

[Posted October 28, 1998]

[Issued October 21, 1998]

To: The Attached Distribution List [redacted]

Re: [Name redacted]

Advisory Opinion No. 98-14

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion, in which you ask whether an existing pharmaceutical restocking program (the "Drug Program") and a proposed medical supplies restocking program (the "Supply Program") (collectively, the "Arrangements") constitute prohibited remuneration under the anti-kickback statute, section 1128B(b) of the Social Security Act (the "Act"), and, if so, whether the Arrangements constitute 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 Arrangements. 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 Arrangements 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 OIG will not subject the Drug 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.

I. FACTUAL BACKGROUND

The requesters of this advisory opinion are four hospital providers located in four counties in the northeast of State X (the "Hospitals"). The first requester is Hospital One ("Hospital One"), which operates one hospital in County A, State X, and three hospitals in County B, State X. The second requester is Hospital Two ("Hospital Two"), which operates one hospital in County A, State X, one hospital in County B, State X, and one free-standing emergency facility in County C, State X. The third requester is Hospital Three ("Hospital Three") located in County D, State X. The final requester is Hospital Four ("Hospital Four") located in County B, State X. These Hospitals represent all of the hospital providers in the greater [four county] metropolitan emergency medical services area (the "Four County EMS Area").⁽¹⁾

Each Hospital is a member of at least one of the three emergency medical services ("EMS") councils operating in the four-county area (the "EMS Councils"). The first EMS council is Council F ("Council F"), which operates in County A. Council F'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 county and to encourage the implementation of EMS standards and criteria pursuant to local, state, and national guidelines.

Hospital One and Hospital Two are members of Council F. The second EMS council is Council G ("Council G"), which operates in Counties B and D. Council G's mission includes upgrading emergency medical care in the region; serving as a central coordinating body; and implementing and monitoring systems of quality assurance for EMS in the region. Hospitals One, Two, Three, and Four are all members of Council G. The third EMS council is Council H ("Council H"). Council H was formed to oversee pre-hospital emergency medical care in the county, including promulgating standard, community-wide pre-hospital EMS operating protocols. Hospital Two is a member of Council H. Each EMS Council has diverse membership, including, among others, local physicians, hospital representatives, paramedics, EMS technicians, consumer representatives, EMS education providers, and local officials.

The Hospitals participate in a pharmaceutical restocking program (the "Drug Program") with area ambulance providers in connection with emergency medical transports. Typically under the Drug Program, a receiving hospital restocks an ambulance with the medications used in connection with emergency pre-hospital services provided by the ambulance provider to the transported patient. The EMS units are not charged, and do not pay, for restocked items. As part of the exchange, the EMS unit must provide documentation of the drugs used during the ambulance run. All hospitals in the Four County EMS Area participate in the Drug Program; any other hospital located within the four-county area may participate. The restocked pharmaceuticals are provided to any ambulance provider that transports an emergency patient to the hospital.

Council F, Council G, and Council H have facilitated the Drug Program within the four-county area in various ways. The EMS Councils' activities have included, for example: initiating drug exchange programs; approving policies and protocols that govern drug exchange programs; creating and implementing protocols for the administration of drugs used during patient transport; and coordinating efforts between public and private pre-hospital providers, hospital emergency staff, and consumers to promote the highest quality medical care for victims of sudden illness or injury.

The Hospitals also propose a limited medical supplies restocking program (the "Supply Program"), pursuant to which the Hospitals would restock certain supplies used by ambulance providers during emergency pre-hospital transportation. To initiate, coordinate, and monitor the Supply Program, the Hospitals have established a joint committee, comprised of the EMS coordinator or a higher level employee from each Hospital. Any hospital located within the four-county area may participate. The restocked medical supplies will be provided to any ambulance provider that transports an emergency patient to a participating hospital.

The Hospitals want to establish a limited supply exchange program targeting specific supplies that they believe will enhance efficient coordination and integration between their emergency rooms and emergency pre-hospital care providers. To this end, the joint committee developed the following list of medical supplies to be restocked under the auspices of the Supply Program: intravenous solutions; intravenous tubing; intravenous catheters and needles; oxygen cannulas and oxygen masks; endotracheal tubes; tuberculin, intramuscular and 10 cc syringes; blood collection tubes; and linens.⁽²⁾

The Supply Program will allow ambulances to be fully stocked with a standard complement of these supplies, making it easier, for example, for patients arriving by emergency ambulance to be connected to Hospital emergency room systems without interruption.

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.⁽³⁾

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 and may violate the anti-kickback statute if one purpose 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.

With respect to the Drug Program, the factual circumstances presented here are substantially similar to those present in the factual circumstances addressed by OIG Advisory Opinions 98-7 and 98-13. Thus, for the reasons stated in those opinions, we conclude that the OIG would not subject the Drug Program, as described in the request letter and supplemental submissions, to sanctions under section 1128B(b), 1128(b)(7), or 1128A(a)(7) of the Act.⁽⁴⁾ As in those opinions, the involvement of the entire EMS community in the Drug Program, including hospitals, EMS physicians, ambulance providers, paramedics, EMS education providers, consumer representatives, and local officials, provides adequate assurance that the plan is designed to improve and enhance the delivery of EMS in the Four County EMS Area for the benefit of the entire community.

While we recognize that the Supply Program may also provide a community benefit, we are unable to reach a similar conclusion with respect to the application of the anti-kickback statute to that program. The Supply Program would be implemented under the auspices of a committee formed exclusively of Hospital representatives, rather than an EMS council or similar group more broadly representative of the EMS community at large. The involvement of a broad range of representatives of the EMS community provides substantial assurance that an ambulance restocking program will operate for the benefit of the local community and will not be undertaken solely for the benefit of a single provider or group of providers.

We wish to make clear that this opinion does not mean that the Supply Program (or similar ambulance restocking programs) would violate the anti-kickback statute. Rather, because it involves the provision of free goods to potential referral sources, the Supply Program might violate the statute if one purpose of the Program is to induce Federal health care program business. Thus, whether the proposed Supply Program would, in fact, be unlawful requires a case-by-case determination of the actual intent of the parties based on all relevant facts and circumstances. We cannot determine intent based solely on documentary submissions; accordingly, a determination of intent is beyond the scope of the advisory opinion process. See 62 Fed. Reg. 7351 (Feb. 19, 1997).

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 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. We are further persuaded that, taken as a whole, the aspects of the Drug Program described above -- including, but not limited to, the Hospitals' relationships with coordinated regional EMS systems, the role of the regional EMS councils,

and the Program's limitation to emergency medical services -- create sufficient limitations, requirements, or controls so as to give adequate assurance that the Drug Program will not lead to program abuse under the anti-kickback statute.⁽⁵⁾ The Supply program does not contain similar safeguards.

Accordingly, we conclude that while the Arrangements 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 in connection with the Drug Program 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. The OIG cannot give a similar assurance that the Supply Program would not be subject to sanction if the parties were to have the requisite intent to induce referrals of Federal health care program business.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to the Hospitals 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 Arrangements.
- 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 Office of Inspector General ("OIG") will not proceed against the requesters with respect to any action that is part of the Arrangements 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 Arrangements in practice comport 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

[Attached Distribution List Redacted]

FOOTNOTES

1. There are other hospitals in the four-county area that are geographically distant from the Hospitals and therefore not part of the Four County EMS Area.
2. Linens are included to ensure appropriate compliance with sanitization requirements for laundering linens used by hospital and ambulance patients.
3. Because both the criminal and administrative sanctions related to the anti-kickback implications of the Arrangements are based on violations of the anti-kickback statute, the analysis for purposes of this advisory opinion is the same under both.
4. This advisory opinion only relates 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 opinion.
5. 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 Arrangements.