

Office of Inspector General

Washington, D.C. 20201

[We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestor.]

Issued: August 11, 2009

Posted: August 18, 2009

[Name and address redacted]

Re: OIG Advisory Opinion No. 09-13

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion regarding a proposal for a hospital to provide subsidies to an affiliated ambulance cooperative, to enable the cooperative to provide certain ambulance services currently provided by the hospital (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement 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.

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 Proposed Arrangement could potentially generate

Page -2- OIG Advisory Opinion No. 09-13

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") would 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 Proposed Arrangement. This opinion is limited to the Proposed 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

The requestor is [name redacted], a [state redacted] nonprofit, nonstock corporation that has been recognized by the Internal Revenue Service (the "IRS") as an organization described in section 501(c)(3) of the Internal Revenue Code and as a public charity. It is part of the [name redacted] (the "Health System"), which is also a [state redacted] nonprofit, nonstock corporation recognized by the IRS as a section 501(c)(3) organization.

[Requestor name redacted] owns and operates a 226-bed acute care hospital in [town redacted] (the "Town"), [county redacted] (the "County"), [state redacted] (the "State"). (For purposes of this opinion, [requestor name redacted] and the acute care hospital it operates will be referenced as the "Hospital.") The Hospital has certified that it offers a wide variety of primary, secondary, and tertiary services and is the only hospital in the County or within a radius of 35 miles that has been certified by the State Department of Health as having "comprehensive" emergency services capability. The only other hospital in the County is also a member of the Health System and has only general emergency room capability.

Since 1984, pursuant to an agreement with the Town, the Hospital has provided advanced life support ("ALS") services for the Town and surrounding areas.¹ The ALS services the

¹ The Hospital has certified that, prior to its assuming this responsibility, the Town was providing ambulance services at a loss, was having serious budget problems, and was planning to close a number of fire stations and eliminate the jobs of certain firefighters, which would have resulted in a loss of fire rescue services and inadequate ambulance services to the community. The Hospital states that the Town requested and the Hospital agreed to provide ambulance services to the Town as a subsidized service to the

Page -3- OIG Advisory Opinion No. 09-13

Hospital currently provides include ALS ambulance services and non-transport paramedic services. The ALS ambulance services consist of two ALS ambulance units owned by the Hospital, each staffed with a paramedic and an emergency medical technician ("EMT"). The non-transport paramedic services ("Paramedic Squads") consist of specially-equipped squad units that do not transport patients but carry paramedics. When ALS services are required and an ALS ambulance is not available, a Paramedic Squad meets an ambulance equipped for basic life support ("BLS") that has been dispatched through the 911 emergency dispatch services. The Hospital's ALS ambulance service and Paramedic Squads respond to approximately 7,500 calls per year.

[Name redacted] (the "Ambulance Cooperative" or the "Cooperative") is a [state redacted] nonprofit cooperative corporation that is taxable for Federal income tax purposes. Its members are the Hospital, which has four voting representatives, and three local volunteer fire companies (the "Volunteer Fire Companies"), each of which has one voting representative. Because of its majority voting representation, the Hospital controls the Ambulance Cooperative. Like the Hospital, the Cooperative is part of the Health System.

The Ambulance Cooperative provides ambulance services in the Town and surrounding communities in the County. The Ambulance Cooperative owns one BLS ambulance, one of the Volunteer Fire Companies owns one BLS ambulance, and the other two Volunteer Fire Companies own two BLS ambulances each. These BLS ambulances are staffed by EMTs and are available when the 911 emergency dispatch service determines, using protocols established by the Regional Emergency Medical Services Council, that an ALS unit is not required, or when the Hospital's ALS ambulances are not available because they are already in use.

Under the current arrangement, when an ALS ambulance is dispatched, the Hospital bills for the patient transport at the ALS rate. When a BLS ambulance is dispatched from one of the Volunteer Fire Company stations, the Volunteer Fire Company bills for the patient transport at the BLS rate. If a Hospital Paramedic Squad is also dispatched, the Hospital bills for the services provided by the paramedics, if non-transport services are covered separately. When the BLS ambulance owned by the Ambulance Cooperative is dispatched together with the Paramedic Squad provided by the Hospital, however, the Cooperative bills the ALS rate, and the Hospital does not bill. The Hospital has explained that the Cooperative bills the ALS rate when the ALS portion of the ambulance service actually is

community, to lessen the burdens of the Town, limit the closure of fire stations, and ensure the continued availability of necessary ambulance services.

Page -4- OIG Advisory Opinion No. 09-13

provided by the Hospital Paramedic Squad, because the Cooperative and the Hospital are both members of the Health System and subject to the Health System's global budget.²

In addition to BLS services, the Ambulance Cooperative provides intra-hospital transports and other services that support the Volunteer Fire Company emergency medical service teams. The Ambulance Cooperative also offers specialty needs transport services such as van transports for cancer patients and wheelchair and stretcher van transports. All van transports must begin or end at a facility that offers medical services.

The Hospital recoups only about half the cost of providing ALS services through billings to Medicare and other payers. It has certified that its cost of providing these services is approximately \$1.8 million annually and that it provides them at an annual net loss of approximately \$900,000.

The Hospital cites, among the reasons for these operational losses, the fact that it must provide ALS services to a large geographic area that is sparsely populated and predominantly rural. As a result, it has a low number of patient contacts relative to the geographic area covered and the fixed costs incurred, and its costs per trip are higher than the costs per trip of ambulance suppliers that provide services to smaller, more densely populated areas with a high volume of patient contacts. By way of illustration, the Hospital represents that, according to the State Department of Health, in 2008 there were 18 ambulance calls per square mile in the County, compared to 1720 ambulance calls per square mile in one of the State's more densely populated counties.

According to the Hospital, there are no for-profit entities licensed to provide ALS service in the County, which covers an area of more than 1200 square miles. Two volunteer fire companies that are not part of the Ambulance Cooperative provide ALS service in areas of the County where they have been designated to provide those services through the State EMS System. Except in certain limited situations where they may be called upon to provide back-up service, they do not provide ALS service outside their designated areas.

The Hospital has certified that, when an ALS or BLS ambulance unit transports a patient in response to an emergency call, it is required by state regulations and protocols to transport the patient to the hospital of his or her choice, if the patient is able to express a choice, and otherwise to the nearest hospital with appropriate facilities. It has also certified that, when a patient is transported in situations other than emergencies, the medical facility is always selected by the patient or patient representative.

 $^{^{2}}$ No opinion has been sought, and we express no opinion, regarding this existing billing arrangement.

Page -5- OIG Advisory Opinion No. 09-13

Under the Proposed Arrangement, responsibility for providing the ALS services now provided by the Hospital and the BLS services provided by the Ambulance Cooperative would be consolidated in the Cooperative. The Hospital believes that this would result in improved service delivery, create various efficiencies, and reduce operational costs. In addition, the Cooperative would apply to the IRS for 501(c)(3) status, which would make it eligible for certain funding for ALS services earmarked for tax-exempt entities. Until the Cooperative obtains such funding, however, the Hospital expects it to incur losses in providing the ALS services now provided by the Hospital. Under the Proposed Arrangement, the Hospital and the Cooperative would enter an agreement whereby (1) the Cooperative would assume responsibility for providing the ALS services currently provided by the Hospital; and (2) the Hospital would provide a subsidy to the Cooperative, in the form of cash, equipment, and services, to be used exclusively for the provision of ALS services that would qualify as Section 501(c)(3) charitable health care activities if conducted by a Section 501(c)(3) organization. The Hospital has certified that its donations to the Cooperative would not vary with the number of transports of patients to the Hospital, relative to transports to other facilities.

The Hospital represents that the purpose of the Proposed Arrangement is to provide ALS ambulance service to the community more efficiently and at less cost to the Hospital. The Hospital further represents that there are no alternatives to the Proposed Arrangement that do not involve a subsidy provided by the Hospital. According to the Hospital, the Town has no legal requirement to provide ALS ambulance services and is not financially in a position to do so.

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. <u>See section 1128B(b)</u> 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 <u>one</u> purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. <u>United States v. Kats</u>, 871 F.2d 105 (9th Cir. 1989); <u>United States v. Greber</u>, 760 F.2d 68 (3d Cir.), <u>cert. denied</u>, 474 U.S. 988 (1985). Violation of the statute constitutes a felony

Page -6- OIG Advisory Opinion No. 09-13

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.

B. Analysis

The Proposed Arrangement would continue an essential service to the community—ALS ambulance services—currently provided by the Hospital at a financial loss. The services would be provided just as now, by the same personnel and using the same equipment. Changes would be made in the entity that would be directly responsible for the services and that would bill for the services. Currently, the services are directly provided and billed either solely by the Hospital or by the Hospital in cooperation with the Ambulance Cooperative and its other members. Under the Proposed Arrangement, the services would be provided by the Cooperative, using equipment and other forms of assistance donated by the Hospital.

In assessing the potential risk of kickback abuse from the Proposed Arrangement, we examine the possibility that the Hospital's donation of cash, equipment, and services—things necessary for the Ambulance Cooperative to provide ALS ambulance services—could be remuneration to the Cooperative (and possibly its other members, the Volunteer Fire Companies) to refer or influence referrals of patients to the Hospital. In conducting this analysis, we look not only to whether the ALS-related donations would encourage the referral of ALS patients, but also to whether these contributions might result in the referral to the Hospital of other patients who receive services from the Ambulance Cooperative and its members, including those who receive BLS ambulance services or van transportation to medical appointments.

We conclude that the risk of abuse is sufficiently low, for a combination of the following reasons. <u>First</u>, the Ambulance Cooperative and its members would receive no net benefit from the Proposed Arrangement. The Cooperative would assume from the Hospital, which is its affiliate and majority member, direct responsibility for providing ALS ambulance services; it would receive from the Hospital no more than the means to carry out this responsibility. The individual Volunteer Fire Companies would continue to provide BLS transport service and to bill for it as before. They would receive no direct benefit from the Proposed Arrangement as individual ambulance providers, and no indirect benefit as members of the Cooperative.

Page -7- OIG Advisory Opinion No. 09-13

<u>Second</u>, the Hospital's donations to the Ambulance Cooperative would not vary with the volume or value of referrals to the Hospital by the Cooperative. The donations might vary with the number of transports of patients (because of variation in costs); however, they would not vary with the number of transports of patients to the Hospital, relative to transports to other facilities.

<u>Third</u>, the Ambulance Cooperative and the Volunteer Fire Companies are not in a position to affect referrals to the Requestor in a significant way. The requestor is the only hospital in the County or within 35 miles that has been certified by the State Department of Health as having "comprehensive" emergency services capability. The only other hospital in the County has only general emergency room capability and is, in any event, a member of the same Health System as the requestor and the Cooperative. In addition, the ambulances are required to transport emergency patients to the hospital of the patient's choice, if the patient is able to express a choice, and otherwise to the nearest hospital with appropriate facilities, as defined in State protocols. When a patient is transported in other than emergency situations (such as van transports of wheelchair patients to medical appointments), the medical facility is selected by the patient or patient representative.³

<u>Finally</u>, any risk posed by the Proposed Arrangement is offset by the particular conditions in which the Proposed Arrangement is to be implemented. The Hospital has certified that, due to the expense of operating an ambulance service in a sparsely-populated area, there are no for-profit ambulance services in the County.⁴ The Hospital itself has been unable to provide ALS ambulance services on a break-even basis. The Hospital has certified that such services cannot be provided unless subsidized by the Hospital.

For all of these reasons, we conclude that the risk of anti-kickback fraud and abuse posed by the Proposed Agreement is relatively low and offset by the benefit to the local community of the services to be subsidized.

³ We would not necessarily be persuaded by these points in other circumstances. We are aware that ambulance suppliers may be able to steer patients notwithstanding applicable protocols, and the fact that a hospital is the single provider of a particular type in an area does not mean that it is the best or only appropriate choice for a particular patient. Thus, the risk of patient steering is reduced but not eliminated in the circumstances described here. In reaching our conclusion that the Proposed Arrangement poses minimal risk, we considered this factor along with other factors cited herein.

⁴ Two volunteer fire departments in the County that are not members of the Cooperative are licensed to provide ALS services. They do not present an alternative to the Proposed Arrangement for ALS services outside their designated service areas.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that while the Proposed 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 would 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 Proposed Arrangement. This opinion is limited to the Proposed 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 Proposed 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.

Page -9- OIG Advisory Opinion No. 09-13

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

The OIG will not proceed against [name redacted] with respect to any action that is part of the Proposed Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Proposed Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against [name redacted] 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