DEPARTMENT OF HEALTH & HUMAN SERVICES
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 requestors*.]

Issued: June 26, 2003

Posted: July 3, 2003

[name and address redacted]

Re: OIG Advisory Opinion No. 03-14

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding a proposed arrangement for emergency helicopter transports of trauma patients (the "Proposed Arrangement"). You have asked 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.

You have certified that all of the information provided in your request, including all supplementary letters, 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 the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals were present, but that the Office of Inspector General ("OIG") would not impose administrative sanctions on [S System] or [C Company] 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 other 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 [S System] and [C Company], the requestors of this opinion, and is further qualified as set out in Part V below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

[S System] (the "Hospital") is a non-profit hospital that serves a seventeen-county, predominantly rural area in [State] (the "State") and provides trauma services. [C Company] (the "Ambulance Company") is a for-profit emergency medical services ("EMS") transportation provider.

The State Department of Transportation has concluded that trauma victims in [name of area redacted] in which the Hospital is located (the "Area") experience higher rates of mortality and disability than trauma victims in other parts of the State, due to the considerable geographic distances between appropriately equipped emergency rooms in the area, inadequate ground ambulance coverage, and long response time by emergency personnel. The State has an extensive regulatory structure governing its EMS and trauma care systems.[1] The State is divided into a number of trauma service areas, governed by

[1]Emergency medical transportation in the State is administered through the State's Department of Health in accordance with procedures and standards developed by that Department's Bureau of Emergency Management, pursuant to a comprehensive, statewide EMS and trauma care system established in 1991 by the State legislature in response to the Trauma Care Systems Planning and Development Act of 1990, a federal statute. Congress specifically noted in enacting the legislation that "[t]he establishment of regional trauma systems and designated trauma centers are particularly important for rural regions of the nation." H. R. REP. NO. 101-346, at 13 (1990), reprinted in 1990 U.S.C.C.A.N. 4167, 4171.

regional trauma advisory councils ("RACs"). The RACs are responsible for developing and implementing a regional EMS and trauma care system plan for their areas, including trauma facility designation, the specification of facility bypass and diversion protocols, the development of a trauma reporting and analysis system, and the formulation of rules and guidelines for the triage, transportation, transfer, and care of trauma victims. In accordance with its regional plan, each RAC seeks to coordinate, improve, and integrate its area's available EMS and trauma care resources, including its public safety organizations, public and private ambulance providers, hospitals and other critical care facilities, and local physicians and community groups. RAC membership includes public safety agencies, public and private ambulance providers, trauma facility hospitals, physicians and nurses, and health care educational institutions.

The Hospital and the Ambulance Company propose to provide jointly for the emergency transport of trauma victims twenty-four hours a day within the Area.[2] Specifically, the Ambulance Company would purchase, operate, staff, manage, and maintain a helicopter equipped with a mobile intensive care unit to transport trauma victims. The Hospital would provide a helicopter landing pad adjacent to its facility, as well as modest crew quarters and related utility and security services. The helicopter landing pad and crew quarters would be available for use by any ambulance company bringing or retrieving a patient to or from the Hospital.

In the Area, "9-1-l" emergency calls are generally received by an operator at the local police or fire department and directed according to predetermined criteria to a dispatcher for the appropriate EMS responder. The destination hospital for a trauma victim transported by a helicopter ambulance service is based upon predetermined, objective RAC criteria, including the victim's physiological indications and anatomical injuries, the mechanism of the injury, the appropriateness of resources at any given emergency room facility, and, where necessary, a clinical determination of whether the type or severity of the injuries necessitates treatment of the victim at a Level I, II, III, or IV trauma center.

II. THE 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 federal health care programs. 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

[2]Other than the Proposed Arrangement, the parties have no business relationships.

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.

III. ANALYSIS

The OIG's concern with the provision of goods or 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 Hospital's provision of the helicopter landing pad, crew quarters, and related Hospital resources without charge to the Ambulance Company, a current and future source of referrals, implicates 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 would relate to emergency medical services only, the Proposed Arrangement would present little risk of overutilization or increased costs to any federal health care program. The number of federal program beneficiaries who would be trauma victims requiring emergency air transport in the Area would not be related to the existence or operation of the Proposed Arrangement.

Second, the Proposed Arrangement should not result in the steering of patients to the Hospital. The referral pattern for emergency transport between EMS transport providers and hospitals in the Area, including the Hospital, is governed by extensive State and local regulatory protocols and procedures pursuant to a State-mandated plan for a comprehensive, statewide EMS and trauma care system. The Proposed Arrangement

does not preclude other hospitals in the area from having helicopter landing pads as part of their facilities and does not preclude the Ambulance Company from delivering patients to those hospitals.

Third, the Proposed Arrangement would be consistent with an EMS and trauma care system that seeks to regulate, improve, and safeguard the provision of EMS and trauma care in the Area. The Hospital's interaction with the Ambulance Company would be overseen by the RACs and, ultimately, by the State Department of Public Health. Moreover, the helicopter landing pad, crew quarters, and related Hospital resources would be available to all ambulance companies serving the Area. Thus, the Proposed Arrangement would function in the context of a State-supervised, coordinated emergency services effort to integrate and improve the EMS and trauma care system in the Area and throughout the State.

Fourth, the Proposed Arrangement would be likely to have a positive impact on the quality of patient care in the Area, as well as on timely access to care. The State has identified a clear need for improved EMS transport in the Area. By providing a helicopter ambulance service for the emergency transport of trauma victims, the Proposed Arrangement would be likely to foster fast, efficient, and effective pre-hospital emergency and trauma care for the Area and, thereby, reduce the high rates of mortality and disability of the Area's trauma victims. These significant community benefits, coupled with the safeguards set forth above, persuade us that the Proposed Arrangement poses minimal risk of fraud and abuse under the anti-kickback statute, and therefore the OIG would not subject it to administrative sanctions. These community benefits are specific to this heavily-regulated, State-supervised emergency air ambulance service and would not justify other arrangements between hospitals and ambulance suppliers. (For example, an ambulance supplier's provision of discounted Part A ambulance transports to a hospital or skilled nursing facility in exchange for the exclusive referral of that facility's Part B transports would clearly implicate the anti-kickback statute.)

IV. CONCLUSION

For all of the above reasons, and based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals were present, but that the OIG would not impose administrative sanctions on [S System] or [C Company] 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 other agreements or arrangements disclosed or referenced in your request letter or supplemental submissions.

V. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [S System] and [C Company], which are the requestors of this opinion. This advisory opinion has no application, 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 to 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.

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

The OIG will not proceed against [S System] or [C Company] 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 [S System] or [C Company] 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,

/s/

Lewis Morris
Chief Counsel to the Inspector General