

Nuclear Medicine and the Stark Truth: What Are the Rules?

For years, the Stark Law had little if anything to do with nuclear medicine. The federal prohibition against a physician's referral of a Medicare beneficiary to a health care entity with which that physician (or a member of his or her immediate family) had a financial relationship, unless an exception applied, had no relationship to nuclear imaging, because nuclear studies were not "designated health services" (DHS). Although the statutory Stark provisions defined DHS to include radiology as well as radiation therapy services and supplies, the Centers for Medicare and Medicaid Services (CMS) acted in January 2001 to issue the Phase I Stark II final regulations and declared that nuclear medicine was not a DHS.

But in its 2006 Medicare Physician Fee Schedule final rule, CMS revised the definitions of "radiology services" and "radiation therapy services" to specifically include nuclear medicine. In addition, CMS revised its list of Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) codes that constitute DHS to include codes describing diagnostic and therapeutic nuclear medicine procedures. The list of CPT and HCPCS codes has expanded to include 78000 and 79000 series CPT codes as well as the corresponding A, C, and Q series HCPCS codes used to describe radiopharmaceuticals administered during the performance of the listed procedures. In discussing its reasons for including nuclear medicine in the definition of DHS, CMS noted the rapid growth in utilization (and possible overutilization) of nuclear medicine services over the relatively short period that Medicare has covered such services.

CMS made January 1, 2007, the effective date of this change. As a result, since the beginning of this year a physician could not hold an ownership interest in an imaging center that provides PET and/or other nuclear medicine services and refer Medicare or Medicaid patients to the entity for the provision of such services without running afoul of the Stark prohibition on physician self referrals (unless the physician's financial relationship fit within an exception). It is timely, then, to look at the basic Stark rules as they apply to nuclear medicine practice, including prohibitions and stipulations governing physician referrals of Medicare or Medicaid patients for a nuclear medicine service (both technical and professional components) in the physician's group practice.

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] (42 CFR § 411.353(a)).

The Stark law can be particularly problematic for physicians, because it does not require proof that the physician actually intended to violate the law. The government needs merely demonstrate that a physician referred a Medicare or Medicaid patient to an entity in which the physician (or immediate family member) had 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 in the previous paragraphs has a specific definition under the Stark law.

Direct or indirect financial relationship is defined as: (1) *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 his or her ownership/investment interest directly from the DHS entity. The interest is indirect if at least 1 individual or entity is between the physician and the DHS entity (e.g., a physician is an owner in group A, and group A is the owner of an imaging center). (2) *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 direct or indirect. The arrangement is direct if remuneration is exchanged directly between the DHS entity and the physician. The arrangement is indirect if at least 1 individual or entity is between the physician and the DHS entity (e.g., a physician is an owner of group A, and group A has a contract with a 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 bills and collects payment from Medicare for performing DHS.

(Continued on page 26N)

(Continued from page 24N)

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; or 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 that physician directs the group practice, its members, or its staff to make the referral or if the physician controls referrals made by his or her group practice, its members, or its staff.

DHS. As noted previously, DHS is an abbreviation for "designated health services." DHS 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 made by a physician to his or 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 a nuclear medicine procedure in his or her own office. The requirements that must be satisfied to meet the exception include the supervision, building, billing, and group practice requirements, as detailed here.

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 1 of the following individuals: (1) The referring physician; (2) another physician member of the referring physician's group practice; or (3) 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 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 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 1 of 2 places: the same build-

ing 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, the group practice must satisfy at least 1 of the following 3 sets of circumstances:

- (1) The nuclear medicine 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 the practice's 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 include "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 nuclear medicine 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 8 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 6 hours per week; and (d) the 6 hours per week include "some" physician services unrelated to furnishing of any type of DHS. Services provided by other group practice physician members would not count toward this 6 hour requirement.
- (3) The nuclear medicine 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 8 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 6 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; or
- (5) An independent third-party billing company acting as an agent of any of the previous 4 entities if the arrangement with the billing company complies with applicable regulations.

Group Practice

In addition to meeting the supervision, building, and billing requirements, the group practice must meet the definition of a “group practice” in order to qualify for protection under the in-office ancillary services exception. To qualify, a group practice must satisfy all of the definition’s criteria, which are briefly summarized here:

- (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 2 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 the 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 1 of the requirements of the in-office ancillary services exception or the “group practice” definition, referrals by the group practice

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

Physician Services Exception

The physician services exception must be met if a physician investor in a group practice wishes to refer the professional component of a nuclear medicine service for a Medicare patient to be billed by the group practice. 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 for the group practice. If the interpretation service is performed by an independent contractor nuclear medicine physician, the exception requires that the interpretation service must be performed on site at the group practice’s office. If the professional services of independent contractor physicians are not performed on site, the group practice would be barred by the Stark rules from billing for those services, because the group practice physician’s Medicare referral of the professional component service would not qualify for protection under this exception.

In 2004, Congress amended the Medicare reassignment rules to permit independent contractor physicians to reassign to another Medicare supplier entity their rights to receive Medicare Part B payments and to do so regardless of the location at which the independent contractor actually furnishes services. Although the legislation clearly expanded the Medicare reassignment rules to permit an independent contractor to reassign Medicare payment even if the services are performed off site, the new law did not make any changes or revisions to the Stark law and its separate requirement that certain professional services be performed on site.

In November 2004, CMS added the following statement to 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 [non-physician practitioner] 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, it is the view of CMS that even if a nuclear medicine scan can be transmitted electronically, 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.

The rules for off-site interpretation services are expected to undergo further changes when CMS promulgates

(Continued on page 28N)

McEwan Takes Office as SNM President; Gilmore Begins Term as Technologist Section President

SNM installed new officers and announced the results of its 2007 elections during the society's 54th Annual Meeting June 2-6 in Washington, DC.

Alexander (Sandy) J. McEwan, MD, of Edmonton, Canada, was invested as president of SNM on June 4. McEwan is director of oncologic imaging at Cross Cancer Institute in Edmonton as well as professor and director of the division of oncologic imaging in the oncology department, Faculty of Medicine, University of Alberta (Edmonton). He is a past president of the Canadian Society of Nuclear Medicine.

"SNM faces many opportunities and challenges in bringing the promise of molecular imaging to patients and to personalized medicine," McEwan said.

Robert W. Atcher, PhD, of White Rock, NM, became SNM president-elect. Atcher is program manager for the Department of Health and Human Services Programs with Los Alamos National Laboratory (New Mexico). He is currently the University of New Mexico/Los Alamos professor of pharmacy in the College of Pharmacy at the University of New Mexico, Albuquerque.

Michael M. Graham, MD, PhD, of Iowa City, IA, was elected vice president-elect. Graham is professor of radiology and radiation oncology and director of nuclear medicine at the University of Iowa College of Medicine (Iowa City). He will serve as vice president-elect through June, 2008; then



Alexander (Sandy) J. McEwan, MD



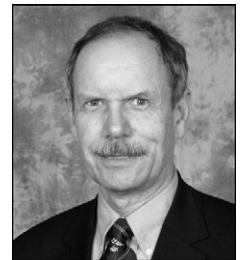
Robert W. Atcher, PhD

as president-elect for 1 year and as president from June 2009 through June 2010.

David Gilmore, MS, CNMT, NCT, RT(R,N), of Boston, MA, was invested as president of the SNM Technologist Section during the section's business meeting on June 5. Gilmore is the program director for the School of Nuclear Medicine Technology at Beth Israel Deaconess Medical Center, an affiliate of Harvard Medical School (Boston, MA).

"Over the next few years, SNMITS will shape and define its role in molecular imaging, developing a curriculum to prepare technologists to take advantage of the opportunities offered by advances in this field," Gilmore said.

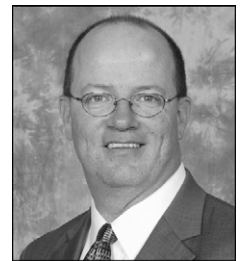
SNMITS announced the election of Mark Wallenmeyer, MBA, CNMT, RT(N), of Springfield, MO, as president-elect. Wallenmeyer is an instructor/clinical coordinator for the University of Arkansas for Medical Sciences (Little Rock), College of Health Related Professions, Nuclear Medicine Imaging Sciences. He is also the chief executive officer and co-owner of Trajecsys Corporation, an online educational data management firm. ✨



Michael M. Graham, MD, PhD



David Gilmore, MS, CNMT



Mark Wallenmeyer, MBA, CNMT

(Continued from page 27N)

its 2008 Medicare regulations. It is expected that the changes could be more permissive of off-site rules while at the same time attempting to curtail some of the perceived abuses of self referral. Payment for the remote read cannot be reassigned to the group practice.

Conclusion

The long-standing uncertainty over whether nuclear medicine services will be part of the Stark antireferral restrictions was finally resolved by CMS. Effective January 1, 2007, nuclear medicine services and supplies came under

the Stark rules. Nevertheless, physicians can still refer their Medicare patients in a manner that permits their group practice to bill for the services, provided the referral fits in the proper Stark exception. But no exception will permit an off-site interpretation by an independent contractor physician to be billed by the referring physician's group practice. The next round of CMS rulemaking may modify this restriction.

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