

[Issued September 23, 1998]

[Posted on the OIG Web Site September 30, 1998]

To: The Attached Distribution List [redacted]

Re: [Name redacted]

Advisory Opinion No. 98-13

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion, in which you ask whether an ambulance restocking program, coordinated through a local emergency medical services council (the "Program"), constitutes prohibited remuneration under the anti-kickback statute, section 1128B(b) of the Social Security Act (the "Act"), and, if so, whether the Program 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 information, is true and correct, and constitutes a complete description of the material facts regarding the Program. 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 Program 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 Program, 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 IV below and in 42 C.F.R. Part 1008.

FACTUAL BACKGROUND

The requesters of this advisory opinion are eight fire departments (listed on the attached distribution list) and The County X Ambulance District located in County X, State Y. All of the fire departments and the ambulance district are owned and operated by municipal governments and provide emergency medical services ("EMS").

The requesters are members of the County X Emergency Medical Services Council (the "Council"), a non-profit association founded in 1980. The Council is an advisory and coordinating organization whose mission is to promote and advance EMS throughout County X. Membership on the Council includes those who are providing EMS and those who are interested in furthering the goals of the Council. The Council's current membership

includes public and private ambulance providers, hospitals, medical directors, and local educational facilities. The Council's goals include: standardization of EMS practices and equipment; provision of education and training for EMS providers; and improvement of EMS capabilities in the Council's service area. Through its Executive Committee, the Council may appoint working committees to accomplish its goals. One such committee is a practice committee.

The practice committee has oversight of the restocking Program and is responsible for standardizing the Program within the local EMS community, educating Council members regarding the Program, and disseminating information about the Program. The Program has been in operation in County X for eighteen years. The Program provides for the free exchange of drugs and medical supplies used by EMS providers when they bring an individual to a hospital for emergency treatment. Currently, all hospitals and EMS providers in the County X service area participate in the Program. Under the Program protocol, the hospital that receives the patient restocks the ambulance with the medications and supplies used in connection with the patient's emergency medical treatment. Both an EMS provider and a representative of the receiving hospital fill out and sign an emergency medical response for each patient (the "Report"). One copy of the Report is placed in the patient's record and one copy of the Report is used for inventory documentation of the expended drugs and medical supplies. The ambulance providers are not charged, and do not pay, for restocked items. The cost of the drugs and medical supplies is charged to the patient by the receiving hospital in the manner of other billing for the services to the patient.

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 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.⁽¹⁾

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 and medications to an ambulance provider 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 provider to bring patients to the hospital. However, the strength

of that inference may vary with the circumstances of the specific arrangement.

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 Program 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 County X, nor the treatment these patients will require or receive at a hospital, is related to the existence or operation of the Program.⁽²⁾

With respect to freedom of choice and unfair competition, 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 provider 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 Program for ambulance personnel to steer patients to a particular hospital, since all area hospitals participate in the Program.

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 an ambulance restocking arrangement that raised concerns under the anti-kickback statute in OIG Advisory Opinion 97-6 (October 8, 1997). Based on the specific facts presented by the hospital requester, 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.

The facts presented here differ in material respects from those presented in OIG Advisory Opinion 97-6 for the following reasons:⁽³⁾

First, the Program is not a unilateral arrangement; rather, it is part of an ongoing effort by the Council and its members to maintain and improve EMS throughout the County X service area. The Council, a non-profit association founded in 1980, 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.⁽⁴⁾ 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 providers, hospitals and other critical care facilities, and local physicians and community groups.

Second, the restocking aspects of the Program are not free-standing; the Program is part and parcel of a coordinated regional effort to integrate and improve the emergency medical care system. In addition to the drug and supply exchange programs, the Council promotes the standardization of practices and equipment within the

emergency medical system and provides education and training for EMS providers. It also evaluates and supports requests for improvements to the local EMS delivery system, sponsors educational programs related to EMS, 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 EMS have been actively encouraged and promoted by the Federal government over the past twenty-five years. In 1973 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 systems at the state, regional, and local levels.⁽⁵⁾ 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 Program 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, the Program is likely to foster fast, efficient, and effective pre-hospital emergency care for the County X service area. These significant community benefits, coupled with the conditions, requirements, and limitations outlined above, persuade us that the Program 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 Program is likely to result in substantial community benefit consistent with longstanding national policy objectives. We are further persuaded that, taken as a whole, the aspects of the Program described above -- including, but not limited to, the Program's relationship to a coordinated regional EMS system, the role of the regional Council, the Program's limitation to emergency medical services, and the uniformity of the Program across providers -- create sufficient limitations, requirements, or controls so as to give adequate assurance that the Program will not lead to program abuse under the anti-kickback statute.⁽⁶⁾

Accordingly, we conclude that while the Program 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 requester 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 Program.

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.

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 Program 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 Program 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 any 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

[Attached Distribution List Redacted]

1. Because both the criminal and administrative sanctions related to the anti-kickback implications of the Program are based on violations of the anti-kickback statute, the analysis for purposes of this advisory opinion is the same under both.
2. This advisory opinion only relates to drugs and supplies directly related to the provision of emergency pre-hospital services in the Program's service area. Restocking of drugs or supplies used in connection with non-emergency services is outside the scope of this opinion.
3. We note that many aspects of the Program are similar to aspects of the proposed arrangement in OIG Advisory Opinion 98-7, which addressed an ambulance restocking arrangement that we concluded would not be subject to OIG sanction.
4. See, e.g. *Accidental Death and Disability: The Neglected Disease of Modern Society*, National Academy of Sciences and National Research Council (September 1966).
5. 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.
6. 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 Program.