Re: OIG Advisory Opinion No. 09-17

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion regarding a joint venture to provide ambulance transportation services in [County and State redacted] (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.

You have certified that all of the information provided in your request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that while the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, the Office of Inspector General (“OIG”) will not impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts...
described in section 1128B(b) of the Act) in connection with the Arrangement. This opinion is limited to the Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request letter or supplemental submissions.

This opinion may not be relied on by any persons other than [name redacted], the requestor of this opinion, and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

[Name redacted] (“Requestor” or the “Ambulance Company”) is a [State redacted] non-profit corporation that provides emergency medical services (“EMS”), and non-emergency and other medical transportation services in [County and State redacted] (the “County”), some parts of which are medically underserved areas. The Ambulance Company has four owners (each an “Owner” and together the “Owners”), each possessing a 25% interest:

1. [Name redacted] (“Owner A”). Owner A provides ambulance services in the County and surrounding area. Owner A is a non-profit subsidiary of a regional non-profit health care system that provides healthcare services for a twenty-county area in [State redacted] and [State redacted]. Owner A’s hospital parent company makes no referrals to the Ambulance Company.

2. [Name redacted] (“Owner B”). Owner B provides ambulance services for its parent health care system, and also provides rehabilitation and community health services in [State redacted] and [State redacted]. Owner B is a non-profit, charitable subsidiary of a non-profit, charitable health care system that provides hospital, ambulance, home health, and skilled nursing services. Neither Owner B nor its parent company owns hospitals or nursing homes in locations where the Ambulance Company is licensed to operate, and neither makes any referrals to the Ambulance Company.

3. [Name redacted] (the “Owner-Manager”). The Owner-Manager is a charitable, non-profit corporation that provides medical transportation services and medical transportation dispatch services in an eight-county area of [State redacted], including the County. As discussed in greater detail below, the Owner-Manager provides management services to the Ambulance Company under a contract. The Owner-Manager does not generally make referrals to the Ambulance Company, but may do so in emergency situations where the Ambulance Company has the closest ambulance to an area outside the County that the Owner-Manager is under contract to cover.1

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1 For example, the Owner-Manager might refer an emergency call to the Ambulance Company if an Ambulance Company ambulance transported a patient from the County to a hospital in a major city near the County, and, while still in the city, was the closest ambulance to that emergency call. Requestor has certified that this occurs only two to three
4. [Name redacted] (the “Owner-Hospital”). The Owner-Hospital is a non-profit community hospital located in the County. The Owner-Hospital does not own, operate, or provide ambulance services. As discussed in greater detail below, the Owner-Hospital contracts with the Ambulance Company for transportation services.

The Owners each possess a 25% ownership interest and 25% voting rights. In order to fund start-up costs, including acquisition of five ambulance vehicles, each Owner made an initial capital contribution of $[amount redacted]. The Owners agreed that the Ambulance Company would apply for a $[amount redacted] bank line of credit that would be guaranteed by the Owners in equal proportions. Further, the Owners agreed to contribute equally in response to any capital calls, upon a vote of the Ambulance Company’s board of trustees. Distributions from the Ambulance Company to the Owners are in proportion to their ownership interests and capital contributions.

The Owners formed the Ambulance Company specifically to bid on a request for proposal (“RFP”) issued by the County’s Emergency Medical Authority (the “EMA”), which contracts with a single EMS provider on behalf of participating local municipalities to provide EMS controlled through its 911 dispatching system. According to Requestor, the EMA historically has had problems with the ambulance companies that had contracted with the EMA, including deficiencies in services and financial failures. The EMA selected the Ambulance Company from several bidders as its EMS provider. Under the terms of the EMA contract, the County’s dispatchers treat the Ambulance Company as the preferred ambulance provider.\(^2\) The Ambulance Company’s sole compensation under the EMA contract consists of payments from patients and their insurers, including Medicare and Medicaid. The EMA contract does not cover non-EMS transports.

**Transport Agreement**

The Owners formed the Ambulance Company in the belief that they would have an acceptable chance of performing under the EMA contract if the Ambulance Company furnished some undefined amount of scheduled transportation business to supplement the EMS provided under the EMA contract.\(^3\) Accordingly, the Ambulance Company entered

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\(^2\) Overflow situations, in which surges in call volume outpace the Ambulance Company’s ambulance capacity, occur approximately once or twice daily; these calls are rotated about evenly to Owner A, Owner B, and the Owner-Manager.

\(^3\) Requestor asserts that the cost of providing scheduled transportation service with the use of idle excess emergency capacity or non-emergency vehicles is low relative to the high fixed
into a non-exclusive preferred provider contract (the “Transport Agreement”) with the Owner-Hospital, under which the Ambulance Company is a preferred source for scheduled medical transportation services for the Owner-Hospital’s patients on an as-needed basis. Specifically, the Owner-Hospital agrees to contact the Ambulance Company and give it first opportunity to provide patient transport services where a transport is required and where the patient has not expressed his or her wishes with respect to identifying an appropriate alternative ambulance service. The Ambulance Company must accept all patients referred to it under the Transport Agreement, regardless of their insurance status or ability to pay.

The Transport Agreement covers ambulance discharge services (i.e., a patient is being discharged from the Owner-Hospital and is not returning), and inter-facility patient transport services (i.e., transports between the Owner-Hospital and other facilities), including services provided to the Owner-Hospital’s patients by other facilities “under arrangements” that are required to be bundled into the Owner-Hospital’s payments from third-party payors, including Medicare. When the Ambulance Company provides transport services in the capacity of a direct participating supplier of services, it bills and collects payment directly from private pay patients, Medicare Part B, or other third-party payors in accordance with the Ambulance Company’s usual billing and collection practices. When the Ambulance Company provides transport services “under arrangements” to the Owner-Hospital, the Ambulance Company bills and collects payment directly from the Owner-Hospital at rates that reflect fair market value for the scheduled transportation services.

The Ambulance Company has certified that for calendar year 2008, its net revenue from transports from the Owner-Hospital amounted to [number redacted]% of its total net revenue.

Management Agreement

The Ambulance Company and the Owner-Manager have entered into a written, four-year Management and Operations Services Agreement (the “Management Agreement”), under which the Owner-Manager provides management and operations services, systems, and personnel for the Ambulance Company. Specifically, the Owner-Manager provides the following services, among others: management; personnel to operate the Ambulance Company’s five ambulances; rate setting for transport services; dispatch, maintenance, repair, and replacement of ambulances and life support equipment; maintenance of separate financial records, licenses, and permits; and purchase and maintenance of supplies to properly maintain and operate ambulance services. The Owner-Manager employs all personnel to perform all of the functions under the Management Agreement. The Owner-Manager also must select and implement management information systems that track costs of providing emergency service, and the fee collection rate for scheduled transportation service is substantially higher than for emergency service.
accounts receivable and payable, finance, ambulance dispatching, and employee communications.

Under the Management Agreement, the Owner-Manager’s management fee is [number redacted]% of the Ambulance Company’s gross revenues. The Ambulance Company has certified that the management fee is fair market value for the Owner-Manager’s management services.

II. LEGAL ANALYSIS

A. Law

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible “kickback” transaction. For purposes of the 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 was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.
Because the Arrangement involves ownership of a non-public entity by interested investors, the small entity investment safe harbor, 42 C.F.R. § 1001.952(a)(2), is potentially applicable. This safe harbor has eight elements, each of which must be satisfied in order for an arrangement to qualify for the exception. Of particular relevance here are the safe harbor’s two “60-40” tests: the “Investor Test,” which requires that no more than 40% of an entity’s investment interests be held by investors that are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity ("Interested Investors"); and the “Revenue Test,” which requires that no more than 40% of an entity’s gross revenues come from referrals or business otherwise generated from investors. 42 C.F.R. § 1001.952(a)(2)(i) and (vi).

The safe harbor for personal services and management contracts, 42 C.F.R. § 1001.952(d), is potentially applicable to the Management Agreement aspect of the Arrangement. This safe harbor has seven elements, each of which must be satisfied in order for an arrangement to qualify for the exception: (i) the agreement is set out in writing and signed by the parties; (ii) the agreement specifies the services to be performed; (iii) if the services are to be performed on a part-time basis, the schedule for performance is specified in the contract; (iv) the agreement is for not less than one year; (v) the aggregate amount of compensation is fixed in advance, consistent with fair market value in an arms’-length transaction, and 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 by Medicare or a State health care program; (vi) the services performed under the agreement do not involve the promotion of business that violates any Federal or State law; and (vii) the services do not exceed those reasonably necessary to accomplish the commercially reasonable business purpose of the services. 42 C.F.R. § 1001.952(d).

B. Analysis

The OIG has longstanding concerns about problematic joint venture arrangements between those in a position to refer business, and those furnishing items or services for which a Federal health care program pays. See, e.g., OIG’s 1989 Special Fraud Alert on Joint Venture Arrangements, reprinted in the Federal Register in 1994, 59 FR 65372, 65373 (Dec. 19, 1994) and Special Advisory Bulletin, “Contractual Joint Ventures,” 68 FR 23148 (Apr. 30, 2003). As noted in both publications, joint ventures may take a variety of forms and may be formed by equity or contract. Joint venture arrangements raise concerns under the anti-kickback statute because they pose a risk that income from the venture may be payment for referrals to the venture or to co-investors. The Ambulance Company, which is owned by a hospital and three ambulance companies, some of which are affiliated with hospitals, is a joint venture. 4

4 We note that two of the ambulance company owners, Owner A and Owner B, are affiliated with hospitals or other facilities that are in a position potentially to make referrals to the
The Arrangement does not fit into the small entity investment safe harbor. Among other reasons, the Investor Test is not met. The Owner-Hospital is in a position to influence referrals to the Ambulance Company by virtue of the Transport Agreement, and the Owner-Manager furnishes “items or services” to the Ambulance Company pursuant to the Management Agreement. Since the Owner-Hospital and the Owner-Manager are each 25% investors, their combined 50% stake as Interested Investors exceeds the 40% permitted by the Investor Test, which means the Arrangement does not qualify for safe harbor protection. Consequently, we must carefully scrutinize the Arrangement in its entirety to determine whether, given all the relevant facts, the risk of fraud and abuse is sufficiently low.

In general, the Arrangement is highly prone to fraud and abuse because of the multiple streams of remuneration flowing between parties that can make referrals and parties that can profit from those referrals. In particular, the Arrangement contains three interrelated features that merit close examination for risk: the Owners’ return on investment through an equity joint venture; the Transport Agreement; and the Management Agreement. Based on the totality of facts and circumstances certified to by the Requestor, we conclude that for the combination of the following reasons, we would not impose administrative sanctions arising under the anti-kickback statute on the Requestor, in connection with the Arrangement. We emphasize that a similar arrangement with different facts and circumstances might lead to a different conclusion.

1. **Return on Investment from Equity Joint Venture**

We examine the Arrangement to determine whether the Owners’ returns on investment are in exchange for making referrals to their co-investors or the Ambulance Company, an equity joint venture, and conclude there is a low risk that this is occurring.

**First**, the substantial majority of the Ambulance Company’s revenue derives from the EMA contract, which consists solely of EMS calls dispatched through the County’s 911 system. No Owner has the ability to control the frequency or volume of 911 emergency calls, which are inherently unpredictable. Moreover, the Ambulance Company won the County EMA contract pursuant to a competitive RFP process.

**Second**, the Arrangement promotes a public benefit in facilitating more stable and reliable 911 emergency medical transportation services for residents of the County, where such services historically have been deficient or failed financially.

Ambulance Company, but have certified that they do not make referrals to the Ambulance Company for purposes of the Arrangement.
Third, the Arrangement does not appear to operate primarily on referrals from the Owners. The small entity investment safe harbor is animated in part by a desire to “assure that no protection is afforded to joint ventures that operate primarily on the referrals of physician investors.” 56 F.R. 35952 (July 29, 1991). Here, the Ambulance Company’s revenue attributable to investor referrals is well below the 40% threshold in the small entity investment safe harbor. The Owner-Hospital’s referrals to the Ambulance Company under the Transport Agreement contributed only [number redacted]% of the Ambulance Company’s total net revenue in 2008. The Owner-Manager’s referrals to the Ambulance Company occur only in rare, emergency situations, and accounted for no more than [number redacted]% of the Ambulance Company’s total net revenue in 2008. In combination with the Ambulance Company’s primary focus on EMS transport services and the fact that only one investor generates appreciable referrals for the Ambulance Company, these amounts suggest a low risk that the Arrangement relies primarily on referrals from the Owners.

Fourth, the Ambulance Company makes distributions of income to the Owners strictly in proportion to each Owner’s 25% ownership interest and capital contribution. This strict pro-rata return on investment further reduces the risk that the Arrangement is a scheme to reward referral sources.

Fifth, the Ambulance Company is an equity joint venture in which each Owner has assumed genuine business risk by committing financial resources. This distinguishes the Ambulance Company from joint ventures where a joint-venturer makes little or no financial investment but instead provides substantial referrals. Each Owner made equal capital contributions of $[amount redacted], guaranteed in equal proportions a $[amount redacted] bank line of credit, and agreed to contribute equally in response to any capital calls.

2. The Transport Agreement

The Transport Agreement merits careful scrutiny. Its general structure, in which a hospital purchases services “under arrangements” from, refers separately billable business to, and has an ownership interest in a provider or supplier, is particularly susceptible to abuse. Such arrangements can raise serious fraud and abuse concerns. By way of background, the Medicare program permits hospitals to furnish services “under arrangements” with other providers or suppliers. For instance, hospitals frequently furnish services “under arrangements” with an entity owned, in whole or in part, by referring physicians.5 As we have previously observed, these relationships will violate the anti-kickback statute if remuneration is purposefully offered or paid to induce referrals, such as paying above-

5 Where physician referrals are present, “under arrangements” relationships may implicate the physician self-referral law, section 1877 of the Act. Section 1877 of the Act falls outside the scope of OIG’s advisory opinion authority.
market rates for the services to influence referrals. See Supplemental Compliance Program Guidance for Hospitals, 70 F.R. 4858, 4866 (Jan. 31, 2005). Here, we find that for the combination of the following reasons the Transport Agreement aspect of the Arrangement does not appear to pose an undue risk of fraud and abuse.

First, there appears to be no substantial risk of “swapping” in the Arrangement. We have previously articulated concerns with arrangements where discounts offered on non-Medicare business are tied to, or conditioned on, referrals of Medicare patients for whom Medicare pays a higher, non-discounted rate. See, e.g., OIG Supplemental Compliance Program Guidance for Hospitals, 70 F.R. 4858, 4869 (Jan. 31, 2005). Services provided “under arrangements” may be susceptible to swapping. For instance, swapping occurs where a provider of services “under arrangements” to a hospital offers discounts on business for which the hospital must bill, in exchange for that hospital’s referrals of Medicare business for which the provider may directly bill Medicare. The Arrangement does not pose a substantial risk of such swapping. Foremost, the Owner-Hospital does not receive pricing discounted below fair market value under the Transport Agreement; rather, it pays fair market value for the transport services provided under arrangements by the Ambulance Company. Moreover, the Transport Agreement requires the Ambulance Company to transport all patients referred to it, including uninsured patients, with respect to whom the Ambulance Company assumes the risk that it will not get paid. Finally, the Transport Agreement is non-exclusive: the Ambulance Company is a “preferred provider” of transport services, but only in cases where it does not interfere with a patient’s choice of an alternate provider. For all of these reasons, we conclude that the Transport Agreement is unlikely to be an illicit swap for Federal health care program business.

Second, the Transport Agreement does not present a significant risk of overutilization. The types of services covered by the Transport Agreement, i.e., discharge services and inter-facility transports, are not particularly susceptible to overutilization: a discharge transport can be performed only once, and inter-facility transports entail a pre-arranged third-party destination, which lowers the risk that there is a scheme to overutilize between the Owner-Hospital and the Ambulance Company. The risk of overutilization also is reduced by the Owner-Hospital’s countervailing incentive to be a prudent consumer of services “under arrangements,” since it bears the risk of billing and collecting from third-party payors and patients for the transport services, but must pay the Ambulance Company a fair market value rate under the Transport Agreement whether or not it collects.

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6 We are not authorized to opine on whether fair market value shall be, or was, paid or received for any goods, services, or property. See section 1128D(b)(3) of the Act. If the amounts being paid under the Transport Agreement are not fair market value, then this opinion is without force and effect.
3. The Management Agreement

The Management Agreement does not fit in the safe harbor for personal services and management contracts. Specifically, the aggregate compensation paid to the Owner-Manager does not meet the requirements set forth in 42 C.F.R. § 1001.952(d)(5). For instance, the compensation is not set in advance; rather, it is set at [number redacted]% of the Ambulance Company’s gross revenues. Accordingly, we must carefully scrutinize the Management Agreement to determine whether it poses a minimal risk under the anti-kickback statute. For the combination of the following reasons, we conclude that the Management Agreement and its role in the overall Arrangement pose an acceptably low level of risk.

First, there is little risk that the management fee is a disguised method of paying the Owner-Manager for referrals to the Ambulance Company. We recognize that the Owner-Manager does have the ability to refer transports to the Ambulance Company; however, since the Owner-Manager directly operates transport services outside the County, any transport services it refers to the Ambulance Company come at its own expense, by precluding it from providing and billing for those transports itself. Billing directly for such services is significantly more lucrative for the Owner-Manager than diverting such referrals to the Ambulance Company in an effort to increase the [number redacted]% share of profits it receives via the management fee. Thus, while the Owner-Manager may, in limited, emergency situations, refer transports to the Ambulance Company, the Owner-Manager has a strong financial incentive against doing so, which substantially lowers the risk that the management fee is a disguised kickback.

Second, the Requestor has certified that the management fee is set at fair market value.7

Third, the Management Agreement appears to satisfy all the other conditions of the safe harbor for personal services and management contracts. The Management Agreement is in writing and signed by the parties, covers a four-year period, and does not involve the promotion of business that violates any Federal or State law. It specifies the services to be performed, including management and dispatch services, provision of personnel, and the maintenance, repair, and replacement of equipment, which services do not appear to exceed those reasonably necessary to accomplish the commercially reasonable business purpose of the Management Agreement.

7 We are not authorized to opine on whether fair market value shall be, or was, paid or received for any goods, services, or property. See section 1128D(b)(3) of the Act. If the amounts being paid under the Management Agreement are not fair market value, then this opinion is without force and effect.
Having examined the Owners’ return on investment, the Transport Agreement, and the Management Agreement as a whole, in light of the totality of facts and circumstances certified to by the Requestor, we conclude that for all of the foregoing reasons, we would not impose administrative sanctions arising in connection with the anti-kickback statute on the Requestor in connection with the Arrangement. As we noted at the outset of our analysis, similar arrangements with different facts and circumstances could be highly prone to fraud and abuse and thus lead us to a different conclusion.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that while the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, the OIG will not impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement. This opinion is limited to the Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request letter or supplemental submissions.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [name redacted], the requestor of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor of this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied 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.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.
This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope.

No opinion is expressed herein regarding the liability of any party 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 the 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 the Requestor with respect to any action 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,

/Lewis Morris/

Lewis Morris
Chief Counsel to the Inspector General