



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 31, 2022

Posted: September 6, 2022

[Address block redacted]

Re: OIG Advisory Opinion No. 22-17

Dear [redacted]:

The Office of Inspector General (“OIG”) is writing in response to your request for an advisory opinion on behalf of [redacted] (the “Health System”) and [redacted] (the “Clinic” and, together with the Health System, “Requestors”) regarding a proposed restructuring of financial relationships between the Health System and the Clinic (the “Proposed Arrangement”). Specifically, you have inquired whether the Proposed Arrangement, if undertaken, would constitute grounds for the imposition of sanctions under the exclusion authority at section 1128(b)(7) of the Social Security Act (the “Act”) or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act (the “Federal anti-kickback statute”).

Requestors have 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 Requestors provided. We have not undertaken an independent investigation of the certified facts and information presented to us by Requestors. This opinion is limited to the relevant facts presented to us by Requestors in connection with the Proposed Arrangement. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that, although the Proposed Arrangement, if undertaken, would generate prohibited remuneration if the requisite intent were present, the OIG would not impose administrative sanctions on Requestors 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.

This opinion may not be relied on by any person¹ other than Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. Overview of Requestors

The Health System is a regional 501(c)(3) not-for-profit health care system located in [redacted] that operates four hospitals. The Clinic is a 501(c)(3) public benefit corporation that offers dental, medical, vision, and behavioral health care to patients, regardless of their ability to pay or their insurance status. Requestors both serve patients, including Medicare and Medicaid beneficiaries, in the city of [redacted] and five counties in [redacted]: [redacted] (the “Service Area”). The Service Area includes geographic areas that the Health Resources and Services Administration (“HRSA”) has designated as medically underserved areas (“MUAs”) and health professional shortage areas (“HPSAs”), as well as populations that HRSA has designated as medically underserved populations (“MUPs”). Requestors certified that the Health System and the Clinic refer patients to one another on a regular basis when it is in the patient’s best interest and with the patient’s consent, though neither the Health System nor the Clinic is under any obligation to make any such referrals.

The Health System supported the establishment of the Clinic in 2015 to address the shortage of primary care services available in the Service Area and reduce overutilization of the emergency departments at the Health System’s hospitals. The Clinic is registered as a Free Clinic with [redacted] and has been designated as a Federally Qualified Health Center (“FQHC”) Look-Alike (“FQHC Look-Alike”) since June 2017.² By virtue of being designated as an FQHC Look-Alike by HRSA, the Clinic is subject to Federal Government oversight of its operations and finances through an annual certification and renewal of designation process (which occurs every 1 to 3 years) and monitoring of its compliance with additional requirements further described in the Health Center Compliance Manual.³ In addition, although the Clinic does not

¹ We use “person” herein to include persons, as referenced in the Federal anti-kickback statute, as well as individuals and entities, as referenced in the exclusion authority at section 1128(b)(7) of the Act.

² For purposes of this Advisory Opinion, an FQHC is a community-based health care provider that receives grant funds under section 330 of the Public Health Service Act. See section 1905(l)(2)(B)(i)-(ii) of the Act. An FQHC Look-Alike is a health center that meets the requirements to be an FQHC but does not receive grant funds under section 330 of the Public Health Service Act. See <https://bphc.hrsa.gov/programopportunities/lookalike/index.html>.

³ See, e.g., HRSA, Fiscal Year (FY) 2023 Look-Alike Annual Certification (AC) Instructions & Resources, <https://bphc.hrsa.gov/funding/funding-opportunities/health-center-program-look-alikes/look-alike-annual-certification-ac-instructions-resources>; HRSA, Fiscal Year (FY) 2023 Look-Alike Renewal of Designation (RD) Instructions & Resources, <https://bphc.hrsa.gov/funding/funding-opportunities/health-center-program-look-alikes/look->

receive grant funds under section 330 of the Public Health Service Act, the Clinic currently receives, and in the past has received, certain Federal grant funds or awards that subject the Clinic to the same or similar oversight and reporting obligations that apply to recipients of section 330 funds.⁴ The Clinic also certified that it will continue to apply for additional Federal grant funds, including section 330 grant funds, in the future.

Since the Clinic's formation, Requestors have collaborated in their shared mission to achieve certain goals and objectives through the Clinic, including: (i) expanding access to health care services for low-income residents, without regard to their insurance status or ability to pay; (ii) improving the overall health of patients served by Requestors; and (iii) reducing financial, environmental, process, and cultural barriers in accessing quality health care services. In furtherance of these shared goals, the Health System has provided financial support to the Clinic since its initial development, both directly and through the Health System's affiliated charitable foundation.

B. Proposed Arrangement

1. Background

Under the Proposed Arrangement, Requestors would restructure three existing agreements between the Health System and the Clinic: a credit line note, a lease, and a master services agreement, each of which is described in greater detail below.

The Health System entered into a credit line note with the Clinic in June 2018 for a loan up to [redacted] (the "Note"). Notwithstanding the payment terms of the Note, which require monthly interest payments on the unpaid principal balance and an application of any excess cash⁵ at the end of a calendar quarter to the loan principal, along with various penalties for non-payment, the Clinic has made only two payments towards the Note balance, totaling [redacted] towards principal and [redacted] towards interest.

The Health System also purchased property and built a medical office building that the Clinic has leased from the Health System since 2017 to use as one of the Clinic's primary locations. Requestors entered into a written agreement that covers use of the premises as well as furniture, fixtures, and equipment (the "Lease"). Requestors certified that the Lease provides for fair market value rent; however, the Clinic has not made any payments to the Health System under

[alike-renewal-designation-instructions-resources](#); HRSA, Health Center Program Compliance Manual (Aug. 2018), <https://bphc.hrsa.gov/compliance/compliance-manual>.

⁴ We consulted with HRSA regarding the Federal grants that the Clinic has received. According to HRSA, some of the grants the Clinic has received are governed by the same standards that apply to section 330 funds awarded to FQHCs, and other grants the Clinic receives contain reporting requirements and standard terms that are similar to those in place for section 330 funds.

⁵ The Note defines "excess cash" as the amount of cash and cash equivalents shown on the Clinic's quarterly balance sheet in excess of [redacted].

the terms of the Lease. All amounts owed under the Lease have been charged against the Note and are reflected in the current total amount due on the Note.

Finally, Requestors entered into a master services agreement in 2019 pursuant to which the Health System provides the Clinic with certain administrative and medical services for which the Clinic is contractually obligated to pay a fair market value payment rate (the “MSA”).⁶ Other than two partial payments for 2 months in 2018, the Clinic has not made any payments to the Health System in accordance with the terms of the MSA. All amounts owed under the MSA have been charged against the Note and are reflected in the total amount due on the Note.

Since Requestors entered into the Note in 2018, the Clinic has requested, and the Health System has approved, several increases to the Note, which now totals more than [redacted] and includes all amounts owed to the Health System under the Lease and the MSA. Requestors certified that these increases on the Note were necessary because the Clinic did not have sufficient revenue to continue operations without extending the Note. Requestors further certified that the financial burden from the obligations created under the Note, the Lease, and the MSA will prevent the Clinic from achieving financial stability.

2. Proposed Restructuring of Financial Arrangements

Under the Proposed Arrangement, the Health System proposes to forgive—in full—the outstanding amount owed (principal and accrued interest) by the Clinic on the Note through a donation in that amount to the Clinic (the “Note Donation”). The Note Donation would include all amounts owed under the Lease and the MSA, as those amounts have been charged against the Note and are reflected in the total amount due on the Note. Requestors also would enter into new agreements to address the Clinic’s use of the premises, furniture, fixtures, and equipment currently covered by the Lease (the “New Lease”) and a revised scope of administrative and medical services to be provided by the Health System to the Clinic, reflecting the Clinic’s growth and maturity since its formation in 2015 (the “New MSA,” and together with the Note Donation and the New Lease, the “New Agreements”).⁷

Under the terms of the New Lease, the Health System would permit the Clinic to use the premises, furniture, fixtures, and equipment covered by the Lease free of charge. Requestors

⁶ Through the MSA, Requestors terminated and consolidated several pre-existing, separate services agreements.

⁷ This advisory opinion applies only to the Proposed Arrangement and specifically to the New Agreements. We have not been asked to opine on, nor do we express an opinion on, the Note, the Lease, the MSA, or any other arrangements between the Clinic and the Health System (or its affiliated charitable foundation) that predate the New Agreements. Likewise, we express no opinion on the operations or conduct of either the Clinic or the Health System related to such arrangements. We also have not been asked to opine on, nor do we express an opinion on, any arrangements between the Health System or the Clinic and any other tenant or sub-tenant who makes use of the premises, furniture, fixtures, or equipment covered by the Lease or the New Lease.

certified that the terms of the New MSA would require the Clinic to pay the Health System fair market value for the services the Health System provides to the Clinic under the New MSA.⁸

Requestors made the following certifications with respect to the New Agreements:

- The New Agreements would be in writing, signed by both Requestors, and would cover and specify the amount of, all goods, items, services, donations, or loans to be provided by the Health System to the Clinic. The Health System would keep a centralized master list of all agreements between the Health System and the Clinic and make it available to the Secretary upon request. The list would be kept current and would preserve the historical record of the parties' arrangements, and each of the New Agreements would cross-reference the master list.
- The amount of goods, items, services, donations, or loans from the Health System to the Clinic under the New Agreements would be for a fixed sum and would not be conditioned on the volume or value of Federal health care program business generated between the parties.
- The goods, items, services, donations, or loans that the Health System would provide to the Clinic pursuant to the New Agreements would be medical or clinical in nature or otherwise relate directly to the services the Clinic provides to its patients consistent with its status as an FQHC Look-Alike.
- The Clinic has determined that the goods, items, services, donations, or loans that the Health System would provide to the Clinic pursuant to the New Agreements would contribute meaningfully to the Clinic's ability to maintain or increase the availability, or enhance the quality of, services provided to a medically underserved population (as that term is defined at 42 C.F.R. § 51c.102(e)) in the Service Area, and the Clinic would document the basis for this expectation prior to entering into the New Agreements with the Health System. The Clinic would make this documentation available to the Secretary upon request. Requestors certified that the New Agreements would not be renewed or renegotiated unless the Clinic reasonably expects this standard to be satisfied for the next term of the applicable agreement. Requestors further certified that the Clinic would make the same determination with respect to any renewed or renegotiated versions of the New Agreements, would document the basis for such determination prior to entering into any such renewed or renegotiated New Agreements, and would make such documentation available to the Secretary upon request.
- The Clinic would re-evaluate the New Agreements at least annually to ensure that the goods, items, services, donations, or loans that the Health System provides pursuant to the New Agreements continue to be expected to contribute meaningfully to the Clinic's ability to maintain or increase, or enhance the quality of, services that the Clinic provides to a medically underserved population in the Service Area. The Clinic would document

⁸ We are precluded by statute from opining on whether fair market value shall be, or was, paid for goods, services, or property. Section 1128D(b)(3)(A) of the Act.

the re-evaluation contemporaneously and would make the documentation available to the Secretary upon request.

- The Health System would not restrict, in the New Agreements or otherwise, the Clinic from referring patients to other providers, and nothing would require either Requestor to refer patients to a particular individual or entity.
- Goods, items, or services that would be provided by the Health System to the Clinic under the New Agreements would be provided to all Clinic patients regardless of their payor status or ability to pay.
- At all times, the Clinic would be free to enter into agreements with other providers or suppliers of comparable goods, items, or services or with other lenders or donors. To the extent the Clinic were to have multiple individuals or entities willing to offer comparable remuneration, the Clinic would employ a reasonable methodology to determine which individuals or entities to select and would document its determination. In making this determination, the Clinic would look to the procurement standards for beneficiaries of Federal grants set forth in 45 C.F.R. § 75.326 through § 75.340.
- The Clinic would provide effective notice to patients of their freedom to choose any willing provider or supplier. Upon request, the Clinic would disclose the existence and nature of the New Agreements to its patients. This notification would be provided in a timely fashion and in a manner reasonably calculated to be effective and understood by the patient.
- If the Clinic elects to require the Health System to charge a referred Clinic patient the same rate that the Health System charges other similarly situated patients not referred by the Clinic or to charge a Clinic patient a reduced rate, the Health System would comply with any such requirement.

II. LEGAL ANALYSIS

A. Law

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.⁹ 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.¹⁰ For purposes of the Federal anti-kickback

⁹ Section 1128B(b) of the Act.

¹⁰ Id.

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.¹¹ 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, the OIG may initiate administrative proceedings to impose civil monetary penalties on such person under section 1128A(a)(7) of the Act. The OIG also may initiate administrative proceedings to exclude such person from Federal health care programs under section 1128(b)(7) of the Act.

Congress has developed several statutory exceptions to the Federal anti-kickback statute.¹² In addition, the U.S. Department of Health and Human Services has promulgated safe harbor regulations that specify certain practices that are not treated as an offense under the Federal anti-kickback statute and do not serve as the basis for an exclusion.¹³ However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor. Compliance with a safe harbor is voluntary. Arrangements that do not comply with a safe harbor are evaluated on a case-by-case basis. The statutory exception and regulatory safe harbor for certain transfers of goods, items, services, donations, or loans from an individual or entity to an FQHC are potentially applicable to the Proposed Arrangement (the “FQHC Safe Harbor”).¹⁴

B. Analysis

The Proposed Arrangement would implicate the Federal anti-kickback statute because it would involve remuneration from the Health System to the Clinic that could induce the Clinic to make referrals to the Health System. Specifically, the Note Donation would alleviate a significant financial debt owed by the Clinic to the Health System, and the terms of the New Lease would provide for free use of the premises (including its furniture, fixtures, and equipment) that the Clinic currently uses as one of its primary locations.

The Proposed Arrangement would not qualify for protection under the FQHC Safe Harbor because that safe harbor only protects remuneration to an FQHC, and the Clinic is an FQHC Look-Alike. In the preamble to the 2007 rule that finalized the FQHC Safe Harbor (the “2007 Final Rule”), we declined to extend safe harbor protection to remuneration provided to FQHC

¹¹ 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).

¹² Section 1128B(b)(3) of the Act.

¹³ 42 C.F.R. § 1001.952.

¹⁴ See section 1128B(b)(3)(I) of the Act; 42 C.F.R. § 1001.952(w).

Look-Alikes because Congress specifically provided that the safe harbor should apply to FQHCs and “the lack of section 330 funding, which entails a higher level of Government oversight, constitutes a significant distinction between section 330-funded health centers and look-alike facilities.”¹⁵

We evaluate arrangements that implicate the Federal anti-kickback statute and that do not have safe harbor protection on a case-by-case basis, based on the totality of the facts and circumstances. For the combination of the reasons discussed below, we conclude that the Proposed Arrangement poses a sufficiently low risk of fraud and abuse under the Federal anti-kickback statute.

First, Requestors’ certifications indicate that the Proposed Arrangement would be structured and operated in a manner that aligns with all of the requirements of the FQHC Safe Harbor, except for the fact that the Clinic is not an FQHC and does not receive grant funds under section 330 of the Public Health Service Act. For example, Requestors certified that the Health System would not restrict the Clinic’s ability to refer patients to other providers and that the Clinic has determined that the remuneration under the New Agreements would contribute meaningfully to the Clinic’s ability to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population in the Service Area. Requestors also certified that the Clinic would re-evaluate this determination at least annually over the course of the Proposed Arrangement. With respect to the requirement at 42 C.F.R. § 1001.952(w)(2) that the goods, items, services, donations, or loans be medical or clinical in nature or relate directly to services provided by the health center as part of the scope of the health center’s section 330 grant, Requestors certified that the goods, items, services, donations, or loans that the Health System would provide to the Clinic pursuant to the New Agreements would be medical or clinical in nature or otherwise relate directly to the services the Clinic provides to its patients consistent with its status as an FQHC Look-Alike. These features, along with the other features of the Proposed Arrangement set forth in the bullet points in section I.B.2. of this advisory opinion, support that the Proposed Arrangement would be implemented in a manner that aligns with all of the requirements of the FQHC Safe Harbor, which, when assessed in combination with the other factors described below, mitigates the risk of fraud and abuse of the Proposed Arrangement.

Second, although the Clinic does not receive section 330 funding, HRSA has designated the Clinic as an FQHC Look-Alike, and by virtue of that designation, HRSA conducts regular oversight of the Clinic’s operations and finances. In addition, the Clinic currently receives, and in the past has received, certain Federal grant funds or awards that subject the Clinic to the same or similar oversight and reporting obligations that apply to recipients of section 330 funds. The Clinic also certified that it will continue to apply for additional Federal grant funds, including section 330 grant funds, in the future. Recognizing the distinction made in the preamble to OIG’s 2007 Final Rule, we believe the risk of fraud and abuse from the Health System’s support of the Clinic under the Proposed Arrangement is reduced by: (i) the oversight associated with

¹⁵ OIG, Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbor for Federally Qualified Health Centers Arrangements Under the Anti-Kickback Statute, 72 Fed. Reg. 56,632, 56,636 (Oct. 4, 2007).

HRSA's designation of the Clinic as an FQHC Look-Alike; (ii) the government oversight associated with the Federal grant funds the Clinic receives; and (iii) the Clinic's certification that it will continue to apply for additional Federal grant funds, including section 330 grant funds, going forward.

Third, certain attributes of the Proposed Arrangement reduce the risk that it would result in inappropriate patient steering from the Clinic to the Health System. In particular, while Requestors certified that the Health System and the Clinic refer patients to one another on a regular basis when it is in the patient's best interest and with the patient's consent, neither the Health System nor the Clinic is under any obligation to make any such referrals. In addition, the Clinic would be free to enter into agreements with other providers or suppliers of comparable goods, items, or services or with other lenders or donors, and to the extent the Clinic were to have multiple individuals or entities willing to offer comparable remuneration, Requestors certified that the Clinic would employ a reasonable methodology to determine which individuals or entities to select and would document its determination. Further, one of the Health System's stated aims for the Clinic is to reduce overutilization of the emergency departments at the Health System's hospitals.

Lastly, the remuneration that would be provided under the Proposed Arrangement is a continuation of the Health System's longstanding support of the Clinic as part of their shared mission to: (i) expand access to health care services for low-income residents, without regard to their insurance status or ability to pay; (ii) improve the overall health of patients served by Requestors; and (iii) reduce financial, environmental, process, and cultural barriers in accessing quality health care services. We believe this history of alignment, based on the specific and unique facts and circumstances of the Proposed Arrangement, reduces the likelihood that the Proposed Arrangement would be a novel artifice to generate referrals from the Clinic.

III. CONCLUSION

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that, although the Proposed Arrangement, if undertaken, would generate prohibited remuneration if the requisite intent were present, the OIG would not impose administrative sanctions on Requestors 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.

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 Requestors. 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 Requestors to prove that the person did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.
- This advisory opinion applies only to the statutory provisions specifically addressed in the analysis above. We express no opinion herein with respect to the application of any other Federal, State, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Proposed Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act (or that provision's application to the Medicaid program at section 1903(s) of the Act).
- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.
- We express no opinion herein regarding the liability of any person under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

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

The OIG will not proceed against Requestors 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. The 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, the OIG will not proceed against Requestors 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 the OIG.

Sincerely,

/Robert K. DeConti/

Robert K. DeConti
Assistant Inspector General for Legal Affairs