

[Posted December 21, 1998]

[Issued December 14, 1998]

[names redacted]

Re: [names redacted]

OIG Advisory Opinion No. 98-19

Gentlemen:

We are writing in response to your request for an advisory opinion, in which you asked whether an arrangement whereby an independent physician association would acquire an equity interest in a managed care organization would constitute grounds for the imposition of sanctions under the anti-kickback statute, section 1128B(b) of the Social Security Act (the "Act"), the exclusion authority for kickbacks, section 1128(b)(7) of the Act, or the civil monetary penalty provision for kickbacks, section 1128A(a)(7) of the Act.

In accordance with our regulations at 42 C.F.R. Part 1008, your request for an advisory opinion disclosed a number of additional arrangements involving Company A ("Company A"), about which no opinion has been sought. For purposes of this advisory opinion, the term "Proposed Arrangement" collectively includes only the following arrangements described in your request for an advisory opinion and supplemental submissions (as described in greater detail below): the acquisition by Company B (the "IPA") of a [less than 15 percent] equity interest in Company A and the consequent return on the equity investment; the assignment of physician services agreements as consideration for Company A's equity investment; the Network Service Agreement; the Administrative Service Agreement; and the Incentive Stock Plan.

You have certified that all of the information provided in your request, including all supplementary materials, 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 facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Office of Inspector General ("OIG") will not subject the Proposed Arrangement to sanctions arising under the anti-kickback statute pursuant to sections 1128(b)(7) or 1128A(a)(7) of the Act, provided that all compensation in connection with the Proposed Arrangement is fair market value as you have certified. We express no opinion about the Medical Management Program Agreement (or any agreement entered into in accordance with its terms) or about any arrangement disclosed or referenced in your request letter or supplemental submissions other than the Proposed Arrangement.

This opinion may not be relied on by any persons other than the Requesters⁽¹⁾ of this advisory opinion and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. The Parties

1. The Managed Care Organization

Company A is a managed care organization organized pursuant to the laws of the state of Y. Company A traces its corporate roots to the early 1980s, when a group of local hospitals formed a preferred provider organization ("PPO"). Several years ago, the preferred provider organization merged with a licensed health maintenance organization ("HMO") in an effort to develop HMO capabilities. Company A was formed as the holding company for the PPO and HMO as part of the merger transaction.

Company A currently has eight shareholders, each of which is either a hospital, the owner of a hospital facility, or a related entity of a hospital located in the City X metropolitan area (collectively, the "Shareholder Hospitals"). Company A is the parent company of four wholly-owned subsidiaries. The two subsidiaries relevant to the Proposed Arrangement are Company C, a preferred provider organization ("Company C" or the "P.O.") incorporated in State Y, and Company D, a health maintenance organization domiciled in the State of Y and authorized to do business in State Y and State Z ("Company D" or the "HMO").⁽²⁾

As a preferred provider organization, the P.O. contracts with various physicians and hospitals in the City X metropolitan area in order to form a network of providers that may be utilized by various third-party payers in offering covered health care services to their subscribers. For its services in establishing and maintaining the network, the P.O. receives a fee from each of its network hospitals, including the Shareholder Hospitals;⁽³⁾ the fee varies in direct proportion to the amount of revenue each hospital earns as a result of its participation in the P.O.'s P.O. network.⁽⁴⁾

The P.O. contracts with third-party payers (typically employers or other entities in the commercial group health insurance market), who pay a negotiated fee to the P.O. for access to the PPO network. As part of its services, the P.O. assists the third-party payers in establishing the discounted rates they will pay network providers for covered health care services. The third-party payers set and collect their own subscriber premiums. There are no Medicaid enrollees in the P.O.'s P.O. product lines, but there may be some Medicare enrollees. The PPO lines of business currently constitute approximately []% of Company A's business.

The HMO -- Company A's HMO subsidiary -- offers its own plans directly to subscribers in the City X metropolitan area. These plans include non-governmental sponsored plans and a Medicare risk contract. The HMO also participates in the State Y and State Z Medicaid managed care programs. Unlike the P.O., the HMO receives no access fees from its network providers or from third-party payers. The HMO charges and receives premiums directly from contracting subscribers or receives capitation payments from Medicare or Medicaid.

The HMO pays its network hospitals and physicians in accordance with negotiated provider contracts. Some hospitals are paid on a per diem basis, while others are paid under a full or modified risk arrangement. Primary care physicians are generally paid a capitated amount per subscriber who selects the physician, while specialists are paid on a discounted fee-for-service basis. The amount to be paid to a physician for services, whether a capitation or fee-for-service amount, will be fixed by the HMO in advance.

The substantial majority of the P.O. and the HMO business is derived from the commercial group health insurance market, including virtually all of the PPO business..

2. The Independent Physician Association

The IPA ("Company B" or the "IPA") is a State Y corporation established in 1984 and organized as an independent physician association. Its approximately 2200 shareholders are primary care and specialty care physicians, all of whom practice in the City X metropolitan area. Profit distributions are made to the IPA's shareholders based on their IPA share ownership, which has no relationship to any past, present, or future referrals to Company A. Currently, each physician-shareholder has a single share in the IPA; pursuant to the proposed Incentive Stock Plan described below, future shareholdings will be based, in part, on physician performance on a number of pre-set quality indicators and performance standards.

The IPA enters into physician service agreements ("PSAs")⁽⁵⁾ with its shareholder physicians and with non-shareholder physicians and contracts with health plans on behalf of its physician panel. The IPA physicians, along with other physicians in outlying areas, serve as network providers for Company A health plans, as well as for competing health plans. The IPA physicians admit patients to hospitals in the Company A health plan networks, including the Shareholder Hospitals.

B. The Proposed Arrangement

Company A seeks to expand its HMO business in the City X metropolitan area. To facilitate this expansion, Company A desires to ensure a stable and sufficient network of physicians for the additional HMO business. Accordingly, Company A proposes selling a [less than 15 percent] interest in Company A to the IPA and entering into certain ancillary agreements with the IPA, as described below.

1. The Stock Purchase and the Assignment Agreement

Pursuant to a subscription agreement and a shareholder agreement, the IPA will purchase shares of Company A stock equal to a [less than 15 percent] equity interest. The shares would constitute a separate class of non-voting stock (Class B shares) with the right to elect no less than one Company A board member. Both the Shareholder Hospitals and the IPA will have made substantial investments in Company A, and the distribution of profits will be in direct proportion to the fair market value of such investments.

As consideration for the stock, the IPA will assign to Company A the IPA's contract rights under certain long-term PSAs with its shareholder (and potentially some non-shareholder) physicians. Specifically, the IPA will assign PSAs for no less than []% of its existing primary care physicians and []% of its specialty physicians. The exact percentages of assigned PSAs will be fixed prior to the stock transfer. The Requesters have certified that the Proposed Arrangement will not be consummated unless the aggregate value of the assigned PSA contract rights is fair market value for the Company A stock based on an arms-length transaction and not based on the volume or value of referrals or business otherwise generated between the parties.

In connection with the stock transfer, the IPA will become the exclusive physician provider panel for all managed care arrangements in which Company A participates (including the P.O. and the HMO plans) and will agree not to serve as a provider panel for any other health care entity. Individual IPA physicians, however, will be permitted to serve on panels for other health plans, subject to certain limitations applicable to physicians with significant ownership or control interests in a competing health care plan.

The Requesters have certified that there will be no financial arrangements or intentional efforts by Company A or any of its health care plans to have IPA physicians enroll persons in any of the Company A health care plans or to have IPA physicians encourage persons to enroll in any of the Company A plans.

2. The Ancillary Agreements

The Proposed Arrangement includes three ancillary personal services agreements between the IPA and Company A: a Network Service Agreement, a Medical Management Program Agreement, and an Administrative Services Agreement.

The **Network Service Agreement** is intended to ensure that Company A health plans have sufficiently large panels of available physicians to meet subscriber demand. Pursuant to the Network Service Agreement, the IPA will be responsible for developing and maintaining the provider network for the Company A plans for a term of ten years. It will fulfill these obligations by entering into PSAs with primary and specialty care physicians. Company A will pay the IPA an annual fee for access to the IPA's network of physicians and for maintenance of the network. The fee will be set at \$[] per covered employee in the PPO health plans per year, with a minimum payment of \$[] per year and a maximum of \$[] per year for the first five years. The Requesters have certified that compensation to be paid under the Network Service Agreement will be consistent with fair market value in arms-length transactions and will not be determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties.

The IPA and Company A will also enter into a ten-year **Medical Management Program Agreement**, pursuant to which the IPA shareholder physicians will develop and implement various programs for Company A health plans, including, but not limited to, programs in the areas of credentialing, utilization management, quality improvement, and case management. The IPA and Company A will negotiate separately the scope of services and specific compensation for each medical program developed under the Medical Management Program Agreement.

The Medical Management Program Agreement is, in essence, an agreement to enter into an undetermined number of future consulting contracts. Pursuant to the Medical Management Program Agreement, each of these future contracts will provide for "fair and reasonable" compensation in accordance with pre-set guidelines that establish the following principles:

- the nature, scope, and duration of services shall be agreed upon before the amount of compensation is established;
- the compensation shall be established at fair market value rates based upon the level of experience, education, or professional qualifications deemed necessary to carry out the services;
- the services will not exceed the level of services necessary and reasonable to fulfill the business purpose of the arrangement;
- the compensation, duties, and obligations of the parties shall be set forth in writing;
- the compensation shall be established for no less than one year and shall not be based upon, or related to, the value or volume of any referrals to any physicians being compensated by the IPA to participate in any medical management program established pursuant to the Medical Management Program Agreement, or based on any other business relationship between the IPA and Company A; and
- the compensation and services shall not involve the counseling or promotion of a business arrangement or other activity that violates any state or Federal law.

The Requesters have certified that all compensation to be paid under the future contracts will be consistent with fair market value in arms-length transactions and will not be determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties.

Finally, the IPA and Company A will enter into a ten-year **Administrative Services Agreement**, pursuant to which Company A will provide the IPA with certain administrative services, such as credentialing, accounting and auditing, utilization and quality management, and office administration. The IPA will pay Company A a predetermined rate, which will initially be an annual fee of \$[] per physician with an executed PSA. The Requesters have certified that compensation to be paid under the Administrative Services Agreement will be consistent with fair market value in arms-length transactions and will not be determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties.

3. The IPA Incentive Stock Plan

In accordance with its proposed shareholder agreement with Company A and to provide its shareholder physicians with a personal investment in the success of Company A, the IPA will offer additional shares of stock to those of its shareholder physicians who agree to assume certain levels of financial risk (the "Incentive Stock Plan"). Benefits under the Incentive Stock Plan are tied to physician acceptance of risk, HMO participation, and quality of service, and will vary depending on the degree of a physician's participation in systems of care that have assumed financial risk and responsibility for provision of medical services to the HMO subscribers. The Requesters estimate that approximately 90% of the IPA physicians will be eligible to participate in the Incentive Stock Plan.

Shareholder physicians who choose to participate in the Incentive Stock Plan will be required to have entered into a PSA with for a term of at least five years.⁽⁶⁾ These PSAs will establish certain rights and restrictions, including the following: (i) the physician will be permitted to contract with any other payer and/or health system; (ii) the physician will be required to have active medical staff privileges at a Company A affiliated hospital; (iii) the physician will not be permitted to be employed by, or have "prohibited affiliations"⁽⁷⁾ with, a medical group that is owned by a health system or managed care plan that competes with Company A or the Company A health plans; (iv) subject to Company A approval based on product or plan needs, the physician will be required to participate in all Company A health plans; and (v) the physician's ability to transfer shares in the IPA will be restricted.⁽⁸⁾ The PSAs will require physicians to comply with the health plans' quality improvement and utilization management programs.

4. Payments for Provider Services

The IPA physician shareholders and the Shareholder Hospitals will receive reimbursement from the HMO and from the PPO third-party payers for health care services they provide. The Requesters have certified that the remuneration paid to

physicians and hospitals for services provided to the PPO or the HMO subscribers will represent fair market value in an arms-length transaction for the services the physicians or hospitals provide and will not take into account the volume or value of referrals or other business generated between the parties.

II. LEGAL ANALYSIS

A. The Law

The anti-kickback statute makes it a criminal offense knowingly and wilfully to offer, pay, solicit, or receive any remuneration to induce referrals of items or services reimbursable by Federal health care programs. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce referrals of items or services paid for by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, in cash or in kind, directly or indirectly, covertly or overtly.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration is to obtain money for 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 (3rd Cir.), cert. denied, 476 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 health care programs or to impose civil monetary penalties for fraud, kickbacks, and other prohibited activities under sections 1128(b)(7) and 1128A(a)(7) of the Act.⁽⁹⁾

The Department has published safe harbor regulations that protect certain arrangements that might otherwise technically violate the anti-kickback statute from prosecution. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is only afforded to those arrangements that precisely meet all of the conditions set forth in the safe harbor. Notwithstanding, arrangements that do not fit squarely within a safe harbor do not necessarily violate the anti-kickback statute. See, e.g., 56 Fed. Reg. 35952, 35954 (July 29, 1991).

B. The Proposed Arrangement

1. The Stock Purchase and Assignment Agreements

Although the Proposed Arrangement involves a complex web of contracts, the basic business transaction is straightforward: the IPA is purchasing an equity interest in Company A in exchange for its physicians' long term commitment to serve as the exclusive provider panel and provide medical management services for the Company A health plans. In other words, the Shareholder Hospitals and the IPA are joint venturing in a managed care organization. Accordingly, we start by applying a joint venture analysis to the Proposed Arrangement.

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. In 1989, the OIG issued a Special Fraud Alert specifically discussing joint venture arrangements that may violate the anti-kickback statute. In general, joint ventures between physicians and hospitals in which they practice may be suspect, because distributions from the joint ventures may be disguised remuneration paid in return for referrals. Like any kickback scheme, these arrangements can lead to overutilization of services, increased costs for Federal health care programs, corruption of professional judgment, and unfair competition.

a. The Proposed Arrangement Does Not Fit the Safe Harbor for Investment Interests in Small Entities

The safe harbor for investments in small entities, 42 C.F.R. § 1001.952(a)(2), has eight elements, each of which must be satisfied in order for an arrangement to qualify for the exception. The eight elements address three areas of concern in abusive joint ventures: (i) how investors are selected and retained; (ii) the nature of the business structure; and (iii) the

financing and profit distributions. Although the Requesters have certified that the IPA's assignment of the PSAs will represent fair market value for the equity interest, the stock purchase arrangement fails to meet several of the elements of the safe harbor; in particular, all of the proposed investors will be furnishing items or services to Company A health plans, and the investment opportunity is only being offered to the IPA shareholders.

b. The Proposed Arrangement Potentially Violates the Anti-Kickback Statute

The initial question to be addressed is whether equity ownership in a managed care organization by an independent physician association may provide physicians with remuneration for referrals of their patients to the managed care organization. This Office has recognized that Congress did not intend the anti-kickback statute to bar all forms of investment or ownership in health care providers by referral sources. See, e.g., 54 Fed. Reg. 3090 (Jan. 1, 1989). Recent legislation permitting provider-sponsored organizations to enter into Medicare + Choice contracts reflects an implicit determination by Congress that physician-hospital ownership of managed care organizations is acceptable, provided such organizations comply with all relevant statutory and regulatory authorities, including the anti-kickback statute. The literal language of the anti-kickback statute encompasses any knowing or willful payment to a physician to induce the physician to recommend a health plan pursuant to which services are reimbursed by a Federal health care program. For example, payments to physicians by a health plan for marketing the plan clearly implicate the statute.

With respect to joint ventures, the major concern is that the profit distributions to investors in the joint venture that are also referral sources to the joint venture may potentially represent remuneration for those referrals. A related concern is that, where the investing parties have a referral relationship wholly apart from the joint venture, distributions from the joint venture could potentially represent remuneration to one party for referrals to the other party based on those independent relationships. In either case, the remuneration could result in increased utilization of services or increased costs to Federal health care programs. Accordingly, all aspects of all relationships between the parties must be examined.

c. Distributions from Company A to the IPA Are Unlikely to Constitute Remuneration for Referrals to Company A

Our initial inquiry is whether the distributions from the joint venture may be "disguised" remuneration to the IPA physician-shareholders for referrals of their patients to the joint venture. In other words, do the IPA's physician-shareholders refer patients to Company A's health plans and, if so, do the physicians receive remuneration for those referrals either directly or indirectly? For purposes of this opinion, we are addressing only the potential return on the IPA's equity investment in Company A, in the absence, as certified by the Requesters, of any financial arrangement or intentional effort by Company A or any of the Company A health care plans to have physicians enroll persons in the Company A plans or to have physicians encourage persons to enroll in the Company A plans.

On the threshold issue of whether a physician's recommendation of a particular health plan to a patient would potential implicate the anti-kickback statute, we recognize that in many instances a physician's ability to influence a patient's enrollment in Company A's HMO or PPO products may be limited. Unlike the referrals in many illegal joint venture arrangements, in which a physician's order almost always results in the delivery of the item or service ordered, a physician's recommendation of a health plan is only one of many factors that may influence a person's choice of an insurance plan. For example, other considerations may include (i) whether a plan is available under a patient's employer plan; (ii) the benefit package in light of the patient and other family member needs; (iii) premium and other costs; (iv) recommendations from other family members' physicians; and (v) other health plans in which the physician participates. [\(10\)](#)

With respect to Company A, most of its business is in the group health insurance market, including virtually all of its PPO business. In the group market, employers or other sponsors select the plans, and price is usually the most important consideration. With respect to such group business, a physician's ability to influence significantly plan revenues through enrollment recommendations is marginal. Accordingly, in the absence of any specific marketing efforts by the IPA's physician-shareholders to promote enrollment in Company A's group HMO and PPO plans, we do not think it likely that their recommendations, if any, would result in appreciable revenues to Company A.

With respect to individual enrollment in Company A's Medicare and Medicaid risk contracts, we believe a physician's recommendation may carry more weight. Accordingly, the second focus of our inquiry is to determine whether, assuming that a physician successfully recommends a Company D HMO to a patient, the possible return on the IPA's investment in Company A would constitute direct or indirect remuneration to the referring physician. Historically in most suspect joint ventures, there are relatively direct connections between the referral, the generation of a fee, the consequent profit to the joint venture, and the return to the referral source as dividends or otherwise. By contrast, HMOs assume significant financial risk by agreeing to provide comprehensive coverage to enrollees for a fixed price over a fixed period of time. Profitability depends on successful management of the risk and not simply on the delivery of medical services. In managed care, physician or provider support, or even high enrollment, is not sufficient to guarantee success, as demonstrated by the recent failures of a number of provider-owned managed care entities.

Certain characteristics of the IPA provide further assurance that any distributions to the IPA's shareholder-physicians are unlikely to constitute prohibited remuneration for referrals. The IPA is a pre-existing and functioning entity that has not been formed for the purpose of entering into the Proposed Arrangement. Moreover, ownership in the IPA presently is based on a *per capitashare* distribution; under the Incentive Stock Plan, future shareholdings will be based, in part, on physician assumption of risk and performance on a number of pre-set quality and performance standards, but not on referrals to Company A plans. Given these factors, the interposition of the IPA as the equity owner in Company A will further dilute any potential financial nexus between a physician's recommendation to a patient of a Company A plan and his or her return on the Company A investment. Simply put, any distribution from Company A will go to the IPA, not the physician, and will be proportional to the IPA's share of the total investment in Company A. To the extent the IPA's board distributes any monies received from Company A to the IPA's shareholders, that distribution will be based on the shareholders' share ownership in the IPA, which has no relationship to any past, present, or future referrals to Company A.

Finally, assuming that physicians can influence the selection of an HMO, the Proposed Arrangement is unlikely to result in increased costs to Federal health care programs or overutilization of services, since the Company D HMO plans provide services on a capitated basis, discouraging unnecessary services.

In sum, in the circumstances presented here, these factors -- the limited ability of physician-shareholders in the IPA to influence referrals to Company A health plans or to generate revenues through recommending Company A health plans, the interposition of an investor that is a pre-existing and functioning entity with a stock distribution structure unrelated to referrals to the investment entity, and the minimal risk of increased program costs -- significantly reduce the likelihood that the Proposed Arrangement will result in unlawful remuneration for referrals.

d. Prohibited Remuneration for Referrals Outside of Joint Venture Is Unlikely

The Shareholder Hospitals may derive a substantial amount of revenue from patients referred to them by the IPA physicians wholly apart from any Company A-related business. This raises the possibility that the joint venture may be a vehicle by which the hospitals may indirectly reward the physicians for revenues the hospitals receive as a result of the physicians' referrals of fee-for-service patients to the hospitals.

In determining whether the joint venture may be a vehicle for illegally remunerating one investor for referrals to another investor, we examine initially whether the party making the referrals receives a disproportionate return on its investment compared to the return on the investment of the party receiving the referrals. Any excess or disproportionate return on the investment may be remuneration for referrals. Based on the facts and circumstances as represented by the Requesters, all equity owners in Company A will have made substantial investments in the venture and distribution of profits will be in direct proportion to the fair market value of such investments. Thus, all investors' returns on investment will be commensurate with their undertakings; the IPA's return will not include any "unearned" remuneration to the IPA or its physician-shareholders attributable to their referrals to the Shareholder Hospitals. Accordingly, any profit distributions from Company A would not represent compensation to physicians for their referrals to the hospitals.

However, even in situations where each party's return is proportionate with its investment, the mere opportunity to

invest (and consequently receive profit distributions) may in certain circumstances constitute illegal remuneration if offered in exchange for past or future referrals. Such situations may include arrangements where one or several investors in a joint venture control a sufficiently large stream of referrals to make the venture's financial success highly likely, or where one investor has an established track record with similar ventures or the financial investment required is so small that the investors have little or no real risk. By contrast, here there are no such indicia that the Proposed Arrangement will generate any profits for its investors, since the managed care industry is highly competitive. Nor are there any indicia that the physicians control a stream of referrals to the managed care joint venture. In light of the substantial financial investment being made by the IPA, the mere opportunity to participate as an investor in Company A is unlikely to constitute remuneration for referrals from the IPA or the IPA's physicians to the Shareholder Hospitals.

2. The Ancillary Contractual Arrangements

In addition to the stock purchase and assignment agreements that effectuate the joint venture, there will be a number of ancillary agreements that obligate the parties in connection with the joint venture and therefore must be considered.

a. The Network Service Agreement

The first ancillary agreement is the ten-year Network Service Agreement, pursuant to which the IPA will become the exclusive provider of professional health care services for all managed care arrangements in which Company A participates and will develop and maintain Company A's provider networks during the term of the agreement. As consideration for the IPA's services, Company A will pay the IPA an annual fee of \$[] per covered employee in Company A's preferred provider programs. For the first five years, the fee will be no less than\$[] and no more than\$[]. The Network Service Agreement will be a full-time agreement.

The safe harbor potentially relevant to the Network Service Agreement is the personal services and management contracts safe harbor, 42 C.F.R. § 1001.952(d), which protects certain arrangements that comply with the following conditions:

- the agreement is in writing and signed by the parties;
- the agreement specifies the services to be provided;
- if the agreement is intended to be for services on a periodic, sporadic, or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals;
- the term of the agreement is for not less than one year;
- the aggregate compensation paid over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business generated between the parties for which payment may be made in whole or in part under Medicare or a State health care program; and
- the services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.

42 C.F.R. § 1001.952(d).

The Network Service Agreement does not fit into the personal services safe harbor because the aggregate compensation to be paid over the term of the agreement is not set out in advance, as required by the regulation. However, the Requesters have certified that the IPA's compensation will represent fair market value in an arms-length transaction for the services to be rendered by the IPA and will not be determined in a manner that takes into account the volume or value of business generated between the parties. Moreover, the methodology to be used to determine the amount of the compensation -- \$[] per covered PPO employee -- will be established in advance for the term of the contract and will not take into account the volume or value of business generated between the parties. Finally, for the reasons discussed above at section II.B.1.c, payments under the Network Service Agreement are not likely to be disguised payments for referrals from Company A to the IPA.

b. The Medical Management Program Agreement

The second ancillary contract is the Medical Management Program Agreement, pursuant to which the IPA would agree to arrange for its shareholder physicians to participate in the development of credentialing, utilization review, quality improvement, and case management programs and treatment protocols for Company A's managed care products. The IPA and Company A would negotiate separately the specific compensation for each medical program to be developed. As described above, the agreement would establish a detailed set of guidelines for determining the compensation for each program. These guidelines generally reflect the requirements of our personal services and management contracts safe harbor, 42 C.F.R. § 1001.952(d), and expressly provide that services to be rendered will not exceed the level of services necessary and reasonable to fulfill the business purposes of the arrangement.

The Medical Management Program Agreement lacks sufficient specificity to enable us to make a determination regarding its propriety under the anti-kickback statute. For practical purposes, it represents an agreement to agree to enter into unspecified future personal services contracts. Because physician consulting arrangements generally represent an area of significant abuse, personal services contracts for consulting services must be subject to careful, individualized scrutiny. In examining such contracts, we need to know, at a minimum, specific information about the compensation, the nature of the services to be performed, the identity of the particular physicians providing the services, and the existence of any other relationships between the parties. This information is not presently available for contracts that may be entered into pursuant to the Medical Management Program Agreement. Accordingly, we express no opinion with respect to the Medical Management Program Agreement; agreements entered into in accordance with its terms may be subject to sanction if they violate the anti-kickback statute. However, such agreements may be protected to the extent they comply with the personal services and management contracts safe harbor.

c. The Administrative Services Agreement

The third ancillary contract is the Administrative Services Agreement. Under this agreement, the IPA will pay Company A \$[] annually per network physician with an executed PSA for performing certain designated services specified in the Agreement, such as credentialing and office administration, for the IPA and its physicians. The term of the contract will be ten years.

The analysis of the Administrative Services Agreement is the same as the Network Service Agreement described above. The contract does not meet the personal services safe harbor because the aggregate compensation to be paid for the term of the agreement is not set out in advance; rather, the compensation will vary over time based on the number of the IPA physicians in the network. Nevertheless, the Requesters have certified that the compensation to be paid under the Agreement will represent fair market value and will not take into account the value or volume of business generated between the parties, and the methodology to be used to determine the amount of the compensation -- \$[] per network physician -- will be established in advance and will not take into account the value or volume of business generated between the parties. Also for reasons discussed above, the payments are not likely to be disguised remuneration for referrals.

d. The IPA Incentive Stock Plan

Integral to the joint venture arrangement is the Incentive Stock Plan to be offered by the IPA to its shareholder physicians. Under the Plan, the IPA will grant additional shares of the IPA stock to shareholder physicians who have executed a PSA with the IPA and who meet specified performance goals related to quality of HMO services, acceptance of HMO risk arrangements, and total number of HMO patients. The goal of the Plan is to create incentives for physician shareholders to act in a manner that will contribute to the success of Company A, thereby benefitting the IPA.

The Incentive Stock Plan will not implicate the anti-kickback statute, since the physicians receiving the stock are not in a position to refer business to the IPA, an IPA that does not provide items or services reimbursable by a Federal health care program. Nor could the receipt of such stock be construed as indirect remuneration from Company A in exchange for referrals; eligibility for additional the IPA stock is tied not to referrals to the managed care organization, but to the assumption of risk by physicians and to measures of enrollee satisfaction.

e. Provider Reimbursement for Services to Company A Plans' Enrollees

The Requesters have certified that all payments to physicians and hospitals providing health care services to enrollees of the various Company A plans will be at fair market value based on arms-length transactions and will not take into account the volume or value of referrals to, or other business with, Company A or with any of its participating hospitals or physicians. Accordingly, we need not address the possibility that physicians might provide services for some Company A products at below market prices in exchange for the opportunity to obtain more remunerative business reimbursable by a Federal health care program. Similarly, we need not address whether the Shareholder Hospitals may cause Company A to pay physicians above fair market rates for services to plan enrollees in order to induce the physicians to refer their fee-for-service Medicare or other Federal health care program business to the Shareholder Hospitals.

III. CONCLUSION

In sum, for the reasons stated above, we conclude that the Proposed Arrangement, considered in its totality, poses no more than a minimal risk of fraud and abuse. Accordingly, based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the OIG will not subject the Proposed Arrangement to sanctions arising under the anti-kickback statute pursuant to sections 1128(b)(7) or 1128A(a)(7) of the Act, provided that all compensation in connection with the Proposed Arrangement is fair market value as certified by the Requesters.⁽¹¹⁾ We express no opinion about the Medical Management Services Agreement (or any agreement entered into in accordance with its terms) or about any arrangement disclosed in the Requesters' request letter other than the Proposed Arrangement.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to Company A and Company B, the Requesters of this opinion.
- This advisory opinion has no application, and cannot be relied upon, by any other individual or entity.
- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a Requester to this opinion.
- This advisory opinion is applicable only to the statutory provisions specifically noted above and to their application to those arrangements specifically included in the definitions of the Proposed Arrangement contained in this advisory opinion. 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 advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those that appear similar in nature or scope.
- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

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

The OIG will not proceed against the Requesters with respect to any action that is part of the Proposed Arrangement taken in good faith reliance upon this advisory opinion as long as all of the material facts have been fully, completely, and accurately presented, all compensation under the Proposed Arrangement is consistent with fair market value, and the Proposed Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the Requesters with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented, where all compensation under the Proposed Arrangement constitutes fair market value, and where such action was promptly discontinued upon notification of the

modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/s/

D. McCarty Thornton

Chief Counsel to the Inspector General

FOOTNOTES:

1. For purposes of this advisory opinion, Company A and the IPA are the "Requesters".
2. In addition, Company A is the parent of an offshore reinsurance company and a management services organization, which are not involved in the Proposed Arrangement. The management services organization has no employees or current business, and Company A has no plans to develop business for the management company and is considering selling its name to a third party.
3. The PPO network presently is comprised of approximately 42 area hospitals.
4. We express no opinion regarding any access fees paid by these hospitals to the P.O.
5. We express no opinion with respect to the legality of any existing or proposed PSA.
6. As described above, these PSAs will be assigned to Company A as part of the stock purchase transaction.
7. For purposes of the Network Service Agreement, a prohibited affiliation generally means employment of a provider by a competing managed care entity or a provider's ownership interest in a competing health care entity, unless such ownership interest is no more than []% of a publicly traded competing managed care entity's total outstanding equity.
8. Physicians who are not eligible to participate in the Incentive Stock Plan will enter into one-year PSAs with the IPA (renewable at Company A's discretion) and, among other things, will be required (i) to have active medical staff privileges at a Company A-affiliated hospital; (ii) to meet a specific market area or practice area business need, as determined by Company A, the PPO, or the HMO; and (iii) to participate in all Company A health plans, subject to Company A, PPO, or HMO approval based on specific plan needs.
9. 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.
10. The IPA physicians participate in a number of health care delivery systems that compete with Company A plans. Thus, a patient will sometimes have a choice of plans that include his or her preferred physician. In addition, factors other than ownership in a particular plan, such as payment levels, could inform a physician's recommendation of one or another plan in which he or she participates.
11. We are not authorized to opine on "fair market value." See section 1128D(b)(3) of the Act. Therefore, for purposes of this opinion, we have assumed fair market value compensation based on the Requesters' certifications. If the compensation under the Proposed Arrangement is not at fair market value, this opinion will be without force and effect.