for the most part, the Stark Law has little to do with interventional radiology. The Federal prohibition against a physician’s referral of a Medicare beneficiary to a healthcare entity with which the physician (or a member of the physician’s immediate family) has a financial relationship, unless an exception applies, largely is not affected by interventional radiology services, since interventional radiology services are not a “designated health service” (DHS) subject to the Stark anti-referral prohibitions.

But diagnostic radiology (and ultrasound) tests ordered by interventional radiologists (IRs) for their Medicare and Medicaid patients do trigger the need for Stark compliance when referred to entities in which the IR has a financial relationship. That’s because those services are DHS.

Should an IR hold an ownership interest in an imaging center that provides services and refer Medicare and Medicaid patients to the entity for the provision of such services, those referrals would run afoul of the Stark prohibition on physician self-referrals, unless the IR’s financial relationship fit within an exception.

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 DHS for which payment otherwise may be made under Medicare [or Medicaid].

The Stark law can be particularly problematic for physicians because it does not require proof the physician actually intended to violate the law. The government need merely demonstrate 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

Here are specific definitions under the Stark Law for related terms.

Direct or Indirect Financial Relationship is defined as:

Ownership or Investment Interest: An ownership or investment interest by a physician in an entity that provides DHS. The interest may be held through stock, stock options, partnership shares, limited liability company membership, loans, bonds, or other financial instruments secured by property or revenues of the DHS entity. The physician’s interest may be direct or indirect. The interest is direct if the physician personally receives a return on their ownership/investment interest directly from the DHS entity. The interest is indirect if there is at least one individual or entity between the physician and the DHS entity (e.g., physician is an owner in Group A and Group A is the owner of an Imaging Center).

Compensation Arrangement: A compensation arrangement between a physician and an entity that provides DHS. A compensation arrangement is any arrangement that involves the payment of remuneration between the physician and the DHS entity. The arrangement may be either direct or indirect. The arrangement is direct if remuneration is exchanged directly between the DHS entity and the physician. The 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 either: (1) bills and collects payment from Medicare for performing DHS, or (2) “performs” the DHS services. The addition of “performance” is a very recent change to the definition of “entity” in the Stark regulations.

Immediate Family Member: An immediate family member is a husband or wife, birth or adoptive parent, child, sibling; stepparent, stepchild, stepbrother, stepsister, father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, 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 designated health service (“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 their group practice, its members, or its staff.

DHS: As noted above, DHS is an abbreviation for the phrase “designated health services.” Designated health
services include radiology and certain other imaging services identified by CPT and HCPCS codes on the CMS Web site.

**In-Office Ancillary Services Exception**

The exception most often used to protect referrals by a physician back to their 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 a nuclear-medicine procedure in their own office. The requirements that must be satisfied to meet the exception include the: a) supervision; b) building; c) billing; and d) group-practice requirements.

**Supervision:** Under the supervision requirement, the technical component of the nuclear-medicine procedure (i.e., DHS) must be furnished to the Medicare/Medicaid patient 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. For an independent-contractor physician to qualify as a group practice physician who can supervise a technologist or other individual performing the nuclear-medicine service, there must be a contractual arrangement between the group practice and the independent contractor for the physician to provide patient-care services to the group practice’s patients in its facilities. The contract must contain the same restrictions on compensation that apply to a physician member of a 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: the same building or a centralized building of the group practice. 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 nuclear-medicine 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, a group practice must each satisfy at least one of the following three sets of circumstances:

1. The imaging 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 30 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 any type of DHS, although these services may lead to ordering DHS (i.e., services unrelated to DHS).

2. The imaging 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 this site at least six hours per week; 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 imaging 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 nuclear medicine or the referring group practice physician or another group practice physician member is present while the nuclear medicine is furnished.

**Billing:** Under the billing requirement, the technical component of the nuclear-medicine 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 its definition to qualify for protection under the in-office ancillary services exception. To qualify, all the following criteria summarized below must be met for the “group practice” definition:

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% 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% 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 group practice would not qualify for the exception and, as a result, would be prohibited under Stark.

Conclusion

Interventional radiologists can order imaging services for their Medicare patients in a manner to permit their group practice to bill for the services, provided the referral fits in the proper Stark exception.

To learn more about author Thomas W. Greeson, JD, see our Contributors section on page 5.

FOOTNOTE
1. 42 C.F.R. § 411.353(a).