



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 22, 2012

Posted: June 29, 2012

[Name and address redacted]

Re: OIG Advisory Opinion No. 12-08

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a proposal for an independent diagnostic testing facility to hire a doctor to read and interpret test results when that doctor is closely related to the owners of the independent diagnostic testing facility and is employed by a company that also employs other potential referral sources (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 [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 “IDTF”) is a new company that intends to operate as an independent diagnostic testing facility providing home sleep testing services. The IDTF would receive an order for a home sleep test from a referring physician, obtain the patient information necessary to perform the test, and ship the home sleep testing equipment to the patient with instructions for the test’s completion. The patient would send the equipment back to the IDTF upon completion of the test. A physician would read and interpret the test results and transmit the information to the referring physician, who would then provide any follow-up care or treatment for the patient. The IDTF would bill the patient’s insurance, including Federal health care programs, for the use of the home sleep testing device and for the physician’s interpretation services and would bill the patient for any applicable cost-sharing amounts. The IDTF would not supply durable medical equipment (“DME”), including constant positive airway pressure (“CPAP”) machines, that could be ordered for patients whose test results indicated a need for the device.¹

Under the Proposed Arrangement, the IDTF would employ Dr. [Name redacted] (the “Physician”) as a bona fide employee to perform the reading and interpretation services. As an employee, the Physician’s primary duty would be performing the reading and interpretation services; he might also assist in drafting policies and procedures and, eventually, supervise other interpreting physicians, should the IDTF need to employ them.

¹ 42 C.F.R. § 424.57(f) prohibits payment to the supplier of a CPAP device if that supplier, or its affiliate, is directly or indirectly the provider of an unattended sleep test used to diagnose the beneficiary with obstructive sleep apnea, such as the tests that would be provided by the IDTF.

The Physician would not order any sleep studies to be performed by the IDTF; he would only interpret results of tests ordered by other physicians. The IDTF also certified that the Physician would not be involved in any of the IDTF's solicitation efforts. Pursuant to the employment agreement, the Physician would receive a set salary that would not be linked to the number of sleep study tests he interprets. Although the Physician does not have an ownership interest in the IDTF, his wife and father constitute two of the three owners (holding 50% and 20%, respectively). The owners are not in a position to refer patients to the IDTF.

The Physician is currently employed by [employer name redacted] (the "Clinic"), and he would continue his employment with the Clinic. His areas of practice include pulmonary medicine and sleep medicine. The Physician does not have an ownership interest in the Clinic and, although the Clinic employs other physicians, none of the other physicians share office space with the Physician, nor are they a group practice. As part of his employment with the Clinic, the Physician orders sleep tests to be completed in the patient's home or in the sleep laboratory at a local hospital. He also interprets sleep study results from tests that he and other Clinic physicians order.² Through his employment with the Clinic, the Physician has home sleep testing equipment available in his office and has access to a nearby hospital laboratory for facility-based testing. Because the Physician has access to the home sleep testing equipment and performs his own interpretation services, the home sleep tests that the Physician personally orders, and those that other Clinic physicians refer to him, do not involve an independent diagnostic testing facility. In addition, neither the Physician nor any of the other physician employees of the Clinic supply DME, including CPAP, to patients.

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.

² Other Clinic physicians refer patients to the Physician for sleep study testing. The IDTF certified that the Physician has performed 10 or less sleep studies ordered by other Clinic physicians in the past 18 months.

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.

The anti-kickback statute excepts from its reach “any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services.” See section 1128B(b)(3)(B) of the Act. The OIG safe harbor regulations provide that the term “remuneration,” as used in the anti-kickback statute, does not include any amount paid by an employer to a bona fide employee for employment in the furnishing of any item or service for which payment may be made in whole or in part under Medicare or a State health care program. For purposes of this safe harbor, the term “employee” has the same meaning as it does for purposes of 26 U.S.C. § 1321(d)(2). See 42 C.F.R. § 1001.952(i).

The paragraph of the investment interests safe harbor applicable to small entities, 42 C.F.R. § 1001.952(a)(2), is also potentially applicable to the Proposed Arrangement. This safe harbor has eight elements, each of which must be satisfied for an arrangement to qualify for the exception. Of particular relevance here, the first element provides that no more than 40% of the value of the investment interests of each class of investment interests may be held by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity. Section 1001.952(a)(4) defines the term “investor” as:

an individual or entity either who directly holds an investment interest in an entity, or who holds such investment interest indirectly by, including but not limited to, such means as having a family member hold such investment interest or holding a legal or beneficial interest in another entity (such as a trust or holding company) that holds such investment interest.

B. Analysis

The IDTF certified that it would hire the Physician as a bona fide employee whose only duties would be to read and interpret sleep tests and perform certain, related administrative duties. Whether an employee is a bona fide employee for purposes of the employee exception to the anti-kickback statute is a matter that is outside the scope of the advisory opinion process. See section 1128D(b)(3)(B) of the Act. Thus, for purposes of rendering this advisory opinion, we assume that the Physician would be a bona fide employee in accordance with the definition of the term set forth at 26 U.S.C. § 3121(d)(2) and IRS interpretations of that provision as codified in its regulations and other interpretive sources. If the Physician is not a bona fide employee under this definition, this advisory opinion is without force and effect. Because the Physician would be a bona fide employee, and he would be compensated for furnishing a service for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care program, we conclude that the Physician's compensation under the Proposed Arrangement would be protected by the statutory exception and regulatory safe harbor for employee compensation.

We must also consider whether the IDTF's owners are investors who have the ability to influence referrals to the IDTF and, if so, whether the investment interest qualifies for protection under the small entity safe harbor. The IDTF certified that its direct owners are not in a position to make or influence referrals to the entity. However, although the Physician himself would not be a direct owner of the IDTF, the safe harbor's definition of "investor" includes indirect ownership interests, such as where a family member holds the investment. In the Proposed Arrangement, the Physician, a potential referral source, has a close family relationship with two of the IDTF's owners who, collectively, constitute 70% of the ownership interests. Therefore, more than 40% of the investment interests would be held by investors who are in a position to make or influence referrals, disqualifying the investment interests from small entity safe harbor protection. The failure to fit in a safe harbor is not fatal, however; arrangements that do not fit in safe harbors must be evaluated on a case-by-case basis based on the totality of facts and circumstances. Under the particular facts presented here, we believe that the Proposed Arrangement is sufficiently low risk.

First, the IDTF certified that the Physician will not make any referrals to the IDTF or otherwise solicit business for it. In addition, the home sleep tests that the Physician orders based on referrals from other Clinic employees are performed using Clinic-owned equipment. Thus, it is unlikely that the Physician could influence these physicians to refer to the IDTF or otherwise direct the referrals to the IDTF. Because, in the facts provided to us, the Physician's own referrals would have been the most apparent way that the investors could have influenced referrals, this safeguard significantly lowers the risk.

Second, neither the IDTF nor the Physician would supply DME, including CPAP. If either party supplied DME that could be ordered for patients whose test results indicated a need for the device, then the Physician could have an incentive to skew the interpretations to demonstrate such a need. Because the Physician would not have a financial interest in the test outcome under the Proposed Arrangement, this risk of overutilization is not present.

For the foregoing reasons, we find that the Physician's compensation would be protected under the employee safe harbor, and the other facts and circumstances of the Proposed Arrangement, as described herein, present a sufficiently low risk under 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 would 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.

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