[*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. 10-24

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a proposed 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 "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") 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 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] ("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 Proposed Arrangement, Requestor intends to contract with [name redacted] (the "Hospital") to provide the equipment, technology, supplies, and staff necessary to operate a sleep testing facility. Requestor would have no ownership interest in, and no other relationship with, the Hospital (apart from the Proposed Arrangement). Requestor would own and maintain the sleep testing equipment and employ the technicians and other specialized staff (e.g., information technology specialists) necessary to run the sleep testing facility. These employees would support the sleep facility on an as-needed basis. Requestor also would provide supplies used in connection with the sleep studies as well as Hospital staff training and educational services related to the sleep studies. The Hospital would own and maintain the space (including the patient rooms, beds, furnishings, and an observation area for sleep technicians and personnel), and would provide utilities, housekeeping, communications, pharmacy, and other necessary support that is provided to other areas and patients throughout the Hospital. The Hospital would also supply a medical director though a separate arrangement between the Hospital and the medical director.[2]

In addition to items and services needed to furnish sleep testing services, Requestor would provide marketing and education services for the benefit of the Hospital by supplying a full-

[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.

time marketing specialist. The marketing specialist would: educate medical staff and patients in the Hospital's service area about the Hospital's sleep testing services and the test ordering process; address patient satisfaction issues or referring physicians' concerns; market the Hospital's sleep testing services at health fairs and community health education events; and 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. After the physician orders the test, Requestor's staff would schedule the overnight sleep study (a "polysomnogram") and confirm the patient's insurance. The Hospital would be responsible for obtaining pre-authorizations from third party payors, if required. Patients who are to receive a sleep study would register at the Hospital as outpatients. Requestor's technicians and technologists would 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 Proposed Arrangement, Requestor would 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 Proposed Arrangement, Requestor would provide services and equipment to the Hospital pursuant to a signed, written agreement with a term of at least one year, which Requestor has certified would set forth all services and equipment to be provided for the term of the agreement. The aggregate equipment rental and services provided would not exceed those which are reasonably necessary to accomplish the commercially reasonable purpose under the Proposed Arrangement.

The agreement memorializing the Proposed Arrangement would incorporate three fees for services and equipment. First, the agreement would include one fixed, annual fee for the use of Requestor's equipment, which would not take into account the volume of value of referrals or other business generated between the parties, and would be consistent with fair

[3] Requestor would not pay any physician to interpret the tests under the Proposed Arrangement. Requestor certified that it has no financial relationships, including ownership or compensation relationships, with any physician who would treat, refer, or interpret tests of patients tested under the Proposed Arrangement. We express no opinion about any arrangements the Hospital may have with such physicians.

market value in an arm's-length transaction.[4] The equipment rental fee would provide the Hospital with use of the equipment on a full-time basis.

Requestor would charge the Hospital a second fee for marketing services, which would be provided on a full-time basis. That fee would also be an aggregate, annual, set-in-advance, fixed fee, which would not take into account the volume or value of referrals or other business generated between the parties, and would be consistent with fair market value in an arm's-length transaction. Requestor has certified that the marketing services would not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.

The third fee under the agreement would be an aggregate, annual, set-in-advance, fixed fee for the other services and supplies specified in the agreement to be provided on an as-needed basis (e.g., for the services of sleep technicians and technologists when sleep tests are scheduled, the services of information technology specialists when needed, etc.). The fee would not take into account the volume or value of referrals or other business generated between the parties, and would be consistent with fair market value in an arm's-length transaction.

The Hospital would bill patients or third party payors for the sleep testing services. The fees payable by the Hospital to Requestor would 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 Requestor's equipment failure or technician error. With respect to Medicare beneficiaries, the Hospital would bill Medicare for these services as services provided by the Hospital "under arrangements." Requestor has certified that the Proposed Arrangement would be in full compliance with Medicare regulations applicable to services secured by hospitals "under arrangements."[5]

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[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 for each of the fees. If the fees under the Proposed Arrangement are not fair market value, this opinion is without force and effect.

[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 harbor for equipment leases and the safe harbor for personal services and management contracts, 42 C.F.R. § 1001.952(c) and (d), respectively, are potentially applicable to the Proposed Arrangement. As described in more detail in the regulations, these safe harbors generally require that an equipment lease or services and management contract: (1) be set forth in a writing signed by the parties; (2) cover all equipment to be leased or services to be provided for the term of the lease or agreement and specify the equipment or services covered by the agreement; (3) if the lease or agreement is intended to be on a periodic, sporadic, or part-time basis, specify the exact schedule of intervals, their

precise length, and the charge for such intervals; (4) be for a term of at least one year; (5) set an aggregate rental or services fee in advance that would be consistent with fair-market value in arm's-length transactions, and would not be determined in a manner that takes into account the expected volume or value of referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare or a State health care program; and (6) include aggregate rental items or services that do not exceed what would be reasonably necessary to accomplish the commercially reasonable purpose for the rental or services agreement. In addition, the personal services and management contract safe harbor requires that the agreement not include any services that would involve counseling or promotion of a business arrangement or other activity that would violate any State or Federal law. The agreement memorializing the Proposed Arrangement, taken as a whole, does not qualify for safe harbor protection because the schedule of intervals, precise interval length, and interval charges are not (and likely cannot be) identified with respect to the "as-needed" services component of the agreement.

B. Analysis

Absence of safe harbor protection is not fatal; rather, the Proposed Arrangement must be analyzed based on the totality of its facts and circumstances.

1. The Proposed Arrangement Includes Many Safeguards Present in the Safe Harbors

As we explained in the preamble to the applicable final safe harbor regulations,[6] we recognize that health care providers may be unable to specify the timing or duration of business arrangements, or the precise compensation involved. We believe that part-time or sporadic leases or service arrangements that do not meet safe harbor standards need to be analyzed on a case-by-case basis under the statute. For example, an optometrist who pays ad hoc "rent" to an ophthalmologist for the time spent in the physician's office examining only referred patients may be impermissibly paying for the referrals.

As noted above, the agreement memorializing the Proposed Arrangement incorporates many key safeguards enumerated in the equipment lease and personal services and management contracts safe harbors, including the use of aggregate, fixed fees that are consistent with fair market value in arm's-length transactions and that do not take into account the volume or value of Federal health care program business. Although certain clinical and other services needed for the sleep center would be provided on an as-needed basis without resort to a predictable schedule, such services would not be separately billable by the Hospital and would be reasonably necessary to accomplish the purpose of an "under

[6] See 56 Fed. Reg. 35978 (July 29, 1991) (preamble to the 1991 safe harbor regulations).

arrangements" sleep center. The as-needed services would be integral to the agreement, which would have a term of at least one year, and the fee for the as-needed services would not reflect referral patterns.

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

Requestor would provide 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" provider) 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 Proposed 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" provider, its direct or indirect owners, or its affiliates, including affiliated providers and suppliers;

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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 Proposed Arrangement does not comply with all "under arrangements" requirements, this opinion is without force and effect.

- 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;
- 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.

Except as described below, the Proposed Arrangement does not appear to include suspect characteristics of the problematic "under arrangements" transactions described in the examples above. For instance: compensation under the Proposed Arrangement would be fair market value (and not at above- or below-market rates); Requestor, the "under arrangements" supplier, is not owned by the Hospital or any physician; and no DME or other items or services (other than those described herein) would be provided by Requestor to the Hospital, Hospital patients, or patients who were previously tested at the sleep testing facility, directly or indirectly in connection with the Proposed Arrangement.

The Proposed Arrangement does include one key risk factor: Requestor, the "under arrangements" entity, would be 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 and, depending on the circumstances, may raise additional issues not addressed here. In this case, even though the Requestor would be in a position to influence the generation of "under arrangements" business, the provision of full-time services combined with the aggregate, set in advance, fair market value fee structure of the Proposed Arrangement (including the fees for the equipment rental, as-needed services and supplies, and marketing), which does not vary based on the value or volume of referrals or

tests performed, would mitigate against any undue or additional incentive to generate unnecessary or an increased volume of sleep tests.

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

We further analyze the Proposed 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 Proposed Arrangement poses an acceptably low risk of improperly influencing or rewarding referrals.

First, the sleep testing services would be ordered and interpreted by physicians without a direct or indirect financial interest in Requestor. Thus, referring physicians would 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).[10]

Second, we rely on Requestor's certification that each form of remuneration under the Proposed Agreement would be consistent with fair market value in an arm's-length

[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).

[10] The potential for abuse if the Hospital had an ownership interest in the "under arrangements" entity would increase further if the contracting parties include referring physicians who might benefit from the awarding of the contract to the Hospital.

transaction; and the fees would not be determined in a way that would take into account the value or volume of referrals or other business generated between the parties. Arm's-length, fair market value fees for reasonable services actually rendered that do not 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, the Hospital would assume business risk and contribute substantially to furnishing the sleep testing services for which it bills, including providing necessary space, equipment, a medical director, and administrative services. The Proposed 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.[11]

Finally, the fees Requestor would charge for equipment, marketing, and other services and supplies would be set in advance. These fees not only would remain constant regardless of the number of patients that receive sleep testing services, but they would also be payable to Requestor regardless of whether the Hospital collects payment from the patient or third party payors. Therefore, the fees would not build in a reimbursement guarantee that would confer an additional financial benefit (i.e., a financial incentive) on the Hospital by immunizing it against failure to receive payment.

Based on the totality of the facts and circumstances described herein, and for the reasons stated above, we conclude that the Proposed Arrangement presents 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 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 [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.

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

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 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 would 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 would 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