POSTED: June 16, 1998

[June 11, 1998]

To: The Attached Distribution List

Re: Advisory Opinion No. 98-7

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion, in which you ask whether an ambulance restocking and continuing education arrangement (the "Arrangement"[1]) constitutes prohibited remuneration under the anti-kickback statute, section 1128B(b) of the Social Security Act (the "Act") and, if so, whether the Arrangement constitutes grounds for the imposition of sanctions under the anti-kickback statute, section 1128B(b) of the Act, the exclusion authority related to kickbacks, section 1128(b)(7) of the Act, or the civil monetary penalty provision for kickbacks, section 1128A(a)(7) of the Act.

You have certified that all of the information you provided in your request, including all supplementary letters, is true and correct, and constitutes a complete description of the material facts regarding the Arrangement. In issuing this opinion, we have relied solely on the facts and information you 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, this opinion is without force and effect.

Based on the facts certified in your request for an advisory opinion, we conclude that the Arrangement could constitute prohibited remuneration under the anti-kickback statute if the requisite intent to induce referrals were present, but that the OIG will not subject the Arrangement, as described in the request and supplemental submissions, to sanctions arising under the anti-kickback statute pursuant to sections 1128B(b), 1128(b)(7), or 1128A(a)(7) of the Act.

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

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[1]Specifically, the Arrangement includes (1) a "drug box" exchange program; (2) a linens and medical supply exchange program; (3) a "pedi bag" exchange program for pediatric supplies; and (4) a continuing emergency medical services education program.

I. FACTUAL BACKGROUND

The requesters of this advisory opinion are twenty non-profit hospitals located in ten counties in the City A area of State B (the "Hospitals") and the City A Hospital Association (the "Association"), a non-profit corporation exempt from federal income tax pursuant to section 501(c)(6) of the Internal Revenue Code.[2] The Hospitals represent all of the hospitals in the City A area.

The Hospitals and the Association are dues paying members of the Region C Emergency Medical Services Council, Inc. (the "Council"), a State B nonprofit and tax exempt corporation founded in 1972, whose membership also includes all private and public ambulance providers in the area, local educational institutions, physicians, and at-large community members. The Council's mission is to coordinate the efforts of public and private ambulance service pre-hospital care providers, hospital emergency department staff, and consumers to ensure the best possible pre-hospital medical care for the victims of sudden illness or injury. The Council develops protocols for, and conducts ongoing evaluation and improvement of, the local emergency medical services ("EMS") delivery system, performs EMS quality assurance audits, distributes drug boxes to the local ambulances, provides continuing education to EMS personnel, sponsors education programs related to EMS for the general public, acts as an information clearinghouse for EMS activities, and otherwise seeks to promote high quality EMS care for the region.

Under the Council's auspices and pursuant to Council-developed protocols, the Hospitals and EMS organizations in the City A area have engaged in various drug and medical supply exchange programs in connection with emergency medical transports since approximately 1973. Typically under these exchange programs, a receiving hospital restocks an ambulance with medications and supplies used in connection with emergency medical pre-hospital services provided to the transported patient. The ambulance providers are not charged, and do not pay, for the restocked items. Drugs are exchanged through a "drug box" program, pursuant to which EMS squads exchange depleted drug boxes used during a patient run for fully-stocked boxes provided by the receiving

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[2]The Hospitals are all members of the Association. The Association has presented itself as an additional requestor on the ground that it facilitates the uniform participation of the Hospitals in the Arrangement. Although trade associations are not typically appropriate requesters on behalf of their members, see 42 C.F.R. § 1008.11, a trade association may be a proper requestor if it is itself a party to an arrangement that is the subject of a request for an advisory opinion.

hospital. Hospital pharmacists review the used drug boxes, replenishing used, outdated, or improperly sealed items, and return them to inventory for future exchange.[3]

Under the linens and medical supplies exchange program, receiving hospitals restock ambulances with linens and medical supplies used on patients during emergency pre-hospital services. The program enables ambulances to be fully stocked at all times and ensures standardization of supplies, so that, for example, tubing used by EMS units can be connected to hospital systems without interruption.

The continuing education programs in which the Hospitals participate serve to update EMS personnel on the latest techniques in patient care. These programs also enable EMS personnel to remain current with emergency room protocols in the Hospitals. Hospital personnel also visit EMS squads to test the skills of EMS personnel, as required by regional standing orders pertaining to EMS certification.

Also under the Arrangement, Hospital Z in City A, the area's children's specialty hospital and a requestor of this opinion, distributes "pedi bags" to EMS providers to ensure that EMS units carry a variety of pediatric-sized airway tubes and related equipment for use with children. These bags have been distributed to all EMS squads in the City A area. Private EMS squads pay a nominal start-up fee of $100 per bag. Hospital Z provides the bags to community and volunteer EMS squads at no charge. As with the other exchange programs, the supplies within the bags are restocked on an exchange basis, and all adult hospitals in the area keep on hand a small supply of these children's items.

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[3]The drug box exchange program has been approved by the State B Board of Pharmacy and complies with [code section redacted], which provides a mechanism for EMS units to obtain drug stocks legally "on a replacement basis" from hospitals to which patients are delivered. We have previously stated our belief that ambulance restocking performed pursuant to a state law mandate would not violate the anti-kickback statute. However, because [code section redacted] permits, but does not require, drug restocking by hospitals, the statute is insufficient by itself to foreclose the possibility of improper intent to induce referrals.

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 referrals of items or services reimbursable by any Federal health care program. See 42 U.S.C. § 1320a-7b(b). 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.

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). "Remuneration" for purposes of the anti-kickback statute includes the transfer of anything of value, in cash or in kind, directly or indirectly, covertly or overtly. 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.[4]

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

The provision by a hospital of free supplies, medications, and services to an ambulance service fits squarely within the meaning of remuneration for purposes of the anti-kickback statute. An inference may be drawn that one purpose of such remuneration is to induce the ambulance company to bring patients to the hospital. However, the strength of that inference may vary with the circumstances of the specific arrangement.

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

In assessing the potential risk of fraud or abuse under the anti-kickback statute, our concerns are principally fourfold: increased risk of overutilization, increased program costs, patient freedom of choice, and unfair competition. Because it is limited to emergency medical services, the Arrangement does not increase the risk of overutilization and is unlikely to lead to increased costs to Federal health care programs. Neither the number of Federal program beneficiaries requiring emergency transport in the City A area, nor the treatment these patients will require or receive at the Hospitals, is related to the existence or operation of the Arrangement.[5]

With respect to freedom of choice and unfair competition, under the Arrangement it appears that emergency ambulance crews have relatively limited opportunities to steer patients to particular hospitals. In life threatening cases, the selection of a receiving hospital will be dictated by the patient's condition. In other circumstances, the choice of receiving hospital will frequently be dictated by the patient, the patient's physician, or the patient's insurer. Notwithstanding, there will inevitably be situations in which ambulance company personnel would be able to steer patients who do not have a preference to a particular facility. In the circumstances presented here, however, there would appear to be no financial reason arising from the Arrangement for ambulance personnel to steer patients to a particular hospital, since all area hospitals participate in the Arrangement.

However, the mere fact that all hospitals may be restocking ambulances without charge does not immunize conduct that might otherwise violate the anti-kickback statute. Some institutions may well participate in the restocking because of fear of adverse competitive consequences if they do not. In short, remuneration that is given to retain or maintain existing referrals may violate the anti-kickback statute.

We previously addressed the application of the anti-kickback statute to an ambulance restocking arrangement in OIG Advisory Opinion 97-6 (October 8, 1997). Based on the specific facts presented by the hospital requestor, we found that, notwithstanding a state administrative regulation that required ambulances to transport patients to the facility of the patient's choice except in exigent circumstances, the hospital's proposed arrangement for free restocking of supplies and medications posed a risk of improper steering and unfair competition. Accordingly, we concluded that the arrangement could potentially violate the anti-kickback statute if the requisite intent to induce referrals were present.

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[5]This advisory opinion only relates to drugs, supplies, and educational programs provided by the Hospitals that directly relate to the provision of emergency pre-hospital services in the City A area. Restocking of drugs or supplies used in the course of non-emergency services and educational programs not directly related to emergency medical services are outside the scope of this opinion.

The facts presented here differ in material respects from those presented in OIG Advisory Opinion 97-6. First, the Arrangement is not a unilateral arrangement; rather, it was developed and implemented pursuant to an ongoing effort by the Council and its members to maintain and improve a regional emergency medical system through a comprehensive program that coordinates all EMS components. The Council, a non-profit corporation founded in 1972, is open to all hospitals and emergency ambulance providers in the area, as well as local educational institutions, physicians, and other community members. Regional EMS councils, like the one at issue here, were formed in the early 1970s in response to a growing recognition of the inadequacy of then existing emergency medical care and the high cost in human lives and physical disabilities due to accidents and sudden illness and injury.[6] EMS councils were established to coordinate emergency care among all levels of a region's EMS system, including public safety organizations, private and hospital-based ambulance services, hospitals and other critical care facilities, and local physicians and community groups.

Second, the restocking aspects of the Arrangement are not free-standing; the Arrangement is part and parcel of a comprehensive and coordinated regional effort to integrate and improve all aspects of the emergency medical care system. In addition to the drug and supply exchange programs, the Council establishes protocols addressing various aspects of the emergency medical system and otherwise administers the exchange and educational programs.[7] It also conducts ongoing evaluation and improvement of the local EMS delivery system, performs EMS quality assurance audits, sponsors educational programs related to EMS for the general public, acts as an information clearinghouse for EMS activities, and otherwise seeks to promote high quality EMS care for the region.

Third, regional and local programs to improve and coordinate the delivery of quality emergency medical services have been actively encouraged and promoted by the Federal government over the past twenty-five years. In 1973 -- the year the first exchange program began in the City A area -- the Federal government enacted the Emergency Medical Services Systems Act of 1973 ("EMSSA"), Pub L. 93-154, 87 Stat. 594 (1973), which provided federal funding for the development of regional EMS

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[6]See, e.g. *Accidental Death and Disability: The Neglected Disease of Modern Society*, National Academy of Sciences and National Research Council (September 1966).

[7]The "pedi bag" program is administered by the local children's medical center, but is part of the comprehensive regional EMS system and is included in the Arrangement for purposes of this advisory opinion.

systems at the state, regional, and local levels.[8] These regional systems were to develop comprehensive programs to improve such areas as communications (including "911" systems); transportation; provision and training of emergency personnel; facilities; critical care units; use of public safety agencies; accessibility to care; consumer participation, education, and information; transfer of patients; standard medical record keeping; independent review and evaluation of EMS; disaster linkage; and mutual aid agreements among communities. EMSSA was one of several Federal legislative efforts to promote EMS delivery systems, including the Highway Safety Act of 1966, Pub. L. 89-594, 80 Stat. 731 (1966), which established an EMS program in the Department of Transportation; the Emergency Medical Services for Children Program, under the Public Health Act, Pub. L. 98-555, 99 Stat. 2854 (1984), which provided funds for enhancing pediatric EMS; and the Trauma Care Systems Planning and Development Act of 1990, Pub. L. 101-590, 104 Stat. 2915 (1990).

Finally — and importantly — the Arrangement is likely to have a positive impact on the quality of patient care. By providing a mechanism to ensure that ambulances are fully stocked with current medications and appropriate supplies compatible with all local hospital emergency rooms and that EMS personnel are adequately trained, the Arrangement is likely to foster fast, efficient, and effective pre-hospital emergency care for the City A area community. This significant community benefit, coupled with the conditions, requirements, and limitations outlined above, persuade us that the Arrangement poses minimal risk of fraud and abuse under the anti-kickback statute, and therefore the OIG would not subject it to sanction.

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 (February 19, 1997). The advisory opinion process permits this Office to protect specific arrangements that "contain[] limitations, requirements, or controls that give adequate assurance that Federal health care programs cannot be abused." Id. 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. Here, we are persuaded that the Arrangement is likely to result in

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[8]EMSSA defined "emergency medical services system" as "a system which provides for the arrangement of personnel, facilities, and equipment for the effective and coordinated delivery in an appropriate geographical area of health care services under emergency conditions . . . and which is administered by a public or nonprofit private entity which has the authority and the resources to provide effective administration of the system." 87 Stat. at 595.

substantial community benefit consistent with longstanding national policy objectives. We are further persuaded that, taken as a whole, the aspects of the Arrangement described above -- including, but not limited to, the Arrangement's relationship to a coordinated regional EMS system, the role of the regional Council, the Arrangement's limitation to emergency medical services, and the uniformity of the Arrangement across providers -- create sufficient limitations, requirements, or controls so as to give adequate assurance that the Arrangement will not lead to program abuse under the anti-kickback statute.[9]

Accordingly, we conclude that while the Arrangement might technically violate the anti-kickback statute if the requisite intent to induce referrals were present, the OIG will not impose sanctions on the requesters under sections 1128(b)(7) (as it relates to kickbacks) or 1128A(a)(7) of the Act, based on the facts certified in the requesters' request for an advisory opinion.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to the requesters listed on the Attached Distribution List, which are the requesters 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 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 Arrangement.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

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[9]We express no opinion regarding liability of the requesters 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 Arrangement.

- 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.

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 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, modify or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against any 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.

Sincerely,

D. McCarty Thornton
Chief Counsel to the Inspector General

DISTRIBUTION LIST FOR OIG ADVISORY OPINION 98-7.

The following are the Requesters of OIG Advisory Opinion 98-7:

[NAMES AND ADDRESSES REDACTED]