MEMORANDUM

TO: HEALTH CARE CLIENTS

DATE: June 9, 2003

RE: OIG Advisory Opinion No. 03-12: Radiology Group and Medical Center Joint Venture Imaging Facility

I. INTRODUCTION

The Office of the Inspector General ("OIG") of the Department of Health and Human Services has issued a new Advisory Opinion, No. 03-12 ("AO 03-12"), which addresses a proposed joint venture imaging center between a radiology group and a medical center. The proposed joint venture is similar in some respects to the proposal in Advisory Opinion No. 97-5 ("AO 97-5"). The combination of these two advisory opinions provides insight into how the OIG might analyze other joint venture arrangements between hospitals and radiology groups and indicates that differently-formed arrangements can survive scrutiny under the anti-kickback statute.

II. THE PROPOSED ARRANGEMENT

In AO 03-12, the proposal is for a joint venture open MRI imaging center ("Imaging Center") between an acute care hospital ("Medical Center") and a radiology group ("Radiology Group"). The details regarding these participants in the Imaging Center are as follows. The Medical Center is a wholly-owned subsidiary of a health care system that also includes provider-based clinics. The Medical Center and its affiliated clinics have relationships with referring physicians, whether employees, independent contractors, or medical staff. The Medical Center owns and operates a radiology department that furnishes radiology services to inpatients and outpatients. (It is not clear from AO 03-12 whether any of the clinics themselves furnish radiology services, or if it is only the Medical Center that furnishes those services.)

The Radiology Group consists of both a physician group practice and a separate holding company that is formed for the purpose of investing in the Imaging Center. The Radiology Group is the exclusive provider of professional radiology services for the Medical Center and its affiliated clinics. For the affiliated clinic patients, the Radiology Group accepts a fee for service that represents fair market value and the Medical Center bills payers globally for any technical and professional component services. (AO 03-12 does not clearly indicate the extent to which the clinics themselves bill payers for any professional or technical component services under reassignment.) For the Medical Center’s hospital inpatients and outpatients, the Radiology Group bills payers directly for any professional component services, and the Medical Center bills payers for any technical component services.

The Imaging Center will be owned 51% by the Medical Center and 49% by the Radiology Group. Profits and losses of the Imaging Center will be distributed according to those percentages, which are based upon capital contributions. The Medical Center will enter into a staffing agreement with the Imaging Center by which it will provide full time clerical staff and technical staff, and a part time administrator. In exchange for the staff and administrative services, the Medical Center will receive payment equal to its own payroll expenses for those personnel, prorated for the part time administrator. This payment will constitute fair market value. The Radiology Group will enter into an exclusive professional services agreement with the Imaging Center and will bill payers directly for any professional component of services furnished to patients of the Imaging Center. The Radiology Group will sublease equipment (which it leases from a third party), including the open MRI equipment, to the Imaging Center. The Radiology Group will assign its own lease for certain space (which it leases from a third party) to the Imaging Center. The equipment sublease and the assigned space lease will be “pass-through” arrangements whereby the Imaging Center will assume the terms of those leases. The payments under those leases will be fair market value.

III. DISCUSSION OF OIG ANALYSIS

The Imaging Center arrangement does not meet any applicable anti-kickback safe harbors. However, the OIG identified various factors in the proposed arrangement of the Imaging Center that weighed against the imposition of administrative sanctions for remuneration made illegal by the anti-kickback statute, detailed as follows:

? The Radiology Group is not a referral source for either the Imaging Center or the Medical Center and its affiliated clinics. This proposition derives from the OIG’s acknowledgment that radiologists typically do not order the tests that they perform and
that, except for limited circumstances, any additional tests that they do recommend for a Medicare beneficiary must be approved by the patient’s treating physician.  

Even though the Medical Center is in a position to direct or influence referrals to the Imaging Center, it will take steps to lessen its ability to do so. These steps are as follows: (1) refraining from any action to require or encourage its affiliated physicians to refer to the Imaging Center, (2) not tracking referrals made by its affiliated physicians to the Imaging Center, and (3) compensation paid to its affiliated physicians will be fair market value in arm’s length transactions and will not be related directly or indirectly to the volume or value of referrals or other business generated by such physicians to or for the Imaging Facility. The Medical Center would notify all affiliated physicians of these three measures annually.  

In addition to the preceding measures, less than 10% of the Imaging Center’s referrals would come from the Medical Center or any physicians employed by the Medical Center. (It is not clear in AO 03-12 what is meant by referrals “from the Medical Center.” Presumably, this refers to referrals by physicians affiliated with the Medical Center or the clinics other than as employees, such as medical staff or independent contractors. There also is no indication of the basis for the “less than 10%” figure.)  

The Medical Center would continue to own and operate its own radiology department. (AO 03-12 takes note of the fact that the Imaging Center will be the only open MRI facility within the service area of the Medical Center. Even though an open MRI may serve a unique patient population, it still is a service that would compete with the Medical Center’s own traditional MRI services with respect to Medicare reimbursement.)  

The return on the investments in the Imaging Center of the Medical Center and the Radiology Group will be proportional to their capital investments and will not be based upon the previous or expected volume or value of referrals, services furnished, or the amount of business that might otherwise be generated from either investor to the Imaging Center.  

The Imaging Center will not pay the Radiology Group for the professional radiology services because the Radiology Group will independently bill payers for any professional component of those services.  

The compensation paid from the Imaging Center to the Radiology Group under the equipment sublease and assigned space lease, and to the Medical Center under the staff lease, will be fair market value in arm’s-length transactions and will not exceed the expenses incurred by the Radiology Group or the Medical Center in fulfilling any of its duties with respect to those arrangements. Stated differently, the Radiology Group would not be providing equipment or space to the Imaging Center at less than fair market value, and the Medical Center will not be compensated at greater than fair market value for the provision of clerical, technical, and administrative personnel.  

The OIG references Medicare Carriers Manual § 15021, which details the circumstances under which a radiologist may furnish additional diagnostic tests in a non-hospital setting without the treating physician’s approval.
Another factor noted by the OIG but not emphasized as weighing against the potential imposition of administrative sanctions is that none of the capital contributed by the Medical Center or the Radiology Group to the Imaging Center is made with funds loaned from or guaranteed by the Imaging Center, any direct or indirect investor, or any individual or entity acting on behalf of the Imaging Center or any direct or indirect investor.

IV. PREVIOUS OIG ADVISORY OPINION 97-5

AO 97-5 also addressed a joint venture imaging center between a radiology group and a hospital. The details of the proposed arrangement in AO 97-5 differ from AO 03-12, as does the focus of the OIG’s analysis of the proposed arrangement.

The entities in AO 97-5 are as follows. There is a hospital system (“System”) that consists of three hospitals. One of those hospitals has its own radiology department. The System employs three physicians. AO 97-5 does not make clear the extent of any relationships that the System has with other physicians such as independent contractors and medical staff. The System will be a member of the joint venture imaging center (“Center”). There also is a radiology group (“Group”) whose physician members also are members of an affiliated company (“Company”) that will be a member of the Center.

The Group is based in the System’s office space, which the System provides as fair market value compensation for the Group’s provision of Departmental Director services to the System. The Group provides professional radiology services to the System’s patients, while the System provides the technical radiology equipment, personnel, and services. Presumably, the Group bills payers for any professional component services and the System bills payers for any technical component services.

The Center would be owned 49% by the System and 51% by the Group. The Center, like the System’s own radiology department, would offer a full range of radiology services. The Group would be the exclusive provider of professional services to the Center, and would itself bill payers for any professional component services. The Center would bill payers for any technical component services.

Although the arrangement of the Center does not meet any anti-kickback safe harbors, the OIG concludes that it would not impose administrative sanctions as a result thereof. The OIG’s rationale for this conclusion is as follows. As in AO 03-12, the OIG concludes that the Group is not a source of referrals for the Center. Similarly, while acknowledging that the System could be a source of referrals to the Center, the OIG notes certain safeguards against the System being such a referral source, as follows: (1) referrals from physicians employed by the System to the Center would not be made, nor would the Center accept such referrals (this restriction is not present in the arrangement in AO 03-12); (2) with respect to staff or admitting physicians, the System would not induce them to refer patients to the Center; (3) physicians would be informed of such restrictions and lack of encouragement; (4) any
referrals that were made by System physicians to the Center would not be tracked; and (5) the System would continue to operate all of its own radiology departments. (Note that in this AO 97-5, it is clear that the Center and the System’s own radiology departments would provide a full range of competing radiology services, whereas in AO 03-12 the Imaging Center’s open MRI services competed with only one modality of the Medical Center’s radiology services.) On the basis of the foregoing, the OIG concludes that neither the System nor the Group would be a source of referrals to the Center that would be a basis for asserting that a profit distribution from the Center constituted prohibited remuneration.

The OIG also focuses on the direct relationship between the Group and the System by which the System is able to influence the referrals of professional component radiology services to the Group, and the possibility that profit distributions from the Center could be an indirect form of prohibited remuneration from the Group to the System. The OIG notes that the profit distributions from the Center to the System and the Group are proportionate to each of their investments in the Center. It also notes that there are not indications that the mere opportunity to invest in the Center and derive profits constitutes prohibited remuneration, since the System’s capital investment is substantial and brings with it genuine business risk. In addition to the profit distributions from the Center, the OIG focuses on the provision by the Group of Departmental Director services to the System. Since the compensation in the form of office space for the Group is commensurate with fair market value, the OIG concludes that the services would not constitute prohibited remuneration.

V. ANALYSIS AND CONCLUSION

In a joint venture imaging center between a hospital and a radiology group, the OIG indicates that the hospital is properly considered a referral source for the imaging center and/or the radiology group, while the radiology group is not properly considered a referral source for either of them, despite radiologists’ limited ability to independently initiate diagnostic tests for Medicare beneficiaries. The imaging center likewise is not a referral source. Therefore, any risk of prohibited remuneration would most likely arise from the flow of remuneration, whether direct or indirect, from either the radiology group or the imaging center to the hospital.

Profit distributions from the imaging center to the hospital that proportionately exceed the hospital’s capital contribution to the imaging center could constitute illegal remuneration indirectly from the radiology group or directly from the imaging center.

Likewise, the provision of services from the radiology group or the imaging center to the hospital at less than fair market value, or the provision of services to the imaging center (e.g., clerical, technical, or administrative personnel) or the radiology group by the hospital at greater than fair market value, could constitute such illegal remuneration. The OIG’s scrutiny of relationships ancillary to the joint venture that could serve as conduits for prohibited remuneration, especially those in which the hospital
is compensated by the imaging center, indicates that these relationships should be very carefully
negotiated and constructed. The goal is to minimize the perception that such relationships are designed
for the radiology group to reward the hospital for its referrals to the imaging center (from which the
radiology group gets economic benefit from professional component reimbursements and the
distributions of technical component revenue), as well as to the radiology group as the provider of
professional services in the hospital (from which the radiology group gets economic benefit from its
professional component reimbursements).

AO 03-12 provides an example of the OIG’s analysis as applied to a joint venture with additional
ancillary relationships other than the simple investment. It demonstrates that each relationship must be
analyzed separately. It also demonstrates that the approval of arrangements that are highly restrictive of
referrals does not necessarily mean that arrangements with less restriction of referrals would not be
approved. This is because the stringent self-imposed limits on hospital referrals from AO 97-5 are not
present in AO 03-12, with the same result that the OIG decides that it would not impose sanctions. One
could tentatively conclude that active restrictions of referrals are not necessary, and that neutral non-
encouragement of referrals would suffice. An even more tentative conclusion could be drawn that
referrals could be encouraged, but not tracked, provided that any remuneration flowing to the source of
those referrals was commensurate with fair market value for services rendered or proportionate to a
capital contribution.

At any rate, both AO 97-5 and 03-12 indicate that sufficient flexibility exists in the anti-kickback
statute to permit carefully structured joint ventures between hospitals and radiologists that can operate as
a viable independent business.

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Please contact Thomas W. Greeson (703/641-4242, tgreeson@reedsmith.com) or any other Reed
Smith health care attorney with whom you work if you would like additional information or if you have
any questions.

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