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: June 6, 2025

Posted: June 11, 2025

[Address block redacted]

Re: OIG Advisory Opinion No. 25-03 (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 Inc.") and [redacted] ("Requestor PC") (collectively, Requestor Inc. and Requestor PC are referred to as "Requestors"),[1] whereby Requestors propose to enter into an agreement with telehealth providers to lease employees and provide certain administrative services (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 the Proposed Arrangement, if undertaken, would not generate prohibited remuneration under the Federal anti-kickback statute. Accordingly, OIG would not impose administrative sanctions on Requestors in connection with the Proposed Arrangement

[1] There is no common ownership between Requestor Inc. and Requestor PC.

under section 1128A(a)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute 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.

This opinion may not be relied on by any person[2] 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. The Parties

Relevant to the Proposed Arrangement, there are several parties:

- Requestor Inc. is a management support organization that provides non-clinical management services to Requestor PC.

- Requestor PC is wholly owned by a physician shareholder and maintains payor contracts with numerous commercial health plans, as well as contracts with commercial entities that administer Medicare Advantage and Medicaid managed care plans. According to Requestors, Requestor PC maintains over 400 contracts with commercial preferred provider organization, exclusive provider organization, and health maintenance organization plans, covering approximately 80 percent of all commercially covered lives. Additionally, Requestor PC maintains contracts covering 65 percent of Medicare Advantage covered lives. Requestor PC does not employ or otherwise contract with staff that provide clinical services.

- Certain independent third parties (each, a "Platform") are management services organizations that provide management services to telehealth providers (each, a "Platform PC") who provide health care items and services through a Platform's website to patients ("Platform Patients"). Each Platform PC provides telehealth services (e.g., urgent care services, rheumatology care, oncology care navigation, menopause care, obesity management care, and mental health care), including services that are reimbursable by a Federal health care program, to Platform Patients. Requestors believe that Platform PCs maintain too few contracts with health plans (including Medicare Advantage and Medicaid managed care plans), such that Platform Patients face reduced access to telehealth services from an in-network provider and may face out-of-pocket expenditures for health care services that could be covered by other health insurance plans. According to Requestors, Platform Patients residing in underserved and rural communities, in particular, are negatively impacted by limited access to insurance-covered telehealth services furnished by Platform PCs. In some instances, a Platform PC and Requestor PC maintain contracts with the same payor, and certain Platform Patients covered by payor contracts held by both a Platform PC and Requestor PC will be referred

[2] 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.

to Requestor PC. For example, a Platform PC may handle patients from a particular State, while referring other patients from a different state to Requestor PC.[3]

- Platform Patients are patients, including Federal health care program enrollees, who visit a Platform's website to obtain various health care items and services and access telehealth services.

- Health Care Professionals ("HCPs") are health care professionals employed by (or otherwise contracted with) a Platform PC.

B. The Proposed Arrangement

Under the Proposed Arrangement, Requestors would enter into an agreement with Platforms and Platform PCs (collectively, "Platform Entities") whereby: (i) Requestor PC would lease HCPs from a Platform PC, and the leased HCPs would provide telehealth services to Platform Patients covered by insurance plans with which Requestor PC maintains a contract; and (ii) a Platform would provide certain administrative services to Requestor PC (the "Agreement"). Under the terms of the Agreement, Requestors would credential the leased HCPs, facilitate the enrollment of the leased HCPs under Requestor PC's existing payor contracts, and submit claims for the telehealth services provided by the leased HCPs through the payor contracts held by Requestor PC. The administrative services the Platform would furnish to Requestor PC would include: (i) accounting services (e.g., collecting the applicable patient financial responsibility (cost sharing)); (ii) marketing services (e.g., providing digital online marketing and campaign management of online advertising related to Requestor PC's provision of specified services); (iii) administrative support (e.g., providing support for patient scheduling of appointments for specified services with Requestor PC); and (iv) information technology services (e.g., providing a HIPAA-compliant platform for the administration of synchronous telehealth care between the leased HCPs and Platform Patients). The Agreement is the only financial relationship among Requestors and the Platform Entities addressed in this advisory opinion.[4]

Under the terms of the Agreement, Requestor PC would pay: (i) a lease fee that is an hourly rate based on the licensure type of each HCP (e.g., MD, NP, PA) (the "HCP Lease Fee"); and (ii) a fee for the non-clinical administrative services (the "Administrative Fee") (collectively, the "HCP Lease Fee" and "Administrative Fee" are referred to as the "Service Fee"). Requestors

[3] Requestors certified that they would not control or influence decisions regarding how to allocate Platform Patients when Platform Patients are covered by payor contracts held by both a Platform PC and Requestor PC.

[4] In their request for an advisory opinion, Requestors noted the existence of several additional agreements between and among Requestors, the Platform Entities, and the HCPs. We have not been asked to opine on, nor do we express an opinion about, these ancillary arrangements. Moreover, we do not express an opinion about whether the Proposed Arrangement would comply with the terms of payor contracts maintained by Requestor PC, including any limitation on the right of Requestor PC to enter into subcontract agreements; such issues are outside the scope of the OIG advisory opinion process.

certified that each component of the Service Fee would be consistent with fair market value as established by a reputable, independent third-party valuator.[5] Requestor PC would pay the HCP Lease Fee regardless of whether Requestor PC is ultimately reimbursed by third-party payors for telehealth services. Requestors certified that the methodology for determining the Service Fee would be set in advance and consistent with fair market value in arm's-length transactions and would not be determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid, or other Federal health care programs.

Requestors certified that the Proposed Arrangement would meet all of the conditions of the safe harbor for personal services and management contracts and outcomes-based payment arrangements at 42 C.F.R. § 1001.952(d)(1). In addition to the elements discussed above, Requestors certified that the Service Fee would be paid pursuant to the Agreement, which would be: (i) set out in writing; (ii) signed by the parties; (iii) for a term of at least 1 year; and (iv) specify all services provided among the parties. Requestors further certified that the services performed under the Agreement would not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law, and the aggregate services contracted for would not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

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.[6] 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.[7] 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] 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.

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

[7] 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.[8] 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.

Congress has developed several statutory exceptions to the Federal anti-kickback statute.[9] 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.[10] 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.

Paragraph (1) of the safe harbor for personal services and management contracts and outcomes-based payment arrangements[11] provides that, for purposes of the Federal anti-kickback statute, "remuneration" does not include any payment made by a principal to an agent as compensation for the services of the agent, as long as all of the following standards are met:

> (i) The agency agreement is set out in writing and signed by the parties.
>
> (ii) The agency agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent.
>
> (iii) The term of the agreement is not less than 1 year.
>
> (iv) The methodology for determining the compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arm's-length transactions, and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in

[8] 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).

[9] Section 1128B(b)(3) of the Act.

[10] 42 C.F.R. § 1001.952.

[11] 42 C.F.R. § 1001.952(d)(1).

whole or in part under Medicare, Medicaid, or other Federal health care programs.

(v) The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.

(vi) The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

B. Analysis

Under the Proposed Arrangement, Requestor PC would offer and pay remuneration to the Platform Entities in the form of the Service Fee. When a Platform PC refers Platform Patients to Requestor PC for services that are reimbursable by a Federal health care program, the Federal anti-kickback statute would be implicated.

However, we conclude that the Service Fee would be protected by the regulatory safe harbor for personal services and management contracts and outcomes-based payment arrangements at 42 C.F.R. § 1001.952(d)(1). Requestors certified that the Proposed Arrangement would meet all of the conditions of the safe harbor for personal services and management contracts and outcomes-based payment arrangements at 42 C.F.R. § 1001.952(d)(1). For example, Requestors certified that the Service Fee would be paid pursuant to the Agreement, which would: (i) be set out in writing; (ii) be signed by the parties; (iii) be for a term of at least 1 year; and (iv) specify all services provided among the parties. Requestors further certified that the methodology for determining each component of the Service Fee would be set in advance and consistent with fair market value in arm's-length transactions and would not be determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid, or other Federal health care programs. Importantly, Requestors would pay the hourly rate HCP Lease Fee for services rendered regardless of whether Requestor PC ultimately is reimbursed by third-party payors for telehealth services, which decreases the likelihood that the Service Fee would be determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties that is reimbursable by a Federal health care program.

Finally, Requestors certified that the services performed under the Agreement would not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law, and the aggregate services contracted for would not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

III. CONCLUSION

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement, if undertaken, would not generate prohibited remuneration under the Federal anti-kickback statute. Accordingly, OIG would not impose administrative sanctions on Requestors in connection with the Proposed Arrangement

under section 1128A(a)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute 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.

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.

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. 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 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 OIG.

Sincerely,

/Susan A. Edwards/

Susan A. Edwards
Assistant Inspector General for Legal Affairs