[April 15, 1998]

[Name Redacted]

Re: Advisory Opinion No. 98-4

Dear [Name Redacted]:

We are writing in response to your request for an advisory opinion, in which you ask whether a proposed management services contract between a medical practice management company and a physician practice, which provides that the management company will be reimbursed for its costs and paid a percentage of net practice revenues (the "Proposed Arrangement"), would constitute illegal remuneration as defined in the anti-kickback statute, §1128B(b) of the Social Security Act (the "Act").

You have certified that all of the information you provided in your request, including all supplementary letters, is true and correct, and constitutes a complete description of the material facts regarding the Proposed Arrangement. In issuing this opinion, we have relied solely on the facts and information you presented to us. We have not undertaken any independent investigation of such information.

Based on the information provided, we conclude that the Proposed Arrangement may constitute prohibited remuneration under §1128B(b) of the Act.

I. FACTUAL BACKGROUND

A. The Parties

Dr. X is a family practice physician who has incorporated as, and practices under the name of, Company A ("Company A"). Company A is proposing to enter into an agreement to establish a family practice and walk-in clinic with a corporation, Company B ("Company B"). Dr. X is the sole Requestor of this advisory opinion.

B. The Arrangement

Under the Proposed Arrangement, Company A will provide all physician services at the clinic. Company A may hire additional physicians and other medical personnel with the mutual agreement of Company B. Company A will pay all physician compensation and fringe benefits, including but not limited to, licensing fees, continuing education, and malpractice premiums.

Company B will find a suitable location for the clinic and furnish the initial capital for the office, furniture, and operating expenses. Once operational, Company B will provide or arrange for all operating services for the clinic, including accounting, billing, purchasing, direct marketing, and hiring of non-medical personnel and outside vendors.

Company B will also provide Company A with management and marketing services for the clinic, including the negotiation and oversight of health care contracts with various payors, including indemnity plans, managed care plans, and Federal health care programs.

In addition to Company B's activities on behalf of Company A, Company B will set up provider networks. These networks may include Company A and, if required by Company B, Company A has agreed that it will refer its patients to the providers in such networks.

In return for its services, Company B's payment will have three components. Company A will be required to make a capital payment equal to a percentage of the initial cost of each capital asset purchased for Company A per year for six years. Company B will also receive a fair market value payment for the operating services it provides and an at-cost payment for any operating services for which it contracts. Company B will receive a percentage of Company A's monthly net revenues for its management services.

If the percentage payment described above is not permitted by law, then the parties will establish a management fee reflecting the contemplated financial results of the arrangement or, if the parties cannot agree to a fixed amount, the parties will hire an accounting firm to determine an appropriate fixed fee (the "Alternative Proposed Arrangement").

II. LEGAL ANALYSIS

A. Anti-kickback Statute

The anti-kickback statute, §1128B(b) of the Act, makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce the referral of business covered by a Federal health care program. Specifically, the statute provides that:

> Whoever knowingly and willfully offers or pays [or solicits or receives] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person -- to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony.

§1128B(b) of the Act. In other words, the statute prohibits payments made purposefully to induce referrals of business payable by a Federal health care program. The statute ascribes liability to both sides of an impermissible "kickback" transaction. The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985).

Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid.

This Office may also initiate administrative proceedings to exclude persons from Federal and State health care programs or to impose civil monetary penalties for fraud, kickbacks, and other prohibited activities. See §§1128(b)(7), 1128A(a)(7) of the Act.[1]

B. Safe Harbor Regulations

In 1991, the Department of Health and Human Services (the “Department”) published safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. Failure to comply with a safe harbor provision does not make an arrangement per se illegal. For this Proposed Arrangement, the only safe harbor regulation potentially available is the personal services and management contracts safe harbor. See 42 C.F.R. §1001.952(d).

The personal services and management contracts safe harbor provides protection for personal services contracts if all of the following six standards are met: (i) the agreement is set out in writing and signed by the parties; (ii) the agreement specifies the services to be performed; (iii) if the services are to be performed on a part-time basis, the schedule for performance is specified in the contract; (iv) the agreement is for not less than one year; (v) the aggregate amount of compensation is fixed in advance, based on fair market value in an arms-length transaction, and not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made by Medicare or a State health care program; and (vi) the services performed under the agreement do not involve the promotion of business that violates any Federal or State law.

We conclude that the Proposed Arrangement does not qualify for this safe harbor. In order for an agreement to be protected by this safe harbor, strict compliance with all six standards is necessary. In this case, the compensation is not an aggregate amount, fixed in advance, as the safe harbor requires. Accordingly, the safe harbor standards are not satisfied.

C. Percentage Compensation Arrangement

Because compliance with a safe harbor is not mandatory, the fact that the Proposed Arrangement does not fit within a safe harbor does not mean that the Proposed

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[1]Because both the criminal and administrative sanctions related to the anti-kickback implications of the Proposed Arrangement are based on violations of the anti-kickback statute, the analysis for the purposes of this advisory opinion is the same under both.

Arrangement is necessarily unlawful. Rather, we must analyze this Proposed Arrangement on a case-by-case basis.

Percentage compensation arrangements for marketing services may implicate the anti-kickback statute. In our preamble to the 1991 final safe harbor rules, 56 Fed. Reg. 35952 (July 29, 1991), we explained that the anti-kickback statute "on its face prohibits offering or acceptance of remuneration, *inter alia*, for the purposes of 'arranging for or recommending purchasing, leasing, or ordering any . . . service or item' payable under Medicare or Medicaid. Thus, we believe that many marketing and advertising activities may involve at least technical violations of the statute." 56 Fed. Reg. at 35974.

This Proposed Arrangement is problematic for the following reasons.

- **The Proposed Arrangement may include financial incentives to increase patient referrals.** The compensation that Company B receives for its management services is a percentage of Company A's net revenue, including revenue from business derived from managed care contracts arranged by Company B. Such activities may potentially implicate the anti-kickback statute, because the compensation Company B will receive will be in part for marketing services. Where such compensation is based on a percentage, there is at least a potential technical violation of the anti-kickback statute. In addition, Company B will be establishing networks of specialist physicians to whom Company A may be required to refer in some circumstances. Further, Company B will presumably receive some compensation for its efforts in connection with the development and operation of these specialist networks. In these circumstances, any evaluation of the Proposed Arrangement requires information about the relevant financial relationships. However, Company B is not a requestor for this advisory opinion, and Company A does not have information regarding Company B's related business arrangements.

  Accordingly, we have insufficient information to ascertain the level of risk of fraud or abuse presented by the Proposed Arrangement.[2]

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[2]We are also precluded from reaching a conclusion about the Alternative Proposed Arrangement. Such a determination would require us to evaluate whether the agreed

- **The Proposed Arrangement contains no safeguards against overutilization.** In light of the proposed establishment of provider networks with required referral arrangements, there is a risk of potential overutilization. Under the Proposed Arrangement, we are unable to determine what, if any, controls will be implemented under managed care contracts negotiated for Company A by Company B. Without such controls, we can not be assured that items and services paid for by Federal health care programs will not be overutilized.

- **The Proposed Arrangement may include financial incentives that increase the risk of abusive billing practices.** Since Company B receives a percentage of Company A's revenue and will arrange for Company A's billing, Company B has an incentive to maximize Company A's revenue. This Office has a longstanding concern that percentage billing arrangements may increase the risk of upcoding and similar abusive billing practices.

III. CONCLUSION

The advisory opinion process permits the OIG to protect specific arrangements that "contain[] limitations, requirements, or controls, that give adequate assurances that Federal health care programs cannot be abused." <u>See</u> 62 Fed. Reg. 7350, 7351 (February 19, 1997). Based on the facts we have been presented, the Proposed Arrangement appears to contain no limitations, requirements, or controls that would minimize any fraud or abuse.

Therefore, since we cannot be confident that there is no more than a minimal risk of fraud or abuse, we must conclude that the Proposed Arrangement may involve prohibited remuneration under the anti-kickback statute and thus potentially be subject to sanction under the anti-kickback statute, §1128B(b) of the Act. Any definitive conclusion regarding the existence of an anti-kickback violation requires a determination of the

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upon fee is fixed at fair market value. We are prevented from making that determination by §1128D(b)(3)(A) of the Act, which prohibits our opining on fair market value in an advisory opinion.

parties' intent, which determination is beyond the scope of the advisory opinion process.[3]

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to Dr. X, who is the Requestor of this opinion. This advisory opinion has no application, and cannot be relied upon, by any other individual or entity.

- This advisory opinion is applicable only to the statutory provision specifically noted above. No opinion is herein expressed or implied with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Proposed Arrangement.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

Sincerely,

/s/

D. McCarty Thornton
Chief Counsel to the Inspector General

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[3]Our conclusion regarding the risk of fraud or abuse in relation to the anti-kickback statute should not be construed to mean that a finding of fraud or abuse is an implied element necessary to establish a violation of the statute.