DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL
WASHINGTON, DC 20201

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information, unless otherwise approved by the requestor(s).*]

Issued: July 9, 2026

Posted: July 14, 2026

[Address block redacted]

Re: OIG Advisory Opinion No. 26-16 (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 Requestor's provision of produce boxes and produce vouchers to a group of patients who have been diagnosed with certain health conditions (the "Arrangement"). Specifically, you have inquired whether the Arrangement constitutes grounds for the imposition of sanctions under: the civil monetary penalty provision at section 1128A(a)(7) of the Social Security Act (the "Act"), as that section relates to the commission of acts described in section 1128B(b) of the Act (the "Federal anti-kickback statute"); the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Act (the "Beneficiary Inducements CMP"); or the exclusion authority at section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute and the Beneficiary Inducements CMP.

Requestor has certified that all of the information provided in the request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties in connection with the Arrangement, and we have relied solely on the facts and information Requestor provided. We have not undertaken an independent investigation of the certified facts and information presented to us by Requestor. This advisory opinion is limited to the relevant facts presented to us by Requestor in connection with the 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 Arrangement would generate—if the requisite intent were present—prohibited remuneration under the Federal anti-kickback statute, OIG will not impose administrative sanctions on Requestor in connection with the Arrangement under sections 1128A(a)(7) or 1128(b)(7) of the Act, as those sections relate to the commission of acts

described in the Federal anti-kickback statute; and (ii) although the Arrangement generates prohibited remuneration under the Beneficiary Inducements CMP, OIG will not impose administrative sanctions on Requestor in connection with the 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 advisory opinion may not be relied on by any person[1] other than Requestor, has no applicability to any arrangements other than the 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 designated as a federally qualified health center, consistent with Section 330 of the Public Health Service ("PHS") Act,[2] and serves predominantly low-income individuals, including Federal health care program beneficiaries. Requestor is required to provide a variety of services, including medical, dental, and pharmaceutical services. Pursuant to its scope of project, as approved by the Health Resources and Services Administration ("HRSA"), Requestor is also authorized to provide additional services, such as nutrition services like food banks or meals.

Under the Arrangement, Requestor is providing a food-as-medicine program for a 6-month period to a group of 50 financially needy patients with diabetes or hypertension who have been selected to participate ("Participants"). As part of the program, Participants: (i) receive weekly produce boxes or produce vouchers; and (ii) undergo three health assessments consisting of an initial, midpoint, and final assessment designed to allow Requestor to establish baseline health metrics and develop individualized care plans for them. Requestor certified that the purposes of the Arrangement are to improve patient knowledge and management of diabetes and hypertension, promote healthy eating and sustained lifestyle changes, and reduce the incidence of complications related to chronic health conditions, among other things.

Produce Boxes and Produce Vouchers

Requestor provides the produce component of the Arrangement without charge to Participants. Requestor provides one group of Participants with weekly produce boxes worth $30 each consisting of fresh fruits and vegetables that are delivered directly to Participants' homes. Requestor provides the other group of Participants with weekly produce vouchers worth $20 each. Participants are able to use the produce vouchers at local grocery store chains and farmers markets to purchase only healthy food options.

[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] 42 U.S.C. § 254b.

Requestor certified that a company administers the vouchers on behalf of Requestor (the "Voucher Company") and that the Voucher Company has represented and warranted to Requestor that it engages in the following practices to ensure Participants are able to use the vouchers to purchase only healthy food:

(i) Tracks and collects data on participation, voucher distribution, and redemption patterns and shares the data with Requestor;

(ii) Checks receipts on a regular basis;

(iii) Conducts site visits and cashier trainings; and

(iv) Signs memoranda of understanding with all retailers regarding the parameters for using the vouchers, including the types of items for which Participants may use the vouchers.

Health Assessments

Participants undergo an initial, midpoint, and final health assessment, each of which involves various services. The assessments are with a registered dietician (or when unavailable, a family medicine or internal medicine provider) and behavioral health consultant and involve a nutrition assessment, meal plan development, clinical laboratory testing, and counseling, among other services. In addition to these health assessments, the Arrangement involves physician oversight of the process, one-on-one consultations with the registered dietician, and individual and group therapy sessions. Requestor's employees provide the dietician, counseling, and physician services, and a third-party laboratory provides the clinical laboratory testing.[3]

Billing

While Requestor provides the produce boxes and produce vouchers free of charge, Requestor bills Participants and their insurers, as applicable, in accordance with Requestor's fee schedule and Sliding Fee Discount Policy[4] (subject to contractual obligations to collect cost sharing from insured patients) for all reimbursable services provided as part of the Arrangement, including nutrition services provided by a registered dietician. In addition to billing for services, Requestor funds the Arrangement through grants. Requestor certified that, contingent on additional grants and funding becoming available, it will scale the program beyond the initial 50 Participants and also will include in the program patients with the following nutrition-sensitive diagnoses: hyperlipidemia; obesity and metabolic syndrome; chronic kidney disease; coronary artery disease; and congestive heart failure.

[3] Requestor certified that it does not receive any remuneration from the third-party laboratory.

[4] HRSA Health Center Program, Chapter 9: Sliding Fee Discount Program, https://bphc.hrsa.gov/compliance/compliance-manual/chapter9 (accessed June 1, 2026).

Participant Eligibility

To be selected as a Participant, a patient must meet the following criteria:

(i) Be an existing patient of Requestor between 18 and 85 years of age;

(ii) Have a diagnosis of either:

- diabetes with a most recent A1c reading of at least 7.0 within the past 3 months, with or without hypertension; or
- hypertension with an official systolic blood pressure reading of at least 140 mmHg or a diastolic blood pressure reading of at least 90 mmHg within the past 12 months, with or without diabetes or obesity;

(iii) Be willing to receive nutrition counseling from a registered dietician up to three times and behavioral modification counseling from a behavioral health consultant;

(iv) Have the ability to participate in optional group sessions without the need for on-site translation services; and

(v) Meet Requestor's established criteria for financial hardship.

Requestor certified that, in selecting Participants for the Proposed Arrangement, it does not take into account a patient's insured status.

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.

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

[6] Id.

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." Section 1128A(i)(6) of the Act contains an exception to the definition of "remuneration" that may apply in the context of the Arrangement. Section 1128A(i)(6)(H) of the Act (the "Financial Need-Based Exception") provides that, for purposes of the Beneficiary Inducements CMP, the term "remuneration" does not apply to the offer or transfer of items or services for free or less than fair market value if the items or services: (i) are not advertised; (ii) are not tied to the provision of other reimbursable items or services; (iii) are reasonably connected to the medical care of the individual; and (iv) are provided only after a good-faith determination that the recipient is in financial need.

B. Analysis

1. Federal Anti-Kickback Statute

The Arrangement implicates the Federal anti-kickback statute because Requestor provides produce boxes or produce vouchers to Participants without charge, which could induce Participants who are Federal health care program beneficiaries to receive items and services from Requestor that are reimbursable by Federal health care programs, such as the billable services Requestor provides as part of the three health assessments Participants undergo. No safe harbor applies to the Arrangement. We have longstanding and continuing concerns regarding the provision of free items and services to Federal health care program beneficiaries. However, for the following reasons, we believe the risk of fraud and abuse presented by the Arrangement is

[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).

sufficiently low under the Federal anti-kickback statute for OIG to issue a favorable advisory opinion.

First, the Arrangement is unlikely to result in overutilization or inappropriate utilization or increased costs to Federal health care programs. The Arrangement aligns with Requestor's designation as a federally qualified health center under Section 330 of the PHS Act, and specifically, the provision of the produce boxes and produce vouchers is consistent with the HRSA-approved additional services Requestor may provide. The remuneration Requestor offers is in-kind (i.e., produce boxes and produce vouchers) and narrowly tailored to the stated purposes of the Arrangement, including disease management through access to healthy food. Although the required health assessments under the Arrangement involve the provision of items and services that may be reimbursable by Federal health care programs to Participants, nothing in the facts indicates that such items and services are inappropriate. In fact, Requestor certified that the health assessments are designed to allow Requestor to establish baseline health metrics and develop individualized care plans for the Participants, which could improve patient outcomes and reduce Federal health care program costs over time.

Second, the Arrangement is unlikely to result in inappropriate steering or unfair competition. The Arrangement is limited in value and duration, and Participants are still responsible for any applicable cost sharing for the items and services provided as part of the required health assessments, which reduces the likelihood that the produce boxes or produce vouchers will materially influence a beneficiary's provider selection over the long term. Under the Arrangement, Participants get only one produce box or produce voucher per week for a 6-month period, and various safeguards reduce the risk that the produce vouchers could confer unintended value by being used for purchases beyond those aligned with the stated purposes of the food-as-medicine program. Participants are able to use the produce vouchers at local grocery store chains and farmers markets to purchase only healthy food options. Additionally, the Voucher Company represented and warranted to Requestor that it: (i) tracks and collects data on participation, voucher distribution, and redemption patterns and shares the data with Requestor; (ii) checks receipts on a regular basis; (iii) conducts site visits and cashier trainings; and (iv) signs memoranda of understanding with all retailers regarding the parameters for using the vouchers, including the types of items for which Participants may use the vouchers.

2. Beneficiary Inducements CMP

With respect to the Beneficiary Inducements CMP, we conclude that the Arrangement could influence Federal health care program beneficiaries to select Requestor for the receipt of items and services that may be reimbursable by a Federal health care program, including nutrition services and laboratory testing furnished during the health assessments that comprise part of the Arrangement. Therefore, the Arrangement implicates the Beneficiary Inducements CMP. The Arrangement does not satisfy the Financial Need-Based Exception because the free produce boxes and produce vouchers are tied to the provision of other reimbursable items and services that are provided during the health assessments. Nevertheless, for the reasons stated above, in an exercise of our enforcement discretion, we will not impose sanctions under the Beneficiary Inducements CMP in connection with the Arrangement.

III. CONCLUSION

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) although the Arrangement would generate—if the requisite intent were present—prohibited remuneration under the Federal anti-kickback statute, OIG will 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 Arrangement generates prohibited remuneration under the Beneficiary Inducements CMP, OIG will not impose administrative sanctions on Requestor in connection with the 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 advisory opinion include the following:

- This advisory opinion is limited in scope to the 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 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 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. 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 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,

/Tamara T. Forys/

Tamara T. Forys
Acting Assistant Inspector General for Legal Affairs