

[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.]

Date Issued: December 8, 2000

Date Posted: December 21, 2000

[name and address redacted]

**Re: [name redacted]
Advisory Opinion No. 00-9**

Dear [name redacted]:

We are writing in response to your request for an advisory opinion, in which you ask whether a proposed ambulance restocking arrangement (the "Proposed Arrangement") constitutes prohibited remuneration under the anti-kickback statute, section 1128B(b) of the Social Security Act (the "Act"), and, if so, whether the Proposed Arrangement would constitute grounds for the imposition of sanctions arising under the anti-kickback statute.

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, we conclude that the Proposed Arrangement described in your advisory opinion request and supplemental submissions could constitute prohibited remuneration under the anti-kickback statute, if the requisite intent to induce referrals of Federal health care program business were present, but that the Office of Inspector General (“OIG”) will not subject Hospital A to sanctions in connection with the Proposed Arrangement, as described and certified in the request letter and supplemental submissions, arising under the anti-kickback statute pursuant to sections 1128(b)(7) or 1128A(a)(7) of the Act.

This opinion may not be relied on by any persons other than Hospital A and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

Hospital A (the “Hospital”) is a non-profit, tax-exempt corporation organized under the laws of the State of Y. The Hospital is located in City X, State Y, and is the only hospital in the greater City X area. Emergency medical services (“EMS”) ambulances in the greater City X area transport the majority of their patients – in excess of 85% – to the Hospital due to the Hospital’s proximity to area towns.

In State Y, the Department of Public Health oversees regional EMS councils throughout the state. These councils plan, coordinate, and administer local emergency medical services. The greater State Y area is located within the jurisdiction covered by the Z Emergency Medical Services Regional Council (the “EMS Council”). The Z Region is the largest in the State, covering forty-three towns and six hospitals. The EMS Council’s mission is, among other things, to coordinate the various levels of EMS, educational programs, and interaction between pre-hospital care providers and other health care providers in the region and to encourage the implementation of EMS standards and criteria pursuant to local, state, and national guidelines. The EMS Council is composed of representatives from EMS providers, health care entities, and consumers and has oversight responsibilities for the provision of EMS in the region. As part of its oversight responsibilities, the EMS Council reviews protocols for EMS developed by each hospital in the region. The EMS Council has established a Medical Advisory Committee with representatives from each hospital in the region, including the Hospital. In addition, the Hospital serves as the “sponsor hospital” for twelve area EMS services pursuant to an agreement with the State Y. In this capacity, the Hospital provides medical control for the EMS providers and helps to ensure a well-structured EMS system in the greater City X area.

To further its mission to promote quality EMS, the EMS Council is working to coordinate a region-wide ambulance restocking program to ensure timely and appropriate restocking throughout its jurisdiction.

Four of the eleven EMS transport services that convey patients to the Hospital are volunteer ambulance services that do not charge insurers or patients for transport services (the “Non-Billing Volunteer Services”).¹ Under the Proposed Arrangement, the Hospital will restock the Non-Billing Volunteer Services’ ambulances with certain medical supplies² and pharmaceuticals used in connection with emergency pre-hospital services provided by the Non-Billing Volunteer Services. The Non-Billing Volunteer Services will not be charged, and will not pay, for the restocked items, and neither the Non-Billing Volunteer Services nor the Hospital will bill or otherwise seek reimbursement, directly or indirectly, from any Federal health care program or other party for restocked items. To qualify for exchanges of pharmaceuticals, the Non-Billing Volunteer Services must provide documentation of the drugs used during emergency ambulance runs. Restocked supplies will also be documented. The Proposed Arrangement seeks to ensure that the Non-Billing Volunteer Services’ ambulances are fully stocked with a standard complement of the supplies and drugs covered by the Proposed Arrangement. This will make it easier, for example, for patients arriving by emergency ambulance to be connected to the Hospital’s emergency room systems without interruption. The Proposed Arrangement will be consistent with the restocking practices promoted by the EMS Council.

The Hospital restocks, and will continue to restock, other ambulance services with supplies and medications used during emergency pre-hospital transports, but those ambulance services must pay fair market value for the restocked items.

II. LEGAL ANALYSIS

¹The other emergency ambulance services will not participate in the Proposed Arrangement. They consist of volunteer companies that charge for their services and a private ambulance company managed through a subsidiary of the Hospital.

²The medical supplies covered by the Proposed Arrangement are intravenous solutions, intravenous tubing, intravenous catheters and needles, oxygen cannulas and oxygen masks, endotracheal tubing, tuberculin, intramuscular syringes, blood collection tubes, sterile gauzes, and linen.

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 any Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce referrals of items or services for which payment may be made 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. This Office may also initiate administrative proceedings to exclude persons from Federal and state health care programs or to impose civil monetary penalties for fraud, kickbacks, and other prohibited activities under sections 1128(b)(7) and 1128A(a)(7) of the Act.³

This Office’s concern with the provision of goods and services for free 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 provision by a hospital of free supplies and medications to an ambulance provider fits squarely within the meaning of remuneration for purposes of the anti-kickback statute.⁴ Under certain circumstances, an inference may be drawn that one purpose of such remuneration is to induce the ambulance provider to bring patients to that particular

³Because both the criminal and administrative sanctions related to the anti-kickback implications of the Proposed Arrangement are based on violations of the anti-kickback statute, the analysis for purposes of this advisory opinion is the same under both.

⁴Pursuant to the Secretary’s authority under section 1128B(b)(3)(E) of the Act, we have published a notice of proposed rulemaking for a “safe harbor” for certain ambulance restocking arrangements that pose a minimal risk of fraud or abuse. See 65 Federal Register 32060 (May 22, 2000). The final rule is pending.

hospital. However, the strength of that inference may vary with the circumstances of the specific arrangement.

Based on the totality of facts and circumstances presented, we conclude that the OIG would not subject the Hospital to sanctions in connection with the Proposed Arrangement under sections 1128(b)(7) or 1128A(a)(7) of the Act. The relationship of the Proposed Arrangement to the overall EMS system in the community provides adequate assurance that the Proposed Arrangement is designed to improve and enhance the delivery of EMS for the benefit of the entire community and will not be undertaken solely for the benefit of a single provider or group of providers. Regional and local programs to improve and coordinate the delivery of quality EMS are consistent with longstanding Federal policy. The Proposed Arrangement will be limited to free restocking of supplies and drugs related to emergency transports.

In the circumstances presented, the fact that the Hospital offers free restocking *only* to volunteer emergency ambulance companies that do not bill for their services does not change our analysis. The Hospital has a legitimate interest in containing the cost of its ambulance restocking program. Limiting the scope of free restocking to the Non-Billing Volunteer Services represents a reasonable distinction drawn by the Hospital that is not related to the volume or value of referrals or other business generated for the Hospital.

III. CONCLUSION

The advisory opinion process is a “means of relating the anti-kickback statute to the particular facts of a specific arrangement.” 62 Fed. Reg. 7350, 7351 (Feb. 19, 1997). The issuance of an advisory opinion is not necessarily indicative of a government enforcement priority, nor does it mean that we consider the subject matter of the opinion to represent a significant area of fraud and abuse. In evaluating an arrangement’s potential to lead to fraud or abuse of Federal health care programs, no one fact or element is necessarily dispositive. We are persuaded that, taken as a whole, the aspects of the Proposed Arrangement described above -- including, but not limited to, the Hospital’s relationship with a coordinated regional EMS system, the role of the regional EMS council, and the fact that free restocking will be offered only for emergency transports -- create sufficient limitations, requirements, or controls so as to give adequate assurance that the Proposed Arrangement will not lead to program abuse under the anti-kickback statute.⁵ Accordingly, we conclude that while the Proposed Arrangement might

⁵This advisory opinion only applies to the restocking of drugs and supplies directly related to the provision of emergency pre-hospital services. Restocking of drugs or supplies used in connection with non-emergency services are outside the scope of this

technically violate the anti-kickback statute if the requisite intent to induce referrals were present, the OIG will not impose sanctions on the Hospital in connection with the Proposed Arrangement under sections 1128(b)(7) (as it relates to kickbacks) or 1128A(a)(7) of the Act, based on the facts certified in the Hospital's request for an advisory opinion and supplemental submissions.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to Hospital A, the requester of this advisory 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 of this opinion.
- This advisory opinion is applicable only to the statutory provisions specifically noted in the first paragraph of this advisory opinion. 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 arrangements described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope.

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 requester 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

opinion. We express no opinion regarding liability of the Hospital under the False Claims Act or other legal authorities in connection with any improper billing or claims submission directly or indirectly related to, or arising from, the Proposed Arrangement.

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 requester 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/

D. McCarty Thornton
Chief Counsel to the Inspector General