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:** August 20, 2024

**Posted:** August 23, 2024

[Address block redacted]

**Re: OIG Advisory Opinion No. 24-07 (Favorable)**

Dear [redacted]:

The Office of Inspector General ("OIG") is writing in response to your request for an advisory opinion on behalf of [redacted] ("Requestor") regarding a proposed patient assistance program ("PAP") through which Requestor would subsidize certain cost-sharing obligations for low-income Medicare enrollees who have diabetes and reside in a specified rural area (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement, if undertaken, would constitute grounds for the imposition of sanctions under: the civil monetary penalty provision at section 1128A(a)(7) of the Social Security Act (the "Act"), as that section relates to the commission of acts described in section 1128B(b) of the Act (the "Federal anti-kickback statute"); the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Act (the "Beneficiary Inducements CMP"); or the exclusion authority at section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute and the Beneficiary Inducements CMP.

Requestor has certified that all of the information provided in the request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties in connection with the Proposed Arrangement, 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 Proposed 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 Proposed Arrangement, if undertaken, would generate—if the requisite intent were present—prohibited remuneration under the Federal anti-kickback statute, OIG would not impose administrative sanctions on Requestor in connection

with the Proposed 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) although the Proposed Arrangement, if undertaken, would generate prohibited remuneration under the Beneficiary Inducements CMP, OIG would not impose administrative sanctions on Requestor in connection with the Proposed Arrangement under the Beneficiary Inducements CMP or section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Beneficiary Inducements CMP.

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

## I. FACTUAL BACKGROUND

### A. Overview

Requestor is a nonprofit grant-making organization that is exempt from taxation under section 501(c)(3) of the Internal Revenue Code. Requestor does not furnish any items or services for which payment may be made under a Federal health care program. Requestor was created from the net proceeds of the sale of a nonprofit hospital. Its mission is to improve the health and wellbeing of residents of the former service area of the hospital, which constitutes 19 zip codes in a rural community (the "Service Area"). According to Requestor, many Medicare enrollees who reside in the Service Area face significant financial challenges but do not meet the financial eligibility criteria to qualify for Medicaid. Requestor reported that it is aware of situations in which these Medicare enrollees forgo filling their prescriptions because they cannot afford the cost-sharing obligations associated with them. Failing to take medically necessary prescription drugs can create substantial health risks, particularly for patients who rely on prescription drugs (such as insulin) to control their diabetes.

To address these situations, under the Proposed Arrangement, Requestor would establish a PAP through which it would subsidize certain diabetes drug cost-sharing obligations for low-income Medicare enrollees in the Service Area who qualify to be a participant in the PAP based on Requestor's eligibility criteria (the "Participants"). The PAP would pay for 100 percent of the Participants' cost-sharing obligations for all prescription medications, including generic or bioequivalent drugs, approved by the U.S. Food and Drug Administration ("FDA") for the treatment of diabetes and covered by Medicare Part D—including, but not limited to, insulin (the "Covered Drugs"). The PAP would cover all cost-sharing obligations, including deductibles, copayments, or other required cost sharing owed for the Covered Drugs in any coverage phase of the standard Medicare Part D benefit.[2] The PAP would provide assistance to

[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] Due to funding limitations, the PAP would not provide assistance to enrollees covered by a Medicare Advantage plan that provides qualified prescription drug coverage (as opposed to a

Participants on a first-come, first-served basis for so long as funding remains available in a given calendar year.[3]

Requestor's operations originally were funded through the net proceeds of the nonprofit hospital sale described above. Although Requestor does not solicit donations from any specific individual or entity, it occasionally receives donations from the public in the regular course of business, including via a "Donate" section of its website. Requestor does not solicit and has not knowingly received donations from any person affiliated with any of the following types of entities (each, a "Pharmaceutical Entity"): (i) pharmaceutical manufacturers or distributors; (ii) drug wholesalers; (iii) pharmacy benefit managers; (iv) group purchasing organizations; (v) pharmacies; or (vi) entities owned or controlled by, or that have an ownership or control interest in, any of the foregoing types of entities. Before implementing the Proposed Arrangement, Requestor would add a requirement on the "Donate" section of its website for all donors to certify that the donor is not a Pharmaceutical Entity and is not donating to Requestor on behalf of a Pharmaceutical Entity, and Requestor would not accept any donations from a donor that could not make these certifications. Furthermore, Requestor certified that no member of its Board of Trustees and none of its corporate officers have a financial relationship with a Pharmaceutical Entity. Finally, Requestor certified that it is not owned or controlled by, and does not have an ownership or control interest in, any Pharmaceutical Entity.

### B. Eligibility and Enrollment

Requestor would utilize various means to inform residents of the Service Area about the PAP, such as its website, newspaper and radio advertisements, social media notices, and direct mail to community leaders (such as religious leaders and elected officials) in the Service Area. To be eligible for assistance under the PAP, individuals would need to: (i) reside in the Service Area; (ii) be enrolled in a Medicare Part D plan; (iii) not have secondary insurance coverage (such as Medicaid or commercial insurance); (iv) have a household income below 400 percent of the Federal Poverty Level; and (v) have a diabetes diagnosis with a treatment regimen prescribed by a licensed health care practitioner. Individuals would need to submit an enrollment application to Requestor that would include providing proof and an attestation that they meet these eligibility criteria. According to Requestor, a patient's eligibility would not be contingent on the selection of a particular treating provider or pharmacy and would not be contingent on the use of a particular drug.

Once Requestor approves an application for an individual to be a Participant, the individual would be enrolled in the PAP and eligible to receive assistance through December 31st of the then-current calendar year. Requestor would require Participants to reapply every calendar year.

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standalone Medicare Part D plan). In addition, the PAP would not provide cost-sharing assistance for drugs covered under Medicare Part B.

[3] Requestor would dedicate an initial $250,000 from its existing funds to the PAP. Once the initial funding is exhausted, Requestor intends to dedicate an additional $250,000 pending approval by its Board of Trustees after review of the PAP's impact and viability.

### C. Obtaining Covered Drugs

Under the Proposed Arrangement, Participants would be able to obtain Covered Drugs at any pharmacy of their choosing. However, Requestor would designate particular pharmacies as "participating" pharmacies (the "Participating Pharmacies"), and those pharmacies would provide certain conveniences to Participants as compared to other pharmacies (the "Non-Participating Pharmacies").[4] Specifically, when a Participant obtains a Covered Drug at a Participating Pharmacy, the Participant would not be prompted to pay cost sharing for the medications out of pocket at the point of sale. Instead, the Participating Pharmacy would submit a claim to Requestor for reimbursement of 100 percent of the Participant's cost-sharing amount and would not charge the Participant for this amount.[5] In contrast, when a Participant obtains a Covered Drug at a Non-Participating Pharmacy, the Participant would be prompted to pay 100 percent of their cost-sharing amount for the medications to the Non-Participating Pharmacy. Then, the Participant would submit a claim for reimbursement of such amount to Requestor. Requestor anticipates that it would reimburse Participants for these cost-sharing amounts in an average of approximately 30 days after receiving each reimbursement request.

Initially, there would be three Participating Pharmacies. Requestor chose the initial Participating Pharmacies based on the pharmacies having the following characteristics:

- familiarity with and participation in Medicare Part D;
- independently owned rather than part of a chain;[6]
- physically located within the Service Area;
- geographically distanced from one another within the Service Area so that Participants would not have to travel far to access a Participating Pharmacy;
- history of compliance with Federal, State, and local laws;
- sufficient infrastructure to effectuate any necessary administrative tasks;

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[4] Requestor certified that it is not owned or controlled by, and does not have an ownership or control interest in, any pharmacy, including any of the Participating Pharmacies.

[5] Requestor would allocate a capped annual funding amount to each Participating Pharmacy for Requestor's internal budgeting purposes. To the extent a Participating Pharmacy's budgeted annual funding is exhausted, a Participant utilizing that Participating Pharmacy would have to pay 100 percent of the cost-sharing amount for the Covered Drugs to the Participating Pharmacy at the point of sale, and then the Participant would be able to submit a claim for reimbursement of such amount to Requestor. As a result, after a Participating Pharmacy reaches its budgeted annual funding cap, the Proposed Arrangement would function the same at that Participating Pharmacy as it does at a Non-Participating Pharmacy.

[6] Requestor reported that it would like Participating Pharmacies to be visible and known to their communities and to have a relationship with local residents. Requestor further reported that, based on its experience, it believes that pharmacies that are independently owned and local to this particular community meet these criteria, but chain pharmacies in the area may not.

- serving a racially and socioeconomically diverse patient population; and
- providing services in multiple languages.

Additional pharmacies could be added as Participating Pharmacies after the launch of the Proposed Arrangement. Requestor would consider the same characteristics as those identified above when determining whether to add a particular pharmacy as a new Participating Pharmacy.

Requestor would inform Participants that they can obtain Covered Drugs at a Participating Pharmacy or a Non-Participating Pharmacy. With respect to Participating Pharmacies, Requestor would provide Participants with the identity and contact information of such pharmacies and would inform Participants that they would not be prompted to pay cost sharing for Covered Drugs out of pocket at the point of sale at such pharmacies. With respect to Non-Participating Pharmacies, Requestor would inform Participants about how to seek reimbursement for cost-sharing amounts for Covered Drugs paid to such pharmacies. Finally, Requestor would notify each Participant, upon enrollment in the PAP and annually thereafter, that they are free to switch providers, practitioners, suppliers, or products at any time without affecting their continued eligibility for financial assistance through the PAP.

## 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.[7] 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.[8] 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.[9] Violation of the statute constitutes a felony punishable by a maximum fine of

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

[8] Id.

[9] 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).

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

Congress has developed several statutory exceptions to the Federal anti-kickback statute.[10] In addition, the U.S. Department of Health and Human Services has promulgated safe harbor regulations that specify certain practices that are not treated as an offense under the Federal anti-kickback statute and do not serve as the basis for an exclusion.[11] However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor. Compliance with a safe harbor is voluntary. Arrangements that do not comply with a safe harbor are evaluated on a case-by-case basis. There is a statutory exception and regulatory safe harbor to the Federal anti-kickback statute that protect certain non-routine waivers by pharmacies of cost-sharing obligations,[12] which potentially apply to the Proposed Arrangement.

2. Beneficiary Inducements CMP

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

## B. Analysis

1. Federal Anti-Kickback Statute

The Proposed Arrangement would involve remuneration from Requestor to Participants in the form of: (i) cost-sharing subsidies; and (ii) enabling Participants to avoid upfront out-of-pocket expenses when they obtain Covered Drugs at a Participating Pharmacy as opposed to a Non-Participating Pharmacy. Below, we analyze each stream of remuneration under the Federal anti-kickback statute.

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[10] Section 1128B(b)(3) of the Act.

[11] 42 C.F.R. § 1001.952.

[12] Section 1128B(b)(3)(G) of the Act; 42 C.F.R. § 1001.952(k)(3).

*a) Cost-Sharing Subsidies*

Under the Proposed Arrangement, Requestor would offer and pay remuneration in the form of subsidies of Medicare Part D cost-sharing obligations for particular items (i.e., Covered Drugs) directly to Participants (i.e., reimbursing Participants for cost-sharing amounts they paid to Non-Participating Pharmacies and, under certain circumstances, to Participating Pharmacies) or indirectly to Participants (i.e., paying Participating Pharmacies the cost-sharing amounts they otherwise would have collected from Participants). This remuneration would implicate the Federal anti-kickback statute because it could induce Participants to purchase items reimbursable by a Federal health care program—in particular, diabetes drugs covered by Medicare Part D.

As a threshold matter, OIG has long recognized that PAPs can provide important safety net assistance to patients, especially patients who cannot afford their cost-sharing obligations for prescription drugs.[13] OIG supports efforts of charitable organizations and others to assist financially needy enrollees as long as the assistance is provided in a manner that does not run afoul of the Federal anti-kickback statute or other laws. OIG has consistently warned that, in order to reduce fraud and abuse risks, PAPs should be independent of pharmaceutical manufacturer influence and "not function as a conduit for payments by the pharmaceutical manufacturer to patients."[14] The risks OIG has identified in connection with cost-sharing subsidies funded by manufacturers include: the potential for improperly increased drug prices, which could result in improperly increased costs to Federal health care programs and certain patients; the possible steering of Medicare enrollees to certain drugs, which could result in enrollees taking drugs that are not as safe and efficacious for them as other drugs; and the prospect of anti-competitive effects.

The cost-sharing subsidies under the Proposed Arrangement would not be protected by a statutory exception or regulatory safe harbor to the Federal anti-kickback statute. For example, the subsidies would not meet the statutory exception or regulatory safe harbor for certain non-routine waivers by pharmacies of cost-sharing obligations because: (i) Requestor is not a pharmacy; and (ii) the Proposed Arrangement would operate as a subsidy, rather than a waiver, of the cost-sharing obligations. Nevertheless, for the combination of the following reasons, we believe the risk of fraud and abuse presented by the subsidies is sufficiently low under the Federal anti-kickback statute for OIG to issue a favorable advisory opinion.

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[13] See, e.g., OIG, Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31,120 (May 30, 2014), https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/independent-charity-bulletin.pdf (hereinafter the "2014 Bulletin"); OIG, Special Advisory Bulletin: Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70,623 (Nov. 22, 2005), https://oig.hhs.gov/fraud/docs/alertsandbulletins/2005/2005PAPSpecialAdvisoryBulletin.pdf (hereinafter the "2005 Bulletin").

[14] 2014 Bulletin, 79 Fed. Reg. at 31,121; 2005 Bulletin, 70 Fed. Reg. at 70,627.

First, and importantly, the cost-sharing subsidies under the Proposed Arrangement would not function as a conduit for payments by a pharmaceutical manufacturer—or any other Pharmaceutical Entity—to patients. This is because, as Requestor certified: (i) Requestor's operations originally were funded through the net proceeds of a nonprofit hospital sale; (ii) Requestor does not solicit and has not knowingly received donations from any person affiliated with a Pharmaceutical Entity; (iii) Requestor would ensure that, to the extent it was to receive any donations from the public in the future, the donations would not be made by or on behalf of a Pharmaceutical Entity (due to the required certifications on the "Donate" section of its website); (iv) no member of Requestor's Board of Trustees and none of its corporate officers have a financial relationship with a Pharmaceutical Entity; and (v) Requestor is not owned or controlled by, and does not have an ownership or control interest in, any Pharmaceutical Entity.

Second, the design of the Proposed Arrangement reduces the likelihood that the cost-sharing subsidies would steer Medicare enrollees to a particular product based on the availability of the subsidy. While the Proposed Arrangement would provide assistance for only particular items (i.e., Covered Drugs), a Covered Drug is any prescription medication, including a generic or bioequivalent drug, approved by the FDA for the treatment of diabetes and covered by Medicare Part D. This means that a patient's eligibility would not be contingent on the use of a specific diabetes drug manufactured by a specific manufacturer. Moreover, Requestor would notify Participants that they are free at any time to switch providers, practitioners, suppliers, or products without affecting their continued eligibility for financial assistance through the PAP.

Finally, eligibility for financial assistance under the Proposed Arrangement would be based on a good-faith determination of financial need. Specifically, Participants would need to have a household income below 400 percent of the Federal Poverty Level and would need to provide proof of, and an attestation regarding, their household income level. Further, individuals would not be able to have secondary insurance coverage (such as Medicaid or commercial insurance) that could cover the cost-sharing amounts for them. In addition, Participants would need to reapply each year to participate in the PAP, so Requestor would verify on an annual basis that Participants continue to meet the eligibility criteria. This would be a reasonable, verifiable, and uniform measure of financial need that would be applied in a consistent manner. Furthermore, the assistance would be narrowly tailored to address a particular community need that Requestor has identified in the Service Area, and assistance would be limited in scope (i.e., limited to individuals who meet specified enrollment criteria), time (i.e., subject to annual re-enrollment), and amount (i.e., subject to Requestor's funding limitations).

*b) Enabling Participants to Avoid Out-of-Pocket Expenses*

Under the Proposed Arrangement, Requestor would offer and pay remuneration to Participants in the form of enabling Participants to avoid upfront out-of-pocket expenses when they obtain Covered Drugs at a Participating Pharmacy (unless the Participating Pharmacy has reached its annual funding cap). In contrast, when a Participant obtains a Covered Drug at a Non-Participating Pharmacy, the Participant would: (i) pay 100 percent of the cost-sharing amount for the medications out of pocket to the pharmacy; (ii) submit a claim for reimbursement of such amount to Requestor; and (iii) wait an average of approximately 30 days after Requestor receives the claim to receive the reimbursement. The conveniences to Participants who obtain Covered Drugs at a Participating Pharmacy (as compared to a Non-Participating Pharmacy) constitute

remuneration from Requestor to Participants that implicates the Federal anti-kickback statute because it could induce Participants to purchase certain items reimbursable by a Federal health care program (i.e., Covered Drugs) from a Participating Pharmacy.

Enabling Participants to avoid upfront out-of-pocket expenses would not be protected by a statutory exception or regulatory safe harbor to the Federal anti-kickback statute. Nevertheless, for the combination of the following reasons, we believe the risk of fraud and abuse presented by this remuneration is sufficiently low under the Federal anti-kickback statute for OIG to issue a favorable advisory opinion.

First, we recognize that enabling Participants to avoid upfront out-of-pocket expenses may factor into a Participant's decision to purchase Covered Drugs from a Participating Pharmacy instead of a Non-Participating Pharmacy, which raises concerns of steering to a particular pharmacy. However, under the Proposed Arrangement, these concerns are mitigated because: (i) other important convenience factors, including location, availability, and medication management considerations, also could inform a Participant's choice of pharmacy; (ii) Requestor chose the initial Participating Pharmacies based on objective criteria (e.g., the pharmacy being located within the Service Area) and would consider the same objective criteria when adding any additional pharmacies as Participating Pharmacies after the launch of the Proposed Arrangement; and (iii) the ultimate dollar value of the cost-sharing subsidies for Covered Drugs would not differ based on the pharmacy a Participant chose.

Second, enabling Participants to avoid upfront out-of-pocket expenses would be unlikely to result in interference with clinical decision-making, overutilization, or inappropriate utilization. Participants would obtain the same Covered Drugs whether they select a Participating Pharmacy or Non-Participating Pharmacy for the purchase of those drugs. Even if a Participant would be more likely to purchase Covered Drugs from a Participating Pharmacy than a Non-Participating Pharmacy in order to take advantage of this remuneration, there is no indication that it would induce Participants to purchase prescription drugs they would not otherwise purchase.

Finally, enabling Participants to avoid upfront out-of-pocket expenses would be unlikely to increase costs to Federal health care programs because Federal health care programs would pay the same amount for Covered Drugs regardless of whether Participants obtain those drugs from a Participating Pharmacy or Non-Participating Pharmacy.

2. Beneficiary Inducements CMP

Under the Beneficiary Inducements CMP, we must analyze whether Requestor knows or should know that the remuneration it would provide under the Proposed Arrangement would be likely to influence a beneficiary's selection of a particular provider, practitioner, or supplier for the order or receipt of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program. The facts here implicate the Beneficiary Inducements CMP because pharmacies that would dispense Covered Drugs (whether Participating Pharmacies or Non-Participating Pharmacies) are suppliers, and Requestor would offer remuneration to enrollees that could induce them to select a Participating Pharmacy for the receipt of Covered Drugs, which are items payable by Medicare.

Under the Proposed Arrangement, Requestor would offer and pay remuneration to enrollees in the form of: (i) subsidies of Medicare Part D cost-sharing obligations for Covered Drugs; and (ii) enabling Participants to avoid upfront out-of-pocket expenses when they obtain Covered Drugs at a Participating Pharmacy as opposed to a Non-Participating Pharmacy. Having established that Requestor would offer or pay remuneration to enrollees, the next question under the Beneficiary Inducements CMP is whether this remuneration would be likely to influence patients to select a particular pharmacy as their supplier for the receipt of Covered Drugs.

With respect to cost-sharing subsidies, we believe the answer is no. Specifically, eligibility for the PAP and continued enrollment in the PAP would not be dependent on the Participant's use of a particular pharmacy to dispense Covered Drugs—rather, Participants could obtain Covered Drugs at any pharmacy of their choice, and the ultimate dollar value of the cost-sharing subsidies for Covered Drugs would not differ based on the pharmacy a Participant chose. Furthermore, upon enrollment in the PAP and annually thereafter, Requestor would notify Participants that they are free at any time to switch providers, practitioners, suppliers, or products without affecting their continued eligibility for financial assistance through the PAP.

With respect to enabling Participants to avoid upfront out-of-pocket expenses, it is possible that this remuneration could influence patients to select a particular pharmacy (i.e., a Participating Pharmacy) as their supplier for the receipt of Covered Drugs. However, for the reasons stated above in section II(B)(1)(b) and in an exercise of our discretion, we would not impose sanctions in connection with the Proposed Arrangement under the Beneficiary Inducements CMP.

## III. CONCLUSION

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

## IV. LIMITATIONS

The limitations applicable to this opinion include the following:

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

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

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

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

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

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

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

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

Sincerely,

/Susan A. Edwards/

Susan A. Edwards
Assistant Inspector General for Legal Affairs