OFFICE OF INSPECTOR GENERAL

SPECIAL ADVISORY BULLETIN

CONTRACTUAL JOINT VENTURES

April 2003 (C)

Introduction

This Special Advisory Bulletin addresses certain complex contractual arrangements for the provision of items and services previously identified as suspect in our 1989 Special Fraud Alert on Joint Venture Arrangements.[1] While much of the discussion in the 1989 Special Fraud Alert focused on investor referrals to newly formed entities, we observed that:

> [t]he Office of Inspector General has become aware of a proliferation of arrangements between those in a position to refer business, such as physicians, and those providing items or services for which Medicare or Medicaid pays. Some examples of the items or services provided in these arrangements include clinical diagnostic laboratory services, durable medical equipment (DME), and other diagnostic services. Sometimes these deals are called "joint ventures." *A joint venture may take a variety of forms: it may be a contractual arrangement between two or more parties to cooperate in providing services,* or it may involve the creation of a new legal entity by the parties, such as a limited partnership or closely held corporation, to provide such services. [Emphasis added.]

Notwithstanding that caution, the Office of Inspector General (OIG) is concerned that contractual joint venture arrangements are proliferating.[2]

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[1] The 1989 Special Fraud Alert was reprinted in the Federal Register in 1994. See 59 FR 65372 (December 19, 1994). The Special Fraud Alert is also available on our web page at http://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html.

[2]The kinds of contractual arrangements addressed in this Special Advisory Bulletin are sometimes referred to as "joint ventures" or "contractual joint ventures" or may be referenced by other terminology. For purposes of the analysis set forth in this Bulletin, a "joint venture" is any

A. Questionable Contractual Arrangements

The federal anti-kickback statute, section 1128B(b) of the Social Security Act (the Act), prohibits knowingly and willfully soliciting, receiving, offering, or paying anything of value to induce referrals of items or services payable by a federal health care program. Kickbacks are harmful because they can (1) distort medical decision-making, (2) cause overutilization, (3) increase costs to the federal health care programs, and (4) result in unfair competition by freezing out competitors unwilling to pay kickbacks. Both parties to an impermissible kickback transaction may be liable. Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to 5 years, or both. The OIG may also initiate administrative proceedings to exclude persons from the federal health care programs or to impose civil money penalties for kickback violations under sections 1128(b)(7) and 1128A(a)(7) of the Act.

This Special Advisory Bulletin focuses on questionable contractual arrangements where 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.

Some examples of potentially problematic contractual arrangements include the following:

- A hospital establishes a subsidiary to provide DME. The new subsidiary enters into a contract with an existing DME company to operate the new subsidiary and to provide the new subsidiary with DME inventory. The existing DME company already provides DME services comparable to those provided by the new hospital DME subsidiary and bills insurers and patients for them.

- A DME company sells nebulizers to federal health care beneficiaries. A mail order pharmacy suggests that the DME company form its own mail order pharmacy to provide nebulizer drugs. Through a management agreement, the mail order pharmacy runs the DME company's pharmacy, providing personnel, equipment, and space. The existing mail order pharmacy also sells all nebulizer drugs to the DME company's pharmacy for its inventory.

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common enterprise with mutual economic benefit. The application of this Bulletin is not limited to "joint ventures" that meet technical qualifications under applicable state or common law.

- A group of nephrologists establishes a wholly-owned company to provide home dialysis supplies to their dialysis patients. The new company contracts with an existing supplier of home dialysis supplies to operate the new company and provide all goods and services to the new company.

These problematic arrangements typically exhibit certain common elements. First, the Owner expands into a related line of business, which is dependent on referrals from, or other business generated by, the Owner's existing business.[3] The new business line may be organized as a part of the existing entity or as a separate subsidiary. Typically, the new business primarily serves the Owner's existing patient base.

Second, the Owner neither operates the new business itself nor commits substantial financial, capital, or human resources to the venture. Instead, it contracts out substantially all the operations of the new business. The Manager/Supplier typically agrees to provide not only management services, but also a range of other services, such as the inventory necessary to run the business, office and health care personnel, billing support, and space. While the Manager/Supplier essentially operates the business, the billing of insurers and patients is done in the name of the Owner. In many cases, the contractual arrangements result in either practical or legal exclusivity for the Manager/Supplier through inclusion of non-competition provisions or restrictions on access. While the contract terms of these arrangements may appear to place the Owner at financial risk, the Owner's actual business risk is minimal because of the Owner's ability to influence substantial referrals to the new business.

Third, the Manager/Supplier is an established provider of the same services as the Owner's new line of business. In other words, absent the contractual arrangement, the Manager/Supplier would be a competitor of the new line of business, providing items and services in its own right, billing insurers and patients in its own name, and collecting reimbursement.

Fourth, the Owner and the Manager/Supplier share in the economic benefit of the Owner's new business. The Manager/Supplier takes its share in the form of payments under the various contracts with the Owner; the Owner receives its share in the form of the residual profit from the new business.

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[3]The Owner's referrals may be direct or indirect and may include not only ordering or purchasing goods or services, but also "arranging for" or "recommending" goods and services. See section 1128B(b) of the Act. For example, a hospital may generate business for a DME company, notwithstanding that orders for specific DME items must be signed by a physician who may or may not be a hospital employee.

Fifth, aggregate payments to the Manager/Supplier typically vary with the value or volume of business generated for the new business by the Owner. While in some arrangements certain payments are fixed (for example, the management fee), other payments, such as payments for goods and services supplied by the Manager/Supplier, will vary based on the number of goods and services provided. In other words, the aggregate payment to the Manager/Supplier from the whole arrangement will vary with referrals from the Owner. Likewise, the Owner's payments, that is, the difference between the net revenues from the new business and its expenses (including payments to the Manager/Supplier), also vary based on the Owner's referrals to the new business. Through these contractual payments, the parties are able to share the profits of the new line of business.

B. Safe Harbor Protection May Be Unavailable

Under the kickback statute, a number of statutory and regulatory "safe harbors" immunize certain arrangements that might otherwise violate the anti-kickback statute. (See 42 U.S.C. 1320a-7b(b)(3); 42 CFR 1001.952.) To qualify for safe harbor protection, an arrangement must fit squarely in one of these safe harbor provisions. Some parties attempt to carve otherwise problematic contracting arrangements into several different contracts for discrete items or services (e.g., a management contract, a vendor contract, and a staffing contract), and then qualify each separate contract for protection under a "safe harbor." Such efforts may be ineffectual and leave the parties subject to prosecution for the following reasons.

First, many of these questionable joint venture arrangements involve contracts pursuant to which the Manager/Suppliers agree to sell items and services to the Owners at a discounted price. However, where a discount is given as part of an overarching business arrangement, it cannot qualify for protection under the discount safe harbor. Simply put, the discount safe harbor does not protect – and has never protected – prices offered by a seller to a buyer in connection with a common enterprise. To be protected under the discount safe harbor, a price reduction must be based on an *arms length transaction*. (See 42 CFR 1001.952(h) under which "the term *discount* means a reduction in the amount a buyer . . . is charged for an item or service based on an arms-length transaction."). As we expressly stated in the preamble to the 1991 safe harbor regulations, the provision of items or services to a joint venture by a participant in the venture is not an "arms length" transaction:

> "Another problem exists where an entity, which is both a provider and supplier of items or services and joint venture partner with referring physicians, makes discounts to the joint venture as a way to share its profits with the physician partners. Very often this entity furnishes items or services to the joint venture, and also acts as the joint venture's general partner or provides management services to the joint venture. . . . *These*

> *arrangements are not arms length transactions where the joint venture shops around for the best price on a good or service. Rather it has entered into a collusive arrangement with a particular provider or supplier of items or services that seeks to share its profits with referring physician partners. [We did] . . . not intend to protect these types of transactions which are sometimes made to appear as 'discounts'. . . .*" [Emphasis added] (See 56 FR 35977; July 29, 1991).

In short, a discount is not based on arms length transaction if it is provided by a seller to a purchaser in connection with a common venture, regardless of whether the venture is memorialized in separate contracts.

Second, even if the various contracts could fit in one or more safe harbors, they would only protect the remuneration flowing from the Owner to the Manager/Supplier for actual services rendered. In the contractual arrangements that are the subject of this Bulletin, however, the illegal remuneration is often the difference between the money paid by the Owner to the Manager/Supplier and the reimbursement received from the federal health care programs. By agreeing effectively to provide services it could otherwise provide in its own right for less than the available reimbursement, the Manager/Supplier is providing the Owner with the opportunity to generate a fee and a profit. The opportunity to generate a fee is itself remuneration that may implicate the anti-kickback statute.

C. Indicia of a Suspect Contractual Joint Venture

To help identify the suspect contractual joint ventures that are the focus of this Special Advisory Bulletin, we describe below some characteristics, which, taken separately or together, potentially indicate a prohibited arrangement. This list is illustrative, not exhaustive.

New Line of Business. The Owner typically seeks to expand into a health care service that can be provided to the Owner's existing patients. As illustrated in Part A, examples include, but are not limited to, hospitals expanding into DME services, DME companies expanding into the nebulizer pharmacy business, or nephrologists expanding into the home dialysis supply business.[4]

Captive Referral Base. The newly-created business predominantly or exclusively serves the Owner's existing patient base (or patients under the control or influence of the Owner). The Owner typically does not intend to expand the business to serve new

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[4]These examples are illustrative only. This list is not intended to suggest that other analogous ventures are not equally suspect.

customers (i.e., customers not already served in its main business) and, therefore, makes no or few *bona fide* efforts to do so.

Little or No *Bona Fide* Business Risk. The Owner's primary contribution to the venture is referrals; it makes little or no financial or other investment in the business, delegating the entire operation to the Manager/Supplier, while retaining profits generated from its captive referral base. Residual business risks, such as nonpayment for services, are relatively ascertainable based on historical activity.

Status of the Manager/Supplier. The Manager/Supplier is a would-be competitor of the Owner's new line of business and would normally compete for the captive referrals. It has the capacity to provide virtually identical services in its own right and bill insurers and patients for them in its own name.

Scope of Services Provided by the Manager/Supplier. The Manager/Supplier provides all, or many, of the following key services:

- day-to-day management;
- billing services;
- equipment;
- personnel and related services;
- office space;
- training;
- health care items, supplies, and services.[5]

In general, the greater the scope of services provided by the Manager/Supplier, the greater the likelihood that the arrangement is a contractual joint venture.

Remuneration. The practical effect of the arrangement, viewed in its entirety, is to provide the Owner the opportunity to bill insurers and patients for business otherwise provided by the Manager/Supplier. The remuneration from the venture to the Owner (i.e., the profits of the venture) takes into account the value and volume of business the Owner generates.

Exclusivity. The parties may agree to a non-compete clause, barring the Owner from providing items or services to any patients other than those coming from Owner and/or barring the Manager/Supplier from providing services in its own right to the Owner's patients.

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[5]The Manager/Supplier may also provide marketing services, although in many instances no such services are required since the Owner generates substantially all of the venture's business from its existing patient base.

As noted above, these factors are illustrative, not exhaustive. The presence or absence of any one of these factors is not determinative of whether a particular arrangement is suspect. As indicated, this Special Advisory Bulletin is not intended to describe the entire universe of suspect contractual joint ventures. This Bulletin focuses on arrangements where substantially all of the operations of a new line of business are contracted out to a would-be competitor. Arrangements involving the delegation of fewer than substantially all services, or delegation to a party not otherwise in a position to bill for the identical services, may also raise concerns under the anti-kickback statute, depending on the circumstances.

The Office of Inspector General (OIG) was established at the Department of Health and Human Services by Congress in 1976 to identify and eliminate fraud, abuse, and waste in the department's programs and to promote efficiency and economy in departmental operations. The OIG carries out this mission through a nationwide program of audits, investigations, and inspections.

The Fraud and Abuse Control Program, established by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), authorized the OIG to provide guidance to the health care industry to prevent fraud and abuse and to promote the highest level of ethical and lawful conduct. To further these goals, the OIG issues Special Advisory Bulletins about industry practices or arrangements that potentially implicate the fraud and abuse authorities subject to enforcement by the OIG.