DEPARTMENT OF HEALTH AND 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: March 21, 2006

Posted: March 28, 2006

[name and address redacted]

Re: OIG Advisory Opinion No. 06-02

Dear [name redacted]:

We are writing in response to your request for advisory opinions regarding two proposed programs to manage the delivery of durable medical equipment and orthotics to be offered to physicians by [name redacted], a durable medical equipment and orthotics manufacturer and supplier (collectively, the "Proposed Programs"). Specifically, you have inquired whether the Proposed Programs 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 requests, 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 requests for advisory opinions and supplemental submissions, we conclude that the Proposed Programs, together or individually, 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 Proposed Programs. 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 "Requestor") is a durable medical equipment (DME) and orthotics manufacturer and supplier that designs, develops, manufactures, and markets [products redacted]. The Requestor has submitted for consideration by the OIG two programs it plans to offer to physicians and physician practice groups.[1] One program would involve exclusively items and related services furnished to non-Federal health care program patients. The second program would cover items and services furnished to both non-Federal and Federal health care program patients.

The Requestor intends to offer physician practices the option of choosing between the two programs. Physician practices would be permitted to switch between the two programs, although they would only be permitted to enroll in one program at any given time. The Requestor would not offer a new program to a physician practice already enrolled in one of the programs unless the practice had fewer than ninety days left on its existing program contract.

A. The First Proposed Program - Non-Federal Patients Only

The first proposed program would offer physician practices the opportunity to become DME suppliers for items and services furnished to patients who are not beneficiaries of any Federal health care program. This proposed program would involve four related components pursuant to a written agreement between the Requestor and the physician practice. First, the Requestor would sell DME and orthotic products to the physician practice under a pre-arranged fee schedule. The Requestor has certified that the prices offered to the physician practice would be consistent with commercial practice, and that any discount offered to a physician practice would fit in the discount safe harbor (42 C.F.R. § 1001.952(h)). The

[1]Individual physicians and physician practice groups are referred to as "physician practices" for convenience in this advisory opinion.

physician practice would obtain its own supplier identification numbers with commercial health plans and would bill plans or patients directly for any covered DME or orthotic products sold to non-Federal program patients. The prices at which the physician practices would be able to purchase the products under the pre-arranged fee schedule may be less than the amounts billed for those products by the physician practices to payors.

Second, the Requestor would rent Continuous Passive Motion[2] ("CPM") devices to the physician practice on an as-needed basis at daily rental amounts set forth in a fee schedule. The rental arrangement between the Requestor and the physician practice would be for a period of one year, would be set forth in writing, would be signed by both parties, and would specify the equipment covered. The Requestor has certified that the rental amount would be consistent with fair market value in an arms' length transaction. However, the aggregate rental amount and the schedule and length of the rental would not be set in advance. The physician practice would then rent the CPM device to its non-Federal program patients. The rental amounts paid by the patients (or their insurers, if applicable) could exceed the rental amount paid by the physician practice to the Requestor for the CPM device.

Third, the Requestor would provide the physician practices with the services of a trained technician to fit non-Federal health care program patients for DME and orthotics, complete in-home set-up of equipment, instruct patients on the use and maintenance of the products, monitor patient progress, obtain payor pre-certification, manage product inventory, and procure additional products as necessary. The physician practice would pay a fixed monthly fee for the services of the technician. Technicians would be leased to the physician practice on either a full- or part-time basis, depending on the needs of each individual physician practice. The Requestor has certified that, in either case, the arrangement would satisfy the personal services and management contracts safe harbor (42 C.F.R. § 1001.952 (d)).

Finally, the Requestor would provide comprehensive coding, billing, and collection services to the physician practice for a fixed monthly fee for the DME and orthotics covered by the proposed program. The Requestor has certified that the arrangement would satisfy the personal services and management safe harbor (42 C.F.R. § 1001.952 (d)).

Physician practices that choose this program would not furnish DME or orthotic items or services to Federal health care program patients. Rather, the physician practices would prescribe the items and services for Federal program patients and instruct the patients to

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[2]A CPM device is a motorized machine that moves a patient's joints without requiring the patient to strain his or her muscles. CPM devices typically are used post-operatively for a few weeks and therefore are usually rented by the patient rather than being purchased.

obtain them from any local durable medical equipment prosthetics orthotics and supplies ("DMEPOS") supplier. The prescribed items and services could be manufactured or distributed by the Requestor.

B. The Second Proposed Program - Federal and Non-Federal Patients

The second proposed program would apply to DME and orthotics furnished to Federal and non-Federal patients. Under this program, the Requestor would remain the DME supplier, billing any products sold or rented to the physician practice's patients to the applicable Federal health care program or other payor under the Requestor's name and supplier number. This proposed program would involve three related components pursuant to a written agreement between the Requestor and the physician practice. First, the Requestor would rent product storage space from the physician practice for a fixed monthly fee, and consign orthotic and DME products to the practice to be stored in the rented space. The Requestor would retain title to the consigned products until they were sold or rented to patients. The Requestor has certified that the rent for the storage space would be set at fair market value and that the rental arrangement would conform to the space rental safe harbor (42 C.F.R. § 1001.952 (b)).

Second, the Requestor would pay the physician practice a percentage of the revenues generated from the sale and rental of DME and orthotic products to the physician practice's patients who are not Federal health care program beneficiaries in return for the physician practice's provision of inventory management and various other administrative services related to the consignment and storage of the Requestor's products. The Requestor has certified that no compensation for administrative services would be made to the physician practice out of the Federal funds the Requestor obtains in return for the sale and rental of DME and orthotic products to the physician practice's Federal health care program beneficiaries.

Finally, the Requestor would provide the physician practice with the services of a trained technician to fit Federal and non-Federal patients for orthotics and DME, complete in-home set-up of equipment, instruct patients on the use and maintenance of the products, monitor patient progress, obtain payor pre-certification, manage product inventory, and procure additional products as necessary. Under this arrangement, the physician practice would pay a fixed monthly fee for the services of the technician. Technicians would be leased to the physician practice on either a full- or part-time basis, depending on the needs of each individual practice. The Requestor has certified that, in either case, the arrangement would satisfy the personal services and management contracts safe harbor (42 C.F.R. § 1001.952 (d)).

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.), 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 space rental, 42 C.F.R. § 1001.952(b), equipment rental, 42 C.F.R. § 1001.952(c), personal services and management, 42 C.F.R. § 1001.952(d), and discounts, 42 C.F.R. § 1001.952(h) are potentially applicable to the Proposed Programs.

B. Analysis

While the Requestor characterizes the proposed programs as separate arrangements, we believe the arrangements to be sufficiently related that we consider them together for

purposes of this advisory opinion.[3] For the reasons given below, we conclude that the Proposed Programs, together or individually, pose a significant risk of fraud and abuse.

A. The First Proposed Program

The first proposed program would essentially amount to a "contractual joint venture" for private pay business.[4] The proposed program offers physician practices the potentially lucrative opportunity to expand into the DME and orthotics business with little or no business risk and to retain a share of profits from DME and orthotics business generated by the physician practice. The Requestor, a would-be competitor of the new physician practice supplier, would provide virtually all of the key items and services, including, without

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[3]The ability of the physician practices to switch between the two Proposed Programs heightens the risk of fraud and abuse. With that said, however, our concerns with the Proposed Programs would still exist even if the physician practices were prohibited from switching between the two programs.

[4]Indeed, the proposed program is structurally similar to, and bears the hallmarks of, the kinds of arrangements described in the OIG's Special Advisory Bulletin on "Contractual Joint Ventures." See 68 Fed. Reg. 23148 (April 30, 2003) (the "Special Advisory Bulletin"):

> a health care provider in one line of business (hereafter referred to as the "Owner") expands into a related health care business by contracting with an existing provider of a related item or service (hereafter referred to as the "Manager/Supplier") to provide the new item or service to the Owner's existing patient population, including federal health care program patients. The Manager/Supplier not only manages the new line of business, but may also supply it with inventory, employees, space, billing, and other services. In other words, the Owner contracts out substantially the entire operation of the related line of business to the Manager/Supplier – otherwise a potential competitor – receiving in return the profits of the business as remuneration for its federal program referrals.

68 Fed. Reg. at 23148. See also OIG's 1989 Special Fraud Alert on Joint Venture Arrangements, reprinted in 59 Fed. Reg. 65372, 65373 (Dec. 19, 1994).

limitation, the DME and orthotics products, personnel, day-to-day management, patient support services, inventory management, and billing and collections services.[5]

The only significant difference between the first proposed program and the problematic contractual joint ventures identified in the Special Advisory Bulletin is the absence of Federal health care program business. The "carve out" of Federal business is not dispositive, however, on the question of whether the proposed program potentially violates the anti-kickback statute. The OIG has a long-standing concern about arrangements pursuant to which parties "carve out" referrals of Federal health care beneficiaries or business generated by Federal health care programs from otherwise questionable financial arrangements. Such arrangements may violate the anti-kickback statute by disguising remuneration for Federal referrals through the payment of amounts purportedly related to non-Federal business. Here, physicians participating in the private-pay only program may still prescribe the Requestor's DME and orthotic items and services for Federal health care program beneficiaries. Thus, we cannot conclude that there would be no nexus between the potential profits physicians may generate from the private pay DME and orthotics business and prescriptions of the Requestor's products for Federally insured patients. For example, we cannot preclude the possibility that participating physicians might have an extra incentive to steer beneficiaries to the Requestor's products and services to demonstrate commitment to the Requestor and potentially secure more favorable pricing on private pay products.

B. The Second Program

The second proposed program for inventory management and related services of Requestor's products to be sold to both Federal and non-Federal patients also poses substantial risk. Again, physician practices would be offered a set of interrelated arrangements that appear designed to align the physician practices with the Requestor's products and services. The

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[5] For the reasons noted in the Special Advisory Bulletin, safe harbor protection may not be available for the component parts of a contractual joint venture, and there may be residual, non-protected streams of remuneration created by a contractual joint venture arrangement. See 63 Fed. Reg. at 23149. Here, the Requestor has certified that a number of the component parts of the Proposed Programs would comply with various safe harbors. Given our conclusion that the Proposed Programs pose an unacceptable risk of fraud and abuse, we have not examined any of the individual components of the Proposed Programs for compliance with any particular safe harbor and express no opinion on the legality of any component part of the Proposed Programs. An attempt to carve otherwise problematic contracting arrangements into several different contracts for discrete items or services and then qualify each separate contract for protection under a safe harbor may be ineffectual and place parties at risk for prosecution. Id.

Requestor has certified that two of the three components would comply with applicable safe harbors. These certifications are insufficient to persuade us to protect the proposed second program.

We begin with the inventory management services component of the second proposed program. This arrangement cannot qualify for safe harbor protection because the aggregate compensation is not set in advance. The fee for inventory management services is based on a percentage of non-Federal revenues from the sale of the Requestor's products and services. Percentage compensation arrangements are inherently problematic under the anti-kickback statute, because they relate to the volume and value of business generated between parties. Here, the fact that the percentage fee relates wholly to non-Federal business and will be paid wholly out of non-Federal funds is not dispositive under the anti-kickback statute. Simply put, the source of the funding for a potential kickback payment is not determinative of the intent of the payment. Moreover, by using historical utilization information on both Federal and non-Federal business, it might be relatively easy for the Requestor to manipulate the compensation arrangement and reward the generation of Federal business by inflating the percentage portion of the non-Federal revenues allocated to the inventory management fee.

Next, the leased technician and consignment components of the second proposed program are also problematic, notwithstanding the Requestor's certification that they will meet the applicable safe harbors. The Requestor intends to lease a trained technician to the physician practices to perform duties related to the sale and distribution of DME. These duties include inventory management services[6], which may overlap with duties covered by the inventory management services agreement. We have been unable to obtain from the Requestor an adequate explanation of the technician component of the services agreement. Moreover, while we are precluded from determining whether the rental amount under the consignment closet portion of the arrangement would be fair market value[7], a key element of compliance with the space rental safe harbor, we have a long-standing concern that such rents may

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[6]It is unclear why a physician practice would pay a DME supplier to lease a technician to fulfill what largely appear, on the face of the contract, to be supplier obligations. Given this, we must consider the possibility that the leased technician services agreement may have purposes not revealed on the face of the contract or through the advisory opinion request submissions. Given this lack of clarity, we cannot conclude that the agreement would result in arms'-length fair market value payments for services actually needed and rendered (or that other conditions of the safe harbor would be met).

[7]We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 1128 D(b)(3)(A). While the Requestor has certified that the rental payments are consistent with fair market value, we do not rely on that certification in this opinion, nor have we have made an independent fair market value assessment.

exceed fair market value and may be disguised kickbacks to a physician-landlord for Federal program referrals. See 63 Fed. Reg. 9274 (Feb. 24, 2000).

Finally, we observe that arrangements in which manufacturers and suppliers furnish physician practices with "management" or similar services related to the manufacturer's or supplier's products must be subject to close scrutiny under the fraud and abuse laws. These arrangements may provide the manufacturer or supplier with a physical presence in the physician practice's office or an administrative presence in the physician practice's business, creating additional opportunities to influence and reward referrals. No apparent business rationale would appear to exist for a manufacturer or supplier to forge these ties to physician practices, apart from the potential for generating additional business.

Overall, the Proposed Programs, taken individually or as a whole, and focusing on the totality of facts and circumstances, represents a significant risk of fraud and abuse.

III. CONCLUSION

Based on the facts certified in your requests for advisory opinions 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.

- 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