



[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: September 17, 2009

Posted: September 24, 2009

[Name and address redacted]

Re: OIG Advisory Opinion No. 09-16

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion regarding a proposed arrangement between your professional organization and a referral service (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement would constitute grounds for the imposition of sanctions under the exclusion authority at section 1128(b)(7) of the Social Security Act (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 while 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 the [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 the [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

The requestor is the [name redacted] (the “Association”), a [state redacted] not-for-profit corporation formed under section 501(c)(6) of the Internal Revenue Code. Under the Association’s by-laws, any chiropractor of good character, licensed to practice in [state redacted], is eligible for membership. Approximately [number redacted] chiropractors are licensed to practice in [state redacted], and approximately [number redacted] of these are members of the Association.

The [name redacted] (the “Network”) is a [state redacted] for-profit corporation. It does not provide any items or services payable by Federal health care programs, and it is not affiliated with any individual or entity that provides such items or services. It is a start-up entity that intends to advertise chiropractic services in the [state redacted] metropolitan area and provide referrals for such services. The Network intends to advertise its chiropractor referral service through internet, print, radio, or television advertising. A prospective patient who contacts the Network for a chiropractor referral will be asked to provide a zip code. The Network will provide contact information for a participating chiropractor who practices in that zip code or, if no participating chiropractor practices in that zip code, in a nearby zip code. If more than one participating chiropractor is in the particular zip code, a name will be provided in sequence from a rotating list.

The Association has certified that the Network will make all the disclosures required by the safe harbor for referral services at 42 C.F.R. § 1001.952(f)(4). These disclosures will be made on the Network’s website and orally when the Network receives telephone requests for referrals to chiropractors. The Association also has certified that written records for the website will be maintained and that voice recordings will be made for the call center, with written notations documenting the above-described disclosures and signed by the person making the disclosures. The Network will impose no requirements on the manner in which participating chiropractors provide services to referred persons.

The referral service will be open to participation by any chiropractor licensed to practice in [state redacted], for a standard flat fee of \$200 per month. Under the Proposed Arrangement, the Association and the Network would enter an agreement by which the Association's members would have access to the Network's referral service for a reduced fee of \$60 per month. Except for this discount, the Association's members would not be treated any differently than other chiropractors who participate in the referral service. Their names would be provided to prospective patients who contact the Network on exactly the same basis as the names of participating chiropractors who are not members of the Association.

Also under the Proposed Arrangement, the Association would form a for-profit subsidiary (the "Subsidiary"). The Network would pay the Subsidiary a flat fee of \$10 per month for each of the Association's members who participate in the Network's referral service. In return for this compensation, the Association would advertise and promote the Network's referral service through e-mails and faxes to its members and to non-members, through its quarterly publication, and at its statewide conventions, conference calls, webinars, and other meetings.

II. LEGAL ANALYSIS

A. Law

The anti-kickback statute makes it a criminal offense knowingly and willfully to 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. 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. 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.

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. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for referral services, 42 C.F.R. § 1001.952(f), is potentially applicable to the Proposed Arrangement. It provides that, for purposes of the anti-kickback statute, the term “remuneration” does not include payments or exchanges of anything of value between a referral service and a participant in the service, provided certain conditions are met. Among these conditions are requirements that the referral service not exclude any person or entity that meets its qualifications for participation; that referral fees be assessed uniformly against all participants, be based only on the cost of operating the referral service, and not vary with the volume or value of referrals of Federal health care program business; and that the referral service make certain disclosures to persons seeking a referral.

B. Analysis

The Proposed Arrangement does not qualify for protection by the safe harbor for referral services. It does not meet the requirement that referral fees be assessed uniformly against all participants. See 42 C.F.R. § 1001.952(f)(2). The fact that the Proposed Arrangement does not fit in a safe harbor does not end the inquiry, however. We must examine the totality of facts and circumstances to determine the extent of the risk posed.

We note, at the outset, that the Proposed Arrangement has certain characteristics in common with the facts addressed in OIG Advisory Opinion 08-19, in which an internet advertiser forwarded e-mails and calls to chiropractors who paid a fee for each such contact. We analyzed those facts as an advertising arrangement, noting that the arrangement “is unlike a typical, non-profit referral service operating for the convenience and support of patients and is not the type of referral service for which the safe harbor at 42 C.F.R. § 1001.952(f) was designed.” The Proposed Arrangement also does not involve a non-profit referral service and has some characteristics of an advertising arrangement. Whether we analyze the Proposed Arrangement as an advertising arrangement or as a referral service is not determinative of the outcome, however; the critical question is to what extent the Proposed Arrangement poses a risk of fraud or abuse.

To answer this question, we first address the fact that the Network would not charge the same fee to all participants in its referral service; members of the Association would receive a discount. The participation fee would not vary, however, on the basis of referrals of Federally payable business. Referral of potential patients to participating chiropractors would be on a rotating basis, by geographic area, and would not be influenced by the variation in fees paid by participants. Under these circumstances, we find that the variation in fees charged to participating chiropractors poses a minimal risk of fraud or abuse.

We next address the Network's proposed payment to the Association's for-profit Subsidiary of \$10 per month for each Association member who participates in the Network. This compensation paid to the Association would vary with the amount of business generated for the Network, but would not vary with referrals of items or services payable by Federal health care programs. Indeed, unlike some sponsors of referral services, such as hospitals, the Network does not provide items or services payable by Federal health care programs. Under the circumstances of the Proposed Arrangement, we conclude that this payment does not implicate the anti-kickback statute.

The Network's referral service will be open to participation by any chiropractor licensed to practice in the state, and participating chiropractors will receive referrals on an equal basis. The Network will impose no requirements on the manner in which participating chiropractors provide services to referred persons, and the Network will make all the disclosures required by the safe harbor for referral services at 42 C.F.R. § 1001.952(f)(4). Given these particular facts and circumstances, we conclude that the Proposed Arrangement poses a minimal risk of fraud and abuse.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that while 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 the [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 the [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 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 Proposed Arrangement, including, without limitation, the physician self-referral law, section 1877 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 the [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 the [name redacted] 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,

/Lewis Morris/

Lewis Morris
Chief Counsel to the Inspector General