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 18, 2026

Posted: August 21, 2026

[Address block redacted]

Re: OIG Advisory Opinion No. 26-17 (Favorable)

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 arrangement whereby certain donors—including pharmaceutical manufacturers of drugs used to treat the illnesses for which Requestor's support is available (the "Funding Manufacturers")—would fund, through Requestor, health insurance premium assistance and copayment assistance for eligible patients who are diagnosed with certain rare and chronic diseases (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 advisory 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, have been misrepresented, or change, then this advisory 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) the Proposed Arrangement, if undertaken, would not constitute grounds for the imposition of sanctions under the Beneficiary Inducements CMP.

This advisory opinion may not be relied on by any person[1] other than Requestor, has no applicability to any arrangements other than the Proposed Arrangement, and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

Requestor is a non-profit, tax-exempt organization that provides financial assistance to patients with certain rare and chronic illnesses (the "Diseases"), including: [redacted].

Requestor provided data demonstrating that the per-patient, per-year cost for patients with a rare disease is three-to-five times greater than the per-patient, per-year cost for patients without a rare disease.[2] According to Requestor, the average annual cost of clotting factor therapies for patients with [redacted] is approximately $300,000, and the cost of their medical expenses can be up to an average of $600,000 per year. Requestor certified that, relative to the Medicare program, most of the products used to treat the Diseases are reimbursable under Medicare Part B and are not reimbursable under Medicare Part D. For example, Medicare Part B covers the infused and injected drugs used to treat [redacted] (e.g., [redacted]).[3] Requestor certified that all but one of the Diseases have multiple products approved by the U.S. Food & Drug Administration ("FDA") that treat the relevant Disease.

Requestor operates several patient assistance programs ("PAPs") that provide financial assistance to patients who are diagnosed with one of the Diseases, including an "[redacted] PAP."[4] The [redacted] PAP currently pays health insurance premiums and copayments on behalf

[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] A. Tisdale et al., *The IDeaS initiative: pilot study to assess the impact of rare diseases on patients and healthcare systems*, ORPHANET J. RARE DISEASES (Oct. 22, 2021), https://ojrd.biomedcentral.com/articles/10.1186/s13023-021-02061-3.

[3] Requestor certified that it conducted a comprehensive review to identify all of the FDA-approved therapies to treat the Diseases and identified 87 such therapies in total. Of this number, 8 percent of the therapies are covered and reimbursed by Medicare Part D only. About 13 percent of the therapies may be covered and reimbursed by either Medicare Part B or Part D, depending on how and where the therapy is administered.

[4] Examples of Requestor's PAPs other than the [redacted] PAP that is the subject of this advisory opinion include: (i) Requestor's [redacted] PAP, which provides financial assistance for utilities, food, housing, clothing, communication, and transportation to patients who have been diagnosed with a Disease; and (ii) a [redacted] PAP, which provides financial assistance or a tangible item

of eligible patients diagnosed with any Disease, but Requestor excludes Federal health care program beneficiaries from receiving this type of assistance. Under the Proposed Arrangement, Requestor intends to expand the [redacted] PAP to establish funds for each Disease ("Disease Funds"), each of which would be further divided between: (i) a premium assistance fund; and (ii) a copayment and coinsurance fund, that would be available to Federal health care program beneficiaries who are diagnosed with a Disease on a first-come, first-served basis pursuant to a financial need policy that Requestor would uniformly administer. With respect to the financial need policy, Requestor certified that it would determine eligibility according to a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner.

Requestor certified that it would not limit its copayment assistance to high-cost or specialty drugs. Instead, Requestor would make copayment assistance available, at a minimum, for all prescription medications, including generic or bioequivalent drugs, approved by the FDA for treatment of the relevant Disease covered by the Disease Fund. Relative to the one Disease Fund supporting the Disease for which the FDA has approved only one drug, Requestor certified that it would provide support for other medical needs of patients with the Disease, in addition to copayment support for the FDA-approved treatment of the Disease. At a minimum, Requestor would provide copayment support for all prescription drugs used by a patient for an FDA-approved indication related to managing the Disease, including, but not limited to, drugs to treat symptoms of the Disease, such as pain medications, and prescription drugs to treat side effects of treatments, such as anti-nausea medications.

Requestor certified that it would define the Disease Funds in accordance with widely recognized clinical standards and in a way that covers a broad spectrum of available products. Requestor certified that it would not define its Disease Funds by reference to specific symptoms, severity of symptoms, method of administration of drugs, stages of a particular disease, type of drug treatment, or any other way of narrowing the definition of widely recognized disease states.

Requestor intends for patients to learn about the subsidies available under the Proposed Arrangement in the same manner they learn about Requestor's existing PAPs. According to Requestor, individuals currently seek assistance from Requestor only after they have been diagnosed with a Disease, and after they, along with their physician(s), have determined an appropriate course of treatment. Individuals learn about Requestor's existing PAPs from a variety of sources, including Requestor's marketing and publication efforts, other support organizations, and physician offices. According to Requestor, the Funding Manufacturers also frequently operate patient assistance hotlines staffed by social workers that patients may call for assistance in locating or arranging for insurance coverage or financial assistance. Patients also may learn about Requestor's services through patient support groups, many of whose websites may list Requestor as a valuable resource and provide a link to Requestor's homepage.

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that could positively impact a patient's treatment or quality of life to patients who have been diagnosed with a Disease and who are experiencing a costly financial hardship resulting from a health-related event that requires medical treatment. We have not been asked to opine on, and express no opinion regarding, the specific terms of any program other than the Proposed Arrangement.

Requestor certified that it would not promote the Proposed Arrangement through any direct-to-consumer advertisement of any product manufactured by a Funding Manufacturer.

Requestor certified that it would make all financial eligibility determinations using its own objective criteria. Applications would be considered on a first-come, first-served basis to the extent of available funding. Requestor certified that it would award assistance in a truly independent manner that severs any link between donors and patients. Before applying for assistance available through the Proposed Arrangement, each patient already would have selected their health care providers, practitioners, suppliers, and products and would have a treatment regimen in place. Requestor certified that, while receiving the assistance available through the Proposed Arrangement, all patients would remain free to change their health care providers, practitioners, suppliers, or products. Requestor further certified that it would not refer any patient to any donor or to any provider, practitioner, supplier, or product. Requestor certified that it would award assistance without regard to any donor's interests and without regard to the applicant's choice of provider, practitioner, supplier, or product; when determining patient eligibility for the assistance available under the Proposed Arrangement, Requestor certified that it would not take into account the identity of any provider, practitioner, supplier of items or services, or drug or other product the patient may use; the identity of any referring person or organization; or the amount of any contributions made by a Funding Manufacturer.

Under the Proposed Arrangement, the assistance that Requestor would provide to eligible patients would be made possible through donations that Requestor would receive from a variety of sources, including the Funding Manufacturers, as well as financially disinterested persons. Donors have the option to earmark donations to specific Disease Funds within the [redacted] PAP or a general donation to Requestor's organization or to Requestor's [redacted] PAP, as a whole. When a donation to a specific Disease Fund is made, Requestor has absolute discretion on how funds are used or applied to patients enrolled in the specific Disease Fund. Donors have no influence or input in how any funds donated are used or applied, and in the case of general donations, Requestor has absolute discretion regarding the use of the donor's contributions. Requestor certified that no Funding Manufacturer or affiliate of any Funding Manufacturer would exert direct or indirect control over Requestor or the Proposed Arrangement. Requestor certified that it is an independent, nonprofit, tax-exempt organization that operates with absolute, independent, and autonomous discretion as to the use of donor contributions. Requestor certified that it would not provide the Funding Manufacturers with any data that would facilitate the Funding Manufacturer in correlating the amount or frequency of its donations with the amount or frequency of the use of its products or services. No individual patient information would be conveyed to any Funding Manufacturer nor would any data related to the identity, amount, or nature of products or services subsidized under the Proposed Arrangement. Some aggregate data may be provided to donors as a courtesy, but this would be limited to aggregate numbers of applicants, aggregate numbers of qualifying patients enrolled in a Disease Fund, and aggregate amounts disbursed from a Disease Fund. Patients would not receive any information regarding donors, and donors would not receive any information regarding other donors, except that Requestor's annual report and list of donations may be publicly available, as required by the Internal Revenue Service ("IRS").

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.[5] 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.[6] 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.[7] Violation of the statute constitutes a felony punishable by a maximum fine of $100,000, imprisonment up to 10 years, or both. Conviction also will lead to exclusion from Federal health care programs, including Medicare and Medicaid. When a person commits an act described in section 1128B(b) of the Act, OIG may initiate administrative proceedings to impose civil monetary penalties on such person under section 1128A(a)(7) of the Act. OIG also may initiate administrative proceedings to exclude such person from Federal health care programs under section 1128(b)(7) of the Act.

2. Beneficiary Inducements CMP

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

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

[6] Id.

[7] 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).

B. Analysis

1. OIG Guidance on Independent PAPs

OIG has long recognized that PAPs, including programs sponsored predominantly by drug manufacturers, can provide important safety net assistance to patients, especially patients who cannot afford their cost-sharing obligations for prescription drugs.[8] OIG also recognizes that prescription drug costs have increased dramatically in recent years, exacerbating this financial challenge for some patients.[9] OIG supports efforts of charitable organizations and others to assist financially needy beneficiaries, as long as the assistance is provided in a manner that does not run afoul of the Federal anti-kickback statute or other laws. PAPs organized by purportedly independent charitable organizations, which OIG has in the past referred to as "independent charity PAPs," can provide meaningful and important safety net assistance to patients with financial need.

Nevertheless, independent charity PAPs that rely heavily on donations from pharmaceutical manufacturers present significant fraud and abuse risks. OIG has consistently warned that, in order to reduce fraud and abuse risks, independent charity PAPs should be independent of pharmaceutical manufacturer influence and "not function as a conduit for payments by the pharmaceutical manufacturer to patients."[10] OIG's substantial enforcement experience, various OIG appraisals of the administration of the Medicare Part D program, increasing drug prices, and recent peer-reviewed economic analyses have amplified our understanding of how these PAPs operate and the risks they pose to Federal health care programs. Our enforcement experience involving the "independent charity PAP" model reinforces that the model both implicates the Federal anti-kickback statute and is susceptible to abuse. 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 Part D 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 other anti-competitive effects.

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[8] 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").

[9] See, e.g., Arielle Bosworth et al., Price Increases for Prescription Drugs, 2016-2022, ASPE Issue Brief (Sept. 30, 2022), https://aspe.hhs.gov/reports/prescription-drug-price-increases; Juliette Cubanski & Tricia Neuman, Prices Increased Faster Than Inflation for Half of all Drugs Covered by Medicare in 2020 (Feb. 25, 2022), https://www.kff.org/medicare/prices-increased-faster-than-inflation-for-half-of-all-drugs-covered-by-medicare-in-2020/.

[10] 2005 Bulletin, 70 Fed. Reg. at 70,627; 2014 Bulletin, 79 Fed. Reg. at 31,121.

We have previously stated that, while we understand that many charities have limited resources and seek to use them to assist patients with the greatest financial need, assessing a patient's financial need is a separate concern from determining which drugs to include in a disease fund. Narrowly defining disease funds or limiting disease funds to provide assistance only for expensive drugs can result in steering patients to the drugs for which assistance is available. This type of steering increases the likelihood that the donors could use the PAPs as improper conduits to provide a subsidy to patients who use the donors' own products. This potentially increases costs to the Federal health care programs in cases where a lower cost, equally effective drug is available. Moreover, the ability to subsidize copayments for their own products may encourage manufacturers to increase prices, potentially at additional cost to Federal health care programs and beneficiaries who are unable to obtain copayment support. We have previously stated that disease funds should be defined in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of products and that disease funds should not be defined for the purpose of limiting the drugs for which the independent charity PAP provides assistance.[11]

2. Federal Anti-Kickback Statute

The Proposed Arrangement implicates the Federal anti-kickback statute. Under the Proposed Arrangement, the Funding Manufacturers, through Requestor, provide remuneration to patients, including Federal health care program beneficiaries, who have been diagnosed with a Disease that can be treated by a drug produced by one or more of the Funding Manufacturers. With respect to the Federal anti-kickback statute, that remuneration could induce the purchasing or ordering, or the arranging for the purchase or order, of a prescription drug reimbursable by a Federal health care program. For the combination of the reasons described below, we believe the risk of fraud and abuse presented by the Proposed Arrangement is sufficiently low under the Federal anti-kickback statute for OIG to issue a favorable advisory opinion.

First, the Proposed Arrangement includes many of the features that OIG has highlighted in the past when analyzing independent charity PAP arrangements as potentially mitigating the risks of steering, overutilization, and increased costs to Federal health care programs:

- Requestor certified that it would not provide the Funding Manufacturers with any data that would facilitate the Funding Manufacturer in correlating the amount or frequency of its donations with the amount or frequency of the use of its products or services. No individual patient information would be conveyed to any Funding Manufacturer nor would any data related to the identity, amount, or nature of products or services subsidized under the Proposed Arrangement. Some aggregate data may be provided to donors as a courtesy, but this would be limited to aggregate numbers of applicants, aggregate numbers of qualifying patients enrolled in a Disease Fund, and aggregate amounts disbursed from a Disease Fund. Patients would not receive any information regarding donors, and donors would not receive any information regarding other donors, except that Requestor's annual report and list of donations may be publicly available, as required by IRS.

[11] 2014 Bulletin, 79 Fed. Reg. at 31,122.

- Requestor would pay health insurance premiums and copayments for Federal health care program beneficiaries who are diagnosed with a Disease on a first-come, first-served basis pursuant to a financial need policy that Requestor would uniformly administer. With respect to the financial need policy, Requestor certified that it would determine eligibility according to a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner. Before applying for assistance, each patient would already have selected their health care providers, practitioners, suppliers, and products and would have a treatment regimen in place. While receiving the assistance available under the Proposed Arrangement, all patients would remain free to change their health care providers, practitioners, suppliers, or products. Requestor would not refer any patient to any donor or to any provider, practitioner, supplier, or product. Requestor certified that it awards assistance in a truly independent manner that severs any link between donors and patients.

- Requestor would award assistance without regard to any donor's interests and without regard to the applicant's choice of provider, practitioner, supplier, or product. When determining patient eligibility for the Proposed Arrangement, Requestor would not take into account the identity of any provider, practitioner, supplier of items or services, or drug or other product the patient may use; the identity of any referring person or organization; or the amount of any contributions made by a Funding Manufacturer.

- Requestor certified that no Funding Manufacturer or affiliate of any Funding Manufacturer exerts or would exert direct or indirect control over Requestor or its program. Requestor is a nonprofit, tax-exempt organization that operates with absolute, independent, and autonomous discretion as to the use of donor contributions.

- Requestor defines the Disease Funds in accordance with widely recognized clinical standards and in a way that covers a broad spectrum of available products. Requestor would not define a Disease Fund by reference to specific symptoms, severity of symptoms, method of administration of drugs, stages of a particular disease, type of drug treatment, or any other way of narrowing the definition of widely recognized disease states. Requestor would cover, at a minimum, all drugs that are approved by the FDA for the relevant Disease in the Disease Fund.

- Requestor would not limit its assistance to high-cost or specialty drugs. Instead, Requestor would make assistance available for all prescription medications, including generic or bioequivalent drugs, approved by the FDA for treatment of the relevant Disease in the Disease Fund.

- Requestor certified that all but one of the Diseases have multiple products approved by the FDA that treat the relevant Disease. Relative to the one Disease for which the FDA has approved only one drug, Requestor certified that it would provide support for other medical needs of patients with that Disease in addition to copayment support for the FDA-approved treatment of the Disease. At a minimum, Requestor would provide copayment support for all prescription drugs used by a patient for an FDA-approved indication related to managing that Disease, including, but not limited to, drugs to treat symptoms of the Disease, such as pain medications, and prescription drugs to treat side effects of treatments, such as anti-nausea medications.

It is therefore unlikely that the Proposed Arrangement would serve as a disguised conduit for financial assistance from a Funding Manufacturer to induce patients to use its drugs.

Second, the Proposed Arrangement would provide assistance that could be highly impactful for patients with rare and chronic diseases by increasing access to care that patients may not otherwise be able to afford. Given the increasing cost of prescription drugs generally and the extra financial burden borne by patients with rare and chronic diseases—supported by data furnished by Requestor—the Proposed Arrangement would provide assistance that may result in improved health outcomes for these patients.

Therefore, for the combination of the reasons described above, we believe the risk of fraud and abuse presented by the Proposed Arrangement is sufficiently low under the Federal anti-kickback statute for OIG to issue a favorable advisory opinion. Nonetheless, as explained above, our enforcement experience has shown that arrangements involving independent charities can be susceptible to abuse. Moreover, certain relevant provisions of the Inflation Reduction Act ("IRA"), including the Medicare Prescription Drug Inflation Rebate Program, have only recently taken effect.[12] Therefore, if Requestor undertakes the Proposed Arrangement, then OIG may seek additional information from Requestor approximately 2 years after the issuance date of this advisory opinion to confirm its assessment of the Proposed Arrangement. In particular, OIG may seek certain non-patient-identifiable data regarding donors, allocation of donations, and distribution of assistance to allow us to determine how the Access to Care PAP that is the subject of this advisory opinion operates, including with respect to the changes to the law enacted through the IRA.[13] By way of example, these data may allow us to assess whether patients have

[12] The IRA eliminated Medicare Part D enrollees' 5 percent cost sharing in the catastrophic phase beginning in 2024 and also capped enrollees' annual out-of-pocket costs for Part D drugs at $2,000 beginning in 2025 (with the cap updated annually thereafter). This reduction in cost-sharing obligations could ease demand for the type of cost-sharing subsidies provided under the Proposed Arrangement. Moreover, the IRA requires pharmaceutical manufacturers to pay a rebate if they raise their prices for certain drugs faster than the rate of inflation. The IRA establishes Medicare Part B prescription drug inflation rebates for certain drugs and biologicals with prices increasing faster than the rate of inflation and provides for lower Part B beneficiary coinsurance on these drugs and biologicals.

[13] See 42 C.F.R § 1008.45; see also Medicare and State Health Care Programs: Fraud and Abuse; Issuance of Advisory Opinions by the OIG, 63 Fed. Reg. 38,311, 38,320 (Jul. 16, 1998) ("The regulations reserve the right of the OIG to rescind, terminate, or modify an advisory opinion after

improved access to costly drugs such that the public interest requires rescission, modification, or termination of this advisory opinion.

3. Beneficiary Inducements CMP

In evaluating the Proposed Arrangement under the Beneficiary Inducements CMP, we consider whether Requestor would know or have reason to know that the remuneration it directly would offer (and the Funding Manufacturers indirectly would offer) to eligible Medicare and State health care program beneficiaries would be likely to influence their 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. Requestor is not a provider, practitioner, or supplier, nor does Requestor furnish any items or services reimbursable by Federal health care programs. For purposes of the Beneficiary Inducements CMP, pharmaceutical manufacturers are not "providers, practitioners, or suppliers" unless they also own or operate, directly or indirectly, pharmacies, pharmacy benefits management companies, or other entities that file claims for payment under the Medicare or Medicaid programs. Requestor certified that the Proposed Arrangement would be available without regard to a beneficiary's choice of provider, practitioner, or supplier. Therefore, we conclude that the remuneration that would be offered directly by Requestor (and indirectly by the Funding Manufacturers) under the Proposed Arrangement would not be likely to influence a beneficiary to select 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.

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

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its issuance solely in circumstances 'where the public interest requires.' We expect that rescissions, terminations, and modifications of advisory opinions will…occur[]…when the OIG learns after the issuance of the opinion that the arrangement in question may lead to fraud or abuse, and the potential for such fraud or abuse was not foreseeable at the time the advisory opinion was issued. Situations that might lead to termination or modification of an advisory opinion may include the following circumstances—…changes in the law or the business operations of the health care industry….''). The public interest may require that we consider whether—after the full impact of the IRA can be assessed—the assistance provided under the Proposed Arrangement, which is intended to facilitate patient access to costly drugs for rare and chronic illnesses, may lead to fraud or abuse. Furthermore, given the significant risks attendant with arrangements that subsidize cost-sharing obligations, OIG may request data to confirm that: (i) Requestor is operating the arrangement in accordance with the certifications underlying this favorable advisory opinion; and (ii) if so, that our analysis and conclusions remain the same after full implementation of the Proposed Arrangement.

sections relate to the commission of acts described in the Federal anti-kickback statute; and (ii) the Proposed Arrangement, if undertaken, would not constitute grounds for the imposition of sanctions under the Beneficiary Inducements CMP.

IV. LIMITATIONS

The limitations applicable to this advisory opinion include the following:

- This advisory opinion is limited in scope to the Proposed Arrangement. This advisory opinion has no applicability to any other arrangements, including, without limitation, any 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 advisory 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,

/Peter A. Taschenberger/

Peter A. Taschenberger
Acting Assistant Inspector General for Legal Affairs