

2009 Medicare Physician Fee Schedule

July 16, 2008

Introduction

The proposed 2009 Medicare physician fee schedule (MPFS) regulations published in the Federal Register on July 7, 2008, cover a wide range of topics that affect not just physician compensation, but also the manner in which physicians may provide and be paid for services other than traditional professional services. As in other years, the Centers for Medicare and Medicaid Services (CMS) is using the rulemaking to address subjects such as purchased services and standards applicable to independent diagnostic testing facilities (IDTFs). CMS also has proposed a new Stark Law exception relating to gainsharing and pay-for-performance programs, but does not address some of the other Stark Law issues that remain outstanding from prior rulemakings. This proposed rulemaking was published in the midst of congressional consideration of Medicare legislation that includes provisions affecting several key aspects of Medicare physician payment rates and policy. The legislation, which was approved by Congress on July 15, 2008, despite a presidential veto, impacts this rulemaking in several ways.

This *White Paper* summarizes some of the notable provisions of the proposed 2009 MPFS. In addition, more detailed discussions of the proposed diagnostic test “anti-markup” rule and Stark Law exception for gainsharing and pay-for-performance are found in two additional newsletters located at <http://www.mwe.com/info/news/ots0708f.htm> and <http://www.mwe.com/info/news/wp0708a.htm>.

Overview of Scheduled Physician Payment Cuts

Under the Medicare statute, CMS is required to adjust payments to physicians annually on the basis of a formula. This formula has directed a negative update for physician services in each of the last four years. Congress has acted each year since 2003 to specify an update outside of the formula to avert a scheduled negative update to the physician fee schedule conversion factor. For the first half of 2008, Congress enacted legislation that blocked CMS from implementing the scheduled 10.1 percent reduction and required that payments be increased by 0.5 percent. Congress, however, failed to address the payment reduction for the final six months of 2008 before it expired on June 30, 2008. Thus, effective July 1, 2008, CMS implemented a 10.6 percent across-the-board reduction in payments to physicians, but it directed its Medicare Administrative Contractors (MACs) to withhold payments for 10 days in hopes that Congress would remedy the situation in that time. On July 15, 2008, Congress enacted legislation that freezes payment rates for the final six months of 2008, thereby blocking implementation of the 10.6 percent cut; the legislation also provides a 1.1 percent increase for 2009. CMS’s proposed rule does not reflect this payment update because it was published before Congress passed the legislation.

Physician Quality Reporting Initiative

The Tax Relief and Health Care Act of 2006 – Medicare Improvements and Extension Act of 2006 (MIEA-TRHCA) required CMS to establish a physician quality reporting program, which CMS named the Physician Quality Reporting Initiative (PQRI). The MIEA-TRHCA, as amended by the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA), authorizes CMS to make incentive payments to physicians who satisfactorily report quality measures in accordance with the requirements of the PQRI in 2007 and 2008. This pay-for-reporting scheme is comparable in effect and practice to the pay-for-reporting programs that have been operating for hospitals and other providers for several years. Specifically, for 2007 and 2008, eligible providers who have satisfied the PQRI reporting criteria are entitled to an incentive payment of 1.5 percent of the estimated total allowed charges for all covered professional services furnished during the reporting period. At the time CMS published the proposed rule, Congress had not yet authorized CMS to make such incentive payments for PQRI data reported in 2009. Consequently, CMS proposed to discontinue the incentive payment program, effective January 1, 2009. However, on July 15, 2008, Congress enacted legislation that provides for a 2 percent incentive payment for 2009 and 2010.

CMS also is proposing a number of updates to the PQRI for 2009, including expanding the number of measures and incorporating new “measures groups” for reporting focused on specific conditions or focus areas. In addition, the proposed rule reflects CMS’s continuing efforts to develop and refine policies and procedures for claims-based, registry and electronic health record reporting of PQRI data.

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

Physicians bill for administration of intravenous immune globulin (IVIG) under the physician fee schedule using CPT codes. Since 2006, CMS has paid an additional fee to physicians for pre-administration services. This payment, billed under a separate G-code (HCPCS code G0332), was adopted by CMS 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. This separate payment was extended by CMS for CY2007 and CY2008. (Medicare currently pays physicians approximately \$75 for these pre-administration services.) However, CMS now is proposing to discontinue the separate payment for pre-administration services based on its conclusion that the instability in the IVIG market has resolved. CMS also proposed to discontinue separate pre-administration payments under the hospital outpatient prospective payment system by packaging the payment for G0332 into the drug payment amount effective January 1, 2009.

Prohibition Concerning Providers of Sleep Tests

Presently, there is no federal rule prohibiting providers of sleep tests from having financial relationships with suppliers of devices used to treat sleep apnea. However, CMS is concerned that these financial relationships, which are becoming increasingly common, may lead to program abuse and beneficiary harm. CMS is particularly concerned about providers who administer sleep tests on patients who are diagnosed with obstructive sleep apnea (OSA), the most common form of sleep apnea, and who either themselves, or through an affiliate, also supply the continuous positive air pressure (CPAP) device used to treat the patient's OSA. CMS believes that the provider's vested interest in the outcome of the sleep test may influence the frequency with which the provider orders the test and/or may lead to bias in reading the test results. In order to address this concern, CMS has proposed to amend 42 C.F.R. § 424.57 to prohibit payment to a supplier of a CPAP device if that supplier, or its affiliate, is directly or indirectly the provider of the sleep test used to diagnose the beneficiary with OSA.

Physician Practices Offering Diagnostic Testing Services Must Enroll as IDTFs

In the 2007 MPFS final rule and the 2008 MPFS rule, CMS established a number of quality and performance standards for independent diagnostic testing facility (IDTFs). The proposed 2009 MPFS rule expands on the quality and program safeguard activities that were previously implemented and would, if adopted, require all physician and non-physician practitioner (NPP) organizations providing diagnostic testing services to enroll as an IDTF for each practice location providing these services.

WHAT PROMPTED THE PROPOSED CHANGE?

The proposed expansion of IDTF enrollment to physician and NPP organizations performing diagnostic testing services is driven in part by CMS's concerns that standards for imaging services were not being applied consistently for all imaging centers and that two different standards of regulatory compliance have emerged based on how an imaging center is enrolled in the Medicare program. In particular, CMS expressed concerns that group practices and certain other types of physician entities could avoid the IDTF performance standards even though they were offering the same types of services as an IDTF.

IMPACT ON SHARED ANCILLARY ARRANGEMENTS AND SUPERVISING PHYSICIANS

The rule change, if implemented, is likely to stir some controversy, as physician and NPP organizations adapt to the more rigorous and complex IDTF Medicare standards, including the prohibition against the sharing of space and equipment with any other Medicare supplier and the requirement that the diagnostic procedure be supervised by a physician who is proficient in the performance and interpretation of each type of diagnostic procedure furnished in the office.

In particular, the current regulations prohibit an IDTF from sharing space or equipment with any other Medicare supplier. As a result, block leasing and other shared ancillary service arrangements, a number of which had become standard in the medical imaging industry, had to be restructured or terminated. The current prohibition, however, applies only to IDTFs. Accordingly, shared imaging arrangements could continue to be structured among physician practices without any IDTF involvement.

The 2009 MPFS rule would effectively preclude any multi-practice shared ancillary arrangements (even those in which the imaging facility or ancillary service is located in the same building) by subjecting all physician and NPP organizations to the space-and-equipment-sharing prohibition. This position is difficult to reconcile with prior CMS commentary regarding the Stark Law, which indicated that shared ancillary arrangements were permissible if properly implemented, and with CMS's proposed adoption of a "same building" location standard with respect to the anti-markup rule (discussed below).

The supervising physician standard will likely also be controversial because it has been interpreted by local Medicare carriers to require, with limited exceptions, that the supervising physician for imaging services must be a board certified radiologist. This standard would likely require physician organizations providing any imaging to engage (and incur the cost of) a radiologist. To the extent direct supervision is required (e.g., for MRI with contrast), the practice will not only be required to engage a radiologist, but the radiologist will have to be on-site during the performance of the diagnostic procedure. Many in the industry believe that having a radiologist on-site is not only impractical, but unnecessary for proper medical supervision, since physicians in other specialties are both proficient in the performance and interpretation of diagnostic tests and better situated to address medical emergencies that might arise in performing the test (e.g., an adverse reaction to contrast).

WOULD THE RULE APPLY TO ALL PHYSICIAN AND NPP ORGANIZATIONS AND TO ALL TESTS?

With the exception of diagnostic mammography, the proposed 2009 MPFS would impose the IDTF enrollment requirements upon all physician or NPP organizations regardless of the type of diagnostic testing services they furnish. CMS is, however, considering whether to limit the IDTF enrollment requirement to a subset of diagnostic testing services, such as procedures that generally involve more costly equipment (e.g., diagnostic imaging services) or whether it should also exclude other diagnostic testing services frequently furnished by primary care physicians from these enrollment requirements.

CMS is also seeking comments on the following issues: (i) whether CMS should consider establishing additional exceptions to the IDTF performance standards for physician and NPP organizations providing diagnostic testing services; (ii) whether physicians or NPPs should be permitted to conduct diagnostic tests without the benefit of qualified non-physician personnel and under what circumstances the testing occurs; and (iii) whether with respect to imaging services, IDTF enrollment should be limited to advanced diagnostic testing procedures (e.g., MRI, CT and nuclear medicine).

COMPLIANCE DATE

Since this change, if adopted, would take time to implement, CMS has proposed an effective date of September 30, 2009, for existing providers of diagnostic testing services, and January 1, 2009 for newly enrolling suppliers. Failure to enroll as an IDTF and satisfy the enrollment conditions could subject such provider to claims denial for diagnostic testing services or a revocation of billing privileges.

Other IDTF Issues

MOBILE ENTITY BILLING REQUIREMENTS

CMS proposes a new performance standard for mobile entities that would require suppliers furnishing mobile diagnostic services to enroll in Medicare and bill directly for the mobile diagnostic services that they furnish, regardless of where the services are performed and to otherwise comply with the IDTF performance standards, including the use of qualified physicians or non-physician personnel to perform diagnostic testing procedures. If adopted, the effective date would be the same as the effective date of the final rule.

CLAIMS SUBMISSION FOLLOWING REVOCATION OF IDTF ENROLLMENT AND BILLING PRIVILEGES

CMS proposes that an IDTF that has had its enrollment or billing privileges revoked must submit all outstanding claims for not previously submitted items and services provided within 30 calendar days of the revocation, as compared to the current deadline of 27 months after the revocation effective date.

Physician and Non-Physician Practitioner (NPP) Enrollment Issues

CMS proposes 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 proposed changes.

EFFECTIVE DATE

Under current rules, Medicare contractors enroll physicians, NPPs, and physician and NPP organizations (each, a supplier) 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, CMS is seeking public comment on two approaches for establishing an effective date for Medicare billing privileges for suppliers. The first approach would establish the enrollment effective date as the date of enrollment approval by the Medicare contractor. The second approach would establish the effective date as 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.

Under either proposed approach, to assure Medicare reimbursement, it would be essential for a supplier to file a Medicare enrollment application before providing services to Medicare beneficiaries.

REPORTING REQUIREMENTS FOR SUPPLIERS

CMS is proposing to shorten the time frame for reporting changes in Medicare enrollment information by suppliers, including physician organizations. Under the proposal, 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 proposes that the failure to timely report such changes would be a basis for revocation of billing privileges.

MAINTAINING ORDERING AND REFERRING DOCUMENTATION

CMS proposes 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. 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 proposes various 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 proposes to revise the required qualifications for respiratory therapists in CORFs to be consistent with current qualification requirements recommended by the American Association for Respiratory Care. The proposed rule would also amend the duties of a CORF physician to include medical supervision of non-physician staff.

SOCIAL AND PSYCHOLOGICAL SERVICES

CMS proposes to create a new G-code 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, under the proposal the Medicare limitation on reimbursement for mental health services would 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 proposes 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.

Diagnostic Test Anti-Markup Rule

In the final 2008 MPFS rule, effective January 1, 2008, CMS made sweeping changes to the Medicare diagnostic test anti-markup rule (the "Anti-Markup Rule"). The Anti-Markup Rule implements a statutory prohibition on a billing physician receiving payment in excess of the net charge for a diagnostic test that is not performed or supervised by the billing physician or another physician with whom the billing physician shares a practice, e.g., the test is purchased from an outside supplier (the "payment limitation"). Last year, CMS extended the Anti-Markup Rule to the professional component (interpretations) of diagnostic tests, and added a new site-of-service basis for the payment limitation. Specifically, CMS applied the Anti-Markup Rule (in addition to diagnostic tests that are actually purchased outright), to diagnostic tests ordered by a physician, but not performed in the same office suite where the physician's medical practice provides the full range of patient care services that the practice provides generally (the "same office suite" test). However, due to an outcry from the many group practices that had developed expensive, advanced imaging facilities in reliance on the specific location test of the Stark law's in-office exception, CMS delayed implementation of these revisions to the Anti-Markup Rule until January 1, 2009, except as applied to anatomic pathology arrangements.

In the proposed 2009 MPFS rule, CMS proposes two alternatives to its original same office suite test. First, CMS proposes a "same building" test. Under this alternative, the Payment Limitation would apply to diagnostic tests that are purchased outright, as well as tests that are not performed in the same building where the ordering physician provides substantially the full range of patient care services that the ordering physician provides generally. Under CMS's second alternative, a physician practice would be subject to the Payment Limitation if: (i) the practice purchases a diagnostic test outright; or (ii) the physician who performs the interpretation (the professional component) or supervises the technical component of the diagnostic test performs such services for any other billing physician or physician organization, i.e., medical practice. Under the proposal the performing (interpreting or supervising) physician could be an employee or contractor, full or part-time, of the physician practice, but could not perform interpretations or supervise technical component diagnostic testing for any other medical practice but the ordering physician's practice.

For a more detailed discussion of these two alternatives, their implications for existing arrangements, and other aspects of CMS's proposals for implementing the Anti-Markup Rule, see CMS Revisits the Diagnostic Test Anti-Markup Rule, <http://www.mwe.com/info/news/ots0708f.htm>.

Stark Exception for Pay-for-Performance and Gainsharing Programs

In response to increasing governmental and private interest in innovative programs to improve quality and control costs, CMS proposes 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 includes highly prescriptive requirements that relate to the structure of the programs, the types of and limits on payments made to physicians participating in the programs, and specific elements that must be included in the program participation agreements between hospitals and physicians.

Although several commenters urged CMS to develop a broad exception allowing flexibility in program design, the proposed rules closely follow the model of gainsharing programs initially developed by Goodroe Consulting and approved by the Office of Inspector General (OIG) in a series of advisory opinions. The primary difference between the proposed rule and the previously approved programs is that the proposed rule covers both pay-for-performance and gainsharing arrangements. CMS proposes to allow some variation in specific elements of program design, such as selection of measures for shared savings programs. However, several of the criteria are not “bright line” rules and thus, under the proposed rule as drafted, a hospital seeking certainty under the Stark Law will still need to consider using the OIG and/or the CMS Advisory Opinion process to obtain assurances that its program falls within the exception and will not be subject to sanctions under the Civil Monetary Penalties (CMP) statute.

The proposed rule, like all other regulatory exceptions, includes a requirement that the program not violate the Anti-kickback Statute or any Federal or State law or regulation governing billing or claims submission. Presumably, CMS does not view the CMP statute to be a law or regulation governing billing or claims submission given that the favorable OIG opinions uniformly conclude that gainsharing programs do violate that statute. Express clarification from CMS on this point would be welcome, however.

The proposed rule also prohibits any remuneration that takes into account the volume or value of referrals or other business generated between the parties. In the past, some in the health law bar have argued that any payment based on a portion of cost savings generated by a referring physician would take into account the value of that physician’s admissions to the hospital. Since CMS intends to allow such arrangements under the proposed rule, it would appear that CMS does not believe that gainsharing programs of the type approved by the OIG take into account the value of referrals generated by the physician.

The requirements of the proposed rule, as well as alternative approaches presented in the preamble to the proposed rule, are detailed in a separate *White Paper* entitled “Proposed Stark Exception Covers Pay-for-Performance and Gainsharing Programs,” found at <http://www.mwe.com/info/news/wp0708a.htm>.

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