Participation of Interventional Radiologists in Hospital Joint Ventures

BY THOMAS W. GREESON AND PAUL PITTS

Many diagnostic radiology groups around the country have robust interventional radiology practices that provide minimally invasive procedures using imaging for guidance, such as angiography, angioplasty, biopsy, stenting, cryotherapy, and embolization. Because many interventional radiologists practice clinically, as treating physicians, and may order diagnostic radiology and ultrasound tests as part of their practice, they sometime refer Medicare and Medicaid patients to the radiology group’s imaging center. When an interventional radiologist holds an ownership interest in the imaging center, directly or indirectly through the group, the federal physician self-referral law (commonly referred to as the “Stark Law”) requires that the interventional radiologist’s financial interest fit within an exception to the general prohibition on self-referrals.

Historically, the exception to the Stark Law, most often used to protect referrals by an interventional radiologist to their own group practice, is the in-office ancillary services exception. The in-office ancillary services exception is intended to protect the in-office provision of certain designated health services (DHS), including diagnostic radiology and other imaging services that are genuinely ancillary to the medical services provided by the group practice. In order for a physician practice to protect self-referrals under the in-office ancillary services exception, the physicians must, among other things, meet the definition of a “group practice.” A referral to an imaging center owned by a joint venture does not qualify as a referral to a “group practice” and cannot meet the requirements of the in-office ancillary services exception.

When interventional radiologists participate as investors in a joint venture and refer Medicare or Medicaid patients to the joint venture for diagnostic tests, the in-office ancillary services exception does not protect the interventional radiologist’s referrals and, because of recent regulatory changes, no other exception permits the interventional radiologist to hold an ownership interest in the joint venture imaging center.

The limitation on the participation of interventional radiologists is proving to be increasingly troublesome to radiology groups as a whole. Because of declining reimbursement, rising technology costs, and escalating competition, radiology groups are inclined, more than ever, to joint venture existing and new imaging centers with hospitals, rather than to go at it alone in a freestanding center. In this environment, the Stark Law presents a significant problem for structuring a hospital joint venture when the radiology group includes an interventional practice.

Background on the Stark Law

In general, the Stark Law prohibits an interventional radiologist from referring Medicare and Medicaid patients to a joint venture for a diagnostic test if the interventional radiologist has a direct or indirect ownership interest in the joint venture. However, until October 1, 2009, radiology groups that faced this prohibition on self-referrals had a work-around. Those groups could “purchase” a diagnostic test from the joint venture for those tests referred by the interventional radiologists so that the referral was made to the radiology group practice, not the joint ventured imaging center. Under the “purchased test” approach, the radiology group would bill the test through the group’s National Provider Identifier for those Medicare patients referred for a diagnostic test by the investing interventional radiologist. After October 1, 2009, however, even that approach is prohibited with the new definition of an “entity” as either the “billing” entity or the “performing” entity. While the October 1, 2009 change to the definition of “entity” has been widely discussed, its impact on interventional radiologists appears to have been under reported and under appreciated.

Changes to the Stark Law and Expansion of the Definition of “Entity”

The Stark Law is triggered by a physician’s referral to an “entity” with which he or she (or an immediate family member) has a direct or indirect financial relationship. The 2009 Hospital Inpatient Prospective Payment System final rule (Final Rule) amended the definition of “entity” beginning on October 1, 2009. Prior to this date, an entity “furnished” DHS if it was the entity or person to which CMS made payment for DHS. Effective October 1, 2009, an entity “furnishes” DHS if it (1) is the person or entity that has performed services that are billed as DHS or (2) is the person or entity that has presented a claim to Medicare for DHS.

As a result of the expanded definition, it is now possible that through a referral of a single Medicare patient for DHS, a physician would actually be making a referral to two different DHS “entities,” each of which may need to be protected under an exception to the Stark Law if the physician has a financial relationship with each entity. Physician investors must satisfy an ownership exception under the Stark Law in order to refer patients to a provider that contracts with an entity that performs the DHS and is directly or indirectly owned by the same physician.

In the preamble to the Final Rule, CMS declined to further define the phrase “performed DHS” and, instead, stated that the phrase should be interpreted as having “its common meaning.” CMS noted that the Social Security Act and the Medicare regulations already use the term perform, or a variation thereof, without a specific definition. CMS stated, however, in the preamble to the final rule that it does not consider an entity that: (1) leases or sells space or equipment used for the performance of the DHS; (2) furnishes supplies that are not
separately billable but are used in the performance of DHS; or (3) provides management, billing services or personnel to an entity that is performing the DHS, to itself be “performing” DHS.\(^3\)

**Exception for Tests Not “Marked Up” (The “Purchased Test” Approach)**

Prior to the adoption of the Final Rule, the Stark Law included an exception to the definition of entity that permitted a physician group to purchase a test from an entity with which the group had a compensation or ownership interest so long as the test was not marked up. The Stark Phase II Interim Final Rule provided that a physician group practice is not considered to be a DHS “entity” covered by Stark if the group practice purchases the technical component of a diagnostic test pursuant to Section 30.2.9 of the Medicare Claims Processing Manual and subsequently bills Medicare for the purchased test.\(^4\)

Although this clarification of what is not an “entity” permits a radiology group to purchase the technical component of a test and bill it to Medicare program, it no longer provides an exception for an ownership interest in the joint venture entity that is “performing” the test. Even if the radiology group purchased the technical component from the joint venture and billed it in accordance with the anti-markup rule, the joint venture entity still would be “performing” the DHS. As a consequence, investor interventional radiologists are prohibited from referring Medicare patients to the joint venture to perform such DHS. The fact that the radiology group would subsequently bill Medicare under its number for the technical component does not negate or eliminate the fact that a referral was also made to the joint venture (i.e., the entity that “performed” the DHS).

**Possible Options to Consider in the Joint Venture**

There are several options for radiology groups to consider when approached with an opportunity to partner with a hospital on the technical component. First, the interventional radiologist could change his or her practice so no referrals of Medicare or Medicaid patients are made to the joint venture. This option presents a significant challenge to the interventional radiologist(s) and the radiology group as a whole.

Second, the diagnostic radiologists could invest in the joint venture individually without the participation of the interventional radiologists. If, however, the imaging center is owned through the group practice, the interventional radiologists would have to divest their ownership interest in the group in order to avoid an indirect ownership interest. Fortunately, group practice ownership in the joint venture is rare. Most joint venture investments are made via investment entity LLCs. In this option, the interventional radiologists would remain employed by the group but not participate in the ownership of the joint venture, directly or indirectly. This approach would not permit the interventional radiologist to have the same financial rewards and risk of investing in the joint venture.

A third approach is to limit the scope of the joint venture’s involvement in the imaging center so that it would not be considered to have “performed” DHS and, therefore, not be considered an “entity” under the new definition. For example, the joint venture might provide the space and equipment required for the hospital to operate an imaging center but not the patient care staff or other aspects of administration. This approach may be easier to achieve for a new venture, rather than an existing imaging center looking to contribute all of its assets to a joint venture. However, the economics of such a leasing or management company joint venture are usually not as attractive to the investors as with fully operational joint ventures.

Each of these options presents significant clinical and financial limitations to the interventional radiologist(s) and the radiology group as a whole.

**Final Thoughts**

Any radiology group with interventional radiologists should carefully consider the potential impact of the Stark Law when discussing joint venture opportunities with a local hospital. The Stark Law’s restrictions on an investor interventional radiologist’s referrals may present a significant challenge to groups considering a joint venture, especially if a significant portion of the practice income is derived from diagnostic tests ordered by the group’s interventional radiologists. Any radiology group considering a joint venture should consult with its legal counsel before proceeding.

**FOOTNOTES**

3. Id. at 48726
4. 42 C.F.R. § 411.351.

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THOMAS W. GREENSON is a partner in the Falls Church, VA office of Reed Smith LLP. His practice focuses on the regulatory and transactional needs of diagnostic imaging providers. He served as general counsel of the America College of Radiology for many years before entering private practice in 1998. Thomas serves as chair of the Virginia Bar Association Health Law Section. Thomas can be reached at 703.641.4242 or tgreeson@reedsmith.com.

PAUL PITTS is a member of the Life Sciences Health Industry Group, practicing in the area of healthcare regulatory law. Paul’s practice focuses on advising hospitals, radiology and diagnostic imaging facilities, physician groups, and other healthcare providers on fraud and abuse laws, reimbursement and coverage issues, and participation in Medicare and Medicaid. Paul can be reached at 415.659.5971 or ppitts@reedsmith.com.