



[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 28, 2010

Posted: November 4, 2010

[Name and address redacted]

Re: OIG Advisory Opinion No. 10-23

We are writing in response to your request for an advisory opinion regarding an arrangement between a sleep testing provider and a hospital to provide certain sleep testing equipment and services, including marketing services, for a hospital-owned sleep testing facility (the "Arrangement"). Specifically, you have inquired whether the Arrangement constitutes 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 the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute and that the Office of Inspector General ("OIG") could potentially 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 Arrangement. Any definitive conclusion regarding the existence of an anti-kickback violation requires a determination of the parties' intent, which determination is beyond the scope of the advisory opinion process.

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"), a corporate entity with no physician ownership,¹ provides sleep disorder diagnostic testing and related services in both freestanding facilities and in hospital-owned facilities in multiple states. Under the Arrangement, the Requestor contracts with [name redacted] (the "Hospital") to provide the equipment, technology, supplies and staff necessary to operate a sleep testing facility at the Hospital. The Requestor has no ownership interest in, and no other relationship with, the Hospital (apart from the Arrangement). The Requestor owns and maintains the sleep testing equipment and employs the technicians and other specialized staff (e.g. information technology specialists) necessary to run the sleep facility. The Requestor also provides supplies used in connection with the sleep studies, as well as Hospital staff training and educational services related to the sleep studies. The Hospital owns and maintains the space (including the patient rooms, beds, furnishings, and an observation area for sleep technicians and personnel), and provides utilities, housekeeping, communications, pharmacy, and other necessary support that is provided to other areas and patients throughout the Hospital. The Hospital also supplies a medical director through a separate agreement between the Hospital and the medical director.²

Under the Arrangement, the Requestor also provides the Hospital with marketing services. These services include part-time services of a marketing manager who visits offices of physician referral sources to educate the physicians and their staffs about the Hospital's sleep testing services and the test ordering process. The manager addresses patient satisfaction issues or referring physician concerns. Additionally, the Requestor markets the Hospital's sleep testing services at health fairs and community health education events.

¹ The Requestor has certified that no physicians directly or indirectly own the Requestor or any of its affiliates.

² We express no opinion regarding this agreement between the Hospital and the medical director.

Lastly, the Requestor's personnel assist the Hospital's own marketing department with issues related to sleep testing services.

Patients would be referred to the Hospital's sleep testing facility by a physician, who typically would be a primary care or family practice doctor, or a consulting specialist. Requestor's technicians and technologists perform the sleep study, evaluate (or "score") the data, and transmit the results to an interpreting physician.³ If, as a result of the sleep study, the patient's physician determines that the patient would benefit from continuous positive airway pressure ("CPAP") therapy, then Requestor may need to perform a second polysomnogram to determine the proper CPAP pressure levels for the patient. Under the Arrangement, Requestor does not provide the CPAP device or other items of durable medical equipment, directly or indirectly, to the Hospital, to Hospital patients, or to patients who were previously tested at the Hospital's sleep testing facility.

Under the Arrangement, the Requestor provides clinical services, equipment, and marketing services to the Hospital pursuant to a signed, written agreement with a term of at least one year, which the Requestor certified sets forth all clinical services, equipment, and marketing services to be provided for the term of the agreement. Pursuant to the Agreement, the Requestor charges the Hospital a per-test fee that covers all items and services furnished in connection with the sleep test, including marketing services. The Requestor certified that the individual per-test fee is consistent with fair market value in an arm's-length transaction and does not take into account the volume or value of any referrals or business generated by the Hospital.⁴ The Hospital bills patients or third party payors for the sleep testing services. With respect to Medicare beneficiaries, the Hospital bills Medicare for the sleep testing services as services provided by the Hospital "under arrangements." The Requestor has certified that the Arrangement is in full compliance with Medicare regulations applicable to services secured by hospitals "under arrangements."⁵

³ Requestor does not pay any physician to interpret the tests under the Arrangement. Requestor certified that it has no financial relationships in connection with the Arrangement, including ownership or compensation relationships, with any physician who treats, refers, or interprets tests of patients tested under the Arrangement. We express no opinion about any arrangements the Hospital may have with such physicians.

⁴ We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A).

⁵ Section 1861(s) of the Act expressly states that diagnostic services ordinarily furnished by a hospital (or others under such arrangements) to its outpatients for the purpose of diagnostic study are considered to be "medical and other health services" reimbursable under the Act.

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. 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 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 harbors for equipment rental and for personal services and management contracts, 42 C.F.R. § 1001.952(c) and (d), respectively, are potentially applicable to the Arrangement. One condition of both safe harbors is that the aggregate compensation to be paid under the contract must be set in advance. Under the Arrangement, the Hospital pays the Requestor on a per-test basis. Because of this payment methodology, the aggregate charges are not set in advance and, therefore, the safe harbors do not apply to the payments from the Hospital to the Requestor.

B. Analysis

The fact that the Arrangement does not fit in a safe harbor does not end the inquiry under the anti-kickback statute. We must examine the totality of facts and circumstances to determine the extent of the risk posed by the Arrangement. Careful scrutiny is especially warranted in this case because, in our experience, sleep testing services may be particularly susceptible to the risk of overutilization. Moreover, the Arrangement involves a “per-click” fee structure, which is inherently reflective of the volume or value of services ordered and provided, and the Arrangement includes marketing by a party with a direct financial stake in the success of the promotional efforts.

The Requestor provides sleep testing services “under arrangements” to the Hospital. Under the applicable coverage and payment rules, a provider (such as a hospital) may have another person or entity (an “under arrangements” entity) furnish covered items or services to its patients through arrangements under which receipt of payment by the provider for services discharges the liability of the beneficiary or any other person to pay for the service, if the provider applies quality controls and exercises professional responsibility over the arranged-for services. For example, the provider must: accept the patient for treatment in accordance with its admission policies; maintain a complete and timely clinical record on the patient; maintain contact with the attending physician regarding the progress of the patient and the need for revised orders; and ensure that the medical necessity of such services is reviewed on a sample basis by the utilization review committee if one is in place, the facility’s health professional staff, or an outside utilization review group.⁶ The Requestor has certified that the Arrangement is in full compliance with these “under arrangements” requirements.

However, even if a provider complies with relevant coverage and payment rules, an arrangement may still run afoul of the anti-kickback statute. For example, an “under arrangements” transaction could implicate the anti-kickback statute if:

- A hospital pays above-market rates for the arranged-for services to influence referrals. An “under arrangements” entity might be in a position to influence referrals to the hospital if it provides marketing services, if it has an independent patient base, or if it is owned directly or indirectly by referral sources for the hospital, such as physicians or physician groups;
- An “under arrangements” entity agrees to accept below-market rates to secure referrals from a hospital to the “under arrangements” entity, its direct or indirect owners, or its affiliates, including affiliated providers and suppliers;

⁶ See CMS, “Medicare General Information, Eligibility, and Entitlement Manual,” Pub. 100-01, Chapter 5, section 10.3, available on CMS’s Web site at <http://www.cms.hhs.gov/manuals/downloads/ge101c05.pdf>.

- A hospital owns an interest in an “under arrangements” entity such that the hospital receives remuneration in the form of returns on investment in exchange for referrals to the “under arrangements” entity or to an affiliate of the “under arrangements” entity (such as an affiliate that furnishes ancillary services or equipment). Hospital ownership would also raise the specter of undue influence in the awarding of a contract and the attendant risk that the contract would be granted on the basis of anticipated or actual referrals;
- A referral source for the hospital, such as a physician or physician group, owns an interest in the “under arrangements” entity. Even if the “under arrangements” services are provided at fair market value, the referral source might have an incentive to condition its referrals to the hospital on the hospital’s use of its “under arrangements” entity or supplier;
- The putative “under arrangements” transaction includes the furnishing of items and services ancillary or additional to the services being furnished “under arrangements” or includes, directly or indirectly, the furnishing of items and services to patients who are not hospital inpatients or outpatients (e.g., patients who have been discharged from the hospital).

This list is illustrative, and not exhaustive, of the potential risks of “under arrangements” transactions.

Although this Arrangement does not appear to include many of the suspect characteristics of problematic “under arrangements” transactions described in the examples above, the Arrangement involves a fee that covers marketing services, which are ancillary or additional to the sleep testing services that are being furnished “under arrangements.” For this reason, the Arrangement must be carefully reviewed. Moreover, the Requestor, the “under arrangements” entity, is in a position to generate referrals for the Hospital’s sleep services because of the marketing aspect of the Proposed Arrangement. Payments for marketing services involving Federal health care program business warrant close scrutiny under the anti-kickback statute.

Marketing fees paid on the basis of successful orders for items or services are inherently subject to abuse because they are linked to business generated by the marketer. Because the Requestor receives a fee each time its marketing efforts are successful, the Requestor’s financial incentive to arrange for or recommend the Hospital’s sleep testing facility is heightened. The more test orders the Requestor’s marketing efforts generate, the more fees the Requestor receives. Moreover, compensation for the part-time and variable marketing services contemplated by the Arrangement is incorporated into the per-test fee for the sleep testing services. This design creates risk and does not allow for the transparent assessment of the marketing services provided and the compensation paid for them.

The Requestor has presented a number of safeguards for our consideration, as described in the facts above. However, having reviewed the totality of the facts and circumstances of the Arrangement closely, we find these safeguards to be insufficient to offset, for our purposes here, the risk posed by the provision of sporadic, variable marketing services in exchange for opaque “success-based” compensation.

For the above reasons, we cannot conclude that the Arrangement poses a sufficiently low level of risk that we should protect it.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Arrangement potentially generates prohibited remuneration under the anti-kickback statute and that the OIG could potentially 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 Arrangement. Any definitive conclusion regarding the existence of an anti-kickback violation requires a determination of the parties’ intent, which determination is beyond the scope of the advisory opinion process.

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 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, 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 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.

Sincerely,

/Lewis Morris/

Lewis Morris
Chief Counsel to the Inspector General