

[Date Issued -- March 16,1999]

[Name and address redacted]

Re: Nephrologist - Home Dialysis Supplies Joint Venture

Dear [Name redacted]:

We are writing in response to your inquiry regarding the potential applicability of the Federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b), to a proposed arrangement among three nephrologists to establish and own a home dialysis supply company (the "Company"). According to the information you have provided, the Company would be managed by a competing supplier of home dialysis supplies ("Management Company") paid a percentage of the Company's revenues. A substantial portion of the Company's business would be derived from referrals of dialysis patients from the investing nephrologists.

We cannot provide a formal binding opinion except through our advisory opinion process. See 42 C.F.R. Part 1008. However, we can make some general observations regarding the practices you have described.

In general, the anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce, or in return for, the referral of items or services for which payment may be made in whole or in part by a Federal health care program. In other words, the statute prohibits payments made purposefully to induce referrals of business payable by a Federal health care program. Violation of the anti-kickback statute is a felony punishable by a maximum fine of \$25,000, imprisonment up to five years, or both. The Department of Health and Human Services may also impose civil monetary penalties on or exclude persons who violate the anti-kickback statute.

In 1989, the Office of Inspector General issued a "Special Fraud Alert" specifically discussing joint venture arrangements that may violate the anti-kickback statute (Special Fraud Alert, "Joint Venture Arrangements" (OIG-89-4), reprinted in 59 Fed. Reg. 65373 (Dec.19, 1994)). The Special Fraud Alert distinguishes between legitimate joint ventures and those that are suspect under the anti-kickback statute. A joint venture may be suspect when physicians are both investors in the joint venture and are in a position to refer to the joint venture. Under these circumstances, remuneration paid to the physicians in exchange for referrals may be disguised as profit distributions. Such suspect joint ventures:

. . . may be intended not so much to raise investment capital legitimately to start a business, but 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.

59 Fed. Reg. at 65373-74. Substantial ownership by investors who are in a position to refer patients to the joint venture is an indicator of a suspect joint venture because such ownership increases the likelihood that one of the joint venture's purposes is to control a stream of referrals and compensate the referring investors indirectly for their referrals. Other factors that could indicate potentially unlawful activity include an investor in a position to refer business receiving a disproportionate return on his or her investment, and participation in the joint venture by an on-going entity that is already engaged in the same line of business as the joint venture.

In 1991, the Department of Health and Human Services ("Department") published safe harbor regulations that define certain practices not subject to the anti-kickback statute because such arrangements would be unlikely to result in fraud or abuse. Rather, the safe harbors set forth specific conditions that, if fully met, assure the entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. One safe harbor regulation addresses investment interests in small entities. See 42 C.F.R. § 1001.952(a)(2). The safe harbor for investments in small entities has eight elements, each of which must be satisfied in order for the arrangement to qualify for the exception. One specific element of the safe harbor that is not met by the arrangement described requires that no more than forty percent of the investment interests may be held by investors who are in a position to make or influence referrals to, furnish items

or services to, or generate business for, the entity.

Even though an arrangement does not fall within a safe harbor, it does not necessarily violate the anti-kickback statute. Arrangements that potentially implicate the anti-kickback statute, but that are not within a safe harbor, must be analyzed on a case-by-case basis. In general, health care joint ventures in which investors are also sources of referrals or suppliers of items or services to the joint venture raise many questions under the anti-kickback statute. Like any kickback scheme, these arrangements can lead to overutilization, increased costs for Federal health care programs, corruption of professional judgment, and unfair competition. With respect to joint ventures, one major concern is that the profit distributions to investors in the joint venture who are also referral sources to the joint venture may potentially represent remuneration for those referrals.

The arrangement described in your letter has many of the hallmarks of a suspect joint venture.

- All investors are physicians in a position to refer patients to the Company.
- Referrals from the physician investors will constitute the majority of the Company's business.
- Because the physicians own 100% of the Company, the return on their investments will be directly related to their referrals.
- The "management company" that actually operates the Company is an on-going entity already engaged in the home dialysis supply business.

Moreover, the Company would appear to pose some of the very risks that the anti-kickback statute is designed to combat. Because home dialysis supplies are reimbursed on a reasonable charge basis (subject to a monthly cap), there is a risk of increased costs to the Federal health care programs. More troubling is the possibility that the physicians' financial interest in home dialysis might influence the type of dialysis treatment recommended to the patient.

Accordingly, we would view such an arrangement as suspect. The physicians' return on their investment may constitute prohibited remuneration under the anti-kickback statute if one purpose of the remuneration is to secure referrals of Federal program business.

We hope this information is helpful.

Yours truly,

/s/

Kevin G. McAnaney
Chief, Industry Guidance Branch