THE STARK RULES: What Are the Implications for Radiology Groups?

INTRODUCTION

The purpose of the Stark Law is simple: to restrict self-referral. The application of the Stark Law is far more complex—and incomplete, such as the example of in-office imaging services that are largely free from the Stark Law’s reach. Because the Stark Law restrictions apply to radiology, as well as radiation therapy services and supplies, radiology groups cannot escape the reach of these rules and, consequently, should be aware of these requirements.

This article will summarize the basic Stark rules impacting when a physician can make a referral of a Medicare or Medicaid patient for radiology services, both technical and professional components. In addition, it will highlight some areas where radiology groups need to be mindful of Stark rule compliance.
BASIC PROHIBITION
The Stark Law generally prohibits a physician from referring a Medicare or Medicaid patient to an entity in which the physician has a financial interest. Specifically, the Stark Law states that:

A physician who has a direct or indirect financial relationship with an entity, or who has an immediate family member who has a direct or indirect financial relationship with the entity, may not make a referral to that entity for the furnishing of designated health services (DHS) for which payment otherwise may be made under Medicare or, in some cases, Medicaid.¹

The Stark Law can be particularly problematic for radiologists, who are in the position of receiving referrals, because it does not require proof that the physician actually intended to violate the law and prohibits the recipient of a prohibited referral from billing Medicare. The government need merely demonstrate that a physician referred a Medicare or Medicaid patient to an entity in which the physician (or immediate family member) has a financial interest and that referral was not protected under an exception. Fines and/or penalties may be imposed even if the physician did not know or did not intend to violate the law.

DEFINITIONS
Each of the words and phrases underlined above has a specific definition under the Stark Law as explained below.

Financial Relationship. This is defined as an ownership interest or a compensation arrangement. The physician’s ownership interest may be either direct or indirect. The interest is direct if physician personally receives a return on his ownership/investment interest directly from the entity furnishing or billing DHS. The interest is indirect if there is at least one individual or entity between the physician and the DHS entity. Likewise, a compensation arrangement is direct if remuneration is exchanged directly between the entity furnishing or billing DHS and the physician. The compensation arrangement is indirect if there is at least one individual or entity between the physician and the DHS entity (e.g., physician is an owner of Group A and Group A has a contract with Hospital to provide medical director services).

Entity. An entity is a physician practice, corporation, partnership, limited liability company, foundation, not-for-profit corporation, or unincorporated association that furnishes DHS.

Immediate Family Member. An immediate family member is a husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

Referral. A referral is the request by a physician for, the ordering of, or the establishment of, a plan of care that includes any DHS for which payment may be made under Medicare Part B. A referral made by a physician’s group practice rather than the physician personally may be attributed to the physician if the physician directs the group practice, its members or its staff to make the referral or if the physician controls referrals made by his/her group practice, it members or its staff.

DHS. DHS is an abbreviation for the phrase “designated health services.” Designated health services include, among other things, radiology and certain other imaging services identified by CPT and HCPCS codes on the CMS website.

IN-OFFICE ANCILLARY SERVICES EXCEPTION
The exception most often used to protect referrals by a physician to his/her own group practice is the in-office ancillary services exception. This is the exception that must be followed for a referring physician who is performing the technical component of an imaging service in his or her own office. The in-office exception includes specific requirements addressing: (1) supervision of the imaging services; (2) building or location of the imaging services; (3) billing; and (4) group practice requirements.

Supervision. Under the supervision requirement, the technical component of the imaging service (i.e., DHS) must be furnished to the Medicare beneficiary personally by one of the following individuals:

- The referring physician;
- Another physician member of the referring physician’s group practice; or
- An individual who is supervised by the referring physician or by another physician in the group practice, provided the supervision complies with all other applicable Medicare payment and coverage rules for the services.

A “physician in the group practice” includes an independent contractor physician. In order for an independent contractor physician to qualify as a group practice
physician who can supervise a technologist or other individual performing the imaging service, there must be a contractual arrangement between group practice and the independent contractor for the physician to provide patient care services to group practice’s patients in its facilities. The contract must contain the same restrictions on compensation that apply to a physician member of the group practice or it must meet the “personal services exception” to compensation arrangements. The contract must also comply with the Medicare reassignment rules detailed in the Medicare Program Integrity Manual.

Building. Under the location, or building, requirement, the DHS must be provided in one of two places: (1) the same building or (2) a centralized building of the group practice. A centralized building is a space used full time by the group practice. This is the most common arrangement.

The Stark Law permits arrangements that don’t include the full time use of the building if the group practice provides other services in the “same building.” The “same building” is a combination of structures that share the same street address issued by the U.S. Postal Service, regardless of suite number. For the technical component of imaging services to be considered as provided in the “same building” (but not necessarily the same space or part of the building) as a group practice medical office, group practice must each satisfy at least one of the following three sets of circumstances:

(1) The radiology service is provided in a building in which the: (a) referring group practice physician or group practice has an office that is normally open to their patients at least 35 hours per week; (b) the referring group practice physician or another group practice physician member regularly practices medicine; (c) the referring group practice physician or another group practice physician member furnishes physician services to patients at least 30 hours per week; and (d) the 30 hours includes “some” physician services unrelated to furnishing of any type of DHS, although these services may lead to ordering DHS (i.e., services unrelated to DHS).

(2) The radiology service is provided in a building in which: (a) the referring group practice physician or group practice has an owned or leased office that is normally open to patients at least eight hours per week; (b) the referred patients “usually” receive physician services from the referring group practice physician or another group practice physician member; (c) the referring group practice physician regularly practices medicine and furnishes physician services to patients at least six hours per week in that office; and (d) the six hours per week includes “some” physician services unrelated to furnishing of any type of DHS. Services provided by other group practice physician members would not count toward this six hour requirement.

(3) The radiology service is provided in a building in which: (a) the referring group practice physician or group practice has an office that is normally open to patients eight hours per week; (b) the referring group practice physician or another group practice physician member regularly practices medicine and furnishes physician services to patients at least six hours per week in that office; and (c) the referring group practice physician is present in the building during a patient visit when ordering the imaging service or the referring group practice physician or another group practice physician member is present while the imaging service is furnished.

Given the complexities of the “same building” requirements, it’s easy to see why locating imaging services in a centralized building used full time by the group practice is a more common and advisable arrangement.

Billing. Under the billing requirement, the technical component of the radiology service must be billed by one of the following entities:

(1) The physician performing or supervising the service.

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

(3) The group practice, if the supervising physician is an independent contractor that meets the definition of a “physician in the group,” under a billing number assigned to the group practice.

(4) An entity that is wholly-owned by the performing or supervising physician or by that physician’s group practice under the entity’s own billing number or under a billing number assigned to the physician or group practice.

(5) An independent third party billing company acting as an agent of any of the above if the arrangement with the billing company complies with applicable regulations.

GROUP PRACTICE

In addition to meeting the supervision, building, and billing requirements, a group practice must meet the Stark
definition of a group practice in order to qualify for protection under the in-office ancillary services exception. In order to qualify as a group practice a physician practice must satisfy all of the following criteria of the group practice definition, which are briefly summarized below.

1. The practice must be organized as a single legal entity formed for the purpose of operating as a physician practice;
2. The practice must have at least two physicians who are owners or employees of the practice and who provide patient care services;
3. Each physician owner or employee must furnish to patients of the practice using the facilities, equipment, and staff of the practice, substantially the full range of patient care services that physician regularly renders to patients, regardless of where the patients are treated;
4. At least 75 percent of the total patient care services furnished by physician owners and employees to all patients treated by the physicians must be furnished to patients of the practice;
5. Physician owners or employees must personally conduct at least 75 percent of the practice's total physician-patient encounters;
6. The practice must be a unified business with centralized decision-making and consolidated billing, accounting and financial reporting;
7. Overhead expenses should be distributed according to a method that does not take into account the amount of income a physician generates;
8. No physician owners or employees receive compensation based on volume or value of referrals by that physician. However, a physician may receive a share of overall group profits or productivity bonus based on personally performed services (subject to certain restrictions).

If a group practice is unable to meet even one of the requirements of the in-office ancillary services exception or the “group practice” definition, referrals by group practice physicians to the group practice would not qualify for the exception and, as a result, would be prohibited under Stark.

PHYSICIAN SERVICES EXCEPTION FOR TELERADIOLOGY SERVICES

In order for a physician partner or shareholder in a group practice to refer the professional component of a radiology service for a Medicare patient to be billed by the group practice, the physician services exception must be met. The exception requires that the professional component services be performed by a physician owner or employee of the group practice or an independent contractor physician of group practice. If the interpretation service is performed by an independent contractor radiologist, the exception requires that the interpretation service must be performed on-site at the group practice’s office. If the professional services of the independent contractor physicians are not performed on-site, the group practice would ordinarily be barred by the Stark rules from billing for those services since the group practice physician’s Medicare referral of the professional component service would not qualify for protection under this exception.

CMS made the following statement in the preamble to the 2005 Medicare Physician Fee Schedule final rule:

“In addition, physician group practices should be mindful that compliance with the physicians’ services exception and the in-office ancillary services exception to the physician self-referral prohibition in Section 1877 of the Act requires that a physician or NPP who is engaged by a group practice as an independent contractor may provide ‘designated health services’ to the group practice’s patients only in the group’s facilities. See the definition of physician in the group at 42 CFR 411.351.”

Thus, even if a diagnostic radiology study is capable of electronic transmission, no Medicare claim for its interpretation by an independent contractor performed off-site can be billed by the group practice of the referring physician. The scan can be read remotely, but the interpreting physician must bill Medicare separately. There is one significant exception to this restriction: The anti-markup test rule.

ANTI-MARKUP TEST EXCEPTION FOR REMOTE INTERPRETATIONS

CMS has acknowledged that if a referring group practice bills the interpretation services as an anti-markup test, and as a result the group does not profit from that interpretation service, the billing of the interpretation service should be exempted from Stark.

CMS amended the Stark rules as follows:

“For purposes of this subpart, 'entity' does not practice when it bills Medicare for the technical component or professional component of a diagnostic test for which the anti-markup provision is applicable.”

Thus, the referring physician or group practice may bill...
for the remote interpretation as an “anti-markup test” without raising a Stark issue. If they do not choose to bill it that way, the radiology group should bill separately for remote interpretation services not performed on the premises of the referring physician’s group practice. The Stark Law prohibits the referring group practice from billing a remote interpretation that is not identified as an anti-markup test on the CMS 1500 claim form.

IMMEDIATE FAMILY MEMBER CONUNDRUM

Perhaps the most frustrating aspect of the Stark rules for a number of radiology groups are the challenges when an “immediate family member” of a radiology group practice shareholder refers a Medicare patient to that radiology group. Most groups recognize the challenges for technical component referrals from such family members. But many groups do not also recognize the challenge for professional component referrals, including services performed in hospitals where the radiologists have exclusive contracts.

As discussed above, the professional component of the radiology service is a designated health service subject to the Stark self-referral prohibition. If a shareholder radiologist and his or her immediate family member who is a referring physician are not in the same group practice, referrals of Medicare patients to the radiology group do not meet requirements of the physician services exception, or any other exception, and would be barred. Those services for Medicare patients must not be billed by the radiology group.

CMS last addressed and reaffirmed its position on immediate family member referrals in the Phase III regulations in 2007. The rule’s impact is the classic example of “unintended consequences” of language in the original legislation. CMS feels it has little room to modify this rule because the statutory language on immediate family member referrals is so explicit.

INTERVENTIONAL RADIOLOGISTS AND INVESTMENT IN JOINT VENTURES

The Stark Law also has the effect of prohibiting an interventional radiologist, who is acting as a treating physician, from referring Medicare patients to the joint venture if the interventional radiologist has a direct or indirect ownership interest in the joint venture. No exception under the Stark Law or its implementing regulations permits such referrals. Until 2009, radiology groups that faced this IR referral barrier had a work-around pathway. 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. Under the “purchased test” approach, the radiology group would bill the test through the group’s National Provider Identifier for those Medicare patients referred to the joint venture by the investing interventional radiologist. After 2009, however, even that approach is prohibited with the new definition of an “entity” as either the “billing” entity or the “performing” entity, since the joint venture performed the DHS.

Thus, interventional radiologists who hold an ownership interest in a joint venture may not make referrals of Medicare beneficiaries to the joint venture entity. This restriction may present a significant challenge to groups considering a joint venture if a portion of the practice is devoted to interventional radiology. This prohibition does not apply to contracted or employed radiologists who do not have an ownership interest in the joint venture. It applies only to interventional radiologists who make referrals to an entity in which the physician has an ownership interest.

CONCLUSION

Although most radiologists do not make referrals, nearly all radiologists receive referrals. As a result, radiologists need to be cognizant of Stark compliance when doing remote interpretations for referring physician groups; when performing services for family members of shareholder radiologists; and when interventional radiologists make referrals to entities in which they have an investment interest.

REFERENCE

1. 42 CFR § 411.353(a).