



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: October 22, 2026

Posted: October 27, 2026

[Address block redacted]

Re: OIG Advisory Opinion No. 26-19 (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 the solicitation and receipt of donations to subsidize the provision of services to certain financially needy Medicare- and Medicaid-eligible beneficiaries (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 person¹ 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 nonprofit organization and is eligible to receive tax-deductible charitable contributions under section 501(c)(3) of the Internal Revenue Code. Requestor formed a pooled special needs trust (the “Trust”) and serves as its trustee. Special needs trusts are irrevocable trusts established under Federal law for the benefit of physically or mentally disabled individuals that allow individuals with disabilities to become eligible and maintain eligibility for public assistance programs like Medicaid and the Qualified Medicare Beneficiary Program (“QMB”).² A pooled special needs trust is a type of special needs trust where the resources of multiple individuals are pooled and must be managed by a nonprofit organization.³ Requestor certified that, pursuant to state laws where it operates, the funds in a pooled special needs trust are not counted as assets or income for public assistance eligibility, provided they are used for the sole benefit of the applicable beneficiary. Requestor certified that the Trust satisfies the requirements for pooled special needs trusts set forth at 42 U.S.C. § 1396p(d)(4)(C).⁴

Requestor currently operates the Trust and charges individuals, including Federal health care program beneficiaries, up to \$200 per month to cover Requestor’s expenses for operating the Trust and for services associated with assisting beneficiaries in maintaining their QMB or QMB

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 Social Security Administration, Program Operations Manual System, SI 01120.203, Exceptions to Counting Trusts Established on or after January 1, 2000, <https://secure.ssa.gov/poms.nsf/lnx/0501120203> (the “SSA POMS”). QMBs are for individuals who are entitled to Medicare Part A, are eligible for Medicare Part B, have incomes below 100 percent of the Federal Poverty Level, and have been determined to be eligible for QMB status by their State Medicaid Agency. Medicaid pays the Medicare Parts A and B premiums, deductibles, co-insurance, and co-payments for individuals enrolled in QMB. See 42 CFR § 435.123.

³ SSA POMS.

⁴ We have not been asked to opine, and express no opinion, regarding whether the Trust satisfies the Federal statutory and regulatory requirements.

for Medicaid (also known as QMB+) status (“User Fees”).⁵ Requestor proposes to solicit and receive donations from individuals and entities that may include health care providers, suppliers, or manufacturers of drugs or devices (“Donors”)⁶ to subsidize its costs of operating the Trust for individuals who meet objective financial need criteria that Requestor has established and which Requestor certified indicate financial need (“Eligible Individuals”). Requestor certified that the Eligible Individuals would be Medicare beneficiaries who are already enrolled in QMB or QMB+, and they would not be informed of the availability of the User Fee subsidy by Requestor until after QMB or QMB+ enrollment.

Requestor made the following additional certifications:

- Requestor would not suggest, guide, or steer Eligible Individuals who receive subsidized User Fees to select any Donor or make care-related suggestions or recommendations.
- Eligible Individuals would receive subsidized User Fees on a first-come, first-served basis, subject to funding availability, with Requestor performing annual and monthly verifications to confirm continued subsidy eligibility.
- Donors would receive the following information from Requestor at the Donor’s request and on an annual basis: (i) the total number of Eligible Individuals who receive subsidized User Fees; (ii) the number of Eligible Individuals qualifying for financial assistance but for whom there is not enough funding for their User Fees to be fully or partially subsidized; (iii) the aggregate amount of the User Fees subsidized; and (iv) projections for future funding needs.
- Donors would not receive any individual-specific information, and Eligible Individuals who receive subsidized User Fees would not be directly informed by Requestor which Donors made donations.⁷
- Donations from the Donors to Requestor would be unrestricted and not contingent upon any future actions by Requestor, including any referrals or recommendations.

⁵ User Fees include fees for Requestor’s services assisting individuals with maintaining eligibility for QMB, QMB+, or Medicaid benefits, which services include monthly account monitoring, handling annual state reviews, bill-paying, and disbursement in connection with distributions from the Trust. While Requestor assists individuals with enrolling in QMB and QMB+, it does not charge individuals for these services and certified it would not use any donations to cover expenses it incurs in connection with providing such services.

⁶ Requestor certified that it employs an individual with experience in fundraising and that they use publicly available contact information to approach potential Donors.

⁷ Requestor would post the list of Donors on its website and in its quarterly and annual reports and make any disclosures required by law.

- Requestor would operate with absolute, independent, and autonomous discretion as to which Eligible Individuals receive the subsidized User Fees. In particular, Requestor would make decisions regarding which Eligible Individuals' User Fees are subsidized with the donations without regard to the interest of any Donor and without regard to the Eligible Individuals' choice of provider, practitioner, supplier, manufacturer, or product.
- When determining eligibility for the Proposed Arrangement, Requestor would not take into account the identity of any provider, practitioner, supplier, or product the Eligible Individuals may use; the identity of any referring person or organization; or the amount of any contributions made by a Donor whose services or products are used or may be used by the Eligible Individuals.
- Donors would have no control over, or influence upon, Requestor's operations.
- Requestor has, and would maintain, an independent board of directors that has adopted and enforces a strict conflict-of-interest policy, and no Donor would be permitted to join its board of directors.

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.⁸ 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.⁹ 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.¹⁰ 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

⁸ Section 1128B(b) of the Act.

⁹ Id.

¹⁰ 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).

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."

B. Analysis

The Proposed Arrangement implicates the Federal anti-kickback statute. Under the Proposed Arrangement, Donors, through Requestor, transfer remuneration to Eligible Individuals, who are Federal health care program beneficiaries, by subsidizing their User Fees, which enables the Eligible Individuals to continue to qualify for QMB or QMB+ and to potentially obtain items or services from the Donors that are payable by Federal health care programs.

As a threshold matter, OIG has long recognized that patient assistance programs ("PAPs") can provide important safety net assistance to patients. 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. OIG has consistently warned that, in order to reduce fraud and abuse risks, PAPs should be independent of donor influence and not function as a conduit for payments by the donor to patients.

For the following reasons, 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.

The Proposed Arrangement is unlikely to lead to overutilization or inappropriately increased costs to Federal health care programs. The donations solicited and received from the Donors would be used to subsidize User Fees that help Eligible Individuals maintain access to QMB and QMB+. While we recognize that continued enrollment in QMB and QMB+ would result in Eligible Individuals receiving health care items and services payable by Federal health care programs, nothing in the facts suggests that such utilization or costs would be inappropriate.

Further, the Proposed Arrangement is unlikely to lead to inappropriate steering. Requestor would not directly inform Eligible Individuals who receive subsidized User Fees which Donors made donations. Requestor is an independent, nonprofit, charitable organization that would

decide which Eligible Individuals' User Fees to subsidize through donations on a first-come, first-served basis (i.e., in an objective manner that is not associated with any donations received from Donors). Requestor provides assistance based upon a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner. The donations from Donors to Requestor would be unrestricted and not contingent upon any future actions by Requestor, including any referrals or recommendations. Requestor certified that it would operate in a truly independent manner that severs any link between Donors and beneficiaries, and with absolute, independent, and autonomous discretion as to which individuals receive the subsidized User Fees. In particular, Requestor certified that it awards assistance without regard to any Donor's interests and without regard to the Eligible Individual's choice of provider, practitioner, supplier, manufacturer, or product. When determining eligibility for the Proposed Arrangement, Requestor would not take into account the identity of any provider, practitioner, supplier, or product the Eligible Individuals may use; the identity of any referring person or organization; or the amount of any contributions made by a Donor whose services or products are used or may be used by the Eligible Individuals. Donors would have no direct or indirect control over, or influence upon, Requestor's operations and, Requestor has, and would maintain, an independent board of directors that has adopted and enforces a strict conflict-of-interest policy, and no Donor would be permitted to join its board of directors. Lastly, Requestor certified that Donors would not receive any individual-specific information about who received the subsidized User Fees or other information that would facilitate Donors correlating the amount or frequency of their donations with the amount or frequency of the use of any of their products or services.

With respect to the Beneficiary Inducements CMP, for the same reasons set forth above, we do not believe that the subsidization of the User Fees by Donors would be likely to influence a beneficiary to choose a Donor who is a provider, practitioner, or supplier for any item or service payable by Medicare or a State health care program, and thus the Proposed Arrangement would not constitute grounds for the imposition of sanctions 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) the Proposed Arrangement, if undertaken, would not constitute grounds for the imposition of sanctions under the Beneficiary Inducements CMP.

III. 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,

/ Kenneth D. Kraft /

Kenneth D. Kraft
Assistant Inspector General for Legal Affairs