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: December 20, 2022

Posted: December 23, 2022

[Address block redacted]

Re: OIG Advisory Opinion No. 22-21

Dear [redacted]:

The Office of Inspector General ("OIG") is writing in response to your request for an advisory opinion on behalf of [redacted] and its Department of Public Health's emergency medical services ("EMS") division operating under the regional name [redacted] ("Requestor") regarding Requestor's sublease of certain space and lease of certain furniture and equipment to a private ambulance company to which Requestor has granted an exclusive contract for the provision of emergency ambulance transports in certain parts of [redacted] County (the "Arrangement"). Specifically, you have inquired whether the Arrangement constitutes 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").

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 you 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 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 Arrangement would generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present, the 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.

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[2] manages EMS in [redacted] County (the "County"). Requestor certified that, in compliance with [redacted] State law governing the Request for Proposal ("RFP") process for government-awarded contracts for EMS, it issued an RFP for an exclusive contract for an ambulance supplier to provide emergency ambulance transports in a geographic area consisting of certain parts of the County (the "Service Area") and operate Requestor's EMS Communications Center, which entails, among other things, dispatching and coordinating emergency ambulance transports.[3] After an open, public, and competitive bidding process, Requestor entered into an EMS provider agreement (the "EMS Agreement") with [redacted] (the "Ambulance Supplier"). As a result, the Ambulance Supplier is the sole supplier of emergency ambulance transports for patients in the Service Area, including Federal health care program beneficiaries, and also operates Requestor's EMS Communications Center.[4] Pursuant to the EMS Agreement, Requestor does not pay the Ambulance Supplier for its provision of emergency ambulance transports except for transports of patients for whom Requestor is financially responsible, such as inmates, jail detainees, and juvenile wards. The Ambulance Supplier's primary compensation for its provision of emergency ambulance transports in the Service Area comes from payments from patients and third-party payors, including Medicare and Medicaid.

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[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] [Redacted], a political subdivision of the State of [redacted], and its Department of Public Health EMS division operating under the regional name [redacted] perform different roles with respect to EMS in the County but for purposes of this advisory opinion are collectively considered to be "Requestor."

[3] The RFP included terms describing the leasing arrangement necessary for the contract awardee to lease space in and operate the EMS Communications Center.

[4] "EMS Communications Center" refers to the center of EMS operations for the Service Area. The EMS Communications Center was housed in an older building when: (i) Requestor issued the RFP; and (ii) the Ambulance Supplier began operating under the EMS Agreement. After entering into the EMS Agreement, Requestor and the Ambulance Supplier agreed to change the location of the EMS Communications Center, but Requestor certified that the material aspects of the operation of the EMS Communications Center did not change as a result of the change in location. Requestor also certified that the purpose of moving the location of the EMS Communications Center was Requestor's immediate need for expanded space to provide EMS dispatching.

Requestor leases space, including a building that houses its EMS Communications Center, from a lessor that is not involved in the delivery of health care pursuant to a lease-purchase agreement (the "Lease-Purchase Agreement").[5] Under the Lease-Purchase Agreement, Requestor has the right to use and sublease the space for EMS dispatching personnel, among other uses. After Requestor entered into the Lease-Purchase Agreement, Requestor and the Ambulance Supplier entered into a sublease agreement (the "Sublease Agreement") pursuant to which Requestor subleases building space and associated parking space (the "Subleased Space") and leases certain furniture and equipment for the Subleased Space (the "Leased Equipment") to the Ambulance Supplier to effectuate the Ambulance Supplier's continued operation of Requestor's EMS Communications Center for the remainder of the term of the EMS Agreement.[6] Requestor certified that the aggregate Subleased Space and Leased Equipment rented under the Sublease Agreement do not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the rental.

Requestor retains a portion of the leased premises for its own use ("Requestor's Space"). Additionally, pursuant to the Lease-Purchase Agreement, Requestor must, at a certain time in the future, expand its leased premises to include building space currently leased by another occupant. Under the Sublease Agreement, Requestor has the option to make such space part of the Subleased Space and certified that, if it exercises that option, the Subleased Space, as expanded by the additional space, would not exceed the space that is reasonably necessary to accomplish the commercially reasonable business purpose of the rental.

Pursuant to the Sublease Agreement, the Ambulance Supplier pays Requestor base rent for the Subleased Space and base rent for the Leased Equipment and pays for the rent-related expenses discussed below (the "Rent-Related Expenses"). Requestor certified that the aggregate rental charge for the base rents and Rent-Related Expenses is consistent with fair market value.[7] Requestor also certified that, if the Subleased Space were expanded by the additional space described above, the aggregate rental charge, which would reflect an increased base rent and increased Rent-Related Expenses for the Subleased Space, still would be consistent with fair market value for the space provided. The Sublease Agreement also provides that the Ambulance Supplier will pay a "reasonable amount" for maintenance services that Requestor performs with respect to certain leasehold improvements to the Subleased Space and the Leased Equipment. Requestor certified that, in accordance with [redacted] State constitutional law, the charge to the Ambulance Supplier for such maintenance services does not exceed the reasonable costs to Requestor to provide the services, meaning that Requestor does not profit from the provision of any such maintenance services. Requestor stated that it has not performed any such maintenance services to date (except for scheduled testing of fire and life-safety system components), but any

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[5] Requestor entered into the Lease-Purchase Agreement after entering into the EMS Agreement.

[6] In connection with the change in location of the EMS Communications Center, Requestor and the Ambulance Supplier terminated the leasing arrangement for the previous location of the EMS Communications Center and began operating under the Sublease Agreement.

[7] 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.

such future maintenance services it performs while the Ambulance Supplier is operating the EMS Communications Center will be necessary or reasonable for purposes of its operation, considering the term of the EMS Agreement.

In addition, the Ambulance Supplier pays Requestor for the following Rent-Related Expenses:

(i) maintenance and management services the lessor performs for the Subleased Space;

(ii) non-metered utilities, including water, sewage, and trash collection, provided by third-party service providers, for which the Ambulance Supplier pays the amount of the non-metered utilities attributable to the Subleased Space; and

(iii) property insurance, taxes, and assessments attributable to the Subleased Space.[8]

The payments from the Ambulance Supplier to Requestor for Rent-Related Expenses do not result in a profit to Requestor because Requestor pays the same amount it receives from the Ambulance Supplier for each of the expenses to the lessor, who then pays the appropriate third parties. Requestor certified that, pursuant to the Sublease Agreement, these expenses are subject to an annual "true-up" process whereby the Ambulance Supplier initially pays Requestor based on estimated itemized cost statements, and Requestor ultimately charges the Ambulance Supplier for the actual costs (i.e., if the actual costs are less than the estimated costs, Requestor refunds the difference to the Ambulance Supplier, and if the actual costs are more than the estimated costs, the Ambulance Supplier pays Requestor the difference). Lastly, under the Sublease Agreement, the Ambulance Supplier pays for the metered utilities for the Subleased Space and Requestor's Space, and Requestor reimburses the Ambulance Supplier for the portion of the metered utilities attributable to Requestor's Space.[9]

Requestor certified—and the Sublease Agreement requires—that, with respect to all rental charges: (i) the rent was not determined in a manner that takes into account the volume or value

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[8] The Sublease Agreement provides that, if the Ambulance Provider fails to keep the required insurance coverages (e.g., personal property insurance) at any time, Requestor may obtain and add the reasonable cost for such coverage to the Rent-Related Expenses charged to the Ambulance Supplier.

[9] The terms of the Lease-Purchase Agreement provide that, with respect to the entire leased premises, Requestor is responsible for the maintenance and management services the lessor performs, the non-metered utilities, and property insurance, taxes, and assessments. The Sublease Agreement, in turn, assigns the responsibility for those expenses, to the extent attributable to the Subleased Space, to the Ambulance Supplier as Rent-Related Expenses. Although the Ambulance Supplier's payment of metered utilities is not considered a Rent-Related Expense for purposes of this advisory opinion because the Ambulance Supplier pays for metered utilities directly to the third-party service provider, the terms of the Lease-Purchase Agreement also provide that Requestor is responsible for metered utilities for the leased premises, and the Sublease Agreement assigns the responsibility for that expense, to the extent attributable to the Subleased Space, to the Ambulance Supplier.

of any referrals or business otherwise generated between Requestor and the Ambulance Supplier for which payment may be made in whole or in part by a Federal health care program; and (ii) the rent was not, and will not be, adjusted to reflect the additional value, if any, that one party would attribute to the Subleased Space or the Leased Equipment as a result of its proximity or convenience to sources of referrals or business otherwise generated for which payment may be made in whole or in part under any Federal health care program.

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.[10] 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.[11] 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.[12] 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.[13] 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.[14] However, safe harbor

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

[11] Id.

[12] 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).

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

[14] 42 C.F.R. § 1001.952.

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 harbors for space rental[15] and equipment rental[16] potentially apply to the Arrangement. Among other requirements, each safe harbor requires that the aggregate rental charge 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 whole or in part under any Federal health care program.[17] Additionally, the safe harbor for personal services and management contracts and outcomes-based payment arrangements[18] potentially applies to the Arrangement. In relevant part for purposes of this advisory opinion, this safe harbor requires that the methodology for determining the compensation paid for services is set in advance.[19]

B. Analysis

The Ambulance Supplier pays remuneration to Requestor in the form of payments for: (i) base rent for the Subleased Space and base rent for the Leased Equipment; (ii) the maintenance services Requestor performs with respect to the Subleased Space and the Leased Equipment; and (iii) the Rent-Related Expenses. Because Requestor has arranged for the Ambulance Supplier to provide emergency ambulance transports in the Service Area for which it receives payments, including from Federal health care programs, the Arrangement implicates the Federal anti-kickback statute.[20] While the safe harbors for space rental, equipment rental, and personal services and management contracts and outcomes-based payment arrangements may apply to the Arrangement, not all remuneration streams satisfy a safe harbor. For example, the Ambulance Supplier's rental payments to Requestor for the Subleased Space would not satisfy the space rental safe harbor because the aggregate rental charge for the Subleased Space would not be set in advance since the Rent-Related Expenses that are part of the aggregate rental charge for the Subleased Space are subject to an annual "true-up" process. In addition, the Ambulance Supplier's payments to Requestor for maintenance services Requestor performs for the Subleased Space and the Leased Equipment do not satisfy the safe harbor for personal services

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[15] Id. § 1001.952(b).

[16] Id. § 1001.952(c).

[17] See id. § 1001.952(b)(5), (c)(5).

[18] Id. § 1001.952(d).

[19] See id. § 1001.952(d)(1)(iv).

[20] Although Requestor does not profit from any amount the Ambulance Supplier pays for the Rent-Related Expenses or the metered utilities, those payments implicate the statute because they relieve Requestor of expenses it otherwise is contractually obligated to pay under the Lease-Purchase Agreement.

and management contracts and outcomes-based payment arrangements. The Sublease Agreement states that the Ambulance Supplier will pay Requestor a "reasonable amount" for the maintenance services it performs. We do not consider a "reasonable amount" to be a verifiable formula; as such, it is not a methodology for determining compensation that is set in advance, as required by the safe harbor.

This advisory opinion addresses the Arrangement as a whole and inclusive of all streams of remuneration. Absent safe harbor protection for all streams of remuneration, we analyze the Arrangement based on the totality of facts and circumstances and conclude that it presents a minimal risk of fraud and abuse under the Federal anti-kickback statute.

The Arrangement appears to be a reasonable means for Requestor to fulfill its obligation to manage EMS in the County by entering into a contract with the Ambulance Supplier to, among other things, provide emergency ambulance transports in the Service Area and operate the EMS Communications Center. The only remuneration being exchanged under the Arrangement stems from the Ambulance Supplier's sublease of the Subleased Space and lease of the Leased Equipment for the purpose of effectuating the Ambulance Supplier's continued operation of Requestor's EMS Communications Center pursuant to the EMS Agreement. In the case of the Rent-Related Expenses, the Ambulance Supplier pays only for those expenses related to the Subleased Space and the Leased Equipment; the Ambulance Supplier does not assume any Rent-Related Expenses for space or equipment used by Requestor. And Requestor does not profit from any of the Rent-Related Expenses it collects from the Ambulance Supplier.

In the case of the maintenance services Requestor provides for the Subleased Space and Leased Equipment, Requestor certified that it also does not profit from such services. While Requestor has not performed any maintenance services to date (except for scheduled testing of fire and life-safety system components), it certified that any future maintenance services it performs while the Ambulance Supplier is operating the EMS Communications Center will be necessary or reasonable for purposes of such operation, considering the term of the EMS Agreement.

Additionally, Requestor certified that the aggregate space, furniture, and equipment rented do not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the rental and that the aggregate rental charge for the base rents and Rent-Related Expenses is consistent with fair market value. Requestor also certified that, if the Subleased Space were expanded by the additional space contemplated in this advisory opinion, the aggregate rental charge, which would reflect an increased base rent and increased Rent-Related Expenses for the Subleased Space, still would be consistent with fair market value for the space provided.

Further, the Sublease Agreement includes certain terms that act as safeguards under the Arrangement. Requestor certified—and the Sublease Agreement requires—that, with respect to all rental charges: (i) the rent was not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between Requestor and the Ambulance Supplier for which payment may be made in whole or in part by a Federal health care program; and (ii) the rent was not, and will not be, adjusted to reflect the additional value, if any, that one party would attribute to the Subleased Space or the Leased Equipment as a result of its proximity

or convenience to sources of referrals or business otherwise generated for which payment may be made in whole or in part under any Federal health care program.

III. CONCLUSION

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that, although the Arrangement would generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present, the 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.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

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

Sincerely,

/Robert K. DeConti/

Robert K. DeConti
Assistant Inspector General for Legal Affairs