (“ICER”), Therapy initially should be administered in manufacturer-accredited centers to ensure the quality and appropriateness of care. See ICER, [cite redacted]. ICER is a nonprofit, independent research organization. See <https://icer-review.org/about/>.

⁵ Currently, approximately 96 Centers nationwide are certified to administer the Drug (22 Centers predominantly prescribe the Drug for Disease A, and 74 Centers prescribe the Drug either for both indications or predominantly for Disease B).

⁶ Leukapheresis is a procedure in which white blood cells are separated from the patient’s blood sample.

Centers, certified that facilities must meet all REMS with ETASU requirements. In addition, to participate in Requestor's network as a Center, a facility must: (i) meet applicable regulatory requirements for third-party cell collection processing and other requirements, including having on-site, immediate access to [drug redacted], which is used to treat severe instances of Therapy-related Syndrome; and (ii) ensure that physicians who prescribe, dispense, or administer the Drug are trained on the management of the Syndrome and potential neurological toxicities. Requestor certified that it does not require either physicians or Centers to prescribe its Drug exclusively and that any facility that meets all REMS with ETASU requirements and Requestor's criteria, which it uniformly applies, may become a Center.

Requestor certified that proximity to the Center following infusion is important for patient safety because providers in a patient's local community may not have the appropriate training to treat the potential reactions to the Drug, including the Syndrome and neurological toxicities. According to Requestor, improper treatment of a potential reaction to the Drug could negatively impact the Drug's effectiveness or harm the patient. Requestor suggested that a patient's local emergency room might administer a contraindicated medication to treat the Syndrome, which could result in patient death. Additionally, Requestor asserted that indigent patients or rural patients could be disproportionately impacted by significant health risks or even death from the Drug if they cannot travel, and stay in proximity, to a Center after receiving the Drug. Without the Arrangement, Requestor noted that physicians may admit patients who are prescribed the Drug to a Center as inpatients to ensure that the patient can receive treatment if the Syndrome occurs, or they may choose not to prescribe the Drug.

B. The Arrangement

Requestor operates the Arrangement for patients, including Federal health care program beneficiaries, who are prescribed and administered its Drug.⁷ Under the Arrangement, Requestor assists eligible Disease A patients, Disease B patients 18-25 years of age, and up to two caregivers with travel, lodging, meals, and certain out-of-pocket expenses they incur during and after the patient's Drug infusion. For Disease B patients 26 and older, Requestor provides the same support for a patient and one caregiver. Requestor does not provide assistance with patient travel or expenses associated with initial patient consultations, leukapheresis, or follow-up visits beyond the post-infusion monitoring required by the Drug's prescribing information. Requestor does not authorize lodging under the Arrangement to a patient treated by a Center when Requestor has knowledge that the patient

⁷ Requestor has an outcomes-based arrangement with certain Centers. We have not been asked to opine, and express no opinion, regarding that arrangement.

is eligible to receive lodging from the Center, and such lodging is available for that patient's use. Requestor certified that it created the Arrangement to help eligible patients: (i) with costs they incur to travel, and remain in proximity, to the Center after receiving the Drug; and (ii) meet the FDA requirements set forth in the Drug's prescribing information to ensure patient safety in connection with administration of the Drug.⁸ Requestor also certified that it does not advertise the Arrangement. Patients do not learn about, or become eligible for, the Arrangement until they have been diagnosed with Disease A or Disease B and are prescribed treatment with the Drug.

Under the Arrangement, Requestor provides reimbursement for gas and tolls or arranges for transportation via bus, rail, rental car, or air travel for a patient and caregiver(s) to and from the closest Center accepting patients using a third-party travel vendor.⁹ Assistance under the Arrangement is available for one round-trip from the patient's and each caregiver's place of residence to a Center. Requestor's travel vendor also arranges for a modest, single, shared hotel room located near a Center for the patient and caregiver(s) during Drug treatment and post-treatment monitoring. Requestor also provides reimbursement for certain out-of-pocket expenses up to \$50 per day per person (*e.g.*, meals, parking or taxi fare between the hotel and the Center). To receive reimbursement for out-of-pocket expenses, patients or caregivers must submit written receipts to Requestor documenting expenses. Patients receive assistance for four weeks post-infusion; however, if the patient's physician determines that it is medically necessary to monitor the patient for risks of the Syndrome and neurological toxicities for longer than four weeks, Requestor provides assistance for the duration of monitoring deemed necessary by the physician.

Eligible patients are patients who have been prescribed the Drug for an FDA-approved indication and have a household income that does not exceed 600 percent of the Federal Poverty Level,¹⁰ who live more than two hours driving distance or 100 miles from the nearest Center accepting patients, and who have no insurance for non-emergency medical travel. Requestor offers the Arrangement to eligible patients regardless of their provider or insurance status (*i.e.*, self-insured, uninsured, commercially insured, or federally insured); enrolled patients are free to change providers. Requestor certified that it has adopted a

⁸ According to ICER, “[s]ome patients [participating in patient advisory boards] highlighted the non-medical costs associated with treatment [as barriers to obtaining treatment]. Most had to travel long distances to centers that offered [t]herapy.” ICER, *supra* note 4.

⁹ Patients traveling more than 300 miles are eligible to receive air transportation. Requestor arranges for the lowest-cost reasonable, coach-class ticket.

¹⁰ Requestor certified that the median household income for patients who received assistance under the Arrangement as of September 30, 2018 was \$28,000 per year.

written policy that specifies the eligibility criteria for the Arrangement and applies that policy uniformly and consistently. Requestor maintains individualized documentation—documenting both a patient’s eligibility and any reimbursement provided to a patient—for each patient for whom it provides support under the Arrangement.

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

II. LEGAL ANALYSIS

A. Law

The anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible “kickback” transaction. For purposes of the anti-kickback statute, “remuneration” includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. See, e.g., United States v. Nagelvoort, 856 F.3d 1117 (7th Cir. 2017); United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000); United States v. Davis, 132 F.3d 1092 (5th Cir. 1998); United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir. 1985), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of \$100,000, imprisonment up to ten years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The U.S. Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being

prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

Section 1128A(a)(5) (the “Beneficiary Inducements CMP”) of the Act provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration to a Medicare or State health care program (including Medicaid) beneficiary that the benefactor knows or should know is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier for the order or receipt of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program (including Medicaid). The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs.

Section 1128A(i)(6) of the Act defines “remuneration” for purposes of 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 applies 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 (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. . . .¹¹

B. Analysis

We must analyze whether the Arrangement implicates the anti-kickback statute, as well as whether 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 reimbursed by Medicare or a State health care program under the Beneficiary Inducements CMP. We address these issues in turn, and for the combination of the reasons discussed below, we

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

conclude that we will not impose sanctions on Requestor under the anti-kickback statute or Beneficiary Inducements CMP in connection with the Arrangement.

1. Anti-kickback Statute

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

Generally, we are concerned that manufacturers that provide travel and lodging for patients who are prescribed their drugs could use the travel and lodging 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 inappropriately increased costs to the Federal health care programs. Although Requestor certified that it does not shift the Arrangement's costs to the Federal health care programs, Requestor can increase the Drug's price to recoup costs related to the 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. Finally, because Requestor sets the eligibility criteria that facilities must meet to participate in Requestor's network as a Center, Requestor theoretically could drive patient volume to a limited group of physicians at Centers that Requestor unilaterally selects in return for an agreement by the physicians at those Centers to exclusively prescribe its Drug. However, for the combination of the following reasons, we will not impose sanctions under the anti-kickback statute on Requestor in connection with the Arrangement.

First, Requestor certified that it created the Arrangement to help financially needy patients travel, and stay in proximity, to a Center for Drug treatment. Indigent patients or rural patients could be disproportionately impacted by significant health risks or even death if they cannot travel to a Center to receive, and stay in proximity to, a Center after receiving the Drug. Additionally, Requestor believes that, absent the Arrangement, physicians either may admit patients to a Center as inpatients to ensure that the patients can access treatment if the Syndrome occurs or may not prescribe the Drug for patients.

The majority of Drug-eligible patients treated for Disease B are Medicare or Medicaid beneficiaries, and approximately 40 percent of Drug-eligible patients treated for Disease A are Medicare or Medicaid beneficiaries. Requestor also certified that, as of September 30, 2018, the median household income for patients who received assistance under the Arrangement was \$28,000 per year. Families with an annual household income of \$28,000 may have difficulty affording travel to, and a month-long stay near, a Center for treatment. These difficulties are further evidenced by ICER’s patient interviews, in which patients indicated that non-medical costs such as travel and living expenses during treatment were concerning. Financially needy patients who return home following infusion due to the non-medical costs associated with post-infusion monitoring would not receive the benefit of FDA-required safety monitoring. A patient’s local physician or hospital may not be properly trained or have immediate access to [drug redacted] to appropriately manage the Drug’s risks. Therefore, to increase access to care for financially needy patients and those living in rural areas, we are permitting Requestor, in these limited circumstances, to provide travel, lodging, and certain other assistance to beneficiaries taking its Drug.

Second, the lodging Requestor provides under the Arrangement enables physicians to meet the FDA requirements in the Drug’s prescribing information and to mitigate patient harm from potentially lethal Drug side effects. The remuneration relates to expenses incurred by a patient to adhere to his or her physician’s instructions to receive treatment at a Center and remain in proximity to the Center. These instructions are required by the FDA-approved prescribing information and the REMS with ETASU.¹² Generally, we are concerned when a manufacturer provides significant remuneration (including a cash payment) to a patient for using the manufacturer’s drug. Here, however, the support allows a financially needy patient and his or her caregiver(s) to follow the requirements of the Drug’s prescribing information.¹³

Third, under the REMS with ETASU imposed by the FDA, only physicians who accept responsibility for implementing necessary safety protocols may prescribe and administer the

¹² OIG relied on the fact that the FDA required a REMS with ETASU to mitigate the Drug’s significant safety risks and did not independently undertake extensive investigation, clinical study, testing, or collateral inquiry to evaluate the Drug’s safety risks or the patient-safety benefits that the Arrangement may provide. We caution that, in instances where such collateral inquiry may be necessary to reach an informed opinion, OIG would be required to reject a requestor’s advisory opinion request. See 42 C.F.R. § 1008.15(b)(3).

¹³ The Arrangement does not provide ambulance transportation, child care, lost wages, stipends, or other expenses. We caution that the provision of such items or services, depending on the facts and circumstances, may not be low risk under the anti-kickback statute.

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

Fourth, the Drug is prescribed only for refractory indications, and the Arrangement is available only when the Drug is prescribed and administered in accordance with its label. Furthermore, the Drug is a one-time, potentially curative treatment, so the Arrangement does not raise the seeding concerns sometimes present in other arrangements. In addition, Requestor does not advertise the Arrangement. These conditions limit the likelihood that the Arrangement serves as a marketing tool to drive patients to Requestor's Drug.

Fifth, to be eligible for the Arrangement, patients must live more than two hours driving distance, or more than 100 miles, from a Center (and must live 300 miles from a Center to receive airfare assistance). Requestor also certified that it does not authorize lodging under the Arrangement to patients treated by a Center when Requestor has knowledge that the patient is eligible to receive lodging from the Center, and such lodging is available for that patient's use. Therefore, the assistance under the Arrangement does not duplicate other available charitable assistance available from a Center. Additionally, Requestor provides travel and lodging only to the Center nearest to the patient that is accepting new patients. Further, requiring patients to reside a significant distance from a Center mitigates the risk that the Requestor uses the Arrangement as a marketing tool for patient referrals.

Lastly, we are not currently aware of any existing authority that would allow the Secretary to pay for these non-medical items and services, such as lodging and travel. For all of the above reasons, we would not impose administrative sanctions under the anti-kickback statute on Requestor in connection with the Arrangement.

2. Beneficiary Inducements CMP

We also must analyze whether the Arrangement is likely to influence a beneficiary's selection of a particular provider, practitioner, or supplier for the order or receipt of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program. Because the 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 would implicate the Beneficiary Inducements CMP.

Under the Arrangement, Requestor assists eligible Disease A patients, Disease B patients, and in certain circumstances, up to two caregivers with travel, lodging, meals, and certain out-of-pocket expenses they incur during and after Drug infusion. These are valuable benefits to Federal health care program beneficiaries. These benefits constitute remuneration for purposes of the Beneficiary Inducements CMP from Requestor to beneficiaries participating in the Arrangement. We conclude that this remuneration could reasonably influence a patient to select a physician or Center in Requestor’s network that the patient may not otherwise have selected to receive federally reimbursable items and services. Accordingly, we have determined that the Arrangement implicates the Beneficiary Inducements CMP.

Once the Beneficiary Inducements CMP is implicated, we next analyze whether an exception applies. We conclude that the Arrangement satisfies the Promotes Access to Care Exception to the Beneficiary Inducements CMP.

To reach this conclusion, we first must examine whether the remuneration offered under the Arrangement improves a beneficiary’s ability to obtain items and services payable by Medicare or Medicaid. We are not currently aware of any existing authority that would allow the Secretary to pay for these non-medical items and services, such as lodging and travel. Also, Requestor certified that it does not authorize lodging under the Arrangement to patients treated by a Center when Requestor has knowledge that the patient is eligible to receive lodging from the Center, and such lodging is available for that patient’s use. Therefore, the assistance under the Arrangement does not duplicate other available charitable assistance from a Center. For these reasons, we believe the travel, lodging, meals, and reimbursement of certain out-of-pocket expenses related to staying near the Center for approximately four weeks following Drug administration remove or reduce economic barriers to receiving necessary patient monitoring required by the Drug’s prescribing information.

Next, we must examine whether the remuneration provided 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 is: (i) unlikely to interfere with, or skew, clinical decision making; (ii) 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. As discussed in detail in the anti-

kickback analysis above, the Arrangement is designed to increase patient safety in connection with the Drug's REMS with ETASU and becomes available to a patient after his or her physician prescribes the Drug. Therefore, to increase access to care for financially needy patients and those living in rural areas, we are permitting Requestor, in these limited circumstances, to provide travel, lodging, and certain other assistance to beneficiaries taking its Drug. We also conclude that the Arrangement presents a low risk of harm and satisfies the Promotes Access to Care Exception to the Beneficiary Inducements CMP.

III. CONCLUSION

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

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [name redacted], the requestor of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.
- This advisory opinion may not be introduced into evidence by a person or entity other than [name redacted] to prove that the person or entity did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.
- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Arrangement, including, without limitation, the physician self-referral law, section 1877 of

the Act (or that provision's application to the Medicaid program at section 1903(s) of the Act).

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.
- This advisory opinion is limited in scope to the specific arrangements described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope.
- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

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

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

Sincerely,

/Robert K. DeConti/

Robert K. DeConti
Assistant Inspector General for Legal Affairs