

October 6, 1997

[Names and addresses of Requestors have been redacted]

Re: Advisory Opinion No. 97-5

Dear Sirs:

We are writing in response to your request for an advisory opinion on behalf of Radiology Group X and Hospital System A. The request asks whether an outpatient radiology imaging center joint venture owned by a medical group specializing in radiology and a hospital care provider (i) generates prohibited remuneration within the meaning of the anti-kickback statute, Section 1128B of the Social Security Act ("Act"); (ii) constitutes grounds for the imposition of an exclusion under Section 1128(b)(7) of the Act (as it applies to kickbacks); (iii) constitutes grounds for criminal sanctions under Section 1128B(b) of the Act; and/or (iv) satisfies the criteria set out in Section 1128B(b)(3) of the Act or associated regulations, 42 C.F.R. § 1001.952.

Radiology Group X and Hospital System A have certified that all of the information provided in the request, including all supplementary letters, is true and correct, and constitutes a complete description of the relevant facts and agreements among the parties regarding the joint venture ("Proposed Arrangement"). Radiology Group X and Hospital System A have also certified that upon our approval, they will undertake to effectuate the Proposed Arrangement.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed, this opinion is without force and effect.

Based on the information provided and subject to certain conditions described below, we have determined that the Proposed Arrangement does not meet any of the statutory or regulatory safe harbors set out in Section 1128B(b)(3) of the Act or 42 C.F.R. § 1001.952. However, we also conclude that the Proposed Arrangement would not generate prohibited remuneration within the meaning of the anti-kickback statute, Section

1128B of the Act, and therefore, does not constitute grounds for the imposition of either an exclusion under Section 1128(b)(7) of the Act (as it applies to kickbacks) or criminal sanctions under Section 1128B(b) of the Act.

This opinion may not be relied on by any person or entity other than the addressees and is further qualified as set out in Part III below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

Radiology Group X and Hospital System A have made the following representations with respect to the Proposed Arrangement. Radiology Group X and Hospital System A are collectively the "Requestors".

A. Parties to the Proposed Arrangement.

Hospital System A. Hospital System A operates three hospitals in State C: Hospital 1, Hospital 2, and Hospital 3. Hospital 1, located in State C, is licensed for 351 beds and is the largest hospital in the several counties surrounding City D. Hospital 1 has a full range of radiological equipment at its facility, including a CT scanner, ultrasound equipment, fluoroscopic radiographic equipment, nuclear radiographic equipment, and magnetic resonance imaging ("MRI") equipment. Hospital 1 will continue to operate its radiology department after the Proposed Arrangement is implemented.

Hospital System A employs three physicians directly or through its subsidiary organizations. These physicians will not make referrals to the Proposed Arrangement's joint venture imaging center, nor will any such referrals be accepted if made.

Radiology Group X. Radiology Group X is a medical group specializing in radiology. It is a State C professional corporation owned and controlled by five radiologists. Dr. Y, serves as the President of Radiology Group X.

The shareholders of Radiology Group X are also the members of Radiology Group X's affiliate, Company Z. Ownership and control interests in Radiology Group X and Company Z are identical. Company Z is a newly-formed State C limited liability company and one of the members of the Proposed Arrangement's joint venture company, Imaging Center [defined below].

Current Relationship Between Radiology Group X and Hospital 1. Radiology Group X and Hospital 1 have represented that they have an informal, unwritten arrangement whereby Radiology Group X provides professional radiology services to the hospital, while hospital employees provide the technical services. The hospital owns all of the radiological equipment and is responsible for employing qualified technicians. As part of

this arrangement, Radiology Group X's president, Dr. Y, serves as Hospital 1's Director of the Department of Radiology. His duties are set forth in the hospital's Medical and Dental Staff By-Laws. In addition, Hospital 1 provides Radiology Group X with space in its facility to perform radiologic interpretations.¹

While there is no written agreement, the hospital has certified that the fair market value of the space used by Radiology Group X is substantially equal to the fair market value for compensation of Dr. Y's duties as the Director of the Department of Radiology. Further, the arrangements whereby Radiology Group X and Dr. Y provide services to Hospital 1 and Hospital 1 provides Radiology Group X with space in its facility are separate from, and not dependent on, the terms and conditions of the Proposed Arrangement.

B. Proposed Arrangement.

Radiology Group X, through its affiliate Company Z, and Hospital System A have proposed to enter into a joint venture to establish an outpatient radiology imaging center ("Imaging Center"). The Imaging Center will be located in the Village of E, at the western edge of City D. The Imaging Center will offer a full range of state-of-the-art imaging techniques, including X-ray equipment, fluoroscope equipment, a superconducting open MRI system, a computerized tomography scanner, and an ultrasound system.

The Imaging Center will be owned and operated by a State C limited liability company, Company B. The members of Company B will be Company Z and Hospital System A. Company Z and Hospital System A will make capital contributions of \$204,000 and \$196,000, respectively. In return, each member will receive voting and distribution rights proportional to its investment. Additional capital contributions will be apportioned to Company Z and Hospital System A based upon their respective ownership interests.²

¹ Radiology Group X does not have any non-hospital based office space.

² If either member of Company B is unable or unwilling to make any part of an additional capital contribution, the other member has a right to make up the difference, treat such amount as either an additional capital contribution or as a loan, and adjust the

The Imaging Center will be staffed by employees hired by Company B. Radiology Group X radiologists will be the exclusive providers of professional services to the Imaging Center. The president of Radiology Group X, or his designee, will be in charge of supervising and administering all aspects of the clinical services rendered at the Imaging Center, including quality assurance. The Radiology Group X radiologists will not be employees of the Imaging Center, but will enter into a service provider agreement with Company B. Under the service agreement, Radiology Group X will not receive any compensation from the Imaging Center. Radiology Group X will bill patients and third-party payers, including Medicare and Medicaid, for the professional component of radiological services directly. The Imaging Center will bill separately its technical component to patients and third-party payers.

II. LEGAL ANALYSIS

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit or receive any remuneration to induce referrals of items or services reimbursed by Federal health care programs. 42 U.S.C. § 1320a-7b(b). Where remuneration is paid purposefully in exchange for referrals of items or services paid for by a Federal health care program, the kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible “kickback” transaction.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration is 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, 476 U.S. 988 (1985). Violations of the statute constitute 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.

The Office of Inspector General may also initiate an administrative proceeding to exclude an individual from Federal health care programs for fraud, kickbacks and other prohibited activities. Section 1128(b)(7) of the Act. Because both the criminal and administrative

proportional percentages of ownership accordingly. For purposes of this opinion, we have assumed that any loan would be at fair market value.

sanctions related to the Proposed Arrangement are based on the anti-kickback statute, the analysis is the same under either provision.

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 Office of Inspector General issued a “Special Fraud Alert” specifically discussing joint venture arrangements that may violate the anti-kickback statute.³ In general, joint ventures between radiologists and health care providers in a position to order imaging services 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 such services, increased costs for Federal health care programs, corruption of professional judgment, and unfair competition.

A. The Proposed Joint Venture Does Not Meet the Safe Harbor For Investment Interests in Small Entities.

In 1991, the Department of Health and Human Services (“Department”) published safe harbor regulations which define practices that are not subject to the anti-kickback statute because such arrangements 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. Rather, the safe harbors set forth specific conditions that, if fully met, would assure the entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. The only safe harbor regulation potentially available to the Proposed Arrangement addresses investment interests in small entities. See 42 C.F.R. § 1001.952(a)(2).⁴

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. 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. The eight elements are:

³ See Special Fraud Alert, “Joint Venture Arrangements” (OIG-89-4), reprinted in 59 Fed. Reg. 65373 (December 19, 1994).

⁴ The Requestors had suggested that the “shared risk” statutory exception to the anti-kickback statute added by Section 216 of the Health Insurance Portability and Accountability Act, Pub. Law No. 104-191 (Aug. 21, 1996), potentially applied. That provision, however, applies only to contractual arrangements where a person supplying items or services is at risk for the cost or utilization of such items or services and is obligated to provide them, as in some managed care contracts.

- no more than forty percent of the investment interests may be held by investors who are in a position to make or influence referrals, furnish items or services, or generate business (“Interested Investors”);
- interests offered to passive investors who are Interested Investors cannot be made on terms different from those offered to other investors;
- the terms on which an investment is offered to Interested Investors cannot take into account any previous or expected volume of referrals, services furnished, or amount of business generated from such investors;
- there is no requirement that a passive investor make referrals to, or otherwise generate business for, the entity as a condition of remaining an investor;
- the entity cannot market or furnish the items or services differently to passive investors and non-investors;
- no more than forty percent of the gross revenue of the entity may come from Interested Investors;
- the entity cannot loan or guarantee funds to an Interested Investor if the loan or guarantee is used to obtain the investment interest; and
- an investor’s return on investment must be directly proportional to the amount of capital investment of that investor.

Strict compliance with all elements is required. See 56 Fed. Reg. 35952, 35954 (July 29, 1991).

The Proposed Arrangement fails to meet at least one of the eight elements. More than 40% of the investment interest is owned by persons who furnish items or services to the new venture; Radiology Group X owns 51% of the entity and will provide the professional services to the venture. Accordingly, the Proposed Arrangement does not meet the only relevant safe harbor.

B. The Proposed Arrangement Will Not Result in Prohibited Remuneration.

Even though the Proposed Arrangement does not fall within a safe harbor, it does not necessarily violate the anti-kickback statute. With respect to joint ventures, the 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. 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. Accordingly, all aspects of all relationships between the parties must be examined.

1. There Is No Prohibited Remuneration For Referrals To The Imaging Center.

Our initial inquiry is whether the distributions from the joint venture may be “disguised” remuneration for referrals by the investors to the joint venture. Based upon the information and representations provided, we find that neither Radiology Group X nor Hospital System A will be able to generate referrals to the joint venture.

A threshold issue is the proper characterization of Hospital System A’s role in relationship to the joint venture. In many instances, hospitals are capable of influencing, and do influence, referrals to other health care providers, such as through discharge planning with respect to post-discharge care. In addition, hospitals are in a position to influence the flow of radiology work performed at the hospital, because the hospital controls to whom radiologic interpretations are referred. See Financial Arrangements Between Hospitals and Hospital-Based Physicians, OEI-09-89-00330, 1991. In this instance, however, and subject to the conditions set out below, we do not believe that the Hospital System A hospitals will be able to generate referrals to the Imaging Center.

First, Hospital System A has represented that its employed physicians will make no referrals to the Imaging Center, and the Imaging Center will not accept any referrals from those physicians. Second, Hospital System A has agreed that it will take no actions, either overt or covert, financial or otherwise, to induce its medical staff (i.e., any physician with admitting or staff privileges) to use the Imaging Center. Third, Hospital System A has agreed that it will inform the medical staff of the preceding agreement. Fourth, physician referrals to the Imaging Center will not be tracked by Hospital System A, its hospitals, Company Z, or Radiology Group X. Fifth, Hospital System A hospitals will continue to operate and use their own radiology units. In these circumstances, referrals from physicians with admitting or staff privileges at the Hospital System A hospitals would not be attributable to Hospital System A.

Moreover, the Radiology Group X radiologists are also unlikely to be able to generate an appreciable number of referrals to the Imaging Center. In general, radiologists do not order the radiological tests they perform; such tests are ordered by a patient’s attending

physician. Although there may be situations in which a radiologist can recommend additional testing to the attending physician during the course of a consultation and, as a practical matter, indirectly generate some additional business, those tests must be approved by the patient's attending physician.⁵ In these limited circumstances -- the recommendation of additional testing by a radiologist to an attending physician with whom the radiologist has no financial arrangements and pursuant to a bona fide medical consultation -- we conclude that a Radiology Group X radiologist's recommendation is not prohibited under the anti-kickback statute.⁶

In sum, since neither Radiology Group X nor Hospital System A will be in a position to generate or influence an appreciable number of referrals to the Imaging Center, the

⁵ See 61 Fed. Reg. 59490, 59497 (November 22, 1996) (with respect to when Medicare will cover diagnostic tests, the Health Care Financing Administration has stated, "we believe that the physician interpreting the diagnostic tests has an obligation to discuss any changes in or additions to the original order with the patient's physician.").

⁶ Radiology Group X radiologists receive no remuneration from patients' attending physicians, and none of the attending physicians which refer to Radiology Group X have any financial relationships with Radiology Group X.

distributions of any profits would not constitute illegal remuneration in exchange for referrals.

2. There Is No Prohibited Remuneration For Referrals Outside Of The Joint Venture.

Radiology Group X derives a substantial amount of its revenues from its position as the exclusive provider of professional radiology services for Hospital 1.⁷ This raises the possibility that the joint venture may be a vehicle by which Radiology Group X may indirectly reward Hospital System A for revenues Radiology Group X receives as a result of its arrangement with Hospital 1.⁸

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 Radiology Group X and Hospital System A, both parties have made substantial financial investments in the venture, and control of the venture and

⁷ Radiology Group X radiologists are not in a position to make referrals to the Hospital System A hospitals for the same reasons that they cannot make appreciable referrals to the Imaging Center. Accordingly, the potential profit distributions from the Imaging Center to the Radiology Group X radiologists would not represent disguised remuneration for any possible referrals to Hospital System A hospitals.

⁸ Specific problems with financial arrangements between hospital-based physicians, such as radiologists, and hospitals were discussed in a 1991 Management Advisory Report entitled Financial Arrangements Between Hospitals and Hospital-Based Physicians, OEI-09-89-00330 (1991).

distribution of profits will be in direct proportion to such investments. Thus, both parties' return on investment is commensurate with their undertakings and would not appear to include any "unearned" remuneration to Hospital 1 attributable to its arrangements with Radiology Group X. Accordingly, any profit distributions from the Proposed Arrangement would not appear to represent compensation to Hospital System A or Hospital 1 for their referrals to Radiology Group X.

Moreover, based on the representations by Radiology Group X and Hospital System A that the value of the premises and equipment provided to Radiology Group X are substantially equal to the value of Dr. Y's services to Hospital 1, we conclude that any profit distribution from the Imaging Center will not represent illegal remuneration for the use of space and equipment at Hospital 1.⁹

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, there are no such indicia that the Proposed Arrangement will generate any profits for its investors, since neither party is in a position to influence appreciable referrals to the joint venture nor has successfully operated a freestanding imaging center before. In light of the substantial financial investment being made by Hospital System A, we find no evidence that the mere opportunity to participate as an investor in the Imaging Center constitutes illegal remuneration to Hospital System A.

III. CONCLUSION

For the above reasons, we have determined that the Proposed Arrangement does not contain any prohibited remuneration within the meaning of the anti-kickback statute,

⁹ We are not, however, making any independent finding as to the legality of the current arrangement between Radiology Group X and Hospital 1.

1128B of the Social Security Act (“Act”), and consequently does not constitute grounds for the imposition of either an exclusion under section 1128(b)(7) of the Act (as it applies to kickbacks) or criminal sanction under 1128B(b) of the Act.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to the Radiology Group X and Hospital System A, which are the Requestors 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 Requestor to this opinion.
- This advisory opinion is applicable only to the statutory provisions 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, including any laws relating to insurance or insurance contracts.
- 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 prospective only. It has no application to conduct which precedes the date of this opinion.
- This advisory opinion does not make any determination as to whether any amounts paid by one party to another are representative of fair market value.
- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope.

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 Requestors with respect to any action taken in good faith reliance upon this advisory opinion as long as all of the material facts have been fully, completely, and accurately presented, and the 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, modify or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the Requestors 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 and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion.

Sincerely,

/S/

D. McCarty Thornton
Chief Counsel to the Inspector General