ReedSmith

MEMORANDUM

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TO: RADIOLOGY CLIENTS & FRIENDS

DATE: November 6, 2007

RE: Final Rule / 2008 Medicare Physician Fee Schedule

As described in our July 5, 2007, memorandum the Centers for Medicare and Medicaid Services ("CMS") recently proposed a number of significant and controversial revisions to the Medicare program rules in its 2008 Medicare Physician Fee Schedule ("MPFS") Proposed Rule, including revising the independent diagnostic testing facility ("IDTF") performance standards, expanding the scope of the anti-markup rule for diagnostic tests and narrowing the exceptions available under the physician self-referral regulations. On November 1, 2007, CMS released an advanced copy of the final rule for 2008 MPFS which, in addition to a projected 10.1 percent payment decrease[1], finalizes the proposed revisions to the IDTF performance standards and the anti-markup rules.[2] Notably, CMS declined at this time to adopt as final any of the controversial changes it proposed to the physician self-referral regulations. The changes become effective for services rendered on or after January 1, 2008.

This memorandum describes the changes to the IDTF performance standards and anti-markup rules and discusses the potential impact those changes could have on radiology practices and diagnostic imaging arrangements. Many radiologists who own and operate IDTFs – as well as those who have technical component and/or professional interpretation agreements with referring physicians – may need to review and perhaps modify their arrangements to assure compliance with the new rules.

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1 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 percent in 2008 and 2009 and possibly replacing the sustainable growth rate with six separate service expenditure targets.

2 The advance text is posted at: http://www.cms.hhs.gov/physicianfeesched/downloads/CMS-1385-FC.pdf. Note that this is an unofficial version; the official text will be published in the Federal Register on November 27, 2007.

I. IDTF Performance Standards & Conditions of Participation

As part of the 2007 MPFS final rule, CMS expanded the conditions of participation for IDTFs to require that, at the time of enrollment or re-enrollment, an IDTF must certify that it meets a list of fourteen additional performance standards.[3] CMS subsequently set forth in the Proposed Rule a number of substantive changes it was proposing to make to certain of the fourteen performance standards as well as the Medicare conditions of participation. As described below, CMS adopted the majority of its proposed revisions, albeit with certain modifications in response to public comment. Several of the revised performance standards adopted through this rulemaking following notice and comment are policies and enrollment requirements that were first revealed by CMS in its infamous Transmittal 187 issued and rescinded in January, 2007.[4]

A. Liability Insurance – § 410.33(g)(6)

Under the current standard, 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. As highlighted in the redlined regulatory text below, 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. In the Proposed Rule, CMS had also added a requirement that the IDTF name its designated Medicare contractor as a certificate holder on the policy. However, in response to numerous public comments criticizing the requirement as too administratively burdensome, obtrusive and unnecessary, CMS withdrew this requirement from the final rule.

> **§ 410.33(g)** ***Application certification standards.***
> * * * *
> 6) Have a comprehensive liability insurance policy of at least $300,000 per location that covers both the place of business and all customers and employees of the IDTF. The policy must be carried by a nonrelative-owned company. ~~and list the serial numbers of any and all diagnostic equipment used by the IDTF, whether the equipment is stationary, in a mobile unit, or at the beneficiary's residence.~~ Failure to maintain required insurance at all times will result in revocation of the IDTF's billing privileges retroactive to the date the insurance lapsed. IDTF suppliers are responsible for providing the contact information for the issuing insurance agent and the underwriter. In addition, the IDTF must –

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3 For a list of the original fourteen performance standards, see 71 Fed Reg 69784 (Dec. 1, 2006) at http://a257.g.akamaitech.net/7/257/2422/01jan20061800/edocket.access.gpo.gov/2006/pdf/06-9086.pdf.

4 Transmittal 187 at http://www.cms.hhs.gov/transmittals/downloads/R187PI.pdf.

(i) Ensure that the insurance policy must remain in force at all times and provide coverage of at least $300,000 per incident; and

(ii) Notify the CMS designated contractor in writing of any policy changes or cancellations;

B. Enrollment Changes – § 410.33(g)(2)

Currently, an IDTF is required to report any changes to its Medicare enrollment application within 30 calendar days. In order to decrease the administrative burden of this requirement on both IDTFs and the Medicare contractors, CMS has revised the standard as follows:

§ 410.33(g) ***Application certification standards.***
* * * *

(2) Provides complete and accurate information on its enrollment application. ~~Any change in the enrollment information~~ Changes in ownership, changes of location, changes in general supervision, and adverse legal actions must be reported to the Medicare fee-for-service contractor on the Medicare enrollment application within 30 calendar days of the change. All other changes to the enrollment application must be reported within 90 days.

C. Beneficiary Questions & Complaints – § 410.33(g)(8)

CMS has expanded the original performance standard to not only require that the IDTF answer beneficiaries' questions and respond to their complaints, but that the IDTF 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. The documentation of clinical complaints must include:

(i) The name, address, telephone number, and health insurance claim number of the beneficiary.

(ii) The date the complaint was received; the name of the person receiving the complaint; and a summary of actions taken to resolve the complaint.

(iii) If an investigation was not conducted, the name of the person making the decision and the reason for the decision.

Initially, the Proposed Rule would have required that an IDTF maintain documentation of all beneficiary complaints. In response to public comments that such a requirement was unduly burdensome and costly, CMS restricted the scope of the documentation requirement to solely complaints that are clinical in nature.

D. Supervising Physician - § 410.33(b)(1)

In the final 2007 MPFS rule, CMS appeared to expand the scope and responsibilities of the physician tasked with general supervision of the IDTF when it revised the existing requirement to state that the supervising physician must be responsible not only for quality-related oversight but also "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 the controversial language.

In addition, CMS clarified that the provision limiting a physician to providing supervision for no more than 3 IDTF sites applies solely to those physicians providing *general* supervision services – not to those physicians who provide direct or personal supervision services at IDTFs. CMS revised the standard as follows:

> **§ 410.33(b)** ***Supervising physician*****.** (1) Each supervising physician must be limited to providing general supervision to no more than three IDTF sites. This applies to both fixed sites and mobile units where three concurrent operations are capable of performing tests. ~~The IDTF supervising physician is responsible for the overall operation and administration of the IDTFs, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations.~~

E. Enrollment Date – § 410.33(i)

Historically, the effective date of a new IDTF's enrollment has essentially been left to the discretion of the IDTF's Medicare contractor and, in many cases, the effective date has been set retroactively to cover a period when the IDTF was not enrolled with and may not have been operating in compliance with Medicare standards. In an effort to establish a more uniform enrollment standard and confirm that IDTFs are in compliance with the Medicare standards prior to billing, CMS finalized its proposal to add the following new requirement to the IDTF conditions of participation:

> **§ 410.33 (i)** ***Effective date of billing privileges*****.** The filing date of the Medicare enrollment application is the date that the Medicare contractor receives a signed provider enrollment application that it is able to process for approval. The effective date of billing privileges for a newly enrolled IDTF is the later of the following:
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> (1) The filing date of the Medicare enrollment application that was subsequently approved by a Medicare fee-for-service contractor; or
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> (2) The date the IDTF first started furnishing services at its new practice location;

This new rule does not entirely preclude an IDTF from retroactively billing for services, but it does limit the period of time for retroactive billing. This could prove to be one of the more controversial provisions in the new rule. If the enrollment staff at the Medicare contractor determines that the application is incomplete or otherwise is not ready for processing (which could be several months from the date the application was submitted), the effective date for the IDTF's billing privileges will be further delayed until such time as the Medicare contractor receives a correct and complete application. Delays in authority to bill for services could be extremely problematic for many capital intensive diagnostic imaging centers that must make large investments in sophisticated diagnostic imaging equipment as well as in the space and personnel necessary to provide their testing services. Thus, it will be important under this new rule for a prospective IDTF to scrupulously complete its 855B (Attachment 2) enrollment application prior to submission in order to avoid a delay in billing privileges.

F. Prohibition on Sharing – § 410.33(g)(15)

Understandably the most significant policy decision made in these IDTF performance standards was the decision by CMS to adopt its controversial proposal to preclude an IDTF from sharing space or equipment with any other Medicare-enrolled individual or entity (which would include a radiology group).[5] The new standard provides that:

> **§ 410.33(g)** ***Application certification standards.***
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> (15) With the exception of hospital-based and mobile IDTFs, a fixed base IDTF does not include the following:
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> (i) Sharing a practice location with another Medicare-enrolled individual or organization;
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> (ii) Leasing or subleasing its operation or its practice location to another Medicare-enrolled individual or organization; or
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> (iii) Sharing diagnostic testing equipment used in the initial diagnostic test with another Medicare-enrolled individual or organization.

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

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5 Rescinded Transmittal 187 would have imposed the same restriction on IDTFs without formal rulemaking.

The clear effect of the new rule is that fixed IDTFs that are located somewhere other than in a hospital building will now be precluded from entering into any type of arrangement with a physician, physician practice or other entity that involves: 1) subleasing the IDTF's office space and/or imaging equipment to a radiology group to perform interventional procedures; 2) subleasing the IDTF's office space for a referring physician practice to establish a medical office location in the building; or 3) offering even 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 since they generally do not make referrals to the IDTF. CMS declined to create any exceptions for radiologists or any other specialty-specific exceptions.

Although the regulations do not specifically state this, it appears based on CMS's preamble discussion of what constitutes "sharing space" that CMS is applying the "separate post office address" rule. If the IDTF and another Medicare-enrolled individual/entity are in space that has one post office address (i.e., 100 Main Street, Suite A), then the two entities would be "sharing space." If, however, the two entities have different post office addresses (i.e., 100 Main Street, Suite A and 100 Main Street, Suite B) then the two entities are not "sharing space," even if they do happen share common hallways, a common reception area, parking area, etc.

Recognizing that this new standard would require IDTFs currently engaged in space-sharing arrangements to restructure those arrangements, CMS has delayed the implementation date for existing IDTFs until January 1, 2009 in order to provide IDTFs a full year to restructure their relationships.

II. Anti-Markup Provisions

A. Purchased and Reassigned Technical Component and Interpretation Services

Under the Medicare "purchased diagnostic test" rule, 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 essentially 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.[6] Currently, the Anti-Markup Provision has not been triggered by many leasing arrangements, nor does it apply to billings submitted 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 or group practice. In response to CMS's growing realization that overutilization of diagnostic

6 See 42 C.F.R. § 414.50.

testing services may be escalating due to ordering physicians profiting from self-referral, CMS proposed to expand the Anti-Markup Provision and the reassignment rules by: 1) applying the prohibition on marking up charges to professional component services and 2) clarifying that the Anti-Markup Provision applies to any technical or professional component the physician obtains from an "outside supplier," regardless of whether the component is obtained as a "purchased test" or via reassignment from the outside supplier. An "outside supplier" was defined as anyone other than a full-time employee of the physician or medical group.

CMS has, with a few substantial revisions, adopted as final its proposal to revise the Anti-Markup Provisions and reassignment rules in an effort to eliminate the ability of an ordering physician to profit from Medicare billings for technical and/or professional component services that the physician either purchases under contract or obtains via reassignment from another supplier. First, in response to public concern that defining an "outside supplier" as anyone other than a full-time employee would significantly harm a group's ability to use part-time employee or contractors and subsequently drive-up overhead and health care costs, CMS revised the definition of an "outside supplier" to mean someone who is not an employee of the billing physician or other supplier and who does not furnish the test or interpretation to the billing physician or other supplier under a reassignment that meets the requirements of §424.80. In other words, a part-time employee who reassigns his/her right to payment to the billing physician will not be deemed an "outside supplier."

The second and very significant revision CMS made to the language as originally set forth in the Proposed Rule is that CMS created a "bright line" test to determine when the technical or professional component of a diagnostic test is subject to the anti-markup provisions. Specifically, CMS revised the rule to now state that if the professional or technical component of a test is "performed at a site other than the office of the billing physician or supplier" it will be subject to anti-markup prohibition. The "office of the billing physician" is defined as "the medical office space where the physician or other supplier regularly furnishes patient care." Thus, CMS specifically indicated in the preamble discussion that if, for instance, a physician practice entered into an exclusive use or block time lease arrangement with a pathology lab or an imaging center, any tests performed in that leased space would not qualify as being performed "in the office" of that physician practice since the practice does not regularly furnish patient care at the leased diagnostic testing location. As a result, any tests performed at the leased space would be subject to the anti-markup rule, even when such lease qualifies under the same building requirements of the Stark in-office ancillary services exception.

This addition of the "in the office" requirement is significant because it can have the effect of greatly diminishing the financial incentive for a referring physician that has any sizeable Medicare

population to seek any type of leasing arrangement with a freestanding imaging center since any technical component diagnostic testing services that are performed for Medicare patients at the imaging center will be subject to the anti-markup rule.

The new text of the revised regulations is set forth below.

§ 414.50 ***Physician or other supplier billing for diagnostic tests performed or interpreted by an outside supplier or at a site other than the office of the billing physician or other supplier.***

(a) General rule.

(1) The services covered under section 1861(s)(3) of the Act and paid for under part 414 of this chapter (other than clinical laboratory tests paid under section 1833 (a)(2)(D) of the Act, which are subject to the special rules set forth in section 1833(h)(5)(A) of the Act), if a physician or other supplier bills for the technical or professional component of a diagnostic test that was ordered by the physician or other supplier (or ordered by a party related to such physician or other supplier through common ownership or control as described in §413.17 of this chapter) and the diagnostic test is either purchased from an outside supplier or performed at a site other than the office of the billing physician or other supplier, the payment to the billing physician or other supplier (less the applicable deductibles and coinsurance paid by the beneficiary or on behalf of the beneficiary) for the technical or professional component of the diagnostic test may not exceed the lowest of the following amounts:

(i) The performing supplier's net charge to the billing physician or other supplier.
(ii) The billing physician or other supplier's actual charge.
(iii) The fee schedule amount for the test that would be allowed if the performing supplier billed directly.

(2) The following requirements are applicable for purposes of paragraph (a) of this section:

(i) The net charge must be determined without regard to any charge that is intended to reflect the cost of equipment or space leased to the performing supplier by or through the billing physician or other supplier.

(ii) An "outside supplier" is someone who is not an employee of the billing physician or other supplier and who does not furnish the test or interpretation to the billing physician or other supplier under a reassignment that meets the requirements of § 424.80.

(iii) The "office of the billing physician or other supplier" is medical office space where the physician or other supplier regularly furnishes patient care. With respect to a billing physician or other supplier that is a physician organization (as defined at § 411.351 of this chapter), the "office of the billing physician or other supplier" is space in which the physician organization provides substantially the full range of patient care services that the physician organization provides generally.

(b) Restriction on payment.

(1) The billing physician or other supplier must identify the performing supplier and indicate the performing supplier's net charge for the test. If the physician or other supplier fails to provide this information, CMS makes no payment to the billing physician or other supplier and the billing physician or other supplier may not bill the beneficiary.

(2) Physicians and other suppliers that accept Medicare assignment may bill beneficiaries for only the applicable deductibles and coinsurance.

(3) Physicians and other suppliers that do not accept Medicare assignment may not bill the beneficiary more than the payment amount described in paragraph (a) of this section.

42 C.F.R. § 424.80 (d) -*Reassignment to an entity under an employer-employee relationship or under a contractual arrangement.*

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(3) *Reassignment of the technical or professional component of a diagnostic test*. If a physician or other supplier bills for the technical or professional component of a diagnostic test covered under section 1861(s)(3) of the Act and paid for under part 414 of this chapter (other than the clinical diagnostic laboratory tests paid under section 1833(a)(2)(D) of the Act, which are subject to special rules set forth in section 1833(h)(5)(A) of the Act), following a reassignment from a physician or other supplier who performed the technical or professional component, the amount payable to the billing physician or other supplier may be subject to limits specified in § 414.50 of this chapter.

B. Calculating a Supplier's "Net Charge"

In addition to expanding the Anti-Markup Provision to apply to professional component services, CMS is also attempting to prevent "gaming" of the Anti-Markup Provision by clarifying that a "supplier's net charge" cannot include any charge the supplier incurs as a result of leasing equipment or space from the physician or medical group that will be billing for the supplier's services. For example, the Medicare fee schedule payment for the professional component of a Study is $50. A Radiologist agrees to pay Ortho Group $25 per Study for use of office space and computer workstation to perform professional interpretations. The Ortho Group agrees in return for the Radiologist's professional services to pay the Radiologist $50 per Study. The Radiologist's "net charge" to the Ortho Group for the professional services would not be the $50 the Radiologist was paid but, instead, $25 since the Radiologist is essentially paying back $25 of the $50 pursuant to the lease agreement. As a result, the Ortho Group would be limited to billing Medicare $25 for the Radiologist's professional component services rather than a full $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 to 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 would not trigger the Anti-Markup Provision if overhead costs were a concern.

In addition, CMS received numerous comments requesting further guidance on how to determine the "net charge" in those situations where 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 that enter into a purchased diagnostic test or purchased interpretation arrangement that involves payment on some basis other than "per test" may expose themselves to unwanted legal risk in the event CMS ever scrutinizes the claims submissions and disagrees with how the parties arrived at the supplier's "net charge."

C. Elimination of Stark "On-Site" Interpretation Requirement

Under the current Stark rules, the exception for professional interpretation services when the referring physician has an investment interest in the entity to which he refers – and which bills for the Medicare/Medicaid service – is the "physician services" exception available to physician group practices. When an independent contractor radiologist performs a Stark DHS service (such as the professional component of a radiology procedure) for a Medicare/Medicaid patient that is billed by the self-referring physician's group practice, the physician services exception requires that the performance of DHS services by the independent contractor radiologist must be provided *on the group practice's premises*. Under existing Stark requirements, if the radiologist performs the reads for a study from a remote location for a Medicare or Medicaid patient that was referred by an investing physician, the independent contractor radiologist must bill separately for the interpretation services provided since the physician practice would violate the Stark Law if it billed for the services.

CMS has now amended the Stark regulations through the final rule to clarify that a physician or group practice does not violate the Stark Law when that physician or practice "bills Medicare for the technical or professional component of a diagnostic test for which the anti-markup provision is applicable in accordance with 414.50 of this chapter and section 30.2.9 of the CMS Internet-Only Manual, publication 100-04, Claims Processing Manual, Chapter 1 (general billing requirements)." As a result, if an independent contractor radiologist performs reading services off-site from the referring physician's practice, the referring physician will now be able to bill for the professional component services without violating the Stark Law. However, any claims submitted to the Medicare program for the independent contractor radiologist's services provided will now be subject to the anti-markup prohibition. Thus, although the referring physician may bill for the off-site services, the physician cannot profit from those service with respect to Medicare patients.

Should the referring group contract with a local radiology group to read studies for Medicare and Medicaid patients on-site, those services may be reassigned to the referring physician group without application of the anti-markup requirement. Because Stark rules govern the arrangement, the independent contractor must have a direct contractual arrangement with the referring physician group pursuant to the new Stark II, Phase III regulations.[7]

III. Proposed Changes to the Stark Regulations

Other than the one change to the Stark regulations described above, CMS declined to adopt as final any of the other significant and controversial changes it set forth in the Proposed Rule. CMS reported that it received approximately 1,100 comments in response to the proposed Stark changes. CMS apparently decided that, given the significance of the proposal and the volume of public comments it received, 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 CMS's own independent research, CMS intends to finalize revisions to the Stark regulations without requesting or providing any additional public comment period. Specifically, CMS intends to publish a final rule sometime in the future (perhaps sometime next year) that addresses the following proposals:

- Burden of proof;
- Obstetrical malpractice insurance subsidies;
- Unit-of-service (per-click) payments in lease arrangements where the referring physician is the lessor to the entity to which referrals are made;
- The period of disallowance for noncompliant financial relationships;
- Ownership or investment interests in retirement plans;
- "Set in advance" and percentage-based compensation arrangements;
- "Stand in the shoes" provisions;
- Alternative criteria for satisfying certain exceptions; and
- Services furnished "under arrangements."

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7 *Federal Register*; September 5, 2007.

If you have questions regarding the final rule, or if there is any way we can be of assistance, please do not hesitate to contact us.

TWG: HMZ