[*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: August 30, 2010

Posted: September 8, 2010

[Name and address redacted]

Re: OIG Advisory Opinion No. 10-14

Dear [Name redacted]:

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 for a hospital-owned sleep testing facility (the "Arrangement"). Specifically, you have inquired whether the 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 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") will 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 Arrangement. This opinion is limited to the 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] ("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, Requestor contracted with [name redacted] (the "Hospital") to provide the equipment, technology, supplies, and staff necessary to operate a sleep testing facility at the Hospital. Requestor has no ownership interest in, and no other relationship with, the Hospital (apart from the Arrangement). 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 testing facility. These employees staff the sleep testing facility at the Hospital on an as-needed basis. 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, which it specifically renovated to accommodate the sleep testing facility (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 provides a medical director for the sleep testing facility through a separate arrangement between the Hospital and the medical director.[2] Requestor does not provide any marketing or external education services on behalf of the Hospital.

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

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

Patients are referred to the Hospital's sleep testing facility by a physician, who typically would be a primary care doctor, an otolaryngologist, a pulmonologist, or a neurologist. After the physician orders the testing, Hospital employees call the patient to schedule the overnight sleep study (a "polysomnogram"), confirm the patient's insurance, and obtain any pre-authorization that may be required. Patients who are to receive a sleep study register at the Hospital as outpatients. 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 supply 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, Requestor provides services to the Hospital pursuant to a signed, written agreement that specifies all of the services to be provided and the material terms of the Arrangement. Requestor charges the Hospital a set per-test fee, which Requestor and the Hospital negotiated through an arm's-length bargaining process. Requestor has certified that the per-test fee is consistent with fair market value[4] in an arm's-length transaction and does not take into account the volume or value of any referrals or other business generated by the Hospital.[5] According to Requestor, the amount of the per-test fee was determined in a manner that takes into account only items and services integral to furnishing sleep testing services for patients admitted to the Hospital.

The Hospital bills patients or third party payors for the sleep testing services. The fees payable by the Hospital to Requestor do not vary based on the Hospital's success in collecting payment for the claims it submits, unless a claim is denied or lost due to

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[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). For purposes of this advisory opinion, we rely on Requestor's certification of fair market value. If the fees under the Arrangement are not fair market value, this opinion is without force and effect.

[5] In the aggregate, per-test fees are inherently reflective of the value or volume of services. Here, Requestor has certified that the individual per-test fee is consistent with fair market value and does not take into account the number of patients tested at the facility.

Requestor's equipment failure or technician error. With respect to Medicare beneficiaries, the Hospital bills Medicare for these services as services provided by the Hospital "under arrangements." Requestor has certified that the Arrangement is in full compliance with Medicare regulations applicable to services secured by hospitals "under arrangements."[6]

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

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[6] 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.

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 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 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, and because the Arrangement involves a "per-click" fee structure, which is inherently reflective of the volume or value of services ordered and provided.

1. The Arrangement Lacks Characteristics of a Suspect "Under Arrangements" Transaction

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.[7] Requestor has certified that the Arrangement is in full compliance with these "under arrangements" requirements.[8]

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;
- 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.

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[7] 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*.

[8] If the Arrangement does not comply with all "under arrangements" requirements, this opinion is without force and effect.

The Arrangement does not appear to include suspect characteristics of the problematic "under arrangements" transactions described in the examples above. For instance: compensation under the Arrangement is fair market value (and not at above- or below-market rates); Requestor, the "under arrangements" supplier, is not owned by the Hospital or any physicians; no supplemental services, such as marketing, are provided to the Hospital by Requestor; and no DME or other items or services are provided by Requestor to the Hospital, Hospital patients, or patients tested at the sleep testing facility, directly or indirectly, in connection with the Arrangement.

2. Other Characteristics Also Reduce the Risk Under the Anti-kickback Statute

We further analyze the Arrangement in light of our longstanding concern about problematic contractual arrangements that include remuneration to induce or reward referrals between the parties. In some cases, a contractual arrangement so aligns the parties in a common enterprise to provide services and obtain mutual economic benefit that the contract effectively creates a joint venture. However, not all contracts between health care providers or suppliers create joint ventures, nor are all joint ventures problematic. Contractual arrangements between providers or suppliers that are potential referral sources for one another—whether creating a joint venture or not—must be closely scrutinized to determine whether they are disguised vehicles for the payment of improper kickbacks.[9]

Based on the totality of the facts and for the following reasons, we conclude that the Arrangement poses an acceptably low risk of improperly influencing or rewarding referrals.

First, the sleep testing services are ordered and interpreted by physicians without a direct or indirect financial interest in Requestor. Thus, referring physicians do not stand to gain from referrals to Requestor. Similarly, the Hospital has no direct or indirect ownership interest in Requestor that might otherwise create the potential for self-dealing in the awarding of the "under arrangements" contract or an undue incentive to generate sleep testing referrals (beyond the incentive inherent in operating a sleep testing facility at the Hospital).

[9] We have issued guidance describing factors relevant to identifying suspect joint ventures under the anti-kickback statute. See, e.g., OIG's 1989 Special Fraud Alert on Joint Venture Arrangements, reprinted in 59 Fed. Reg. 65372, 65373 (Dec. 19, 1994); OIG's Special Advisory Bulletin on "Contractual Joint Ventures," 68 Fed. Reg. 23148 (April 30, 2003); and OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4858 (Jan. 31, 2005).

Second, we rely on Requestor's certifications that: the per-test fees were arrived at through arm's-length negotiations; the per-test fee amount is consistent with fair market value in an arm's-length transaction; and the per-test fee, taken individually and not in the aggregate, does not take into account the value or volume of referrals or other business generated between the parties. Further, the per-test fee takes into account only items and services provided by Requestor that are necessary to perform sleep testing services for patients admitted to the Hospital and does not include amounts attributable to ancillary services and supplies that Requestor does not provide under the Arrangement (such as marketing or DME) or other items or services not integral to furnishing sleep studies. Arm's-length, fair market value fees for reasonable services actually rendered that do not individually take the volume or value of referrals into account, such as the fees described herein, are less likely to be remuneration to induce referrals.

Third, Requestor charges and collects the per-test fee regardless of whether the Hospital ultimately receives reimbursement from the patient or any third-party payor, including Federal health care programs. Therefore, the Arrangement does not operate as a reimbursement guarantee that confers additional financial benefit (i.e., a financial incentive) on the Hospital by immunizing it against collections risk.

Fourth, the Hospital assumes business risk and contributes substantially to furnishing the sleep testing services for which it bills, including providing necessary space, equipment, a medical director, and administrative services. The Arrangement, taken as a whole, is readily distinguishable from an arrangement in which one provider supplies little more than a billing number and a captive stream of referrals, while another provider that is already in the same line of business furnishes the bulk of the services through a management or similar contract, such as might happen in a "turnkey" arrangement.[10] In addition, based on Requestor's fair market value certifications, the negotiated fee under the Arrangement appears to allow the Hospital and Requestor to each be reimbursed in proportion to their respective contributions (including risk assumption, but not including referrals) to the provision of the sleep studies under the Arrangement.

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

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[10] See OIG's Special Advisory Bulletin on "Contractual Joint Ventures," 68 Fed. Reg. 23148 (April 30, 2003).

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that while the 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 will 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 Arrangement. This opinion is limited to the 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 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 will not proceed against [name redacted] with respect to any action that is part of the 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 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 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