The Beginning of the End of Self-Referral?

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On July 12, 2007, the Centers for Medicare and Medicaid Services (CMS) published in the Federal Register the 2008 Medicare Physician Fee Schedule (MPFS) proposed rule [1], which, in addition to a sharp 9.9% decrease in payment (Congressional committees are reported to be working with organized medicine to halt the payments cuts; House lawmakers are considering a Medicare payment update of at least 0.5% in 2008 and 2009 and possibly replacing the sustainable growth rate with six separate service expenditure targets), includes a number of significant revisions to the independent diagnostic testing facility (IDTF) performance standards, purchased diagnostic test rule, and the physician self-referral prohibition that have the potential to substantially affect the legal or financial viability of certain types of diagnostic imaging ventures [1]. This article summarizes the relevant portions of the proposed rule and discusses the potential impact these proposed changes could have on many existing arrangements.

IDTF Performance Standards

As part of the 2007 MPFS updates, CMS expanded the conditions of participation for IDTFs to require that, at the time of enrollment or reenrollment, the IDTF must certify that it meets a list of 14 additional performance standards [2]. In late January, CMS issued a transmittal to update its Program Integrity Manual with the new IDTF enrollment standards that elicited substantial questions and criticism from the imaging industry [3]. In response to public comments and subsequent discussions with industry representatives, CMS rescinded the controversial language from the transmittal. However, CMS is now proposing to formally rule-making perhaps too far and, as a result, CMS is proposing to delete the controversial language in its entirety and leave in its place solely a provision that limits to three the number of IDTFs that can be supervised by any single physician. We note that, although the text of the proposed regulation does not specifically state this, the preamble discussion clarifies that the three-facility limit is intended to apply only to general supervision services (rather than direct or personal supervision services).

Liability Insurance

Currently, this standard requires that the IDTF “[h]ave a comprehensive liability insurance policy of at least $300,000 per location…” (42 CFR §410.33(g)(6)). Among other changes, CMS is proposing to revise the standard to require that the IDTF add its Medicare administrative contractor as a certificate holder on the policy so that the administrative contractor can at any time directly verify with the insurance underwriter and agent that the IDTF is maintaining the required liability insurance. It remains to be seen, however, whether insurance underwriters will be open to this idea of adding the government as certificate holder on an insurance policy because that could theoretically provide the government with contractual rights to indemnification or payment that it would not otherwise have. We anticipate some resistance regarding this requirement.

Supervising Physician

In the final 2007 MPFS rule, CMS unintentionally expanded the scope of responsibilities for a physician tasked with general supervision of an IDTF when it revised the existing requirement 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” (42 CFR §410.33(b)(1)). In response to negative industry feedback, CMS acknowledged that its earlier rule-making perhaps went too far and, as a result, CMS is proposing to delete the controversial language in its entirety and leave in its place solely a provision that limits to three the number of IDTFs that can be supervised by any single physician. We note that, although the text of the proposed regulation does not specifically state this, the preamble discussion clarifies that the three-facility limit is intended to apply only to general supervision services (rather than direct or personal supervision services).

Prohibition on Sharing

Perhaps the most significant proposal would add a new standard to require an IDTF
to certify that it “[d]oes not share space, equipment, or staff or sublease its operations to another individual or organization” [1]. The stated purpose for this standard is to ensure that an IDTF maintains its operation separate and distinct from the operations of other entities so that CMS can confirm the compliance of the IDTF with the Medicare conditions of participation. In its discussion of the proposed standard, CMS notes that it intends for the prohibition on sharing of office space to apply to shared waiting rooms and the prohibition on shared staff to apply to supervising physicians. We are unclear at this time as to how this prohibition on sharing supervising physicians could possibly be implemented because, in many cases, the supervising physician of an IDTF is, in fact, an individual whose services are shared by one or more IDTFs and that physician’s own group practice. It is likely that CMS will need to further refine this standard to permit or address the sharing of supervising physicians.

If this standard is adopted, it would clearly prohibit an IDTF from having any type of sublease arrangement with a physician practice, a hospital (including “under arrangement” agreements) or any other individual or entity, regardless of whether the sublease was “per click,” “block time,” or any variation thereof. Even arrangements that were structured to fit within a safe harbor to the anti-kickback statute would be prohibited.

**Anti-Markup Applied to Professional Services**

Under the Medicare purchased diagnostic test rule (PDT), also referred to as the “anti-markup provision,” if a physician bills Medicare for the technical component of a diagnostic test performed by an outside supplier, the physician is generally prohibited from marking up the charges submitted to Medicare for the technical component services above what the physician paid to purchase the test from the outside supplier (42 CFR §414.50). Currently, the anti-markup provision does not apply to claims submitted to Medicare for the professional component of a diagnostic test that a physician either purchases under a contract or obtains pursuant to a reassignment from another physician. CMS is proposing to eliminate this ability of a physician to profit from Medicare billings for professional component services that the physician either purchases under contract or obtains via reassignment from an outside supplier by expanding the PDT rule to cover professional services and concurrently adding new provisions to the reassignment rule so that its requirements mirror those of the PDT rule. Notably, CMS would define the phrase “outside supplier” to mean any person or entity other than a full-time employee. As a result, if the professional component of a diagnostic test is performed by a part-time employee, part-time independent contractor, or full-time independent contractor, that service would be subject to the anti-markup provision.

Adoption of these proposed revisions to the reassignment rule would significantly affect the ability of medical groups with in-office imaging equipment and even radiology groups to use independent contractor (and part-time employee) radiologists to perform professional interpretation services because the groups would be limited to billing Medicare no more than the amount actually paid to the radiologist. In fact, the group will not even be able to cover its billing and collection costs associated with billing for the professional services. This proposal will understandably generate a significant amount of public comment.

Under the current Stark rules [4], interpretation services by the independent contractor radiologist must be provided on the premises of a physician group practice when a group practice physician refers and the Medicare or Medicaid patient is to be billed by the group practice. The proposed rules appear to exempt purchased or reassigned interpretation from the on-premises requirements of the Stark rules. The rule would be amended to exclude physicians (or group practices) who bill for purchased diagnostic tests (technical component or professional component) in accordance with a new definition of “entity” under the Stark regulations (42 CFR 411.351 (3)), which currently define an “entity” as the party that bills Medicare for the designated health service (DHS). Although physicians or group practices would still be subject to the proposed anti-markup requirements, it appears that the exemption means that purchased or reassigned interpretation services can be provided remotely, even when performed for Medicare or Medicaid patients whose referral of the technical component of the procedure by an investor in the group required compliance with the in-office ancillary services exception by the referring physician group. CMS may need to further clarify this in the publication of the final rule.

**Putting the Squeeze on Physician Self-Referral?**

The Stark law generally prohibits a physician from referring a Medicare patient for a DHS to be furnished by an entity with which the physician has an ownership interest or compensation relationship [4, 5]. CMS expressed concern in the 2007 MPFS proposed rule regarding the potential for fraud, waste, and abuse of the Medicare program caused by the growth of so-called pod laboratories. Pod laboratories are laboratories that are located off-site from a physician’s office (sometimes in another state) and operated entirely by an independent contractor physician pursuant to a reassignment arrangement for the purpose of performing pathology studies that will be billed globally by the ordering physician’s office. Typically, the physician’s office pays the pod laboratory and the physician a fixed fee per diagnostic test that is less than the global fee the physician can collect from the Medicare program when he or she bills for the test. CMS remains concerned that these arrangements may lead to the ordering of unnecessary tests, involve the payment of kickbacks and fee splitting between the parties, and possibly result in referrals that would otherwise be prohibited under the Stark law. In an effort to protect the Medicare program from what CMS perceives to be a risk of abuse from pod laboratories and similar arrangements for imaging or other services, CMS is proposing several significant revisions to the Stark regulations designed to curtail, if not entirely eliminate, certain types of arrangements.

**Denise of Per-Click Lease Payments?**

Currently, it would be permissible under the space rental and equipment rental exceptions to the Stark law for a cardiologist to lease office space and a CT scanner to an IDTF and structure the lease payments on a per-test or per-click basis. Although the current Stark exceptions for space and equipment rental currently permit per-click lease payments, it should be noted that per-click lease payments do not satisfy the requirements of the corresponding space and equipment rental safe harbors under the federal antikickback statute. In light of public comments regarding the potential for overutilization and abuse created by these types of leasing arrangements, CMS has reconsidered the issue and is now proposing to revise the two rental exceptions to prohibit the use of per-click lease payments in situations in which a physician leases space or equipment to another entity and the physician subsequently refers patients to that other entity for DHS.

For example, under the proposed rule it would not be permissible for a cardiologist to purchase a 64-MDCT scanner and lease the scanner to a hospital on a per-click basis because the cardiologist would be referring
Medicare patients to the hospital for cardiac CTA services. In order for the lease arrangement to qualify for protection under the exception, the lease payments would need to be a fixed, fair market value amount that would not change regardless of the number of studies the hospital actually performs (e.g., $10,000 per month rather than $500 per CT scan).

CMS is soliciting comments on whether it should also consider prohibiting a physician from paying per-click fees to an entity from which the physician leases space or equipment if that entity refers patients to the lessor entity. For example, such prohibition might apply in a situation in which a radiology group owns a 64-MDCT scanner and leases the scanner on a per-click basis to a cardiologist if that cardiologist refers patients to the radiology group for CT interpretation services.

Restricting Percentage-Based Compensation

In addition to eliminating the use of per-click lease fees, CMS is also proposing to eliminate the use of any type of percentage-based fees for office and equipment leases. Currently, the office space rental, equipment rental, and several other exceptions to the Stark law require that the compensation amount be set in advance. The regulations specify that compensation will be considered set in advance if “a specific formula for calculating the compensation is set in an agreement between the parties” (42 CFR §411.354(d)(1)). Thus, the regulations as currently written permit compensation to be paid on a percentage of collections. The only items or services for which the radiologist could be paid on a percentage of collections are his or her professional services.

“Under Arrangements” Under Fire

Medicare generally permits a hospital to contract with a separate provider or supplier to obtain services for its patients “under arrangements.” The hospital bills and is reimbursed by Medicare for the services and, in turn, pays the supplier a negotiated contract rate. For example, a group of cardiologists and radiologists form a joint venture to open a cardiac imaging center on the hospital campus. Rather than enrolling as a supplier with Medicare and other payors, the joint venture enters into an under-arrangements contract with the hospital pursuant to which the joint venture provides imaging services solely to registered hospital outpatients (some of whom are referred by the cardiologists) and the hospital bills for the services provided to Medicare beneficiaries through the Hospital Outpatient Prospective Payment System (HOPPS). The hospital, in return, pays the joint venture a negotiated contract rate for each study it performs. Although at first glance it may appear that the cardiologists would be prohibited from referring Medicare patients to the joint venture for DHS because they have an ownership interest in the joint venture, those referrals would not, in fact, be prohibited because the entity to which the cardiologists are referring is actually the hospital, not the joint venture. This is because the Stark regulations narrowly define the term “entity” to mean the entity that submits a claim to the Medicare program.

CMS noted that, perhaps due in part to the recent Medicare payment reductions for imaging services and surgical services performed in ambulatory surgery centers, these types of under-arrangements contracts with hospitals are proliferating. CMS expressed concern with these types of under-arrangements relationships with physician-owned entities for a number of reasons, including risk that the arrangement encourages the physician-owners to overutilize services “[t]here appears to be no legitimate reason for these arranged for services other than to allow referring physicians an opportunity to make money on referrals” [1, p. 38186]; in many cases, the service furnished under arrangements was previously provided directly by the hospital; and the services furnished under arrangements to hospital patients are typically furnished in a less medically intensive setting than a hospital but billed at the higher HOPPS rates. In fact, CMS explicitly stated that it believes arrangements structured so that referring physicians can own leasing, staffing, and similar entities that do not, themselves, submit claims to Medicare for DHS but, instead, provide items and services to other entities that then bill for the DHS, "raise significant concerns under the fraud and abuse laws" and are “contrary to the plain intent of the physician self-referral law” [1, p. 38187].

In an attempt to prohibit these types of arrangements under which referring physicians supply items and services to entities that bill Medicare for DHS, CMS is proposing what will undoubtedly be a controversial change to the Stark regulations. Specifically, CMS is proposing to expand the definition of “entity” to include not only the entity that submits claims to Medicare for DHS, but also any person or entity, such as the cardiac imaging joint venture, that “performs the DHS” or “caused a claim to be presented for Medicare benefits for the DHS” [1, p. 38224]. Currently, it is clear that a referring physician cannot hold an ownership interest in, for example, an IDTF that is enrolled in the Medicare program and to which that physician would refer Medicare patients for imaging services. An alternative model frequently used to deal with the Stark restrictions is the referring physician forming a joint venture with other referring physicians, radiologists, or a hospital to purchase imaging equipment, lease office space, and essentially operate an imaging center. The joint venture then leases the imaging center to one or more entities such as a radiology group, a hospital, or an IDTF (the “leasing entity”). Provided the lease meets certain requirements of the indirect compensation exception to the Stark law, the referring physician could then refer his patients to the leasing entity because, although the entity is billing Medicare for the DHS, the referring physician does not have an ownership interest in that leasing entity.

If the definition of an “entity” is expanded, the referring physician may not only be making referrals to the leasing entity, but he or she may
also be making referrals to the joint venture because the joint venture is arguably the person or entity that performed the DHS or caused a claim to be submitted to Medicare. Significantly, there is no Stark exception that could be used to protect the referring physician’s Medicare referrals to a joint venture in which he has an ownership interest. The in-office ancillary service exception can be used to protect only a physician’s Medicare referrals to his or her own group practice, not a separate imaging facility joint venture. Notably, the term “performed” is not specifically defined, so we assume that this may generate considerable discussion as to whether a leasing company actually “performs” DHS or merely leases its resources to another entity that then performs the DHS. On the basis of the preamble discussion, we presume CMS will take the former position.

**Conclusion**

Although we believe it is unlikely that all or even most of the proposed changes described in this article will be adopted and implemented by January 2008, when and if the proposed CMS rule is adopted it would significantly limit the ability of referring physicians to bill for imaging services provided to their own Medicare patients. Indeed, many existing imaging arrangements involving referring physicians would most likely have to be restructured or entirely dissolved.

**References**


