Impact of Proposed Changes to the Medicare Physician Fee Schedule on Diagnostic Imaging Providers

By

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On August 8, 2006, the Centers for Medicare and Medicaid Services (CMS) posted on its website the proposed updates to the Medicare Physician Fee Schedule (MPFS) for 2007 which include an overall 5 percent cut in the annual MPFS update, a delay the increase in the multiple imaging procedure reduction, and include a number of important clarifications and revisions to the MPFS, reassignment rules, Stark regulations and conditions of participation for independent diagnostic testing facilities (IDTFs). The proposed changes would undoubtedly impact radiology group practices and other diagnostic imaging providers financially but may also alter the structure of certain existing contractual arrangements.¹ This article summarizes the proposed updates and discusses the potential impact of the proposed rules – and the impact of other issues on which CMS requests comments – on diagnostic imaging providers.²

¹ A copy of the proposed rule can be downloaded from the CMS website at http://www.cms.hhs.gov/physicianfeesched/downloads/CMS1321P_final_8-7-06.pdf?agree=yes&next=Accept. The proposed rule is scheduled to be officially published in the Federal Register on August 22, 2006.

² Congress may intervene to roll back some of the proposed cuts in MPFS payments. The Access to Medicare Imaging Act (H.R. 5704 and S. 3795) would delay the Section 5102 DRA imaging cuts for two years pending a Government Accountability Office (GAO) study of the impact of the cuts on availability of imaging services. And Congress may intervene again to roll back the cuts imposed by application of the sustainable growth rate (SGR) formula as they have done each of the last four years.
A. **Multiple Imaging Procedure Reductions**

The final 2006 MPFS rule implemented a 25 percent reduction in 2006 payment amounts for the second and subsequent diagnostic imaging procedures belonging to one of nine imaging families when certain MR, CT or ultrasound procedures are performed the same day on contiguous body parts. The payment reduction applies solely to the technical component of imaging services; the reduction does not apply to the professional component regardless of whether it is billed separately or globally. In the 2006 rules, CMS indicated that the amount of the reduction would be increased to 50 percent beginning in 2007, but sought comments from the public on the appropriateness of a 50 percent reduction. Congress had exempted the multiple procedure cuts from budget neutrality treatment in Section 5102 of Deficit Reduction Act (DRA) effective on or after 2007 in order to gain federal budgetary savings from the reduction. Thus, the MPFS rule proposed for 2007 would remove from the practice expense relative values the 0.3 percent budget neutrality increase applied in 2006. In the 2007 proposed MPFS rule, CMS is proposing to maintain the multiple procedure reduction at its current 25 percent level rather than increasing the reduction to 50 percent next year based on information it received from the American College of Radiology demonstrating that a 50 percent reduction in multiple procedure technical component payments was not justified.

B. **Limit on TC Payments to Hospital Outpatient Amounts**

Section 5102 of DRA also required that CMS adopt a rule placing a cap on the MPFS payment for the technical component (but not the professional component) of certain imaging services at the lesser of the MPFS or the amount that would be paid for that same imaging service if it was paid at the ambulatory payment classification (APC) rate to a hospital outpatient department. To implement the DRA requirement, the proposed rule would cap the MPFS payment amount for certain imaging services (prior to geographic adjustment) by the CY 2007 APC payment amount (prior to geographic adjustment) for imaging services furnished on or after January 1, 2007. CMS then would apply the MPFS geographic adjustment to the capped payment amount.

The only imaging services CMS specifically excluded from the payment cap are: (a) nuclear medicine services that were either non-imaging diagnostic or treatment services; (b) diagnostic and screening mammography; (c) radiation oncology services that were not imaging or computer-assisted imaging service; and (d) any CPT code that describe a procedure for which fluoroscopy, ultrasound, or another imaging modality which is included in the code, whether or
not it is used or employed peripherally in the performance of the main procedure (e.g., CPT code 36122 – bronchoscopy with or without fluoroscopic guidance). The specific CPT codes to which the payment cap would apply are listed in addendum F of the proposed rule.

For imaging services that are subject to both the multiple procedure reduction and the outpatient hospital cap, CMS proposes to first apply the multiple procedure reduction and then apply the outpatient cap. According to CMS, this approach generally results in higher payments than if the hospital outpatient cap were applied first. CMS illustrated this methodology for first applying the multiple imaging cuts as follows:

<table>
<thead>
<tr>
<th>HCPCS</th>
<th>Pre-OPPS Cap MPFS Rate</th>
<th>25% Multiple Imaging Reduction</th>
<th>OPPS Cap Rate</th>
<th>Final MPFS Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>7XXX1</td>
<td>$341.89</td>
<td>$256.42</td>
<td>$316.55</td>
<td>$256.42</td>
</tr>
<tr>
<td>7XXX2</td>
<td>$552.86</td>
<td>$414.65</td>
<td>$391.83</td>
<td>$391.83</td>
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</table>

C. **SGR Reductions**

As a result of the sustainable growth rate (SGR) formula, CMS has proposed that the overall update in the conversion factor be reduced – absent Congressional intervention – by a negative factor of 5 percent. CMS described the impact on various imaging providers from the combination of the negative update in the conversion factor, combined with the DRA Section 5102 cuts on providers of technical component imaging services and the five-year review modifications CMS proposed in June to the relative values of the physician work and practice expense components of the RB-RVS values, as follows:

|-----------|-----------------------|--------------------------------------------------------------------------|-------------------|-----------------------------------------------------------------|---------------|-----------------------------------|
D. **Changes to the Reassignment Rule**

CMS believes that, as a result of changes to the Medicare reassignment rule\(^3\) that were enacted by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the “MMA”), confusion exists among health care providers as to whether the requirements of the purchased interpretation rule\(^4\) must be applied in situations where a practitioner reassigns his/her right to payment for performing professional interpretations services pursuant to a contractual arrangement\(^5\). Thus, CMS is proposing to amend the reassignment rule to clarify how the requirements of the purchased diagnostic test rule (referred to as the “PDT Rule”)\(^6\) and purchased interpretation rule apply in the case where a practitioner performs professional interpretation services pursuant to the contractual arrangement exception and reassigns his/her right to payment to another individual or entity to bill for those services.

The PDT Rule provides that if a diagnostic test was not either: (a) performed or supervised by the physician billing for the service or (b) performed or supervised by another physician who shares a practice with the billing physician, then Medicare will only pay the lower of the costs charged to the physician by the entity that performed or the reasonable charge of the supplier who performed the test.\(^7\) In other words, the physician billing for a purchased test

<table>
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<tr>
<th>Interventional Radiology</th>
<th>$233</th>
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<th>-9%</th>
<th>-5%</th>
<th>-14%</th>
</tr>
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<tbody>
<tr>
<td>Nuclear Medicine</td>
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<td>-2%</td>
<td>-9%</td>
<td>-5%</td>
<td>-14%</td>
</tr>
<tr>
<td>Radiation Oncology</td>
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<td>0%</td>
<td>-1%</td>
<td>-5%</td>
<td>-7%</td>
</tr>
<tr>
<td>Radiology</td>
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<td>-6%</td>
<td>-11%</td>
<td>-5%</td>
<td>-16%</td>
</tr>
<tr>
<td>Diagnostic Testing Facility</td>
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<td>-17%</td>
<td>-19%</td>
<td>-5%</td>
<td>-25%</td>
</tr>
</tbody>
</table>

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\(^3\) See 42 C.F.R. § 424.80.

\(^4\) See Medicare Claims Processing Manual (Pub. 100-4) Ch. 1, § 30.2.9.1.

\(^5\) See 42 C.F.R. § 424.80(d)(2).

\(^6\) See 42 C.F.R. § 414.50 and MCPM Ch. 1, § 30.2.9.

\(^7\) See Social Security Act § 1842(n)(1)(A).
cannot mark-up the charge for the technical component of the test above what the physician paid to the entity that actually performed the test.

Prior to the change in the Medicare reassignment rule to now permit a physician to reassign via a contractual arrangement even if the services are performed off-site, the only way a diagnostic imaging provider could bill for professional interpretations performed off-site was through the purchased interpretation rule. However, under the purchased interpretation rule a diagnostic imaging provider can only submit a claim for the professional component of a diagnostic test performed by another physician (whether or not the interpretation is performed physically at the provider’s site) if each of the following requirements is met:

- The entity performing the interpretation is enrolled in the Medicare program.

- The diagnostic test was ordered by a physician or medical group that is independent of:
  (a) the person or entity that performed the technical component and (b) the physician or medical group that performed the interpretation.

- The physician performing the interpretations does not see the patient.

- The entity that bills for the professional interpretation performs the technical component of the diagnostic test.

It is primarily because of the second bullet point above that the purchased interpretation rule cannot be used by a self-referring orthopedic, cardiology or other group practice that owns diagnostic imaging equipment to which its physicians refer their patients if the interpretation services are to be performed off-site since the group practice would be both ordering and performing the technical component for their own patients. Once the Medicare reassignment rule was amended, however, to permit reassignment by an independent contractor who performs services off-site, certain providers who previously could not perform services off-site (because they could not meet the requirements of the purchased interpretation rule) sought to take advantage of the changes.

CMS particularly expressed concern regarding the potential for abuse of the Medicare program that could be created by the growth of so-called “pod” or “condo” 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 interpreting physician a fixed fee per diagnostic test that is less than the global fee the physician is able to collect from the Medicare program when he/she bills for the test. CMS is concerned that this arrangement 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, CMS is proposing to amend the reassignment rule to include a new subsection that would specifically incorporate the requirements of the PDT Rule to any arrangement in which a physician bills for the technical component of a diagnostic test pursuant to a contractual reassignment relationship. As a result, the physician billing for the technical component services would be required to identify on any claim submitted to Medicare the identity of the physician or supplier who performed the test and the actual amount the billing paid for the test. The billing physician would be prohibited from marking-up the charge for the test. Additionally, in order to bill for the technical component provided under a contractual reassignment, the billing physician must “directly perform the professional component” of the diagnostic test.

Although CMS is not, at this time, formally proposing an amendment to the reassignment rule, CMS announced that it is considering the possibility of further amending the rule to specifically incorporate and apply all of the requirements of the purchased interpretation rule as summarized above to any contractual arrangement between a billing physician and another physician or medical group to perform professional interpretations of diagnostic tests pursuant to a reassignment. If adopted, this proposal to incorporate the purchased interpretation requirements could potentially be problematic for two types of arrangements: (1) hospital-based radiology groups that utilize independent contractors for official reads via teleradiology, and (2) non-radiology physician practices that desire to contract for professional interpretations services and bill for those services on a global basis.

This proposed change to the reassignment rule could impact those hospital-based radiology groups who contract with independent contractors for teleradiology services to perform official interpretations since it is not uncommon under such arrangements for the hospital-based group to bill the Medicare program for the professional component services under the group’s number pursuant to a reassignment by the teleradiology group. If CMS was to
change the rule as proposed, the hospital-based group would be precluded from billing Medicare for the professional interpretations performed by the teleradiology service for hospital patients since the hospital-based group would not satisfy the requirement that the group perform and bill for the technical component of the service under its supplier number.

The proposed change to the reassignment rule could also affect the ability of non-radiologist, referring physician practices to bill for professional interpretations performed pursuant to a contractual reassignment. If the reassignment rule was amended to require that the entity which performs the test and bills for the professional component be independent from the physician/entity that ordered the test, this would effectively preclude a physician practice that performs and bills for imaging services under the in-office ancillary services exception to the Stark Law from billing for the professional component of those services performed by an independent contractor radiologist since the billing physician practice would be both ordering and performing the technical component of the test.

CMS is not at this time formally proposing to amend the reassignment rule to incorporate the purchased interpretation requirements. Instead, CMS is seeking comments from the public on the proposal. CMS is particularly interested in receiving comments on whether there should be a carve-out from the purchased interpretation requirements for diagnostic radiology and related imaging tests and whether it should also apply the anti-markup provision to the professional component of diagnostic tests performed pursuant to a contractual reassignment arrangement.

**E. Changes to the Stark “Centralized Building” Requirement**

As an additional measure designed to curb (if not entirely eliminate) the proliferation of “pod” laboratories and the perceived risk of abuse such arrangements create, CMS is also proposing to revise the “in-office ancillary services” exception to the Stark Law by changing the definition of what constitutes a “centralized building.” A “centralized building” is currently defined as all or part of a building, mobile vehicle, van or trailer that is owned or leased on a full-time basis (that is, 24 hours per day, 7 days per week, for a term of not less than 6 months) by the group practice and that is used exclusively by that group practice. CMS is proposing to add a requirement that in order for a space to qualify as a “centralized building” the space must be at

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8 See 42 C.F.R. § 411.351 – *Centralized Building*. 
least 350 square feet. In addition, CMS is proposing that the space must, on a permanent basis, contain the necessary equipment to perform substantially all (meaning at least 90 percent) of the designated health services that will be performed in the space in any given calendar year. The equipment cannot be temporarily moved into the space from another space in the same building or from outside the same building.

The one additional requirement which CMS is considering, but not yet proposing, and which could have the most significant impact on group practices that rely on the centralized building requirement to provide diagnostic imaging services to their patients is a requirement that the group practice must staff the space with a nonphysician employee or independent contractor who performs services exclusively for the group practice in that space no less than 35 hours per week. This requirement would essentially limit use of the centralized building to only those practices that have a significant volume of diagnostic testing or other ancillary services such that the group could support the existence of a centralized testing site.

F. Implementing Additional Supplier Standards for IDTFs

The Office of Inspector General (OIG) for the U.S. Department of Health & Human Services recently published the results of a review it conducted of claims billed to Medicare by IDTFs. The OIG concluded that many erroneous payments were made as a result of poor or missing documentation or a lack of medical necessity. In an effort to decrease the volume of erroneous payments identified in the study, CMS is proposing to adopt supplier standards for IDTFs similar to those currently in place for suppliers of durable medical equipment, prosthetics, orthotics and supplies. These supplier standards would be required in addition to all of the existing requirements for IDTFs contained in the Medicare conditions of participation for such entities. If an IDTF fails to meet one or more of the following standards summarize below either at the time of enrollment or re-enrollment, the enrollment application would be denied:

1. Operate in compliance with all applicable federal and state licensure and regulatory requirements.

2. Provide complete and accurate enrollment information and report any change to such information within 30 days of the change.

3. Maintain a physical facility on an appropriate site that contains: (a) the equipment necessary to provide the services identified on the enrollment application; (b)
facilities for hand washing; (c) adequate patient privacy accommodations; and (d) storage of business and medical records.

(4) Have all testing equipment available at the physical site (excluding portable equipment). All portable equipment must be available for inspection within 2 business days of a CMS inspection request. The IDTF must maintain a current inventory of all equipment (including portable equipment) by serial and registration numbers, provide this information upon request by a Medicare contractor and notify the contractor of any changes in the equipment inventory within 90 days.

(5) Maintain a primary business phone at the physical facility and under the name of the designated business. The telephone number must be available in a local directory and through directory assistance.

(6) Have a comprehensive liability insurance policy that covers both the place of business and all customers and employees of the IDTF and that is equal to the greater of $300,000 or 20 percent of the average annual Medicare billings. The policy must be carried by a company that is not owned by a relative and it must list the serial numbers of any and all equipment used by the IDTF.

(7) Agree not to directly solicit patients through any means including, but not limited to, a prohibition on telephone, computer or in-person contacts.

(8) Answer beneficiaries’ questions and respond to complaints.

(9) Post these supplier standards for review by patients and the public.

(10) Disclose to the government the identity of any person who has ownership, financial or a control interest in the IDTF.

(11) Have its testing equipment calibrated in accordance with the equipment instructions and applicable national standards.
(12) Have technical staff on duty with appropriate credentials to perform tests and be able to produce applicable federal or state licensed or certificates for such individuals.

(13) Have proper medical records storage and be able, upon request from CMS, to retrieve such record within 2 business days.

(14) Permit CMS to conduct unannounced, on-site inspections to confirm the IDTF’s compliance with the standards. The site should maintain a visible sign posting the normal business hours and it should be accessible to CMS and beneficiaries during such business hours.

In addition to requiring IDTFs to comply with the above-summarized supplier standards, CMS is also proposing to revise the current requirements for supervising physicians\(^9\) and multi-state entities\(^10\). In an effort to ensure quality care is provided to Medicare beneficiaries, CMS is proposing to amend the supervising physician requirement to limit a supervising physician to providing such supervision services to no more than three IDTF sites. In an effort to clarify the place of service that should be designated on a claim and, thus, ensure the proper payment amount is remitted, CMS is proposing to revise the requirements for multi-state IDTFs to specify that the place where the service is actually delivered should be designated as the “Place of Service” on the claim form.

CMS will be accepting comments from the public sixty days following the date of official publication, which is expected to be August 22, 2006.

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\(^9\) See 42 C.F.R. § 410.33(b).

\(^10\) See 42 C.F.R. § 410.33(e).