

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: June 23, 2004

Posted: June 30, 2004

[name and address redacted]

Re: OIG Advisory Opinion No. 04-08

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding a proposal by a physician group practice to develop and own a comprehensive physical therapy center and to lease the center's space, equipment, and personnel to physicians with patients requiring physical therapy services (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed 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.

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 [name redacted]

Page 2 - OIG Advisory Opinion No. 04-08

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 [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.

1. FACTUAL BACKGROUND

[name redacted] (the "Physician Group") is a professional corporation comprised of five physicians, three of whom hold an ownership interest in the professional corporation. The physicians practice in various fields including neurology, physiatry, and orthopedic medicine. The Physician Group proposes forming a limited liability company (the "LLC") for the purpose of establishing a comprehensive physical therapy center (the "Center"). The Center will lease space, equipment, and the services of a staff therapist to the physicians of the Physician Group and various other licensed physicians with patients requiring physical therapy services (collectively, the "Lessees").

The Center will serve physicians in multiple fields of medicine, including neurology, cardiology, orthopedics, and internal medicine. The Center will be located in the same building as the Physician Group and each of the intended lessees. The Center will be open six days a week for eight hours a day and will be available to the Lessees on an unlimited, first-come, first-served basis. The LLC will act strictly as the owner and landlord of the Center and will not bill Medicare, Medicaid, or any other third-party payor for services provided in the Center. Each Lessee will bill the appropriate health insurance provider for services rendered at the Center to their particular patients.

Each Lessee will enter into a one-year lease with the LLC and pay a monthly rental fee for unlimited use of the Center. Lessees utilizing the staff therapist will pay a higher monthly rental fee than those Lessees who provide their own therapist. The rental fee, excluding charges for the staff therapist, will be calculated at the beginning of the lease term by totaling the monthly rental value of all space, equipment, and administrative services provided in the Center and dividing by the total number of Lessees. Thus, each Lessee would pay the same amount regardless of actual usage. The Requestor has certified that the monthly rental value of all space, equipment, and personnel services will be verified and audited by an independent appraisal firm to ensure that it is consistent with fair market value.

Page 3 - OIG Advisory Opinion No. 04-08

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. <u>See</u> 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 <u>one</u> purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. <u>United States v. Kats</u>, 871 F.2d 105 (9th Cir. 1989); <u>United States v. Greber</u>, 760 F.2d 68 (3d Cir.), <u>cert. denied</u>, 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. <u>See</u> 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 space, equipment, and personal services and management contracts, 42 C.F.R §1001.952(b), 42 C.F.R §1001.952(c), and 42 C.F.R §1001.952(d), respectively are potentially relevant to the Proposed Arrangement.

Page 4 - OIG Advisory Opinion No. 04-08

B. Analysis

The Physician Group and the Lessees are potential sources of referrals of Federal health care program business for one another. As such, the exchange of anything of value between them potentially implicates the anti-kickback statute.

As a threshold matter, safe harbor protection is not available for the Proposed Arrangement. In relevant part for purposes of this advisory opinion, the space, equipment, and personal services and management contracts safe harbors require that the aggregate compensation paid under the arrangement be set in advance and consistent with fair market value in an arms-length transaction.¹ In addition, leases and arrangements that are for periodic intervals of time, rather than a full-time basis, must specify the exact intervals of use, precise length of intervals of use, and exact rent or charge for intervals of use.

The Physician Group has characterized the leases under the Proposed Arrangement as full-time leases; however, the Center is available to the Lessees only on an as-needed, first-come, first-served basis. As such, the Proposed Arrangement is more appropriately characterized as involving multiple, overlapping, part-time leases. These leases do not meet the safe harbor requirements that periodic, sporadic, or part-time leases must specify precisely the timing and duration of the rental periods and the compensation charged for each rental period. In addition, as set forth below, the Proposed Arrangement raises significant concerns with respect to the issue of fair market value.²

While the absence of safe harbor protection is not fatal, several factors make the Proposed Arrangement susceptible to fraud and abuse. Accordingly, based on the facts presented we cannot conclude that the risk of fraud and abuse is acceptably low.

²We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. <u>See</u> 42 U.S.C. 1320a-7d(b)(3)(A).

¹For purposes of the equipment rental safe harbor, "fair market value" means the value of the equipment when obtained from a manufacturer or professional distributor. 42 C.F.R. § 1001.952(c). For purposes of the space rental safe harbor, "fair market value" means the value of the rental property for general commercial purposes. 42 C.F.R. § 1001.952(b). Both the equipment and rental safe harbor require that, when determining fair market value, the value not be adjusted to reflect the additional value that one party would attribute to the equipment or property as a result of its proximity or convenience to sources of referrals or business otherwise generated for which payment may be made in whole or in part under a Federal health care program.

Page 5 - OIG Advisory Opinion No. 04-08

The structure of the Proposed Arrangement, including the overlapping, as-needed aspect of the leases will make it difficult to monitor, assess, and document fair market value. Moreover, the Proposed Arrangement's structure increases the risk that at least some physicians will pay more or less than fair market value for the space, equipment, and administrative services actually used. Depending on the direction in which referrals flow between the Physician Group and the Lessees, there is a risk that these above or below fair market value payments could be remuneration for referrals.

Further, the Proposed Arrangement would appear to permit the LLC, and ultimately the Physician Group, to guarantee a desired maximum income stream from the Center by basing the rental payments from all Lessees on the total rental value of the equipment, space, and personnel services of the Center, rather than the usage of the Center by the Lessees. There is a risk that this guaranteed income stream could be compensation in exchange for referrals.

Accordingly, based on the totality of facts and circumstances, we cannot conclude that the Proposed Arrangement poses a minimal risk of fraud and abuse.

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 [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. 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.

Page 6 - OIG Advisory Opinion No. 04-08

- 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