

- 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.

- 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.<sup>3</sup> 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.

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

<sup>3</sup> 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.