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.*]

Issued: November 21, 2024

Posted: November 25, 2024

[Address block redacted]

Re: OIG Advisory Opinion No. 24-09 (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 a proposal to begin billing patients' insurance plans—and waiving any patient cost-sharing amounts—for treatment-in-place ("TIP") emergency medical services ("EMS") without an associated ambulance transport (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 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[1] 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

Requestor is a municipal corporation in [redacted] (the "State"). Requestor was created pursuant to a joint agreement between [redacted] (the "County") and [redacted] for the purposes of providing EMS to County residents. Requestor is governed by a seven-member Board of Commissioners appointed by the County Board of Commissioners. Requestor is the largest emergency ambulance supplier in the State. Requestor is also the primary 911 response agency for the County, which includes a large city.

Historically, Requestor has not charged either third-party payors or patients when it treats a patient in place without an associated ambulance transport. Under the Proposed Arrangement, Requestor proposes to implement a charge for TIP services furnished in connection with 911 responses. The proposed charge would be limited to emergency responses only (i.e., only responses that meet the definition of "emergency response" at 42 C.F.R. § 414.605). Requestor's charge for TIP services would be based on the level of care furnished to the patient and would not exceed amounts currently submitted for payment for the same level of care furnished in connection with an ambulance transport. Requestor would impose this charge, regardless of the patient's health insurance (e.g., regardless of whether the patient is enrolled in commercial insurance or a Federal health care program),[2] whenever it provides an emergency response and furnishes care to a patient at the scene but does not transport the patient by ambulance.

Requestor further proposes to accept any payment for TIP services from the patient's health insurance as payment in full for the services. More specifically, Requestor would not bill

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[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] Requestor would not charge uninsured patients for TIP services.

patients for any cost-sharing amounts owed to Requestor under the patient's health insurance, including Federal health care programs, for covered TIP services. Requestor certified that its proposal to waive cost-sharing amounts would apply to both County residents and nonresidents and would be applied on a uniform basis to all patients who receive TIP services. Requestor also certified that it would not later claim cost-sharing amounts waived as a bad debt for payment purposes under a Federal health care program or otherwise shift the burden of the cost-sharing waivers onto a Federal health care program, other payors, or individuals (e.g., engage in balance billing).

Neither Medicare Part B nor the State Medicaid program currently covers TIP services. Requestor certified that only a handful of Medicare Advantage plans and some neighboring state Medicaid programs cover TIP services. Consequently, the Proposed Arrangement rarely would result in Federal health care program reimbursement.

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.[3] 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.[4] 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.[5] 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

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

[4] Id.

[5] 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).

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.[6] 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.[7] 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 safe harbor addressing waivers of cost-sharing amounts for municipally owned ambulance suppliers, 42 C.F.R. § 1001.952(k)(4), is potentially applicable to the Proposed Arrangement:

> As used in section 1128B of the Act, "remuneration" does not include any reduction or waiver of a Federal health care program beneficiary's obligation to pay copayment, coinsurance or deductible (for purposes of this subparagraph (k) "cost-sharing") amounts as long as all the standards are met within one of the following categories of health care providers or suppliers.
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> . . .
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> (4) If the cost-sharing amounts are owed to an ambulance provider or supplier for emergency ambulance services for which a Federal health care program pays under a fee-for-service payment system and all the following conditions are met:
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> (i) The ambulance provider or supplier is owned and operated by a State, a political subdivision of a State, or a tribal health care program, as that term is defined in section 4 of the Indian Health Care Improvement Act;
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> (ii) The ambulance provider or supplier engaged in an emergency response, as defined in 42 C.F.R. 414.605;
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> (iii) The ambulance provider or supplier offers the reduction or waiver on a uniform basis to all of its residents or (if applicable) tribal members, or to all individuals transported; and
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> (iv) The ambulance provider or supplier must not later claim the amount reduced or waived as a bad debt for payment purposes under a Federal health care program or otherwise shift the burden of the reduction or waiver onto a Federal health care program, other payers, or individuals.

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

[7] 42 C.F.R. § 1001.952.

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)(A) of the Act provides that, for purposes of the Beneficiary Inducements CMP, the term "remuneration" does not include the waiver of coinsurance and deductible amounts by a person if: (i) the waiver is not offered as part of any advertisement or solicitation; (ii) the person does not routinely waive coinsurance or deductible amounts; and (iii) the person waives the coinsurance and deductible amounts after determining in good faith that the individual is in financial need or fails to collect coinsurance or deductible amounts after making reasonable collection efforts.

B. Analysis

The Proposed Arrangement would result in remuneration in the form of cost-sharing waivers for TIP services and the TIP services provided at no charge to patients, including Federal health care program beneficiaries. This remuneration would implicate both the Federal anti-kickback statute and the Beneficiary Inducements CMP. The Proposed Arrangement would implicate the Federal anti-kickback statute because this remuneration could induce Federal health care program beneficiaries to seek EMS from Requestor that are reimbursable by Federal health care programs. Similarly, the Proposed Arrangement would implicate the Beneficiary Inducements CMP because the remuneration may be likely to influence a beneficiary to receive items and services reimbursable by Medicare or a State health care program from a particular provider or supplier.

The remuneration under the Proposed Arrangement would not fall squarely within any exception to the definition of "remuneration" for purposes of the Beneficiary Inducements CMP or any safe harbor to the Federal anti-kickback statute. For example, with respect to the cost-sharing waivers, the Proposed Arrangement would not meet the exception to the Beneficiary Inducements CMP at section 1128A(i)(6)(A) of the Act for waivers of beneficiary cost-sharing obligations. The cost-sharing waivers would fail to satisfy that exception because, among other reasons, the exception applies only to a waiver of cost-sharing obligations on the basis of financial need or a failure to collect after reasonable collection efforts. Here, Requestor proposes a uniform waiver of any cost-sharing amounts for TIP services performed in connection with emergency responses for all patients treated, regardless of a patient's financial need. Regarding the Federal anti-kickback statute, the safe harbor at 42 C.F.R. § 1001.952(k)(4) potentially would apply to any cost-sharing waivers. However, this safe harbor applies to cost-sharing amounts owed to an ambulance provider for emergency ambulance services for which a Federal health care program pays, which is not the case in the Proposed Arrangement because TIP services are

not covered by Medicare Part B or the State Medicaid program.[8] Nevertheless, 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, and, for the following reasons and in an exercise of our discretion, we would not impose sanctions under the Beneficiary Inducements CMP.

First, Requestor would uniformly apply its cost-sharing waiver policy for all individuals who receive TIP services in connection with an emergency response regardless of payor. This uniformity reduces the risk that the Proposed Arrangement would be a means to favor certain patients; Requestor's certification that it would not balance bill patients further reduces the risk that it would discriminate among patients based on insurance status. In addition, the Proposed Arrangement would be consistent with OIG guidance issued regarding cost-sharing waivers provided by municipally owned ambulance suppliers for EMS ambulance services.[9]

Second, neither Medicare Part B nor the State Medicaid program currently covers TIP services. Only a handful of Medicare Advantage plans and certain Medicaid programs in adjacent states currently cover TIP services. Consequently, in most circumstances, the Proposed Arrangement would result in no costs to Federal health care programs and, to the extent the Proposed Arrangement avoids an ambulance transport or subsequent hospital care, could reduce costs to Federal health care programs overall, thereby mitigating the risk of inappropriately increased costs to Federal health care programs. Further, the TIP services furnished by Requestor under the Proposed Arrangement may result in patients receiving care more quickly and efficiently and at a more appropriate level of care.

Third, even when a Federal health care program pays for the TIP services furnished under the Proposed Arrangement, the Proposed Arrangement appears unlikely to increase costs to Federal health care programs and may ensure an appropriate level of care for patients to whom Requestor furnishes EMS services in response to a 911 call. More specifically, TIP services may be a viable option, in certain circumstances, to improve quality of care and avoid unnecessary transports to hospital emergency departments. Consequently, TIP services have the potential to lower costs for Federal health care programs while also delivering timely, appropriate, and medically necessary care to patients on-site who do not also require transportation to a hospital.

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[8] In the limited circumstances where TIP services could be rendered to enrollees of Medicaid programs in other states or other Federal health care programs that cover TIP services under a fee-for-service payment system, the safe harbor likewise would not apply to waivers of any associated cost-sharing amounts. EMS under the Proposed Arrangement would be TIP—furnished to residents and nonresidents with no associated ambulance transport. The safe harbor requires that "the ambulance provider or supplier offers the reduction or waiver on a uniform basis to all of its residents or tribal members, or to all individuals *transported*." 42 C.F.R. § 1001.952(k)(3) (emphasis added).

[9] See, e.g., OIG Compliance Program Guidance for Ambulance Suppliers, 68 Fed. Reg. 14,245, 14,253 (Mar. 24, 2003).

Finally, neither the cost-sharing waiver associated with TIP services nor the TIP services provided at no charge would be likely to meaningfully affect a patient's decision to use Requestor for future emergency ambulance services reimbursable by Federal health care programs. Patients' future EMS usage is more likely to be impacted by other important factors, including the location of the circumstances requiring EMS, the availability of Requestor's EMS units, and decisions by the 911 dispatcher.

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.

- 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 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