



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



[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: October 26, 2012

Posted: November 5, 2012

[Name and address redacted]

Re: OIG Advisory Opinion No. 12-16

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion regarding a proposal to waive cost-sharing amounts on a non-routine, unadvertised basis for insured patients, including Federal health care program beneficiaries, based on individualized determinations of financial need (the “Proposed Arrangement”). Specifically, you have inquired whether the Proposed Arrangement would constitute grounds for the imposition of sanctions under the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Social Security Act (the “Act”), or under the exclusion authority at section 1128(b)(7) of the Act, or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the Federal anti-kickback statute.

You have certified that all of the information provided in your request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an 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: (i) the Proposed Arrangement would not constitute

grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) although the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of Federal health care program business were present, the Office of Inspector General (“OIG”) would not impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement. This opinion is limited to the Proposed Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

This opinion may not be relied on by any persons other than [name redacted], the requestor of this opinion, and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

[Name redacted] (the “Requestor”) is a not-for-profit corporation that provides emergency-only ambulance services throughout the [city redacted] metropolitan area. It is a volunteer ambulance organization founded to address the special needs of observant Jewish communities, but which provides care to all patients who request its services. Knowledge of the Requestor’s services is generally spread through word of mouth in the communities it serves. The Requestor currently relies on charitable donations to meet its operating costs and does not charge patients for its services. Due to recent economic constraints, however, the Requestor seeks to accept reimbursement from third-party payors, including Medicare and Medicaid.

Under the Proposed Arrangement, the Requestor would continue its historical, charitable practice of treating and transporting uninsured patients free of charge. For insured patients, the Requestor¹ would bill all third-party payors, including Medicare and Medicaid, as well as any applicable supplemental or secondary insurance, for emergency transport services rendered. The Requestor would not routinely waive coinsurance or deductible amounts. However, the Requestor would waive or reduce coinsurance or deductible amounts, if it determines in good faith that the transported patient is in financial need. The Requestor would make all financial eligibility determinations using objective criteria. Any decision to reduce or waive a patient’s cost-sharing obligations

¹ For ease of reference, our use of the term “Requestor” throughout this opinion may also include any billing agent used by the Requestor, as applicable. We have not been asked to opine on, and we are not opining on, the relationship between the Requestor and any billing agent used by the Requestor.

would be made on a case-by-case basis and would be based only on the patient's specific financial situation.

Under the Proposed Arrangement, the Requestor would not advertise waivers of cost-sharing amounts for its emergency transport services. The Requestor would inform an insured patient of a potential waiver only after the Requestor has finished rendering services to the patient, and the patient indicates that he or she is unable to pay.

In shifting from a business model relying entirely on charitable contributions to fund all operations to one that accepts reimbursement from all third-party payors, including Medicare and Medicaid, the Requestor certifies that it would comply with all Federal fraud and abuse laws, as well as applicable Medicare and Medicaid coverage rules for emergency ambulance transports.

II. LEGAL ANALYSIS

A. Law

The anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable 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, directly or indirectly, overtly or covertly, in cash or in kind.

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. See, e.g., United States v. Borrasi, 639 F.3d 774 (7th Cir. 2011); United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000); United States v. Davis, 132 F.3d 1092 (5th Cir. 1998); United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir. 1985), 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. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

Section 1128A(a)(5) of the Act (the "CMP") provides for the imposition of civil

monetary penalties against any person who offers or transfers remuneration to a Medicare or state health care program (including Medicaid) beneficiary that the benefactor knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a state health care program (including Medicaid). The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs. Section 1128A(i)(6) of the Act defines "remuneration" for purposes of section 1128A(a)(5) as including "the waiver of coinsurance and deductible amounts (or any part thereof)." The CMP contains certain exceptions from the definition of remuneration. Waivers of cost-sharing amounts are excepted if:

- (i) the waiver is not offered as part of any advertisement or solicitation;
- (ii) the person [making the waiver] does not routinely waive coinsurance or deductible amounts; and
- (iii) the person [making the waiver]—
 - (I) waives the coinsurance and deductible amounts after determining in good faith that the individual is in financial need; or
 - (II) fails to collect coinsurance or deductible amounts after making reasonable collection efforts.

Section 1128A(i)(6) of the Act. Subsections (i), (ii), and at least one prong of subsection (iii) must be satisfied for the exception to apply.

B. Analysis

The Proposed Arrangement implicates the CMP and the anti-kickback statute because the Requestor would waive cost-sharing amounts for emergency ambulance transports for certain patients, including Federal health care program beneficiaries. However, if the Requestor's Proposed Arrangement satisfies all of the criteria of the CMP's exception for waivers of cost-sharing amounts, it would not involve prohibited remuneration within the meaning of section 1128A(a)(5) of the Act. For the following reasons, we conclude that it satisfies all of the criteria.

First, the Requestor certified that it would not offer the waiver as part of any advertisement or solicitation under the Proposed Arrangement. The Requestor would inform a patient of the waiver only after the Requestor has finished rendering services to the patient, and the patient indicates that he or she is unable to pay. Second, waivers of cost-sharing amounts under the Proposed Arrangement would not be made routinely; rather, they would be contingent on the insured patient's inability to pay amounts owed, which the Requestor would determine on a case-by-case basis. Third, the Requestor would make all financial eligibility determinations using objective criteria. Patients would not be eligible for cost-sharing waivers unless they meet the Requestor's financial

need eligibility criteria. The Requestor has certified that it would make these individualized determinations of financial need in good faith.

Accordingly, the Proposed Arrangement satisfies all of the criteria of the exception for waivers of cost-sharing amounts and would not constitute prohibited remuneration under Section 1128A(a)(5) of the Act. In light of the same safeguards set forth above, we also conclude that we would not subject the Requestor to administrative sanctions under the anti-kickback statute in connection with the remuneration provided to financially-needy, insured patients under the Proposed Arrangement.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Proposed Arrangement would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) although the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of Federal health care program business were present, the OIG would not impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement. This opinion is limited to the Proposed Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [name redacted], 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 by a person or entity other than [name redacted] to prove that the person or entity did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.
- 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, including, without limitation, the physician self-referral law,

section 1877 of the Act (or that provision's application to the Medicaid program at section 1903(s) of the Act).

- 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 [name redacted] 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 [name redacted] with respect to any action that is part of the Proposed Arrangement 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,

/Gregory E. Demske/

Gregory E. Demske
Chief Counsel to the Inspector General