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: April 4, 2025

Posted: April 9, 2025

[Address block redacted]

Re: OIG Advisory Opinion No. 25-02 (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 an arrangement whereby Requestor—designated as a community health center ("Health Center") pursuant to Section 330 of the Public Health Service Act (the "PHS Act")[1]—proposes, during the provision of certain social services to individuals, to: (1) identify individuals in need of primary care services; (2) inform them of the availability of such services; and (3) schedule an appointment for them to receive primary care services from Requestor or refer them to a local primary care provider (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

[1] 42 U.S.C. § 254b.

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[2] 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

Consistent with Section 330 of the PHS Act, in addition to medical services, Requestor provides certain non-medical, social, and educational services that enable individuals to access health care and improve health outcomes (e.g., child care, food banks and meals, employment and education counseling, and legal services) ("Additional Services"). Health Centers are required to provide certain health care and other services to community members.[3] For example, Health Centers are required to conduct "a broad range of culturally and linguistically appropriate activities focused on recruiting and retaining patients" from the Health Center's service area (i.e., outreach services).[4] Health Centers also may provide supplemental health services, which promote and facilitate optimal use of primary health services.[5] Consistent with Section 330 of the PHS Act, Health Centers provide primary health care services to underserved populations, regardless of their ability to pay.[6]

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[2] 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.

[3] See Health Resources and Services Administration ("HRSA"), "Service Descriptors for Form 5A: Services Provided," https://bphc.hrsa.gov/sites/default/files/bphc/compliance/form-5a-service-descriptors.pdf (last updated Feb. 2025; last accessed Dec. 12, 2024); see also 42 C.F.R. § 51c.102.

[4] See HRSA, supra note 3; see also 42 C.F.R. § 51c.102(j)(14).

[5] 42 C.F.R. § 51c.102(c)(1)(ii).

[6] Supra note 1.

The Health Resources and Services Administration ("HRSA") has formally approved the Additional Services furnished by Requestor within Requestor's scope of project.[7] Illustratively, Requestor provides the following Additional Services:

- a program that assists victims of crimes with replacing locks to address safety concerns (worth $150, up to 4 times per year); and

- a program that provides diapers, books, toys, and baby gear for children ages 0-5 (worth up to $50, up to 3 times per year).

According to Requestor, individuals in the community served by Requestor frequently access Requestor's Additional Services but do not seek health care services from Requestor because they do not believe they have the financial means to do so or do not understand how to do so.

Under the Proposed Arrangement, at the time individuals receive Additional Services from Requestor, Requestor would ask each individual whether they have seen a primary care provider within the last year. If the answer is no, then Requestor would provide the individual with a list of primary care providers, which would include Requestor. Requestor certified that the list would include providers other than Requestor and that the list would be: (i) organized in alphabetical order; and (ii) drafted without promoting Requestor (e.g., by not using bold font, underlining, or other emphasis to identify Requestor). In the event a community provider (e.g., Health Center, hospital, primary care physician practice) would like to be included on the list of primary care providers, Requestor would implement an "any willing provider" standard, such that the request for inclusion on the list would be honored at all times. Requestor certified that individuals could continue to receive Additional Services from Requestor without electing to receive primary care services from Requestor.

For individuals who elect to receive primary care services from Requestor, Requestor would schedule an appointment for the individual. If the individual selects a provider other than Requestor from the list, then Requestor would make an electronic referral to the requested provider. The electronic referral to the other provider would include the prospective patient's contact information and reason for referral so that the requested provider could contact the individual and schedule the appointment for the individual. Requestor would provide complete contact information to the individual and requested provider sufficient to effectuate the referral.

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[7] A Health Center's scope of project defines the activities supported by HRSA's Health Center Program project budget. Specifically, scope of project defines the approved service sites, services, providers, service area(s), and target population(s). HRSA, "Scope of Project," https://bphc.hrsa.gov/compliance/scope-project (last updated Dec. 2024; last accessed Dec. 12, 2024).

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 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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[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).

B. Analysis

1. Federal Anti-Kickback Statute

The Proposed Arrangement implicates the Federal anti-kickback statute because it would involve remuneration in the form of Additional Services from Requestor to individuals that could induce them to self-refer to Requestor to obtain health care services. Specifically, Requestor's provision of Additional Services to individuals potentially would be combined with an offer to schedule an appointment for those individuals to receive primary care services from Requestor. However, for the combination of 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.

First, the Proposed Arrangement includes a variety of safeguards that reduce the risk of steering patients to Requestor:

- Individuals in need of primary care services would be identified using an objective criterion (i.e., whether the individual has seen a primary care provider within the last year), which does not promote Requestor.

- The list of primary care providers would be: (i) organized in alphabetical order; and (ii) drafted without promoting Requestor (e.g., by not using bold font, underlining, or other emphasis to identify Requestor).

- Requestor would include at least several providers on the list distributed to patients and also would implement an "any willing provider" standard, such that, if a community provider (e.g., Health Center, hospital, primary care physician practice) would like to be included on the list of primary care providers that is given to individuals receiving Additional Services, then the request for inclusion on the list would be honored at all times.

- Requestor certified that individuals could continue to receive Additional Services from Requestor without electing to receive primary care services from Requestor. In the event an individual receiving Additional Services selects a provider other than Requestor from the list, Requestor would provide complete contact information to the individual and requested provider sufficient to effectuate the referral.

Second, as a Health Center, Requestor endeavors to provide primary care services to underserved populations, regardless of their ability to pay. The Proposed Arrangement, which may increase access to health care services, aligns with Requestor's designation as a Health Center under Section 330 of the PHS Act. Under the statute, Requestor is required to conduct a broad range of activities focused on recruiting and retaining patients from the service area and is permitted to provide supplemental health services that promote and facilitate optimal use of primary care services. Under the Proposed Arrangement, Requestor would be offering HRSA-approved Additional Services and concurrently confirming that a patient has access to primary care

services or offering to facilitate such access, all of which would be consistent with the statutory requirements imposed on Requestor as a Health Center.[11]

2. Beneficiary Inducements CMP

With respect to the Beneficiary Inducements CMP, we conclude that the Proposed Arrangement could influence beneficiaries to select Requestor for the receipt of primary care services that could be reimbursable by a Federal health care program, and therefore the Proposed Arrangement would implicate the Beneficiary Inducements CMP. For the reasons stated above, however, in an exercise of our enforcement discretion, we would not impose sanctions under the Beneficiary Inducements CMP in connection with the Proposed 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 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.

[11] While HRSA has approved the specific Additional Services that Requestor would provide under the Proposed Arrangement, this fact, standing alone, does not establish that the Proposed Arrangement poses a low risk of fraud and abuse under the Federal anti-kickback statute; however, it does contribute to our understanding that Additional Services are commonly provided by Health Centers.

- 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 HHS.

- 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