Imaging Ventures: A Legal Primer

Scott Becker, Emily C. Balfe & Aviva Fisher Rosenberg

Magnetic resonance and other imaging ventures that include physician owners can be characterized principally into two types. First, there are imaging ventures that include only radiologists as owners. Second, there are imaging ventures that include orthopedic physicians, neurosurgeons, obstetricians/gynecologists, and other types of physicians.

Due to certain regulatory schemes enacted by Congress, the Health Care Financing Administration ("HCFA"), and others, including the Ethics in Patient Referrals Act (the "Stark Act") and the Medicare and Medicaid Anti-Kickback Statute (the "Anti-Kickback Statute"), the scenarios under which such groups may have ownership in imaging joint ventures are distinctly varied. The first type of group—that made up solely of radiologists—can have ownership in imaging joint ventures with hospitals, third party management companies, or simply with other radiologists. The second type of group can have ownership interests in imaging joint ventures through a group practice pursuant to the Stark Act "in-office ancillary services" exception, an exception for rural areas, or pursuant to certain less direct methods. For example, a non-radiologist can own an interest in the underlying equipment or facility or may own an interest in and operate a magnetic resonance imaging ("MRI") facility pursuant to time-share arrangements. However, absent compliance with an "in-office" exception or an exception for providing services in a rural area, non-radiologists cannot own interests in a traditional joint venture MRI facility.

This article explores the principal federal regulatory schemes applicable to radiologists' and non-radiologists' operation or ownership of imaging facilities. The article focuses on MRI ventures but is also applicable in large part to other imaging ventures such as positron emission tomography ("PET") and computerized axial tomography ("CAT") scanning ventures.

Imaging ventures have received the particular attention of regulators due to concerns with overuse when physicians have ownership interests in such facilities. For example, in commentary to the Stark Act regulations, HCFA states:

[In 1994, the General Accounting Office (GAO) released an analysis of 2.4 million diagnostic imaging services ordered by 17,900 physicians in the State of Florida.]

Scott Becker is a partner and Emily C. Balfe and Aviva Fisher Rosenberg are associates at Ross & Hardies in Chicago, Illinois.
The GAO found that Florida physicians with a financial interest in joint venture imaging centers had higher referral rates for almost all types of imaging services than other Florida physicians. The differences in the referral rates were greatest for costly high-technology imaging services. For example, owners of joint ventures ordered 54 percent more magnetic resonance imaging scans for patients than did non-owners.

The GAO study also found that Florida physicians, group practices, or other practice affiliations with imaging facilities in their own offices ordered imaging tests more frequently than physicians who referred their patients to imaging facilities outside their practices. The in-practice imaging rates were about 3 times higher for magnetic resonance imaging scans; about 2 times higher for computed tomograph scans; 4.5 to 5.1 times higher for ultrasound, echocardiography, and diagnostic nuclear medicine imaging; and about 2 times higher for complex and simple X-rays. (GAO Report, “Medicare: Referrals to Physician-owned Imaging Facilities Warrant HCFA’s Scrutiny,” No. B-253835; pages 2, 3, and 10, October 1994.)

The Stark Act defines radiology services as including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services. Radiation therapy services and supplies are also deemed a designated health service. The commentary to the Stark Act also reflects HCFA’s intent to carve out screening mammography services and invasive radiology services. With respect to mammography services, HCFA states:

Section 1861(s)(13) includes as medical or other health services screening mammography services, which are defined in section 1861(jj) as a “radiologic procedure” provided to a woman for the purpose of early detection of breast cancer. We believe that screening mammography could qualify as one of the “radiology services” listed in section 1877(h)(6)(D) as a designated health service. However, as we have stated elsewhere, we believe that Congress enacted physician referral prohibition to limit the tendency for referring physicians to overutilize services because they have a financial incentive to do so. It is our view that screening mammography services cannot be subject to overutilization. We base this conclusion on the fact that the statute specifically limits the frequency with which the Medicare program will cover these services. That is, section 1834(c)(2) specifically prescribes how frequently the screenings will be covered for different age groups. In addition, we never consider the covered level of screenings to be unnecessary services—we believe that all women should receive the screenings that are covered for them under the statute.

We wish to make it clear that the only type of mammography that we would exclude from the definition of “radiology services” listed under section 1877(h)(6)(D) would be screening mammography as covered under section 1861(s)(13) and as defined in section 1861(jj). Thus, HCFA has defined the terms “radiology” and “imaging” to mean “any diagnostic test or therapeutic procedure using X-rays, ultrasound and other imaging.
services, CT scans, MRIs, radiation, or nuclear medicine, including diagnostic mammography services.” Of physicians’ professional services, HCFA states the following:

The physician’s professional component—Medicare has traditionally considered a physician’s professional services related to radiology to in general be covered as physician services under section 1861(s)(1) rather than as radiology services under either paragraph (3) or (4) of section 1861(s). However, we believe that it is appropriate for purposes of section 1877 to consider radiology services as including these physician services. We are proposing to include the professional component because radiology always consists of a technical service combined with a physician’s professional service. Whenever a technical radiological service is overutilized, it follows that a physician’s radiological service will also be overutilized.\(^7\)

With respect to invasive or interventional radiology services HCFA states:

We would exclude from the meaning of radiology, for the purposes of section 1877, any “invasive” radiology (also commonly referred to as interventional radiology). Invasive radiology is any procedure in which the imaging modality is used to guide a needle, probe, or a catheter accurately. . . .

. . . .

We would include the following definition at § 411.351:

Radiology services and radiation therapy and supplies means any diagnostic test or therapeutic procedure using X-rays, ultrasound or other imaging services, computerized axial tomography, magnetic resonance imaging, radiation, or nuclear medicine, and diagnostic mammography services, as covered under section 1861(s)(3) and (4) of the Act and §§ 410.32(a), 410.34, and 410.35, including the professional component of these services, but excluding any invasive radiology procedure in which the imaging modality is used to guide a needle, probe, or a catheter accurately.\(^8\)

**Radiologist Ownership in Imaging Facilities**

The Stark Act and the Anti-Kickback Statute have provided significant latitude to radiologists with respect to the ownership and operation of imaging facilities. The Stark Act provides a specific exception for referrals by radiologists and thus for ownership and compensation relationships related to radiologists. Specifically, it provides that the ordering of images by radiologists does not constitute a referral for Stark purposes, as follows:

In accordance with section 1877(h)(5)(C), we would also add the exception to the definition [of a referral for] a request by a radiologist for diagnostic radiology services and a request by a radiation oncologist for radiation therapy.\(^9\)

Thus, such referral and activity is generally not covered by the Stark Act. This means that a radiologist can have an ownership interest in an MRI facility with little concern from a Stark perspective. It also means that radiologists can be paid for
providing imaging services without concern that their ordering of tests will cause scrutiny under the Stark Act.

With respect to the Anti-Kickback Statute, HCFA Advisory Opinion 97-5 provides commentary with regard to MRI and radiology joint ventures. Here, the OIG also articulated comfort with radiology ownership of joint venture MRI facilities. In fact, the OIG indicated its belief that the potential for referrals from radiologists was not generally a concern for HCFA. Rather, HCFA's concern was that a hospital partner or other partner would be brought into the MRI joint venture with the intent of inducing referrals to the MRI joint venture. Thus, a favorable advisory opinion was issued with the condition that the hospital not be in a position to make referrals or cause referrals to the MRI joint venture. For example, the hospital cannot allow its employed physicians to make referrals to the venture. The Advisory Opinion states:

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 traced 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. 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.

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.

OWNERSHIP IN IMAGING FACILITIES BY NON-RADIOLOGISTS

Non-radiologist physicians are significantly curtailed in their ability to invest in joint venture MRI and other imaging facilities. Specifically, because the Stark Act does not provide an exception for non-radiologist ownership and referrals to imaging facilities, the non-radiologist must rely upon other exceptions to actually own an interest in such a facility. The most applicable exception generally is the "in-office ancillary services" exception (the "in-office exception"). The Stark Act also provides an exception for services provided in rural areas under certain circumstances.11

The in-office exception is applicable to group practices as long as they meet a number of conditions. For example, the in-office exception restrains ownership in the operating venture to a single group. This means that the group must have sufficient size and imaging volume to make the venture viable without the inclusion of multiple other partners. In contrast, in the surgery center context, multiple groups are permitted to, and often do, join together to help assure that the surgical center has sufficient volume.

In addition, to meet the in-office exception the practice must comply with several additional conditions, which are set forth in the following discussion of the exception:

In-office ancillary services. Services (including infusion pumps and crutches, but excluding all other durable medical equipment and parenteral and enteral nutrients, equipment, and supplies), that meet the following conditions:

(1) They are furnished personally by one of the following individuals:
   (i) The referring physician.
   (ii) A physician who is a member of the same group practice as the referring physician.
(iii) Individuals who are directly supervised by the referring physician or, in the case of group practices, by another physician member of the same group practice as the referring physician.

(2) They are furnished in one of the following locations:

(i) The same building in which the referring physician (or another physician who is a member of the same group practice) furnishes physician services unrelated to the furnishing of designated health services. The “same building” means the same physical structure, with one address, and not multiple structures connected by tunnels or walkways.

(ii) A building that is used by the group practice for the provision of some or all of the group’s clinical laboratory services.

(iii) A building that is used by the group practice for the centralized provision of the group’s designated health services (other than clinical laboratory services).

(3) They are billed by one of the following:

(i) The physician performing or supervising the service.

(ii) The group practice of which the performing or supervising physician is a member under a billing number assigned to the group practice.

(iii) An entity that is wholly owned by the physician or the physician’s group practice.

(4) In the case of crutches, the physician realizes no direct or indirect profit from furnishing the crutches.12

Here, the critical tests include a supervision test, a billing test, and a location test. For purposes of the Stark Act, HCFA has proposed a slightly more expansive interpretation of the supervision requirement. The commentary to the Stark Act further states:

In the August 1995 final rule, we defined “direct supervision” as supervision by a physician who is present in the office suite and immediately available to provide assistance and direction throughout the time that clinical laboratory services are being performed. We are proposing to apply this definition to referrals for any of the other designated health services that can be excepted under section 1877(b)(2). We also propose to revise this definition to make it clear that “present in the office suite” means the physician must be present in the office suite in which the services are being furnished, at the time they are being furnished. We believe this clarification is necessary for situations in which a physician might be working in more than one suite in a building, such as where he or she provides services other than designated health services in one suite, while the designated health services are furnished in a separate suite in the same building.13

The OIG further elaborates as follows:

However, in the context of physician referrals, we believe the physician’s presence is necessary for “management” purposes (that is, to demonstrate that the physician is there, actively running the practice), rather than for coverage purposes. Thus, the
requirement that the physician be on the premises the entire time that a designated health service is being furnished can have absurd and impractical results, preventing a physician from leaving the office suite for even brief periods when there may be no health and safety standards requiring his presence.

Accordingly, we propose to depart from our interpretation that the definition of "direct supervision" for purposes of the referral prohibition is identical to the definition in the "incident to" context. That is, we propose to continue to require that the services in general be performed by aides or technicians only when the physician is present in the office suite so that they are tied to his or her activities, but allow very limited absences from the office. We propose to amend the definition as follows:

Direct supervision means supervision by a physician who is present in the office suite in which the services are being furnished, throughout the time they are being furnished, and immediately available to provide assistance and direction. "Present in the office suite" means that the physician is actually physically present. However, the physician is still considered "present" during brief unexpected absences as well as during routine absences of a short duration (such as during a lunch break), provided the absences occur during time periods which the physician is otherwise scheduled and ordinarily expected to be present and the absences do not conflict with any other requirements in the Medicare program for a particular level of physician supervision.

Under this definition, a physician must actually be physically present in the office suite at the time designated health services are being furnished, or be absent only under the limited conditions described in the definition. We anticipate that the question of when an absence qualifies as "brief and unexpected" or as a "routine absence of a short duration" will be a determination that only the local carrier can make, based on individual circumstances.

A service will not qualify as an in-office ancillary service during any time period in which the physician is scheduled to be in the office, but in reality is specifically or routinely expected to be somewhere else or during any time period in which the physician is scheduled to be somewhere else. Therefore, laboratory services or other designated health services performed by technicians or aides would not qualify as in-office ancillary services if they are performed during time periods that occur before or after the physician's regularly scheduled office hours. (Aides or technicians can perform other tasks in the absence of the physician, such as setting up equipment or cleaning up, as long as the tasks are not components of designated health services provided to Medicare or Medicaid patients.) Also, a physician's absences to perform medical services outside the office would not be permissible under "direct supervision," such as absences to do hospital rounds or provide care in an outpatient clinic. However, we would allow absences for unexpected medical emergencies.

While this definition for referral purposes would allow a physician to occasionally be absent for short periods, specific coverage requirements for services furnished and billed as "incident to" a physician's services, for diagnostic services, or for any other services with separate supervision requirements would continue to
operate to determine whether a specific service is covered. We recognize that this approach will require a physician to pay close attention to the specific coverage requirements that apply to individual services, as well as the supervision requirement in section 1877(b). Nonetheless, most of the coverage rules have been in effect for many years, so physicians have had experience complying with them. In coordinating the separate supervision requirements with the requirement in section 1877, physicians must only comply with the separate coverage requirement if it is more stringent than the requirement in section 1877, as interpreted in this proposed rule.

We believe that our proposed amendment to the definition of “direct supervision” addresses the concerns of physicians who feel that, as a practical matter, they cannot be in the office every single minute of every day. The amendment will allow physicians who must be called away briefly to avoid the sanctions that could arise from section 1877 if they are not present at the moment when a medical service is furnished, provided there are no health and safety reasons for them to be on the premises.14

Location test

The location test can be met either by having services provided at the group practice’s location or at a separate site used for the group’s performance of designated health services. HCFA has elaborated as follows:

*Where a service is actually furnished.* Section 1877(b)(2)(A)(ii)(I) requires, for a solo or group practice, that the services be furnished in a building in which the referring physician or another member of the group practice furnishes physician services unrelated to the furnishing of designated health services. It is our view that a service is furnished wherever a procedure is actually performed upon a patient or in the location in which a patient receives and begins using an item.

For example, if a patient receives an MRI (magnetic resonance image) in a physician’s office, the service has been furnished there.

...What constitutes the “same building” in which the physician is practicing. We are interpreting “the same building” to mean one physical structure, with one address, and not multiple structures that are connected by tunnels or walkways. In addition, we believe “the building” consists of parts of the physical structure that are used as office or other commercial space. For example, a mobile X-ray van that is pulled into the garage of a building would not be part of that building.

*When a physician is furnishing physician services “unrelated to the furnishing of designated health services.”* To meet this criterion, we believe that a physician must be providing in the same building any amount of physician services (as defined in § 410.20(a)) other than those listed as designated health services as we have defined them in § 411.351. Thus, we would regard as “unrelated to designated health services” a physician’s examination of a patient and diagnosis, even if these lead to the physician requesting a designated health service, such as an X-ray or laboratory test.15
In the case of a group practice, the group has the option of meeting a location test other than the one requiring that the designated health services be provided in the same building in which a group member provides physician services. The group can provide designated health services in any other building that is used by the group for the provision of some or all of the group's designated health services:

A group can furnish the other designated health services in another building that is used by the group for the centralized provision of the group's designated health services. We believe that a location meets this "centralized" requirement if it services more than one of a group's offices, and if it furnishes one or any combination of designated health services. It is also our view that a group can have more than one of these centralized locations. To meet the in-office ancillary exception, a group would be required to have a physician member present in the "centralized" location to perform or directly supervise the performance of designated health services, but the physician would not be required to perform physician services that are unrelated to the designated health services in this location.16

Billing test

Finally, to comply with the Stark Act, the services must be billed through a group number and not by a third party supplier and remitted to the group.

Medicare's antimarkup regulations

Diagnostic test markups prohibited

In addition to the billing requirements that must be met for the in-office exception, HCFA regulations also determine which services may be billed to Medicare per an antimarkup rule as follows:

(1) If a physician's bill or a request for payment for services billed by a physician includes a charge for a diagnostic test described in section 1861(s)(3) (other than a clinical diagnostic laboratory test) for which the bill or request for payment does not indicate that the billing physician personally performed or supervised the performance of the test or that another physician with whom the physician who shares a practice personally performed or supervised the performance of the test, the amount payable with respect to the test shall be determined as follows:

(A) If the bill or request for payment indicates that the test was performed by a supplier, identifies the supplier, and indicates the amount the supplier charged the billing physician, payment for the test (less the applicable deductible and coinsurance amounts) shall be the actual acquisition costs (net of any discounts) or, if lower, the supplier's reasonable charge (or other applicable limit) for the test.

(B) If the bill or request for payment (i) does not indicate who performed the test, or (ii) indicates that the test was performed by a supplier but does not
identify the supplier or include the amount charged by the supplier, no payment shall be made under this part.

(2) A physician may not bill an individual enrolled under this part—
(A) any amount other than the payment amount specified in paragraph (1)(A) and any applicable deductible and coinsurance for a diagnostic test for which payment is made pursuant to paragraph (1)(A), or
(B) any amount for a diagnostic test for which payment may not be made pursuant to paragraph (1)(B).

(3) If a physician knowingly and willfully in repeated cases bills one or more individuals in violation of paragraph (2), the Secretary may apply sanctions against such physician in accordance with section 1842(j)(2)."\n
Practical applications

The Stark Act requirements lead to a number of practical application questions, including whether a group can (1) use independent contractor radiologists; (2) time-share the use of an MRI with other groups; or (3) own the underlying assets of an MRI facility without Stark Act concerns.

Independent contractor

The group practice exception requires that a group supervise the services through its own members and employees. Thus, if a group desires to use a third party radiologist to read images, the radiologist must be supervised by members of the group in a manner that is not common for radiologists. Further, the use of an independent contractor must be done in such a way that the group still provides for 75% of their services directly through employees and members of the group. It is possible that the radiologist could be a member of the group through an employee status on a part-time basis. Here, the group would have to have sufficient control and oversight of the physician to be able to legitimately comply with group practice and Internal Revenue Service employee concepts.

e Time-share methodologies

Increasingly, groups attempt to jointly own MRI facilities with other groups. Then, the actual site is operated pursuant to a time share method whereby different groups operate the MRI facility as a part of the group practice pursuant to a time-share lease. HCFA has commented on the option of shared sites in the context of two groups sharing an office lab:

As we discussed in detail in the August 1995 final rule, this provision can except solo practitioners with certain shared arrangements who do wish to become a group practice. For example, two solo practitioners who share one office and jointly own a laboratory can continue to refer to that laboratory, as long as each physician furnishes physician services unrelated to the designated health services in the office, directly supervises the laboratory services for his or her own Medicare and Medicaid.
patients while they are being furnished, and bills for the services. If only one of the
solo practitioners owns the laboratory in a shared office, the non-owning physician
can refer to the laboratory as long as he or she is not receiving compensation from
the owner in exchange for referrals. We are aware, however, that this exception may
not accommodate the variety of different arrangements physicians have entered
into to share facilities or otherwise group together without losing their status as
solo practitioners. We directly solicit comments on the effects of the referral
prohibition on these arrangements.18

HCFA has not commented on how this issue applies to a time share scenario
(i.e., whether a fully shared location can meet the Stark exception centralized location
test). Here, a number of policies and procedures can be implemented to help assure
that the practice location and site actually acts as and constitutes a practice extension.

**Owning imaging equipment**

The actual ownership of the underlying equipment does not itself violate the
Stark Act. For example, a physician can own an MRI machine and lease it to a third
party without violating the act. However, payment amounts to the lessor cannot
account for referrals from the landlord. HCFA states:

We believe that such leases go beyond the section 1877(e)(1) exceptions, which
except only payments for the use of equipment or space.

*Can a lease provide for payment based on how often the equipment is used?* We have been
asked about situations in which a physician rents equipment to an entity that
furnishes a designated health service, such as a hospital that rents an MRI machine,
with the physician receiving rental payments on a "per click" basis (that is, rental
payments go up each time the machine is used.) We believe that this arrangement
will not prohibit the physician from otherwise referring to the entity, provided that
these kinds of arrangements are typical and comply with the fair market value and
other standards that are included under the rental exception. However, because a
physician's compensation under this exception cannot reflect the volume or value
of the physician's own referrals, the rental payments cannot reflect "per click"
payments for patients who are referred for the service by the lessor physician.19

**Summary and Conclusion**

As the technology for imaging continues to improve, we expect the number of
non-radiologists having some involvement in imaging ventures to increase
significantly. Further, the variations and numbers of types of ventures will also likely
increase.
NOTES

6. Id. at 1675.
7. Id. at 1676.
8. Id. at 1676.
9. Id. at 1664.
11. Designated health services furnished in a rural area (as defined) by an entity if substantially all of the designated health services furnished by the entity are furnished to individuals residing in such rural area.
13. Id. at 1684.
14. Id. at 1684.
15. Id. at 1695.
16. Id. at 1696.
17. 42 U.S.C. § 1395u(n).
19. Id. at 1714.