

Final 2009 Medicare Physician Fee Schedule Rule: An Analysis

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The final 2009 Medicare physician fee schedule rule (Final 2009 PFS) was made public October 30, 2008, and will be published in the *Federal Register* November 19, 2008. The proposed 2009 PFS was summarized in McDermott's *White Paper* entitled "2009 Medicare Physician Fee Schedule," available at <http://www.mwe.com/info/news/wp0708c.htm>. The Final 2009 PFS adopts a number of the original proposals, but did not adopt two of the most controversial proposed changes, which would have required certain physician practices to enroll in Medicare as independent diagnostic testing facilities (IDTFs) in order to provide diagnostic imaging services, and would have added a Stark Law exception for gainsharing. The Final 2009 PFS does, however, include substantial revisions to the diagnostic test anti-markup rule, and adopts many of the other provisions of the proposed rule. The AMR is also described in more detail in McDermott's *On the Subject* "Diagnostic Test Anti-Markup Provisions," available at <http://www.mwe.com/info/news/ots1108j.htm>.

Stark Exception for Pay-for-Performance and Gainsharing Programs

In the proposed 2009 PFS, CMS proposed a new regulatory exception to the Stark Law that would permit hospitals to provide monetary incentives to physicians for improving patient care quality (incentive payment programs) and sharing patient care cost savings with physicians (shared savings programs). The proposed rule included highly prescriptive requirements that generally tracked the safeguards found in the OIG's various gainsharing opinions. In the Final 2009 PFS, CMS declined to finalize such an exception, instead reopening the comment period for an additional 90 days. CMS solicited additional comments in 55 different areas. It appears that most of the comments to date recommended liberalization or elimination of various of the proposed requirements. CMS seeks recommendations on how to accomplish that while ensuring no risk of program or patient abuse. Specifically, CMS seeks to achieve transparency and accountability, ensure quality of care and prevent disguised payments for referrals.

CMS suggested that incentive payment programs and shared savings programs may meet one or more of the existing compensation exceptions (*e.g.*, the personal services or fair market value exception) and also requested comments on whether it would be preferable to modify aspects of existing exceptions rather than promulgating a new regulatory exception.

IDTFs and In-Office Imaging

The Final 2009 PFS will likely be controversial, as much for what CMS declined to change as for the changes that CMS made. Of utmost significance, CMS declined to implement its prior proposal to require a physician practice performing diagnostic testing at a site to enroll that site in the Medicare program as an IDTF. While physician practices were given a pass, mobile imaging providers will be subject to greater scrutiny. Effective January 1, 2009, a mobile imaging provider must be enrolled in the Medicare program as an IDTF. A mobile imaging provider will also be required to directly bill the Medicare program for its services unless it is providing the service to a hospital in connection with an "under arrangements" transaction.

IDTF STANDARDS NOT APPLICABLE TO PHYSICIAN PRACTICES

Earlier in July 2008, CMS had proposed that the IDTF performance standards, including prohibitions against the sharing of space and equipment, apply to physician practices that are performing diagnostic testing services for Medicare beneficiaries. One of CMS's primary reasons for the proposal was based on its concern that physician practices could offer diagnostic testing services without the benefit of qualified non-physician personnel. In the 2009 Final PFS, CMS decided to defer the implementation of this proposed change.

CMS's decline has likely disappointed a number of radiology groups, IDTF management companies and radiology benefit managers that had anticipated that CMS would subject physician practices offering diagnostic testing services to their patients to the same rigorous standards applicable to other non-hospital providers of imaging services. Some of these commenters had previously warned CMS that its failure to adopt such a proposal would result in two distinct compliance and regulatory standards to emerge depending on how similarly situated imaging centers were enrolled in the Medicare program.

The proposed change, however, had certain key controversial aspects. First, CMS recognized that compliance with some of the IDTF performance standards would be costly and burdensome and possibly limit beneficiary access, particularly in rural or medically underserved areas.

Another concern worth noting (but not expressed by CMS) was whether a physician practice would be required to have a radiologist supervise the diagnostic test (which is often required for an IDTF), as opposed to a physician within the practice. Such a result would have likely required a number of physician practices to either forego the provision of imaging services to their patients or restructure their reading arrangements with radiologists. It is quite common for radiologists to perform interpretations and provide general supervision vis-à-vis teleradiology (e.g., PACS). Had the proposed change been adopted, a physician practice would have had to engage a radiologist to be onsite in those instances when direct supervision (i.e., MRI with contrast) or personal supervision is required.

The 2009 Final PFS places these changes in limbo for the moment. CMS suggested that it would be inappropriate to implement such a material change without having had an opportunity to review all public comments received on this matter. Additionally, CMS acknowledged that Section 135 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) requires an accreditation process to be established by January 1, 2012, for those furnishing advanced diagnostic tests, including MRI, CT and PET.

MOBILE IMAGING PROVIDERS

CMS has adopted its proposed IDTF performance standard that requires an entity furnishing mobile diagnostic testing services to enroll in the Medicare program as an IDTF and to directly bill the Medicare program for the services that it furnishes. The new performance standard is effective as of January 1, 2009. The only exception is for an entity performing mobile diagnostic services “under arrangements” with a hospital. While such a mobile company must still enroll in the Medicare program as an IDTF, it is not required to comply with the direct billing requirement. Rather, it must provide CMS with documentation of the arrangement when it submits a CMS Form 855B during its initial or revalidation enrollment application or change in enrollment application.

While the anti-markup rule (for more information, see McDermott’s *On the Subject* “Diagnostic Test Anti-Markup Provisions,” available at <http://www.mwe.com/info/news/ots1108j.htm>) may impose some additional obstacles and limitations, it is likely that a number of physician practices will continue to provide their patients with the convenience of in-office imaging services. Since physician practices will not (at least for the moment) be subject to IDTF performance standards, it is also likely that physician practices will continue to engage in block leasing and other shared imaging arrangements with other non-IDTF providers, while IDTFs and mobile imaging providers cope with an increasingly complex web of Medicare performance standards.

Anti-Markup Rule

The Medicare diagnostic test anti-markup rule (AMR) implements the statutory prohibition against an ordering physician billing Medicare in excess of the net charge for a diagnostic test that is not performed or supervised by the ordering physician or another physician with whom the ordering physician shares a practice. The AMR applies to all diagnostic tests except clinical laboratory tests, which are subject to special Medicare billing and payment rules. Last year CMS made substantial changes to the AMR, but then delayed implementation of the modified AMR until January 1, 2009, except as applied to anatomic pathology. The Final 2009 PFS includes two important new developments for the AMR, effective January 1, 2009.

First, CMS simplified the AMR by abandoning its application to diagnostic tests that are “purchased.” Instead, the revised AMR focuses exclusively on the question of whether the performing or supervising physician shares a practice with the ordering/billing physician practice. Thus, CMS has eliminated the interpretive difficulties in determining what constitutes a purchased test, who is an “outside supplier” and who employs the technologist.

Second, the Final 2009 PFS gives physician practices the option of relying on either of two alternative tests in determining whether a diagnostic test is performed by a physician sharing a practice with the billing physician. The first alternative test provides that the interpreting or supervising physician (as the case may be) shares a practice with an ordering, billing practice if the physician provides at least 75 percent of his or her patient care services through the practice. The second alternative test provides that the interpreting or supervising physician shares a practice with the billing practice if the physician is an owner, employee or contractor of the billing practice, and the ordering physician furnishes substantially the full range of patient care services he or she provides generally in the same building where the test is conducted and supervised. “Same building” is defined by reference to the Stark law’s definition of “same building.”

For a full discussion of the AMR, please see McDermott’s *On the Subject* “Diagnostic Test Anti-Markup Provisions,” available at <http://www.mwe.com/info/news/ots1108j.htm>.

Physician Payment Cuts

Under the Medicare statute, CMS is required to adjust payments to physicians annually on the basis of a formula. In recent years, this formula has repeatedly directed a negative update for physician services, but Congress has acted each year to specify a positive update outside of the formula. In the latest installment of what has become an annual ritual, in July 2008 Congress passed the MIPPA over the veto of President Bush. The MIPPA blocked implementation of a scheduled 10.6 percent cut and provided a 1.1 percent increase for 2009. The proposed rule was published prior to passage of the MIPPA, and thus proposed a 10.6 percent payment cut; the Final 2009 PFS rule reflects the increases provided for in the MIPPA. Absent congressional intervention, however, CMS will once again be forced to implement drastic cuts in physician payments in 2010 based on the statutory formula. Current estimates predict a payment reduction of approximately 20 percent.

Prohibition Concerning Providers of Sleep Tests

CMS finalized its proposal to prohibit payments to a supplier of a continuous positive air pressure (CPAP) device if that supplier, or its affiliate, is directly or indirectly the provider of the sleep test used to diagnose the beneficiary with obstructive sleep apnea (OSA). The Final 2009 PFS rule, however, includes an exception for attended facility-based sleep tests. In adopting this exception, CMS recognized commenters' concerns regarding the impact of the proposed rule on integrated sleep management programs, and stated its view that facility-based tests present less risk of abuse than home sleep tests.

Payment for Pre-Administration Services Related to Intravenous Infusion of Immune Globulin

CMS finalized its proposal to discontinue the separate payment for pre-administration services related to administration of intravenous immune globulin (IVIG). The separate payment, which was made under HCPCS code G0332, was designed as a temporary measure to reimburse physicians for the additional resources needed to locate and acquire IVIG supplies during a period in which IVIG products were perceived to be in limited supply. CMS's decision to discontinue the payment was based on its view that the IVIG market instability has largely been resolved.

Physician Quality Reporting Initiative

The MIPPA directed CMS to continue the Physician Quality Reporting Initiative (PQRI) and provided for an increase in the incentive payment from 1.5 percent to 2 percent for 2009 and 2010. The PQRI is seen by many as a precursor to a pay-for-performance program. The Final 2009 PFS reflects the increased incentive payment directed by the MIPPA, plus new quality measures and additional measures groups for coronary artery bypass graft (CABG) surgery, rheumatoid arthritis, perioperative care and back pain.

Speech-Language Pathologists in Private Practice

In the Final 2009 PFS, CMS adopted regulations to implement its authority under the MIPPA to enroll speech-language pathologists to bill Medicare and receive direct payment for Medicare-covered outpatient speech-language pathology (SLP) services furnished in private practice beginning July 1, 2009. The requirements to bill as a speech-language pathologist in private practice are patterned after the requirements for physical therapists and occupational therapists in private practice. They include the following:

- The supplier possesses a state license or other necessary legal authority to provide SLP services.
- The services are provided in one of the specified private practice office settings.
- Services are provided to patients of the practice and for whom the practice collects the fees for the services furnished.

Like other categories of SLP service providers and suppliers, Medicare reimburses speech-language pathologists in private practice the amounts set forth in the Medicare Physician Fee Schedule for the SLP service.

Physician and Non-Physician Practitioner (NPP) Enrollment Issues

CMS finalized several revisions to its rules governing the enrollment of physicians, NPPs, and physician and NPP organizations (such as incorporated practitioner groups and clinics). Below is a summary of some of the more significant changes.

EFFECTIVE DATE

Under current rules, Medicare contractors enroll physicians, NPPs, physician organizations and NPP organizations (suppliers) in Medicare and grant billing privileges with an effective date retroactive to the later of the supplier's first date of service to a Medicare beneficiary or the date that the supplier met all Medicare program requirements. Once enrolled, the supplier may be permitted to bill Medicare for services rendered up to 27 months prior to the enrollment (depending on the effective date assigned by the contractor). CMS is concerned that such retrospective billing may have resulted in reimbursement to some suppliers for services that failed to meet Medicare program requirements when provided.

Accordingly, in the Final 2009 PFS, CMS amended the current rules to establish a general rule that the effective date is the later of: the date of filing of a Medicare enrollment application that was subsequently approved by the applicable contractor, or the date an enrolled supplier first started rendering services at a new practice location. However, the Final 2009 PFS provides that a newly enrolled supplier may bill for pre-effective-date services to Medicare beneficiaries up to 30 days prior to the effective date if special circumstances precluded enrollment in advance of providing services to Medicare beneficiaries and up to 90 days prior to the effective date in the event of a presidentially declared disaster. To assure Medicare reimbursement, it is essential for a new supplier to file an enrollment application before providing services to Medicare beneficiaries.

REPORTING REQUIREMENTS FOR SUPPLIERS

CMS finalized its proposal to shorten the timeframe for reporting certain changes in Medicare enrollment information by suppliers, including physician organizations, to 30 days. Under the Final 2009 PFS, in addition to a change of ownership (as under current rules), suppliers would be required to report certain adverse legal actions and changes in practice location within 30 days (rather than the 90 days permitted under current rules). CMS also finalized new authority to recoup overpayments resulting from a failure to timely report changes and revoke billing privileges as a result of such a failure. The overpayment would accrue from the date of an applicable adverse event or date of a move to a new practice location in an area with lower Medicare payment rates.

MAINTAINING ORDERING AND REFERRING DOCUMENTATION

CMS proposed to require providers and suppliers to maintain written documentation including the national provider identifier (NPI) of the ordering and referring physician (or NPP) for 10 years from the date of service for all services provided. In the Final 2009 PFS, CMS requires providers and suppliers to maintain written documentation including the NPI of the ordering and referring practitioner for seven years from the date of service. The shorter seven-year period is intended to correspond more closely to the seven years from date of payment standard currently in the Medicare Program Integrity Manual. If adopted, failure to comply with this requirement would be a basis for revocation of billing privileges. It may be necessary for suppliers and providers to review and revise their document retention policies and procedures to comply with this requirement.

Comprehensive Outpatient Rehabilitation Facilities (CORF) and Rehabilitation Agency Issues

CMS finalized various proposed changes to the coverage requirements and conditions for coverage for CORFs and rehabilitation agencies. Below is a summary of some of the more significant proposed changes.

PERSONNEL QUALIFICATIONS

CMS finalized a revision to the required qualifications for respiratory therapists in CORFs to be consistent with current qualification requirements recommended by the American Association for Respiratory Care. CMS also finalized an amendment to the duties of a CORF physician to include medical supervision of non-physician staff.

SOCIAL AND PSYCHOLOGICAL SERVICES

In the Final 2009 PFS, CMS creates a new G-code of G0409 for a CORF's social and psychological services to more accurately describe the social and psychological services that a CORF provides in support of the patient's rehabilitation plan of care. In addition, CMS finalizes its proposal that the Medicare limitation on reimbursement for mental health services will not apply to a CORF's social and psychological services because they are in furtherance of the rehabilitation plan of care.

SOCIAL AND VOCATIONAL SERVICES OF REHABILITATION AGENCIES

CMS finalizes its proposal to delete the requirement that rehabilitation agencies provide social and vocational adjustment services since it believes that such services are properly outside a rehabilitation agency's scope of practice and are not currently reimbursed by Medicare.

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