OIG Will Not Sanction Existing Rural MRI Joint Venture

On June 23, the OIG released another advisory opinion (Opinion) on joint ventures, approving the investment interests of a hospital-physician joint venture in a 13-year-old freestanding magnetic resonance imaging facility (MRI Facility) located on the campus of a rural community hospital (Proposed Arrangement). In this Opinion, the OIG:

- Approved joint venture investment interests retroactive to the initial investments in 1990;
- Indicated that compliance with past OIG guidance offers some protection to entities seeking Advisory Opinions for existing arrangements; and
- Permitted an MRI joint venture where a hospital was both a significant investor and significant referral source for the facility. In making its determination, the OIG relied on: (i) the presence of “indicia of a legitimate, bona fide business,” (ii) the likelihood of substantial community benefit, and (iii) certification that ancillary agreements complied with applicable safe harbors. In particular, the OIG noted that under the Proposed Arrangement, interested investors generate less than 40 percent of MRI Facility revenue, disinterested investors own a significant percentage (30 percent) of MRI Facility, investment interests were offered on the same terms and conditions to all potential investors, and returns on investments always have been and will continue to be based on capital contributions.

While the OIG determined that the Proposed Arrangement could potentially generate prohibited remuneration under the Anti-Kickback Statute and did not meet applicable safe harbors, the OIG declined to impose civil monetary penalties (CMPs) or administrative sanctions on the parties related to their past or present investment interests given the benefits to the rural community MRI Facility serves and given the limited risk that the arrangement disguised kickbacks to its participants.

Impact on Health Care Entities

This Opinion is notable for its insights into the Advisory Opinion process as well as its specific guidance on joint ventures.
Second, the OIG indicates that compliance with past guidance provides some protection to arrangements. Here, the Proposed Arrangement was approved when it complied with rural entity guidance from 1989 and proposed safe harbor guidance from 1993 (though not with the final safe harbor guidance issued in 1999). The OIG indicated that compliance with a proposed safe harbor is not determinative, but gives some legitimacy to the validity of an arrangement.

Finally, in contrast to its May 2003 Advisory Opinion on MRI Joint Ventures [see Client Alert 313], the OIG did not focus on the efforts of a participant hospital to limit the ability of it or of its physicians to refer to the MRI facility. In the May 2003 Opinion, the hospital certified that it would provide less than 10 percent of the referrals for the facility, would continue to operate its own radiology department and would take steps to limit referrals by its physicians. Here, the participant hospital is both a 30 percent owner and a source of 24 percent of referrals for MRI Facility. Nonetheless, the OIG approved the arrangement, relying on indicia that the arrangement was a bona fide business (e.g., characterized by disinterested investor ownership, return on investment based on capital contributions, etc.), rather than a front for kickbacks, to determine that the arrangement presented low fraud and abuse risk. The OIG also emphasized the important service provided by MRI Facility in its rural area.

Joint ventures remain a tricky area under current regulatory guidance. Entities considering such arrangements should consult counsel to analyze the risk under the Anti-Kickback Statute and other fraud and abuse laws.

The Proposed Arrangement

The freestanding MRI Facility has been owned and operated by a limited partnership in a three-county rural area since 1990. The rural area is not designated as a medically underserved area (MUA) under federal law. Nonetheless, when the MRI facility was established, no MRI services were available in the three-county area. Currently, other MRI services are available, but the nearest comparable facility is 20 miles from the town in which MRI Facility is located. The parties have certified that loss of MRI Facility would be a hardship for poor and elderly members of the community who would have to travel much farther for similar services.

When initially established, capital for MRI Facility was raised by offering limited partnership interests to all members of the medical community in the three-county area (regardless of hospital affiliation) and to all former members of the boards of directors of all three area hospitals. The investment interest was offered to all potential investors at a flat per unit price and on the same terms and conditions, regardless of referral capability. Likewise, under the limited partnership agreement, returns on the investments have been, are and will continue to be directly proportional to capital contributions.

Currently, 30 percent of MRI Facility is owned by a local nonprofit hospital (Hospital) and its related foundation (Foundation), 30 percent is owned by parties in a position to influence or generate referrals and 40 percent is owned by parties who are not in a position to influence or generate referrals (because they either practice or have retired from practicing the specialty of radiology).

In 2000 and 2001, investors generated approximately 37 percent of MRI Facility’s revenue (24 percent from Hospital under a contract for MRI Facility to provide MRI services to Hospital patients and 13 percent from interested physicians) and disinterested parties generated the remaining revenues. MRI Facility does not provide information on sources of referrals to investors, other than indicating aggregate number of referrals from interested and disinterested investors.
MRI Facility is located on Hospital campus pursuant to a lease and is managed by a radiology group practice that provides radiology and clinical operational services under a written management contract. MRI Facility has certified that these ancillary agreements meet the space rental and personal services and management contracts safe harbor requirements.7

OIG Will Not Sanction Past or Present Investments

Generally, the OIG looks with disfavor on joint ventures in which investors are referral sources for or suppliers of items or services to the joint venture or to other investors under the theory that distributions from the joint venture could actually be unlawful kickbacks. Joint ventures may be protected if they meet safe harbors, such as those for investments in small entities and investments in rural entities. Here the Proposed Arrangement does not fully comply with either of these safe harbors because (i) more than 40 percent of MRI Facility is owned by interested investors (hospital and physicians who may give referrals), in violation of the small entity investment safe harbor, and (ii) MRI Facility is not located in a MUA, and more than 50 percent of MRI Facility is owned by interested investors, in violation of the rural entity safe harbor.

Nonetheless, the OIG here found that the arrangement survived Anti-Kickback scrutiny because:

Bona Fide Business: The Proposed Arrangement has “indicia of a legitimate, bona fide business.” Less than 40 percent of MRI Facility revenue is generated from interested investors, and disinterested investors own a significant percentage (30 percent) of MRI Facility. Moreover, investment interests were offered on the same terms and conditions to all potential investors and returns on investments always have and will continue to be based on capital contributions.

Compliance With Existing Guidance: The Proposed Arrangement complied with the guidance on rural joint ventures that existed at the time it was established.8

Substantial Community Benefit: The Proposed Arrangement, established as a community-oriented effort to bring access to MRI services to a three-county rural area, provides substantial community benefit. It currently serves a large proportion of elderly and indigent rural patients who would be put in a position of hardship if required to travel long distances for MRI services.

Ancillary Agreements Meet Safe Harbors: MRI Facility certified that the management and space rental agreements comply with applicable safe harbors.

The OIG concluded these factors reduced the fraud and abuse risk sufficiently for both the past and present investment interests in MRI Facility. The OIG expressed no opinion with respect to any future changes in investment interests relating to the Proposed Arrangement or about any other arrangements referenced in MRI Facility’s submission to the OIG.

Conclusion

The OIG approved the Proposed Arrangement, citing a low risk of fraud and abuse resulting from factors demonstrating that MRI Facility is a legitimate business and not a front for kickbacks and citing the significant community benefit the facility provides.

Endnotes


2 We note that failure to comply fully with a safe harbor is not unlawful; rather, it merely subjects an entity to greater scrutiny under the Anti-Kickback Statute for review of intent and other factors.

3 We note that the Opinion is consistent with the May 2003 Advisory Opinion in requiring that return on investment be proportional to capital contributions and that ancillary agree-
ments present little anti-kickback risk.

4 See 42 CFR Part 51c.

5 Foundation is MRI Facility’s managing partner.

6 Radiologist physician-investors are generally not referral sources for MRI facilities or hospitals because treating physicians, not radiologists, generally order MRI services, except in limited circumstances where follow-up tests may be warranted. The percentage of investors not in a position to refer to MRI Facility has increased over time.

7 Neither this radiology group nor any of its physician members is an investor in MRI Facility. Likewise, neither Hospital nor Foundation has a direct or indirect ownership interest in this radiology group.

8 See “Special Fraud Alert on Joint Ventures,” U.S. Department of Health and Human Services, Office of Inspector General (1989). The Proposed Arrangement also complies with the 1993 proposed safe harbor for rural entities, though not with the 1999 final version of the safe harbor. The OIG indicated that this compliance with a proposed rule was not determinative, but did bear on the likelihood of an anti-kickback violation.