In an important Special Advisory Bulletin on Contractual Joint Ventures (the "Bulletin"), the Office of Inspector General of the U. S. Department of Health and Human Services (the "OIG") recently placed an Anti-Kickback Law warning sign on contractual joint ventures. 68 Fed. Reg. 23,148 (April 30, 2003) (available at http://oig.hhs.gov/fraud/fraudalerts.html#2). Specifically, the Bulletin focuses on management agreements pursuant to which a health care provider in one line of business (the "Owner") expands into a related health care business by contracting with an existing provider of the related item or service (the "Manager/Supplier"). Examples cited by the OIG involve a hospital forming a subsidiary to provide durable medical equipment ("DME") that is operated by an existing DME company that otherwise would be a competitor; a pharmacy that "services" an existing DME company; and an agreement between a group of nephrologists, who set up a company to provide home dialysis supplies to their patients, and an existing home dialysis supply company.

These "problematic arrangements" are noted to share the following common elements that "separately or together, potentially indicate a prohibited arrangement":

(i) The Owner's expansion into the related service line primarily serves the Owner's existing patient base either as part of the Owner or as a separate subsidiary.

(ii) The Owner does not (a) assume material financial risk, (b) operate the new business itself, or (c) commit substantial financial, capital or human resources to the venture. Interestingly, in weighing whether the Owner retains financial risk, the OIG refuses to consider the financial risk inherent in a transaction where the Manager/Supplier is paid on a unit basis for each service rendered regardless of whether the Owner is paid. The OIG believes the Owner's ability to influence substantial referrals to the new business, and its knowledge of its historical level of referrals and payor type for the service, virtually eliminates this risk.

(iii) "[S]ubstantially all of the operations" of the new business are contracted out to the Manager/Supplier, including all or many of the following "key services": day-to-day management, billing services, equipment, personnel and related services, office space, training, and health care items, supplies and services.

(iv) These arrangements often "result in either practical or legal exclusivity for the Manager/Supplier."

(v) The Manager/Supplier is already an established provider of the same service as the Owner's new line of business, which would otherwise be a competitor. (*In other words, absent the contractual arrangement, the Manager/Supplier would be a competitor of the [provider's] new line of business, providing items and services in its own right, billing insurers and patients in its own name, and collecting reimbursement.*)

(vi) The Manager/Supplier profits through its contract with the Owner, and the Owner receives its share of the economic benefit by receiving the residual profit of the enterprise (the difference between reimbursement and the cost of the contract).

(vii) The receipt of the residual profit, under (vi) above, establishes, in the OIG's view, that the aggregate payments to each of the Manager/Supplier and the Owner will vary with the value of the volume of business gen-
erated for the new business by the Owner. (In other words, in the OIG’s view, not only does the Owner pay the Manager/Supplier, but the Manager/Supplier also pays the Owner, through an agreement to split the profit from the new business.)

Many of these arrangements involve discounted items and services. However, in keeping with its view that you cannot contract for an entire distinct billable service and treat it as your own, the OIG rejects the application of the Anti-Kickback Law’s discount safe harbor to these joint ventures where “a discount is given as part of an overarching business arrangement.” The OIG explains that the discount safe harbor would not apply because the management arrangement is "in connection with a common enterprise" and therefore not an "arms length transaction."

These OIG arguments are strained and fail to distinguish adequately these discounts from others that appear to be valid. Of course, all discounts for products and services create a "common enterprise," particularly if a large supplier is involved. The critical point would appear to be the OIG’s view that the discount safe harbor does not apply to a “discount” on a comprehensive group of services that together comprise all or virtually all of a separately billable service.

Even more troubling is the OIG’s statement that, even if the contracts could fit into a safe harbor, the safe harbor would not protect the types of remuneration at issue in (vi) and (vii) above. Rather, "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." The OIG thus argues that a discount may be a kickback if offered by an entity on a service that the entity could otherwise provide and for which it could be reimbursed directly in excess of the discounted fee, because the Manager/Supplier is providing the Owner with an opportunity to generate a fee and a profit. This view, of course, has application beyond the DME/Supplier context. For example, contract physicians often provide service on a unit basis for less than they could be reimbursed directly by Medicare or other payors. Under the Bulletin, such unit price relationships would appear to raise risks under the Anti-Kickback Law (42 U.S.C. § 1320a-7b(b)).

The OIG has always struggled to distinguish between self-referrals, where an entity provides services to its own patients, and referrals by the entity of its patients to a third party. For example, the in-office ancillary service exception in the federal Stark Law (42 U.S.C. § 1395nn), which has always been among the Stark Law’s most complicated and widely debated provisions, reflects this tension. In this Bulletin, the OIG makes clear that it will look at the substance and not the form of the contractual relationship to determine the true provider of the referred service. If the true provider of the referred service is an entity that would otherwise furnish the service itself, the provider and the referring entity cannot change that substance through a contract that defines the actual service provider as a "Manager" for the referring provider.

The Bulletin will have application beyond the DME context, and the OIG notes that "[i]n general, the greater the scope of services provided by the Manager/Supplier, the greater the likelihood that the arrangement is a contractual joint venture." All management agreements in which virtually all services are outsourced to an existing service provider that could otherwise compete, without any significant investment or material day-to-day operational control by the primary provider, are suspect and should be reviewed with counsel.

Edward S. Kornreich
212.969.3395
ekornreich@proskauer.com

Has Your Address Changed? Want to Receive Future Health Law Alerts by E-mail?
Please send an e-mail with your name, title, organization, mailing address, e-mail address and phone number to: Healthlaw@proskauer.com

Edward S. Kornreich
212.969.3395
ekornreich@proskauer.com

Proskauer is an international law firm with more than 590 attorneys who handle a full spectrum of legal issues worldwide.