



[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.]

Issued: April 4, 2002

Posted: April 11, 2002

[name and address redacted]

Re: OIG Advisory Opinion No. 02-3

Dear [name redacted]:

We are writing in response to your request for an advisory opinion as to whether a proposed ambulance restocking arrangement (the "Proposed Arrangement") would fit within the safe harbor for ambulance replenishing at 42 C.F.R. § 1001.952(v) and thus would satisfy the criteria set forth in section 1128B(b)(3)(E) of the Social Security Act (the "Act") for activities that do not result in prohibited remuneration.

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.

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 and supplemental submissions, we conclude that the Proposed Arrangement would satisfy the criteria for "general replenishing" set forth in the ambulance replenishing safe harbor at 42 C.F.R. § 1001.952(v) and thus would not constitute prohibited remuneration under the anti-

kickback statute.

This opinion may not be relied on by any persons other than [Council A] (the “Requestor”) and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

The Requestor is a quasi-governmental agency created in 1975 under the laws of [state] and composed of representatives of regional emergency medical services (“EMS”) providers, health care entities, and medical directors. The Requestor is statutorily responsible for planning, implementing, and monitoring the development of the EMS system in the [region] of the State, which comprises [counties]. As part of its oversight responsibilities, the Requestor reviews protocols for EMS developed by each hospital in the region. To further its mission to promote quality EMS, the Requestor has proposed a formal, written, region-wide ambulance restocking program to ensure timely and appropriate restocking throughout its jurisdiction. The Proposed Arrangement will apply to all ambulance providers in the Requestor’s jurisdiction. All ambulances that are restocked are used to provide emergency ambulance services an average of at least three times per week.

Under the Proposed Arrangement, the participating hospitals will restock all ambulance providers on a uniform basis. The hospital receiving a patient will restock the transporting ambulance with the drugs and medical supplies used in connection with the patient’s medical treatment. If first responder agencies furnish drugs and medical supplies to a patient, they will be restocked by the ambulance transporting the patient, which in turn will be restocked by the hospital receiving the patient. The ambulance providers will not be charged, and will not pay for, the restocked items, and participating hospitals will bill or otherwise seek reimbursement, directly or indirectly, from any Federal health care program or other party for the restocked items only to the extent permitted under the payor’s rules and regulations. The ambulance provider will provide documentation to the receiving hospital of the drugs and medical supplies used during the emergency run that are restocked. Both parties will maintain records documenting the specific restocked supplies and drugs for at least five years and will make such records available to the Secretary of the Department of Health and Human Services promptly upon request.

The Requestor has certified that any billing of restocked items by either the participating hospitals or the ambulance providers will comport with applicable Federal health care program payment and coverage rules and regulations and that there will be no duplicate billing for any restocked drugs or supplies. The Requestor has also certified that the

Proposed Arrangement will not take into account the volume or value of any referrals or business otherwise generated between ambulance providers and participating hospitals for which payment may be made in whole or in part under any Federal health care program (other than the delivery to the receiving hospital of the particular patient in connection with whom the drugs and medical supplies are restocked). The Requestor has further certified that the receiving hospital and the ambulance provider will otherwise comply with all Federal, State, and local laws regulating ambulance services, including, but not limited to, emergency services, and the provision of drugs and medical supplies, including, but not limited to, laws relating to the handling of controlled substances.

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.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. Most recently we have published a final safe harbor for certain ambulance restocking arrangements. See 66 Fed. Reg. 62979 (Dec. 4, 2001) (to be codified at 42 C.F.R. § 1001.952(v)). The final rule covers restocking of drugs and medical supplies (including linens) by a hospital or other receiving facility for the purpose of replenishing comparable drugs or medical supplies used by the ambulance provider (or a first responder) in

connection with the transport of a patient by ambulance to the hospital or other receiving facility, provided that all applicable safe harbor conditions are satisfied.

The safe harbor protects three categories of restocking: free or discounted restocking (“general replenishing”), fair market value restocking, and government mandated restocking. In all cases, the ambulance that is replenished must be used to provide emergency ambulance services an average of at least three times per week, as measured over a reasonable period of time. Drugs and medical supplies used by a first responder and replenished at the scene of the injury or illness by the ambulance provider that transports the patient to a receiving facility will be deemed to have been used by the ambulance provider for purposes of restocking by the hospital.

The general replenishing safe harbor covers restocking done without charge or at a discounted charge to the ambulance provider. To come within this category, an arrangement must meet the following requirements:

- (1) Participating hospitals must restock ambulance providers uniformly in one or more of the following categories: (a) all ambulance providers, (b) all non-profit and government providers, or (c) all non-charging providers;
- (2) The restocking arrangement must be conducted in an open and public manner. This condition can be satisfied by the conspicuous posting of a notice at the hospital¹ or by operating under the auspices of a local EMS council or similar organization;
- (3) Any billing of restocked items by either the hospital or the ambulance provider must comport with applicable Federal health care program payment and coverage rules and regulations. There can be no duplicate billing for any restocking: either the ambulance provider (or first responder) or the receiving facility may bill a Federal health care program for replenished drugs or supplies;
- (4) The ambulance provider or receiving facility or both must document the restocking appropriately in accordance with the requirements set out in the final rule, including (a) maintaining records of the replenished drugs and supplies and the patient transport to which they relate, (b) providing a copy of the records to the other party within a reasonable time, and (c) making

¹An optional sample form for such notice is provided in an appendix to the final rule.

the records available to the Secretary promptly upon request;

(5) The restocking arrangement must not take into account the volume or value of referrals from the ambulance provider to the hospital (other than the delivery to the receiving facility of the particular patient for whom the drugs and medical supplies are restocked); and

(6) The parties to the restocking arrangement must comply with all Federal, State, and local laws regulating ambulance services (including, but not limited to, emergency services) and the provision of drugs and medical supplies (including, but not limited to, laws relating to the handling of controlled substances).

The Proposed Arrangement would comport with all of the foregoing requirements and hence will constitute a “general replenishing” arrangement within the terms of the ambulance replenishing safe harbor at 42 C.F.R. § 1001.952(v).

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement would satisfy the criteria for a “general replenishing” arrangement within the terms of the ambulance restocking safe harbor at 42 C.F.R. § 1001.952(v) and thus would not constitute prohibited remuneration under the anti-kickback statute.²

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [Council A], the requestor of this 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 requestor of this opinion.

²We express no opinion regarding liability of any hospital or ambulance company participating in the Proposed Arrangement 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.

- 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.
- 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 [Council A] 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, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against [Council A] 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