MEMORANDUM

TO: HEALTH CARE CLIENTS

DATE: May 2, 2003

RE: OIG Issues Special Advisory Bulletin on Contractual Joint Ventures

I. INTRODUCTION

On April 23, 2003, the Office of Inspector General (“OIG”) of the Department of Health and Human Services issued a “Special Advisory Bulletin” (“Advisory Bulletin”) highlighting the agency’s concerns about certain types of “contractual joint venture” arrangements that may potentially reward health care providers for improper Medicare or Medicaid patient referrals in violation of the federal anti-kickback statute.1 According to an OIG press release accompanying the Advisory Bulletin, the agency believes certain of these arrangements “use a combination of ‘shell’ entities and subcontracting arrangements with freestanding providers of related health services, such as durable medical equipment or home oxygen suppliers, to disguise illegal kickbacks.” While the OIG previously issued guidance on joint venture arrangements in a 1989 Special Fraud Alert on Joint Venture Arrangements (“1989 Fraud Alert”),2 the OIG expressed the view that certain types of these arrangements are proliferating.

1 The Bulletin is available on the internet at: http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/042303SABJointVentures.pdf. As used by the OIG, the term “contractual joint venture” refers to a provider’s contractual arrangements with a manager or supplier, as distinguished from legal co-ownership of an entity, such as a partnership.

In the Advisory Bulletin, the OIG focuses on those arrangements in which a health care provider (“the Owner”) expands into a related health care business by contracting with an existing provider or supplier of a related item or service (the “Manager/Supplier”). The operative fact about the Owner in these situations is its ability to make patient referrals to any new business. The OIG offers several examples of suspect contractual arrangements that it maintains “could provide the basis for law enforcement action.” Such suspect arrangements include, but are not limited to, arrangements whereby:

1. the Owner (referral source) is expanding into a related “new” business that is itself dependent on patient referrals from or other business generated by the existing business;
2. the Owner neither operates nor commits substantial resources to the new business;
3. absent the contractual arrangement, the Manager/Supplier would be a competitor; and
4. the Owner and Manager/Supplier share the economic benefits of the Owner’s new business.

This Memorandum summarizes the Advisory Bulletin and discusses the impact it could have on current business arrangements.

II. BACKGROUND

The federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b), establishes criminal penalties with respect to any person who knowingly and willfully offers, pays, solicits or receives any remuneration to induce or in return for: (i) referring an individual to a person for the furnishing or arranging for the furnishing of any item or service payable in whole or in part under federal health care programs; or (ii) purchasing, leasing, ordering or arranging for or recommending purchasing, leasing or ordering any good, facility, service or item payable under federal health care programs. In addition to criminal sanctions, a violation of the statute constitutes grounds for exclusion from participation in Medicare or Medicaid and imposition of civil money penalties.

In the 1989 Fraud Alert, the OIG expressed concern that certain joint venture arrangements between those in a position to refer business (e.g., physicians), and those providing items or services for which Medicare or Medicaid pays (e.g., clinical laboratory services, durable medical equipment (“DME”), and diagnostic services) could run afoul of the anti-kickback statute. While the 1989 Fraud Alert focused primarily on those joint ventures involving co-ownership, it also referred to joint ventures that involved contractual arrangements between two or more parties to cooperate in providing services, or the creation by the parties of a new legal entity to provide such services, including a limited partnership or a closely held corporation.

While the OIG acknowledged that there may be legitimate reasons to form such a joint venture, such as raising necessary investment capital, the OIG warned that some of these joint ventures may
violate the federal anti-kickback statute by serving to “lock up a stream of referrals from the physician investors and to compensate them indirectly for these referrals. Because physician investors can benefit financially from their referrals, unnecessary procedures and tests may be ordered or performed, resulting in unnecessary program expenditures.” The OIG noted that suspect joint ventures may be indicated by: (1) the manner in which investors are selected and retained; (2) the nature of the business structure of the joint venture; and (3) the financing and profit distributions.

Notwithstanding the prior warning about suspect joint venture arrangements, the OIG states its view that contractual joint venture arrangements currently are proliferating.4

III. PROVISIONS OF ADVISORY BULLETIN

The Advisory Bulletin focuses on those arrangements in which the Owner expands into a related health care business by contracting with the Manager/Supplier who would otherwise be a potential competitor. The Owner provides the new item or service to its existing patient population, which includes federal health care program patients, but the operation of the new business is substantially contracted out to the Manager/Supplier (i.e., a turn-key operation). In fact, the Manager/Supplier not only manages the new line of business, but also may supply the Owner with inventory, employees, space, billing, and other services. According to the OIG, the Owner receives the profits of the business as remuneration for its referrals.

A. Questionable Contractual Arrangements

The Advisory Bulletin sets forth the following examples of potentially problematic contractual arrangements:

? A hospital establishes a subsidiary to provide DME. The subsidiary contracts with an existing DME company to operate the new subsidiary and to provide it with inventory. The existing DME company already provides services comparable to those provided by the new hospital DME subsidiary.

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3 The 1989 Fraud Alert was issued prior to enactment of the Stark law’s restrictions on physician investment in entities to which they refer patients.

4 For purposes of the Advisory Bulletin, a “joint venture” is any common enterprise with mutual economic benefit. This definition -- and the application of the Advisory Bulletin -- is not limited to “joint ventures” that meet technical qualifications under applicable state or common law.
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.

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. ⁵

According to the OIG, the common elements in these “problematic arrangements” include:

1. The **Owner is expanding into a related line of business** that is dependent on referrals from, or other business generated by, the Owner’s existing business. Such referrals may be direct or indirect and may include “arranging for” or “recommending” goods and services. Typically, the new business primarily serves the Owner’s existing patient base.

2. The Owner neither operates the new business itself nor commits substantial resources to the venture. Instead, the **Owner contracts out substantially all the new operations** (i.e., management services, inventory, personnel, billing support, and space). The billing is done in the name of the Owner. The contractual arrangement often results in either practical or legal exclusivity for the Manager/Supplier through inclusion of non-competition provisions or restrictions on access. While the terms of these arrangements may appear to place the Owner at financial risk, the risk actually is minimal because the Owner can influence substantial referrals to the new business.

3. The **Manager/Supplier is an established provider of the same services** as the Owner’s new line of business. Absent the contractual arrangement, the Manager/Supplier would be a competitor of the new line of business, billing and collecting from patients and insurers in its own name for essentially the same items and services.

4. The **Owner and the Manager/Supplier share the economic benefit** from the new business. The Manager/Supplier profits through contractual payments from the Owner, while the Owner receives residual profits from the new business.

5. **Aggregate payments to the Manager/Supplier usually vary with the value or volume of business generated for the new business (i.e., referrals) by the Owner.** While certain payments may be fixed (e.g., the management fee), other payments (e.g., payments for goods and services supplied by the Manager/Supplier) vary based on the number of goods and services provided. Similarly, the Owner’s profits from the new business will vary with the volume or value of the Owner’s referrals.

⁵ The original version of the Special Advisory Bulletin stated that due to implementation of the Stark II regulations (66 FR 856; January 4, 2001), referrals from the physician-owners generally would be prohibited. This reference subsequently was deleted in a second version of the Bulletin because the Stark II regulations still are subject to rulemaking, according to OIG staff.
B. Unavailability of Safe Harbor Protection

There are a number of statutory and regulatory “safe harbors” that protect certain arrangements that might otherwise violate the anti-kickback statute (See 42 U.S.C. 1320a-7b(b)(3); 42 CFR 1001.952). The Advisory Bulletin observes that some parties to a suspect joint venture might 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.’” According to the OIG, these efforts still may subject the parties to prosecution for a variety of reasons.

First, many of these questionable joint venture arrangements involve contracts whereby the Manager/Supplier agrees to sell items or services to the Owner at a discounted price. However, the OIG opines that the discount safe harbor does not protect prices offered by a seller to a buyer in connection with a common enterprise because safe harbor protection only applies to a price reduction based on an arms length transaction.

Second, even if the contracts met one or more safe harbors, only remuneration flowing from the Owner to the Manager/Supplier for actual services rendered would be protected. In certain joint ventures, however, the illegal remuneration can be the difference between the (1) Owner’s payment to the Manager/Supplier; and (2) federal health care program reimbursement. By essentially providing services for the Owner that it could otherwise provide directly, for less than the amount of federal program reimbursement available, the Manager/Supplier allows the Owner to generate a fee (and profit). According to the Advisory Bulletin, this opportunity to generate a fee is itself remuneration that may implicate the anti-kickback statute.

C. Indicia of a Suspect Contractual Joint Venture

The Advisory Bulletin provides an illustrative -- but not exhaustive -- description of some characteristics that potentially indicate a prohibited arrangement:

? **New Line of Business.** The Owner typically seeks to expand into a health care service that can be provided to its existing patients (i.e., hospitals expanding into DME services, DME companies expanding into the nebulizer pharmacy business, or nephrologists expanding into the home dialysis supply business).

? **Captive Referral Base.** The new business predominantly or exclusively serves the Owner’s existing patients (or patients under the control or influence of the Owner). The Owner typically does not intend to expand the business to serve new customers and 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, rather than financial or other investment. The Owner delegates the operation of the venture to the Manager/Supplier while retaining profits generated from its referral
base. Residual business risks (e.g., nonpayment for services) may be determined based on historical activity.

? **Status of the Manager/Supplier.** The Manager normally would compete with the Owner for the captive referrals. It has the ability to provide virtually identical services in its own right and bill insurers and patients under its own name.

? **Scope of Services Provided by the Manager/Supplier.** The Manager/Supplier provides all, or many, of the following services: (i) day-to-day management; (ii) billing services; (iii) equipment; (iv) personnel and related services; (v) office space; (vi) training; and (vii) health care items, supplies, and services. The greater the scope of services provided by the Manager/Supplier, generally the greater the likelihood that the arrangement is a contractual joint venture as described in the Advisory Bulletin.

? **Remuneration.** The practical effect of the arrangement is to provide the Owner with the opportunity to bill for business otherwise provided by the Manager/Supplier. The Owner’s profits from the venture take into account the value and volume of business the Owner generates.

? **Exclusivity.** The parties may adopt a non-compete clause prohibiting the Owner from providing items or services to patients other than those referred by the Owner and/or barring the Manager/Supplier from providing services in its own right to the Owner’s patients.

### IV. ANALYSIS AND CONCLUSION

The Advisory Bulletin reflects the OIG’s concern with joint ventures primarily set up to service a provider’s existing patient base, at minimal financial risk, where the provider has little, if any, involvement in the financing or operation of the new business. It is important to note that the Advisory Bulletin does not restrict Owners (such as hospitals) from establishing and funding their own new independent subsidiary businesses, such as DME supply entities; rather the OIG is concerned with Owners contracting with existing businesses through turn-key arrangements and assuming little or no financial risk. In addition, it is important to remember that the Advisory Bulletin does not create new law, nor does it have the legal status of a notice and comment rulemaking. Nevertheless, it provides guidance on how the OIG is likely to scrutinize these types of arrangements and set its enforcement priorities.

The 2003 Advisory Bulletin focuses on a particular type of arrangement which was previously described in the 1989 Fraud Alert as a suspect “shell” joint venture. However, the latest guidance provides considerably more explicit detail on the criteria the OIG will use to identify those arrangements it views as questionable. While the OIG has previously expressed its belief that joint ventures without significant Owner financial and/or operational participation could be suspect, the Advisory Bulletin contains a new emphasis on the questions that may arise when a new business primarily serves an
Owner’s existing patient base. The fact that most of the “examples” provided in the Advisory Bulletin involve DME and ESRD suppliers may indicate the OIG’s particular concern with these types of joint ventures, although the suspect features discussed could occur in connection with any type of health care business (e.g., home health, rehabilitation, and the like).

The OIG also notes that these ventures typically involve some component of payment to the Manager/Supplier that varies with the volume or value of the Owner’s referrals to the new business, and that this payment methodology allows both parties to share in the profits of the venture. While the term “per click” is not used explicitly, this discussion echoes recent statements in an OIG advisory opinion that “per patient,” “per click,” and similar payment arrangements with federal health care program referral sources are disfavored under the anti-kickback statute.\(^6\)

Since the anti-kickback statute cannot be violated absent improper intent, any assessment of potential liability necessarily requires a very fact-specific analysis. Accordingly, joint ventures which contain one or more of the suspect factors listed in the Advisory Bulletin are not necessarily illegal. Further, the overall approach to joint ventures as described in the Advisory Bulletin remains similar to that set forth in the 1989 Fraud Alert and is consistent with the analysis we have used since that time. Nevertheless, such arrangements, particularly those containing several “questionable” characteristics, as identified in the Advisory Bulletin, may be subject to increased OIG scrutiny. Providers and suppliers, therefore, are well advised to review their arrangements in order to avoid these features whenever possible. Moreover, in addition to structuring new joint ventures with these issues in mind, providers should consider reviewing their existing arrangements, both in terms of how they are structured and how they are implemented, to evaluate whether certain revisions would be advisable.

Health care entities also should take note of the OIG’s warning that satisfying one or more safe harbors does not necessarily mean that the arrangement as a whole does not violate the anti-kickback statute, e.g., because the difference between the money paid by the Owner to the Manager/Supplier (which fits a safe harbor(s)) may be less than the reimbursement the Owner receives from federal health care programs. According to the OIG, the difference between these two amounts may constitute illegal remuneration. In other words, the funds retained by the Owner, over and above what it pays to the Manager/Supplier, could be viewed as a kickback from the Manager/Supplier to the Owner. At least one court has similarly held that the opportunity to generate revenues can constitute remuneration which implicates, and potentially violates, the anti-kickback statute. See, U.S. v. Bay State Ambulance & Hospital Rental Serv., 874 F.2d 20 (1st Cir. 1989). As a result, it remains important to evaluate proposed arrangements for potential anti-kickback problems.

\(^{6}\) Advisory Opinion No. 03-08 (Apr. 10, 2003).
joint ventures, which often involve numerous complex arrangements, in context, rather than simply addressing particular aspects of the arrangements in isolation.

The issuance of the Advisory Bulletin likely signals increased government review of joint venture arrangements, particularly “contractual joint ventures” which contain those features identified as questionable by the OIG. Similarly, publication of the 1989 Fraud Alert was followed by a major enforcement initiative, when the government brought suit against the Hanlester Network joint ventures. Hanlester Network v. Shalala, 51 F.3d 1390 (9th Cir. 1995). However, most of the Hanlester allegations ultimately were dismissed by the court, suggesting a narrower reading of the anti-kickback statute than the one advanced by the OIG in the 1989 Fraud Alert. Thus, while providers and suppliers should carefully consider the guidance contained in the Advisory Bulletin, they should not conclude that all contractual joint ventures, even those which contain some of the so-called “suspect” features, are necessarily improper. As demonstrated by the Hanlester case, courts are likely to uphold appropriately structured joint venture arrangements.

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