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

Issued: May 18, 2001

Posted: May 24, 2001

[name and address redacted]

Re: OIG Advisory Opinion No. 01-5

Dear [name redacted]:

We are writing in response to your request for an advisory opinion on behalf of [name redacted] (the "Foundation") and [name redacted] ("Hospital A") (collectively, the "Requesters"), in which you ask whether a proposed lease of cardiac diagnostic equipment to emergency medical services ("EMS") providers for a nominal charge (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.

You have certified that all of the information provided in your request letter, including all supplementary information, is true and correct, and constitutes a complete description of the material facts regarding the Proposed Arrangement. You have also certified that, upon our approval, you will undertake to effectuate the Proposed Arrangement.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken any 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 the Proposed Arrangement would 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, but that the Office of Inspector General ("OIG") would not impose administrative sanctions on the Requesters 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 may not be relied on by any persons other than the Requesters and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

The Requesters have asked whether a proposed lease of cardiac diagnostic equipment to EMS providers for a nominal amount would constitute grounds for the imposition of sanctions under the Social Security Act's exclusion and civil monetary penalty authorities related to kickbacks.

A. The Parties

The Foundation is a non-profit, tax-exempt corporation organized under the laws of the State of [name redacted] (the "State"). The Foundation is a supporting foundation of Hospital A, an acute care hospital organized as a non-profit, tax exempt corporation. The Foundation and Hospital A share the same board of directors. For purposes of this analysis, given the close relationship between the Foundation and Hospital A, we will consider the Foundation and Hospital A to be one entity.

Hospital A is located in City B, State C, and with its affiliates provides approximately 400,000 patient care visits annually, including 55,000 emergency department visits. Hospital A is [name redacted] County's only Level I trauma center and the State's only burn center with dedicated aftercare and wound service beds. Hospital A is one of only seven open-heart surgery and invasive cardiology centers in the State.

The other parties to the Proposed Arrangement comprise the four EMS providers that provide advanced life support ("ALS") in the area surrounding City B, State C (hereinafter, the "Greater [name redacted] Area" or the "[GXA]"). Two of these are for-profit corporations ([name redacted], and [name redacted], d/b/a [name redacted]), and the remaining two are non-profit volunteer EMS providers ([name redacted] and [name redacted]).

In the State, the Department of Public Health is responsible for the licensure and certification of ambulance operations and related emergency services in the State and oversees regional EMS councils which are responsible for planning, coordinating, and administering the emergency medical services in their respective regions. Regions are further subdivided into areas, each of which has a "Sponsor Hospital" responsible for the provision of medical oversight to local EMS providers. The Sponsor Hospital for the GXA is known as the [name redacted] (the "[ABCD]"), which is actually an unincorporated joint venture of two hospitals – Hospital A and [name redacted] ("Hospital B").[1] For any particular ambulance run, the emergency receiving hospital to

[1]Although [State] law requires that each EMS provider be assigned one Sponsor Hospital, the EMS providers in the GXA actually have two as a result of the ABCD's designation as a Sponsor Hospital.

whom the patient is to be delivered provides active medical direction, which is usually the hospital that is geographically closest to the patient.[2]

The Department of Public Health assigns an EMS provider a primary service area in which it may provide licensed services. The EMS providers that would participate in the Proposed Arrangement comprise all ALS providers in the GXA, all of whom regularly transport patients to Hospital A from their respective primary service areas. The primary service area assignment to an EMS provider is governed, in part, by an EMS Policy and Procedures Manual (the "EMS Manual"). Under State law, transport destination is governed first and foremost by medical need. In most cases, EMS providers are required to transport patients to the closest emergency receiving hospital. See EMS Manual § I.

B. The Proposed Arrangement

The Foundation proposes to lease electrocardiogram equipment ("Life Pack Units") to EMS providers for use in ambulances providing ALS in the GXA. The Life Pack Units would enable the parties to obtain an electrocardiogram prior to arrival at the hospital, reducing the time in which a patient with a cardiac condition could be diagnosed and treated. For example, if a myocardial infarction is diagnosed during transport, the receiving hospital could begin preparations for potentially lifesaving thrombolytic therapy or primary angioplasty prior to the patient's arrival. By two-way radio, the paramedic would operate the Life Pack Unit under the medical direction of medical staff at the receiving hospital. If the receiving hospital has its own electrocardiogram receiving unit (functionally similar to a facsimile machine), it would be able to receive and print its own electrocardiogram reading. Hospital A intends to purchase a receiving unit if the Proposed Arrangement is consummated and the other emergency receiving hospitals in the GXA could purchase their own without great expense.[3] The EMS Council has provided the OIG with its written opinion that the Proposed Arrangement would enhance the quality of care for cardiac patients in the GXA.[4]

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[2]There are four emergency receiving hospitals in the GXA. These are Hospital A, Hospital B, [name redacted], and [name redacted].

[3]The Requesters have certified that a hospital's cost of acquiring a receiving unit is approximately $300. Although the Life Pack Unit is capable of printing its own electrocardiogram reading, it has only one lead, making it considerably less precise and useful than the twelve lead reading by a receiving unit.

[4]The EMS Council's opinion also states that the Proposed Arrangement would have minimal influence, if any, on which hospital receives EMS providers' transports, because EMS providers have little discretion in determining patient destination and the other hospital in City B (Hospital B) could obtain a receiving unit as well.

In order to equip all ALS providers in the GXA, fourteen (14) Life Pack Units are needed. The EMS providers have determined that they are unable to incur the expense of purchasing all fourteen of the Life Pack Units on their own. Under the Proposed Arrangement, each participating EMS provider would agree to purchase half of the number of Life Pack Units needed to provide electrocardiogram service in its own primary service area.

The Foundation would purchase seven (7) Life Pack Units for $80,000, and would lease each of them (under separate leases) to the individual EMS providers for one dollar ($1.00) per year. The leases would be terminable by the Foundation at any time if the equipment is taken out of use in the GXA; or if it is not maintained by the EMS provider consistent with the manufacturer's specifications; or if it is not used in a fashion consistent with the manufacturer's specifications; or if the Foundation, in consultation with the EMS Council, determines that the EMS provider improperly directed patient transports to any hospital, including Hospital A. There would be no other grounds for early termination of the lease. Each lease would run for a five-year term, renewable upon the consent of the Foundation, in consultation with the EMS Council.

Under the terms of each lease, oversight of quality assurance regarding the use of the Life Pack Units would be the responsibility of the ABCD, in consultation with the EMS Council. For example, EMS providers would be required to submit annual maintenance reports regarding their respective Life Pack Units to the ABCD, as well as annual reports describing utilization of the equipment.

II. LEGAL ANALYSIS

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce referrals of items or services reimbursable by Federal health care programs. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce referrals of items or services paid for 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, in cash or in-kind, directly or indirectly, covertly or overtly.

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.

This Office's concern with the provision of goods and services for nominal or at below-market rates to actual or potential referral sources is longstanding and clear: such arrangements are suspect and may violate the anti-kickback statute if one purpose is to induce or reward referrals of Federal health care program business.

The Proposed Arrangement raises issues under the anti-kickback statute because equipment will be leased for a nominal amount to EMS providers that are current and future referral sources. The provision of cardiac equipment by a hospital at a nominal, below-market rate fits within the meaning of remuneration for purposes of the anti-kickback statute.

In the present case, the Proposed Arrangement presents a minimal risk of Federal health care program abuse, while providing significant benefits to the community. First, because it relates to emergency medical services only, the Proposed Arrangement presents little risk of overutilization or increased costs to any Federal health care program. The number of Federal program beneficiaries requiring emergency transport in the GXA is not related to the existence or operation of the Proposed Arrangement. Also, the provision of Life Pack Units does not generate additional ambulance runs for EMS providers. Rather, the Life Pack Units enable them to provide an enhancement (pre-hospital electrocardiograms) to a service that would be provided even in the absence of Life Pack Units.

Second, the Proposed Arrangement should not result in the steering of patients to Hospital A. The referral pattern between the EMS providers and the hospitals in the GXA, including Hospital A, is preexisting and governed by extensive State and local regulatory protocols and procedures. Also, the EMS providers could employ the Life Pack Units in conjunction with any emergency-receiving hospital that operates a receiving unit. Conversely, all of the EMS providers that provide ALS in the GXA are parties to the Proposed Arrangement. The Foundation has not favored any ALS-EMS provider to the exclusion of another. Finally, as Hospital A's co-Sponsor Hospital and co-member of the ABCD and the EMS Council, Hospital B is in a unique position to raise any issues of perceived steering of emergency patients to Hospital A, which is its competitor in the GXA.

Third, the Proposed Arrangement is consistent with a local EMS system that seeks to regulate, improve, and safeguard the provision of EMS in the GXA. In addition to Hospital B oversight (as described above), Hospital A's interaction with EMS providers is overseen by the EMS Council and, ultimately, the Department of Public Health. For example, under the terms of each lease, oversight of quality assurance in the use of the Life Pack Units would be the responsibility of the ABCD, in consultation with the EMS Council. EMS providers would be required to submit annual maintenance reports regarding their respective Life Pack Units to the ABCD, as well as annual reports describing utilization of the equipment. Furthermore, the leases could be renewed only upon consultation with the EMS Council. Thus, the Proposed Arrangement would function in the context of a pre-existing, coordinated effort to integrate and improve the EMS system in the GXA.

Fourth, the Proposed Arrangement is likely to have a positive impact on the quality of patient care. By permitting earlier and more accurate pre-hospital screening, the Proposed Arrangement could reduce the time in which patients having myocardial infarctions or other cardiac conditions receive lifesaving treatment. This significant community benefit, coupled with the conditions, requirements, and limitations outlined above, persuade us that the Proposed Arrangement poses a minimal risk of fraud and abuse under the anti-kickback statute, and therefore the OIG would not subject it to administrative sanction.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement would 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, but that the OIG would not impose administrative sanctions on the Requesters 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.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [name redacted] Foundation, Inc., and to [name redacted] Hospital, the requesters 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 requester to this opinion.

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

- 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 Proposed Arrangement described in this letter and has no applicability to other arrangements or proposed arrangements, even those that 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 Requesters 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, rescind, modify or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the Requesters 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,

D. McCarty Thornton
Chief Counsel to the Inspector General