through a series of rules published in the fall of 2007, the Centers for Medicare & Medicaid Services (CMS) clearly established as one of its top agenda items for 2008 curbing the upward increase in physician self-referral of diagnostic imaging services. This article summarizes the changes set forth in the 2008 Medicare Physician Fee Schedule (MPFS) Final Rule and the Stark II, Phase III Final Rule (Stark III) that are designed to limit a physician’s ability to profit from his or her own referrals of diagnostic testing services. Although just as this article was going to press, CMS announced that certain provisions of the antimarkup rule will be delayed until January 1, 2009, these changes will nevertheless impact existing relationships between some radiologists and referring physicians [1].

Stark III

On September 5, 2007, CMS published the Stark II, Phase III Final Rule, which became effective December 4, 2007 [2]. Although much of Stark III focuses on clarifying and refining the existing regulations, CMS did include a number of significant regulatory changes, some of which may impact diagnostic imaging arrangements involving referring physicians.

**Direct Contract Requirement**

CMS revised the definition under the Stark antireference rules of “physician in a group practice” to require that, in order for a referring group practice to bill for designated health services (DHS) performed by an independent contractor physician, the independent contractor must have a direct contractual relationship with the group. For example, if an orthopedic group enters into an arrangement with a radiology group to provide professional interpretation services, under the new rule each interpreting radiologist must now have a direct contractual relationship with the orthopedic group. It is not sufficient for the radiology group to sign a professional service agreement with the orthopedic group on behalf of its radiologists [3].

**“Stand in the Shoes” Provision**

One of the most significant changes of Stark III is the addition of a new “stand in the shoes” provision. Currently, if a referring physician is an owner in a group practice, for example, and the group practice is a lessor in a lease agreement with an imaging center, the referring physician would have only an indirect compensation relationship with the imaging center. The physician’s referrals would previously have been protected under the “indirect compensation” exception to the Stark Law. Under the new “stand in the shoes” provision, a referring physician is deemed to have a direct compensation relationship with an entity that provides DHS if the only thing standing between the physician and the DHS entity is a “physician organization” [4].

A “physician organization” is defined as a physician, including a professional corporation of which the physician is the sole owner; a physician practice; or a group practice [5].

We note that the term “physician organization” as currently defined does not appear to include an entity that is wholly owned by referring physicians but that does not function as a physician practice, such as a limited liability company (LLC) used by a group of physicians to invest in a medical office building, diagnostic testing center, clinical laboratory, leasing company, or management company.

As a result of the “stand in the shoes” provision, the referring physicians in the example above will now be deemed to have a direct—rather than an indirect—compensation relationship with the imaging center because the
only thing standing between the imaging center and the physician is a physician organization. The consequence is that a lease agreement between an imaging center and a group practice will now need to meet the more stringent requirements of the equipment and space rental exceptions to the Stark Law including the “exclusive use” requirement discussed below.

“Exclusive Use” of Space and Equipment

In response to public comments CMS received regarding lease arrangements in which one or more referring physicians enter into “per-click” lease arrangements and share a diagnostic testing facility, CMS advised that such facility-sharing arrangements may not qualify for protection under the “space rental” and “equipment rental” exceptions to the Stark Law because both exceptions require that the referring physician have exclusive use of the leased space or equipment during the physician’s allotted lease period. CMS stated that “exclusive use” means that lease of space, equipment, or both must be for a predetermined, established block of time (e.g., Mondays, Wednesdays, and Fridays: 10:00 am until 12 noon) and that the leasing physician may use the leased space and equipment only during his or her designated time block [6].

“Consultation Exception” Does Not Protect Services Performed by Other Radiologists

Under the “consultation exception” to the Stark Law, a request by a radiologist for diagnostic radiology services or a request by a radiation oncologist for radiation therapy or ancillary services necessary for and integral to the provision of radiation therapy is not a “referral” that triggers Stark if (a) the request results from a consultation initiated by another physician and (b) the services are furnished: (i) by the radiologist or radiation oncologist; (ii) under the supervision of the radiologist or radiation oncologist; (iii) or under the supervision of a radiologist or radiation oncologist in the same group practice [7].

One commenter asked CMS to clarify whether the consultation exception protects radiation oncology services that are performed by another radiation oncologist in the same group practice as the radiation oncologist who initially requested the services for the patient. CMS responded that the consultation exception cannot be used to protect services performed by another radiation oncologist in the same group practice [8]. As summarized earlier, the radiation oncologist who requests the service may personally perform the service, but if he or she elects not to, the only other alternative is for nonphysician personnel to perform the service under the supervision of the radiation oncologist who ordered the test or another radiation oncologist in the group practice. CMS noted that this same restriction applies to requests by a radiologist for diagnostic radiology services.

We note that in instances in which an order by a radiologist for diagnostic radiology services will not qualify for protection under the “consultation exception” because the service was actually performed by another radiologist in the group, the referral could, nevertheless, possibly qualify for protection under other Stark exceptions such as the “physician services” exception (for professional services) or the “in-office ancillary services” exception (for technical services).

Radiology Services Performed After Nonradiology Procedures

In Phase II of the Stark Law rulemaking, CMS revised the definition of “radiology and certain other imaging services” to exclude any radiology service performed [9]:

- immediately following the nonradiological medical procedure when necessary to confirm placement of an item placed during the nonradiological medical procedure.

CMS received one comment advising that it is better clinical protocol to wait several weeks after prostate brachytherapy before performing CT to confirm proper placement of the seeds because swelling of the prostate is less pronounced than immediately after the procedure. The commenter suggested that CMS expand the time frame to include CT scans obtained within 6 weeks after prostate brachytherapy. CMS rejected the proposal on the basis that, if the radiology service is not performed immediately by the entity that performed the nonradiology procedure, the referring physician will regain discretion and control to choose another entity to perform and bill for the CT scan (including an imaging center owned by the referring physician) [10].

No Expansion of the Exception for Intrafamily Referrals

CMS received a variety of comments stating that the prohibition on intrafamily referrals leads to unfair results in situations in which one family member is a general practitioner or surgeon and the other is a pathologist, radiologist, or radiation oncologist who is part of a group practice that is under contract to provide services to the local hospital. The commenters made various suggestions as to how CMS should expand this exception to permit intrafamily referrals to hospital-based physicians. CMS declined to expand the current exception that permits certain intrafamily referrals in rural areas because it does not believe that it can craft an exception for intrafamily referrals for hospital-based physicians that would be entirely without risk of abuse to the Medicare program. CMS instead offered suggestions as to how physicians who find themselves in this predicament can avoid violating the Stark Law.

First CMS suggested that whenever the hospital-based group receives a referral from a family member of one of its physicians, the hospital-based group can simply forward the referral to another physician or group practice in the area to perform the service. This suggestion conflicts with the concept of exclusive contracting for hospital-based radiology services. Alternatively, CMS suggested that for patients referred by a physician who is a family member of one of the hospital-based group’s physicians, the hospital-based group could have one of its other physicians in the group perform the services and bill them to Medicare directly under his or her national provider identifier (NPI) rather than pursuant to a reassignment to the hospital-based group or the hospital [11]. This recommendation may run counter to most employment arrangements within diagnostic radiology groups. Selective reassignment of billing rights for the family member’s referred services to the hospital is another alternative.

2008 MPFS Final Rule

On November 27, 2007, CMS issued the 2008 MPFS Final Rule that, in addition to a projected 10.1% payment decrease, finalized proposed revisions to the independent diagnostic testing facility (IDTF) performance standards and made a number of significant changes to the Medicare purchased diagnostic test rule (“PDT Rule”) and reassignment rules [12].

A. IDTF Provisions

The following changes to the IDTF performance standards became effective for services rendered on or after January 1, 2008.

Liability insurance — §410.33(g)(6)—

Under the current IDTF standards, an IDTF must have a comprehensive liability insurance
policy of at least $300,000 per location that lists the serial numbers of all diagnostic equipment. CMS revised this standard by: (i) deleting the requirement that the policy list the serial numbers of all diagnostic equipment; (ii) clarifying that the liability policy must provide coverage at each location of at least $300,000 "per incident"; and (iii) requiring that the IDTF notify its designated Medicare contractor of any policy changes or cancellation [13].

Enrollment changes – §410.33(g)(2) — Currently, an IDTF is required to report any changes to its Medicare enrollment application within 30 calendar days. To decrease the administrative burden of this requirement on both IDTFs and the Medicare contractors, CMS revised the standard to only require reporting within 30 days for changes in ownership, location, or general supervision or for adverse legal actions. All other changes can be reported within 90 days [14].

Beneficiary questions and complaints – §410.33(g)(8) — CMS expanded the original performance standard to require not only that IDTFs answer beneficiaries’ questions and respond to their complaints, but also that IDTFs create and maintain on file at the physical site of the IDTF (or home office for mobile units) documentation for all beneficiary complaints that are related to clinical issues. Initially, the proposed rule would have required IDTFs to maintain documentation of all beneficiary complaints of any nature. In response to public comments that the requirement was unduly burdensome and costly, CMS restricted the scope of the documentation requirement solely to complaints that are clinical in nature [15].

Prohibition on sharing – §410.33(g)(15) — The most significant change to the IDTF standards is that CMS adopted its controversial proposal that prohibits IDTFs from sharing space or equipment with any other Medicare-enrolled individual or entity, which includes a radiology group [16]. Rescinded Transmittal 187 [16] would have imposed the same restriction on IDTFs without formal rulemaking. The new standard provides that:

(15) With the exception of hospital-based and mobile IDTFs, a fixed-base IDTF does not include the following: (i) sharing a practice location with another Medicare-enrolled individual or organization; (ii) leasing or subleasing its operation or its practice location to another Medicare-enrolled individual or organization; or (iii) sharing diagnostic testing equipment used in the initial diagnostic test with another Medicare-enrolled individual or organization.

Recognizing that this new standard will require IDTFs currently engaged in space-sharing arrangements, the first provision (i) listed above, to restructure, CMS has delayed the implementation date for existing IDTFs until January 1, 2009, to provide IDTFs a full year to restructure their relationships.

In the proposed rule, CMS had also included a prohibition on sharing staff. However, in response to public comments and criticism, CMS withdrew its proposal to expand the prohibition on sharing to also include staff.

The effect of the new rule is that freestanding IDTFs will now be precluded from entering into sublease arrangements with a physician, physician practice, or other entities including the following: (1) subleasing the IDTF’s office space, imaging equipment, or both to a radiology group to perform interventional procedures; (2) subleasing a portion of the IDTF’s office suite to a referring physician practice to establish a medical office location; or (3) offering safe harbored block-time lease arrangements of the IDTF’s office space and imaging equipment to physician practices. CMS received several comments suggesting that it should create an exception for radiologists and radiology groups because they generally do not make referrals to IDTFs. CMS declined to create exceptions for radiologists or exceptions for any other specialty.

Supervising physician – §410.33(b)(1) — In the 2007 MPFS Final Rule, it appeared as if CMS had expanded the scope and responsibilities of physicians providing general supervision to an IDTF because it had revised the regulation to state that the supervising physician must be responsible not only for quality-related oversight but also for the overall administration and operation of the IDTFs... and for assuring compliance with applicable regulations.

In response to public comments and negative industry feedback, CMS has deleted this controversial language. In addition, CMS clarified that the provision limiting a physician to providing supervision for no more than three IDTF sites applies solely to physicians providing general supervision services—not to physicians who provide direct or personal supervision services at IDTFs [17].

Enrollment date – §410.33(i) — Historically, the effective date for a new IDTF’s enrollment has been left to the discretion of the Medicare contractor [18] and, in many cases, the effective date has been set retroactively. In an effort to establish a more uniform enrollment standard and confirm that IDTFs are in compliance with Medicare standards before billing, CMS added a new standard that does not entirely preclude an IDTF from retroactively billing for services, but it does limit the period of time for retroactive billing. This provision could prove to be one of the more controversial provisions in the new rule because if the Medicare contractor determines that the application is incomplete or otherwise is not ready for processing (which could take several months from the date the application was actually submitted), the effective date for the IDTF’s billing privileges will be further delayed until the Medicare contractor receives a correct and complete application.

B. Regulations That Target Self-Referral Medicare PDT and Reassignment Rules

Currently under the Medicare PDT Rule, if a physician orders a diagnostic test that is performed by another supplier, the physician may subsequently bill Medicare for the technical component of that diagnostic test; however, the physician is prohibited from “marking up” the technical component charges submitted to Medicare above what the physician paid to purchase the test from the outside supplier [19]. For example, if the physician purchases the technical component of an MRI study from an IDTF for $200, the physician cannot bill Medicare more than $200 for the technical component services.

Due to concerns that physicians who profit from their own self-referrals may be fueling the significant increase in diagnostic testing utilization, CMS significantly expanded the scope of both the PDT Rule and the Medicare reassignment rules by applying an antimarkup provision to both the technical and the professional components billed by the ordering physician if the technical or professional component is:

(1) Performed in a location outside the office of the billing physician. If the billing physician is part of a group practice, the “office of the billing physician” is defined as the space where the group practice provides substantially the full range of patient care services that the group practice provides generally. In other words, the...
Calculating a supplier’s “net charge” — In an attempt to prevent parties from circumventing the antimarkup provision, CMS stated that a “supplier’s net charge” to the billing physician cannot include any charge the supplier incurs as a result of leasing equipment or space from the billing physician. For example, the Medicare fee schedule payment for the professional component of a study is $50. A radiologist agrees to pay an orthopedic group $25 per study for use of office space and a computer workstation to perform professional interpretations. The orthopedic group agrees in return for the radiologist’s professional services to pay the radiologist $50 per study. The radiologist’s “net charge” to the orthopedic group for the professional services would not be the $50 the radiologist was paid but, instead, $25 because the radiologist is essentially paying back $25 of the $50 pursuant to use the workstation. As a result, the orthopedic group would be limited to billing Medicare $25 for the radiologist’s professional component services rather than $50.

Although CMS received numerous comments requesting that it revise the definition of “net charge” to account for the fact that the billing physician incurs billing and other overhead costs in addition to the cost the physician pays the supplier that performed the test or interpretation, CMS bluntly rejected all such requests. CMS was entirely unsympathetic to arguments that the billing physician would, in reality, be paid less than his or her costs if limited to billing no more than the charges paid to the performing supplier. CMS essentially responded that the billing physician should simply structure the relationship in a manner that will not trigger the antimarkup provision if overhead costs are a concern.

In addition, CMS received numerous comments requesting further guidance about how to determine the “net charge” in situations in which the performing supplier is paid on some basis other than “per test” or “per interpretation” (i.e., hourly, per diem, monthly). CMS responded that it is leaving the responsibility for determining the net charge for a test with the billing supplier. Suppliers must calculate the net charge in a reasonable manner.

As a result of CMS’s refusal to provide additional guidance, parties participating in purchased diagnostic test arrangements that involve payment on some basis other than “per test” may expose themselves to unwanted legal risk in the event CMS scrutinizes the claims submissions and disagrees with how the parties arrived at the supplier’s “net charge.”

Elimination of Stark “on-site” interpretation requirement — Under the current Stark rules, when an independent contractor radiologist performs a professional interpretation for a Medicare or Medicaid patient and the service is billed by the self-referring physician’s group practice, the “physician services exception” requires that the independent contractor radiologist perform the interpretation on the group practice’s premises. If the independent contractor radiologist performs the interpretation for Medicare or Medicaid from a remote location, the radiologist must bill separately for the interpretation services because the referring physician would not violate the Stark Law if his or her group practice billed for the professional services.

CMS amended the Stark regulations to provide that a referring physician does not violate the Stark Law when that physician or his or her group practice bills Medicare for the technical or professional component of a diagnostic test for which the antimarkup provision is applicable in accordance with 414.50 of this chapter and section 30.29 of the CMS Internet-Only Manual, publication 100-04, Claims Processing Manual, chapter 1 (general billing requirements).

If the antimarkup provisions had gone into effect on January 1, 2008, as originally scheduled, an independent contractor radiologist who performs reading services off-site from the referring physician’s office, would have been able to bill for the professional component services without violating the Stark Law—provided that the charges submitted to Medicare for the professional component were not marked up. Additionally, radiologists who perform professional component services subject to the antimarkup prohibition would not be required to enter into the “direct contract” discussed earlier in this article.

However, because the antimarkup provision will not apply to professional component services until January 1, 2009, radiologists performing interpretation services for referring physicians off-site during the 2008 calendar year will be subject to the same billing restrictions as applied in 2007. If reads are performed off-site in 2008, the radiologist must bill separately for those services in order to be compliant with the Stark Law.

Proposed changes to the Stark regulations — Other than the one change to the Stark regulations described earlier, CMS declined to adopt...
as final any of the other significant and controversial changes it set forth in the 2008 MPFS Proposed Rule. CMS reported that it received approximately 1,100 comments in response to its proposed Stark changes and apparently decided that, given the significance of the proposal and the volume of public comments, it was not prudent to finalize any of the other proposed changes to the Stark regulations. CMS noted, however, that because it received sufficient information both from the commenters and from CMS’s own independent research, CMS intends to finalize revisions to the Stark regulations without requesting or providing an additional public comment period [25]. Specifically, CMS intends to publish a final rule sometime in the future (perhaps as early as the spring of 2008) that addresses issues such as:

- Unit-of-service (per-click) payments in lease arrangements in which the referring physician is the lessor to the entity to which referrals are made;
- Physician ownership in retirement plans that invest in ancillary service entities;
- Limiting percentage-based compensation to arrangements involving physician services;
- Expanding the “stand in the shoes” provision; and
- Restricting “under arrangements” relationships between referring physicians and hospitals.

CMS is clearly making a concerted effort both through this recent round of rulemaking and through future additional changes to the Stark regulations to curb what it perceives to be potential abuses of the physician self-referral laws and possible overutilization of imaging and other diagnostic testing services by referring physicians. Thus, to the extent they have not done so already, it would be prudent for radiologists and imaging facilities to closely reexamine and possibly consider restructuring their relationships with referring physicians in light of CMS’s current and what appears to be continuing scrutiny of such relationships.

References
1. 73 Federal Register 404
2. 72 Federal Register 51012
3. 72 Federal Register 51018
4. 72 Federal Register 51087
5. 72 Federal Register 51083
6. 72 Federal Register 51045
7. 42 CFR §411.351
8. 72 Federal Register 51020–51021
9. 42 CFR §411.351
10. 72 Federal Register 51019
11. 72 Federal Register 51040–51041
12. 72 Federal Register 66222
13. 72 Federal Register 66398
14. 72 Federal Register 66398
15. 72 Federal Register 66398
17. 72 Federal Register 66398
18. 72 Federal Register 66398
19. 42 CFR §414.50
20. 72 Federal Register 66401
21. 72 Federal Register 66318
22. 72 Federal Register 66318
23. 42 CFR §411.351
24. 72 Federal Register 66400
25. 72 Federal Register 66306