DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of Inspector General
Washington, D.C. 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: April 3, 2003

Posted: April 10, 2003

[name and address redacted]

Re: OIG Advisory Opinion No. 03-8

Dear Sir or Madam:

We are writing in response to your request for an advisory opinion regarding a proposed arrangement whereby your company would develop and manage distinct part inpatient rehabilitation units located within general acute care hospitals in exchange for a management fee calculated on a per patient per day basis (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.

You have certified that all of the information provided in your request, including all supplementary letters, 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 Proposed 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 [Company X] 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. 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 [Company X], 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

A. The Proposed Arrangement

[Company X], a corporation doing business as [name redacted] (the "Requestor"), develops and manages distinct part inpatient rehabilitation units. Under the Proposed Arrangement, the Requestor would develop and manage acute inpatient rehabilitation units ("Units") located within general acute care hospitals. For each Unit, the Requestor and the general acute care hospital would enter into a three-year "Management Agreement" pursuant to which the Requestor would develop and operate the Unit, including providing all patient care personnel, other than nurses, who would be provided by the hospital.

For each Unit, the Requestor would also provide a leadership team, consisting of a program director, a community outreach coordinator, and a medical director. The medical director would be a hospital staff physician specializing in neurology or another appropriate specialty. The Requestor would engage the medical director as an independent contractor pursuant to a written agreement. The Requestor has certified that each medical director agreement would meet all of the requirements of the safe harbor for personal services and management contracts, 42 C.F.R. § 1001.952(d), and all of the requirements of the personal service arrangements exception to the physician self-referral law, section 1877(e)(3) of the Act, and that payments under each agreement would be consistent with fair market value in arms'-length transactions. The medical director might also have a separate private medical practice and might refer his or her patients to the Unit.

Members of the leadership team would interact with persons (such as physicians, hospital discharge planning personnel, and third party payors' utilization review personnel) who might have the ability to make or influence referrals of patients to the Unit. These interactions would consist primarily of one-on-one meetings, group educational

presentations and workshops to and for physicians and medical personnel, and the distribution of correspondence, brochures, and other literature. The Requestor would not directly solicit Medicare or Medicaid beneficiaries or other patients, either in person, by telephone, or by mail.

For the development and management services provided under the Management Agreement, each hospital would pay the Requestor a monthly management fee that would be calculated on a per patient per day basis. Specifically, the management fee would be determined by multiplying a pre-established fixed amount per patient per day (the "PPD Amount") by the aggregate number of patient days for all patients receiving care as inpatients in the Unit during each month. Each hospital would be responsible for billing and collecting all charges for services rendered in its Unit, other than fees for physician services, which may be billed by the physicians. The Requestor has certified that the management fee would reflect fair market value.

B. Medicare and Medicaid Reimbursement

The Requestor estimates that approximately seventy percent (70%) of patients in its Units would be Medicare beneficiaries. Medicare has implemented a new per discharge prospective payment system ("PPS") for inpatient hospital services provided by a rehabilitation hospital or by a rehabilitation unit of a hospital ("inpatient rehabilitation facility" or "IRF"). See section 1886(j) of the Act. IRF PPS is applicable to cost reporting periods beginning on or after January 1, 2002.[1] To qualify as an IRF for IRF PPS purposes, the facility must have served an inpatient population at least seventy-five percent (75%) of whom required intensive rehabilitation services for one or more of ten conditions specified in the regulations.[2] 42 C.F.R. § 412.23(b)(2). Moreover, to comply with Medicare regulations, each Unit must have a pre-admission screening procedure under which each prospective patient's condition and medical history are reviewed to

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[1]A transition period, during which IRFs will be paid based on a blend of IRF PPS payment and reasonable cost system payment, is in effect for cost reporting periods beginning on or after January 1, 2002 and before October 1, 2002. For cost reporting periods beginning on or after October 1, 2002, the entire payment will be the IRF PPS payment. An IRF subject to the transition blend may elect to bypass the transition and instead receive payment that is based entirely on the IRF PPS payment.

[2]The ten conditions include stroke; spinal cord injury; congenital deformity; amputation; major multiple trauma; fracture of femur (hip fracture); brain injury; polyarthritis, including rheumatoid arthritis; neurological disorders, including multiple sclerosis, motor neuron diseases, polyneuropathy, muscular dystrophy, and Parkinson's disease; and burns.

determine whether the patient is likely to benefit significantly from the Unit's services. 42 C.F.R. § 412.23(b)(3).

The Medicaid program also provides coverage and payment for inpatient rehabilitation hospital care. See 42 U.S.C. 1396(d)(A)(1); see also 42 C.F.R. 447.250 et seq. Most state Medicaid payments are made under a prospective payment system or under programs that negotiate payment levels with individual providers. The Requestor estimates that less than five percent (5%) of patients in its Units would be Medicaid beneficiaries.

II. LEGAL ANALYSIS

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.), 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 personal services and management contracts, 42 C.F.R. § 1001.952(d), is potentially applicable to the Proposed Arrangement. One condition of the personal services and management contracts safe harbor is that the aggregate compensation must be set in advance, consistent with fair market value in an arms'-length transaction, and not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made by a federal health care program.

The Proposed Arrangement does not qualify for protection under 42 C.F.R. § 1001.952(d), because the aggregate compensation paid by the hospitals to the Requestor under the Management Agreement would not be set in advance. Therefore, we must carefully scrutinize the Proposed Arrangement in its entirety to determine whether, based upon a totality of the facts and circumstances presented, the potential risk of fraud and abuse is sufficiently low.

"Per patient," "per click," "per order," and similar payment arrangements with parties in a position, directly or indirectly, to refer or recommend an item or service payable by a federal health care program are disfavored under the anti-kickback statute. The principal concern is that such arrangements promote overutilization and, in circumstances like those here, unnecessarily lengthy stays. While the Proposed Arrangement has certain features that would appear to reduce the risk, we cannot conclude that the residual risk is sufficiently low to grant protection prospectively.

First, while the IRF PPS payment methodology, under which payment is fixed regardless of length of stay, is likely to offset any concern regarding excessive lengths of stay, it does not reduce the risk of overutilization, since both the Requestor and the hospitals would have the identical incentive to fill all beds. Second, although seventy-five percent of a Unit's patients must have at least one of ten specified conditions, the other twenty-five percent could have more diffuse symptoms or conditions. Moreover, we are not in a position to determine how malleable the criteria are for establishing each of the ten specified conditions. Third, while the nurses performing the pre-admission screenings would not be the Requestor's employees, as workers in the Unit they would share with the Requestor the common goal of making the Unit a programmatic and financial success. Fourth, the Units would be under the medical direction of a physician in a position to generate patients for the Unit. Fifth, the Requestor would be performing community outreach, including marketing. Sixth, while the per patient per day fee may be reflective of the actual costs incurred, it could also simply cloak a success fee. In sum, while aspects of the Proposed Arrangement address some of our concerns about the incentives created by the Management Agreement's per patient per day fee, we cannot conclude that the Proposed Arrangement poses a sufficiently low level of risk that we should protect it prospectively.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute and that the OIG could potentially impose administrative sanctions on [Company X] 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. 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 [Company X], 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 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,

/s/

Lewis Morris
Chief Counsel to the Inspector General