



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: June 4, 2013

Posted: June 11, 2013

[Name and address redacted]

Re: OIG Advisory Opinion No. 13-02

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a proposal to establish a limited liability company that would enter into arrangements with manufacturers and other entities to provide industrial orthotics for use by these entities' employees (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, 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 [names 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 [names redacted], the requestors 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 “Podiatrist”) is a podiatrist who owns and operates [name redacted] (the “Clinic”), a general podiatric medical clinic. Some of the Clinic’s items and services are billed to Federal health care programs. The Podiatrist is a full-time employee of the Clinic. The Podiatrist’s spouse, [name redacted] (the “Spouse”), serves as the Clinic’s vice president, but does not receive any payments from the Clinic. The Podiatrist and the Spouse are the requestors of this advisory opinion (the “Requestors”).¹

The Requestors propose to establish and operate a limited liability company to be called the [name redacted] (the “LLC”). Under the Proposed Arrangement, the LLC would enter into arrangements with various manufacturers and other entities (the “Customers”) to provide industrial orthotics (the “Orthotics”) to the Customers’ employees who spend a significant portion of their time working on their feet. The Requestors believe that some of the employees would be Federal health care program beneficiaries. The LLC also would provide certain services related to furnishing the Orthotics. Specifically, the LLC would conduct employee foot scans and manufacture, deliver, fit, and adjust the orthotics for the employees. The LLC would not provide any other items or services. The Requestors certified that the LLC would not apply for Federal health care program or other insurance credentialing or billing privileges. The Requestors also certified that the LLC would bill only the Customers for the Orthotics and related services and at a price that would be consistent with fair market value in an arm’s-length transaction and would not vary in any way based on the volume or value of referrals to, or total income of, the

¹ We have not been asked to opine on, and offer no opinion concerning, any of the Clinic’s ownership or employment relationships. However, the Requestors certified that the Podiatrist’s ownership interest in the Clinic satisfies all of the criteria set forth in the investments in group practices safe harbor at 42 C.F.R. § 1001.952(p).

LLC, the Clinic, or any other entity owned or operated by the Requestors.² According to the Requestors, the Customers would treat the Orthotics as they do other protective equipment (e.g., hard hats and steel-toed boots) that they provide to their employees, and they would not bill any Federal health care program or third party payor for the Orthotics or related services.

In order to provide the Orthotics and related services, the LLC would employ the Podiatrist and a licensed practical nurse currently employed by the Clinic (the “LPN”). The Podiatrist and the LPN would work part time for the LLC during those days they are not otherwise employed to work at the Clinic. In addition, the LLC would employ the Spouse to serve as its president and to manage its day-to-day business functions. The Requestors certified that any compensation by the LLC to its employees—including the Podiatrist, the Spouse, and the LPN—would be consistent with fair market value in an arm’s-length transaction for the services the employees provide and would not vary in any way based on the volume or value of referrals to, or the total income of, the LLC, the Clinic, or any other entity owned or operated by the Requestors. In addition, the Requestors certified that compensation paid by the Clinic to its employees who are also employed by the LLC would not vary in any way based on the volume or value of referrals to, or the total income of, the LLC, the Clinic, or any other entity owned or operated by the Requestors.

The Requestors certified that some employees of Customers who receive Orthotics pursuant to the Proposed Arrangement may already be patients of the Clinic. The Requestors also certified that it is possible that, in the course of providing the services pursuant to the Proposed Arrangement, it may be determined that a Customer’s employee needs reasonable and medically necessary services that are not provided pursuant to the Proposed Arrangement, but that are available from the Clinic and are payable by Federal health care programs. The Requestors certified that, in such circumstances, the LLC employees would notify the Customers’ employees of the need for such services; however, the LLC employees would not refer any individuals to the Clinic for treatment or other services.

As part of the Proposed Arrangement, the LLC would also lease a foot scanner from the Clinic in order to provide the related services. The Requestors certified that this lease would satisfy all of the requirements of the equipment rental safe harbor set forth at 42 C.F.R. § 1001.952(c).

² We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See Section 112 8d (b)(3)(A) of the Act. For purposes of this advisory opinion, we rely on the Requestors’ certification of fair market value. If the price under the Proposed Arrangement is not fair market value, this opinion is without force and effect.

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.

B. Analysis

Sales transactions between a party in a position to generate Federal health care program referrals or business and a party in a position to receive such referrals or business can implicate the anti-kickback statute. Under the Proposed Arrangement, the LLC would not sell any items or provide any services that would be billed to a Federal health care program. The Clinic, however, bills Federal health care programs for certain items and services it provides. Because of the common ownership between the Clinic and the LLC, we must consider whether there is a connection between the price the LLC would offer the Customers for the Orthotics and related services and any Federally-payable business the Proposed Arrangement would generate for the Clinic.³ We have stated that “[i]n

³ Under certain circumstances, a Customer could be in a position to arrange for or recommend that its employees obtain items or services payable by a Federal health care program. In addition, simply by purchasing items for use by its employees from a

general, fair market value arrangements that are arm's-length and do not take into account in any manner the volume or value of Federal health care program business . . . should not raise concerns under the anti-kickback statute.” 71 Fed. Reg. 45110, 45111 (August 8, 2006) (preamble to the 2006 Final Rule on Safe Harbors for Certain Electronic Health Records Arrangements Under the Anti-Kickback Statute). Here, the Requestors certified that the price the LLC would charge the Customers for the Orthotics and related services would be consistent with fair market value in an arm's-length transaction for the actual items and services that the LLC would provide. Additionally, the price would not vary in any way based on the volume or value of referrals (Federal health care program or otherwise) to, or the total income of, the LLC, the Clinic, or any other entity owned or operated by the Requestors. The facts of the Proposed Arrangement distinguish it from the types of suspect “swapping” arrangements in which a seller ties favorable pricing on an item or service that is not payable by a Federal health care program to the purchase of an item or service—either from the seller or a different company that is under common ownership with the seller—that is payable by a Federal health care program.⁴ Accordingly, under the particular facts presented here, we believe that the LLC's sale of the Orthotics and related services to the Customers would present a sufficiently low risk of fraud or abuse under the anti-kickback statute.

We also consider whether the opportunity for employees of the LLC to market Federally-payable services to Customers' employees poses a risk of abuse. The Requestors have certified that the LLC employees would not refer Customer employees to the Clinic for treatment or other services. They have also certified that compensation paid to these employees by the LLC and the Clinic would be consistent with fair market value for services provided to the LLC and the Clinic, respectively, and that neither the compensation paid to these employees by the LLC, nor the compensation paid to them by the Clinic, would vary with the volume or value of referrals to, or total income of, the

particular vendor, the Customer might be seen as implicitly endorsing the quality or value of that vendor's, or a related company's, items and services, which may be payable by a Federal health care program. Finally, by giving the LLC access to its employees through the Proposed Arrangements, the Customer provides the LLC with the opportunity to generate Federally-payable business for the Clinic, which is under common ownership with the LLC.

⁴ For a discussion of “swapping,” see, for example, OIG Advisory Opinions 99-2, 99-13, 10-26, and 12-09; OIG's September 22, 1999 letter on Discount Arrangements Between Clinical Labs and SNFs; and OIG's April 20, 2000 letter on Discount Arrangements Involving Ambulance Companies, Hospitals, and Skilled Nursing Facilities.

LLC, the Clinic, or any other entity owned or operated by the Requestors.⁵ We thus conclude that the risk of abuse posed by the opportunity for employees of the LLC to market Federally-payable services to Customer employees is sufficiently low.

Based on the totality of facts and circumstances described herein, and for the reasons stated above, we conclude that the Proposed Arrangement would present a sufficiently low risk of fraud and abuse in connection with the anti-kickback statute.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that, 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 [names 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 [names redacted], the requestors 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 [names 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

⁵ We recognize that the Podiatrist has an incentive to refer patients to his wholly-owned Clinic that is independent of the employee compensation he may receive from either the LLC or the Clinic. However, as a Requestor, the Podiatrist has certified that the LLC employees (who include himself) will not refer Customer employees to the Clinic for treatment. The Podiatrist is thus personally responsible for this certification, on which we rely.

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 [names 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 [names 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