



[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. 02-2

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion addressing whether an ambulance restocking arrangement (the "Arrangement") fits in the safe harbor for ambulance replenishing at 42 C.F.R. § 1001.952(v), thus satisfying 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 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 Arrangement described in your advisory opinion request and supplemental submissions satisfies the criteria for "general replenishing" set forth in the ambulance replenishing safe harbor at 42 C.F.R. § 1001.952(v) and, thus, does not constitute prohibited remuneration under the anti-kickback statute.

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

I. FACTUAL BACKGROUND

Company A (the “Ambulance Company”) is a non-profit State X corporation operating a state-licensed ambulance service company providing emergency medical services (“EMS”). It serves several State X counties, including [names redacted] counties (the “Y Region”), and participates in the Medicare and Medicaid programs as a supplier of ambulance services. Each of its ambulances is used on average at least three times per week for emergency runs.

The Ambulance Company routinely provides emergency medical transportation of sick and injured patients to Hospital B and Hospital C (the “Hospitals”), as well as non-emergency and scheduled transports. The Hospitals are non-profit hospitals operating in the Y Region. Each participates in the Medicare and Medicaid program.

The Hospitals restock certain drugs and supplies used during emergency ambulance transports without charge to the Ambulance Company. They do not offer free restocking for non-emergency runs. The restocking has been, and will continue to be done, in accordance with detailed regional protocols established by the County D Medical Control Authority and the County E Medical Control Authority (in conjunction with the Medical Control Authority of County F) and rules promulgated by the State X Department of Community Health (the “State Agency”) pursuant to state law regulating the quality and accessibility of EMS (the “EMS Act”).¹

The Hospitals restock all ambulance companies in the Y Region on a uniform basis. The Hospitals document the specific drugs and supplies that are restocked and provide copies of such documentation to the Ambulance Company. The Ambulance Company has certified that the parties will maintain such records for five years and make them available to the Secretary of the Department of Health and Human Services (the “Department”) promptly upon request.

¹These entities are local medical control authorities (“LMCAs”) established pursuant to the EMS Act, [citation redacted], of the State X Public Health Code. LMCAs are required to establish written protocols for the practice of life support agencies and licensed emergency medical services personnel within their regions, in accordance with procedures set by the State Agency. Ambulance companies must operate in accordance with the EMS Act and the approved LMCA protocols. LMCAs are administered by participating hospitals, which appoint a physician as medical director and an advisory body that includes representatives of each kind of EMS provider and worker in the LMCA’s boundaries.

Presently, neither the Ambulance Company, nor the Hospitals, bills for the restocked drugs or supplies. The Ambulance Company has certified that future billing, if any, of restocked items by either the Hospitals or the Ambulance Company 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 Ambulance Company has also certified that the Arrangement does not, and will not, take into account the volume or value of any referrals or business otherwise generated between the Ambulance Company and the Hospitals for which payment may be made in whole or in part under any Federal health care program (other than the delivery to the Hospitals of the particular patient in connection with whom the drugs and supplies are restocked). Finally, the Ambulance Company has certified that participants in the Arrangement 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 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 or medical supplies (including linens) by a hospital or other receiving facility for the purpose of replenishing comparable drugs or medical supplies used by an 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.

The general replenishing safe harbor covers restocking done without charge or at a discounted charge to the ambulance provider. To come within this category, a restocking arrangement must meet all of 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 hospital² 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

²An optional sample form for such notice is provided in an appendix to the final rule.

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 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 Arrangement comports with all of the foregoing requirements and, hence, constitutes a “general replenishing” arrangement within the terms of the ambulance replenishing safe harbor at 42 C.F.R. § 1001.952(v).³ We note that, while the Arrangement meets the “open and public” condition by operating under the auspices of an organization comparable to an EMS council, it could alternatively satisfy the requirement by posting a notice at the Hospitals.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion, we conclude that the Arrangement described in your advisory opinion request and supplemental submissions satisfies the criteria for “general replenishing” set forth in the ambulance replenishing safe harbor at 42 C.F.R. §1001.952(v) and, thus, does not constitute prohibited remuneration under the anti-kickback statute.⁴

³Whether the Arrangement also fits in the “government-mandated” safe harbor category is a question requiring an interpretation of state law that we need not, and do not, reach here.

⁴We express no opinion regarding liability of any hospital or ambulance company participating in the 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 Arrangement.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to Company 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.
- 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 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 Company A 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, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against Company 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