2009 Medicare Physician Fee Schedule Final Rule

ANTI-MARK UP AND IDTF REQUIREMENTS FOR MOBILE ENTITLES FINALIZED

Health Care Team

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IDTF Enrollment Requirements Anti-Markup Rule Exception for Incentive Payments and Shared Savings Plans

CMS Finalizes Anti-Mark Up and IDTF Requirements for Mobile Entitles; Defers Stark Exception for Incentive Payment/Shared Savings Programs

This Alert summarizes the changes to the Anti-Markup Rule and IDTF enrollment requirements for mobile entities that were finalized by the Centers for Medicare and Medicaid Services ("CMS") in the 2009 Medicare Physician Fee Schedule final rule (the "Final Rule") that are effective on January 1, 2009. CMS had proposed changes to the Anti-Markup Rule and IDTF enrollment requirements in its 2009 Medicare Physician Fee Schedule proposed rule (the "Proposed Rule"), which was published in July of 2008. On October 30, 2008, CMS released a display copy of the Final Rule, which is scheduled to be published in the Federal Register on November 19, 2008. CMS deferred implementation of the requirement in the Proposed Rule that a physician office performing diagnostic testing services must enroll in Medicare as an IDTF. CMS also declined to finalize any exception to the Stark self-referral law for incentive payments to physicians or payments to physicians under a shared savings program with physicians and indicated that CMS was seeking additional information during a re-opened comment period in order to finalize an exception.

IDTF Enrollment Requirements

Physician offices performing diagnostic testing services are not required to enroll as an IDTF.

In the Proposed Rule, CMS proposed to require physicians and non-physician practitioners furnishing diagnostic testing services (other than mammography services) to enroll each practice location furnishing these services with Medicare and to subject these locations to most of the performance standards for IDTFs. CMS, however, did not finalize this proposal. It noted that Section 135 of the Medicare Improvements for Patients and Providers Act of 2008 ("MIPPA") requires the Secretary of the Department of Health and Human Services to establish an accreditation program by January 2012 for entities furnishing advanced diagnostic testing procedures, including MRI, CT, nuclear medicine (including PET) and other procedures (but excluding x-ray, ultrasound and fluoroscopy). CMS also received a number of public comments about the proposed additional requirements. CMS will continue to review the comments and consider whether to finalize the proposal in future rulemaking. Therefore, fixed physician practice locations providing diagnostic testing services currently are not required to enroll as an IDTF. However, ultimately CMS may finalize a rule concerning quality and performance standards applicable to physician practices, and any accreditation

standards established by DHHS as required by MIPPA will apply.

Entities furnishing mobile services will be required to enroll as IDTFs.

CMS finalized a new performance standard for entities furnishing mobile diagnostic services. Mobile entities furnishing mobile diagnostic services are required to enroll in Medicare, to comply with the IDTF performance standards, and to bill directly for the mobile diagnostic services that they furnish regardless of where the services are performed. CMS, however, is not requiring mobile testing entities to bill directly for the services they furnish when such services are furnished "under arrangements" with hospitals as described in Sections 1861(w)(1) and 1862(a)(14) of the Act and 42 CFR §482.12(e). To ensure that IDTFs are furnishing services under arrangements with a hospital, CMS is requiring that mobile IDTFs provide documentation of the arrangement with their initial or revalidation enrollment application or change of enrollment application. The new performance standard is effective January 1, 2009.

Anti-Markup Rule

2009 Finalized Changes

In recent rulemaking, CMS has made several proposals regarding the application of the Anti-Markup Rule both to the technical component ("TC") and professional component ("PC") of diagnostic tests when the TC or PC is purchased from an outside supplier. In the Final Rule, CMS applies the Anti-Markup Rule solely to diagnostic tests that are performed or supervised by a physician who does not "share a practice" with the billing physician or other supplier. To determine whether a performing or supervising physician "shares a practice" with the billing physician or other supplier, CMS adopted an approach that requires providers to analyze the arrangement under two alternatives. Arrangements should first be analyzed under Alternative 1 as discussed below. If the performing physician does not satisfy the requirements of Alternative 1, an analysis under the Alternative 2 requirements may be applied on a test-by-test basis to determine whether the Anti-Markup Rule applies.

Alternative 1 (The "Substantially All" Approach)

Under Alternative 1, where the performing physician performs "substantially all" of his or her professional services for the billing physician or other supplier, none of the services furnished by the physician on behalf of the billing physician or other supplier are subject to the Anti-Markup Rule. CMS defines the performing physician as the physician who supervises the TC or performs the PC, or both.

The Final Rule defines "substantially all" of a physician's professional services means as at least seventy-five percent, bringing this approach in line with the Stark "substantially all" definition. The "substantially all" requirement is satisfied if the billing physician or other supplier has a reasonable belief, when submitting a claim, that: (1) the performing physician has furnished substantially all of his or her professional services through the billing physician or other supplier for the period of 12 months prior to and including the month in which the service was performed; or (2) the performing physician will furnish substantially all of his or her professional services through the billing physician or other supplier during the following 12 months (including the month the service is performed).

CMS clarified that, with respect to locum tenens situations only, whether an arrangement satisfies Alternative 1 depends on whether the permanent physician (that is, the physician for whom the locum tenens physician is substituting) performs "substantially all" of his or her professional services through the billing physician or other supplier.

Alternative 2 (The "Site-of-Service" Approach)

If the performing physician does not meet the "substantially all" services requirement of Alternative 1, then the arrangement must be analyzed under a "site of service" approach. Under the Alternative 2 "site-of-service" approach, only TCs conducted and supervised, and PCs performed, in the office of the billing physician or other supplier by an employee or independent contract physician will avoid application of the anti-markup payment limitation. Diagnostic services are performed or interpreted in the "office of the billing physician or other supplier" if they are performed or interpreted in the "same building" (as defined in the regulations for the Stark Law) as the space in which the ordering physician or other ordering supplier regularly furnishes care. CMS clarified that a mobile unit would not meet the "same building" definition and therefore would not satisfy Alternative 2.

CMS noted in the Final Rule that it is permitting shared space arrangements for diagnostic testing services that occur in the "same building" because it believes that such arrangements can promote efficiency without raising the same concerns for overutilization or other abuse as arrangements that involve centralized buildings for diagnostic testing. CMS cautioned, however, that it continues to have concerns with the present use of the in-office ancillary exception and that it may issue a proposed rulemaking in the future to address its concerns.

CMS also reiterated that the TC must be both conducted and supervised in the office of the billing physician or other supplier. CMS noted that the requirement that the supervising physician be present in the office of the billing physician or other supplier may be more restrictive than some Medicare coverage and payment regulations governing the supervision of tests, but stated that it believes this revision is necessary in order to minimize the potential for overutilization and program abuse. CMS clarified that the supervising physician does not have to be the physician responsible for interpreting test results or images.

Definition of "Net Charge"

Although CMS solicited comments in the Proposed Rule on how it should define the term "net charge" and whether it should allow some overhead costs to be recovered by billing suppliers, it declined to make any changes to what may be included in the calculation of "net charge" in the Final Rule. CMS refused to allow any overhead costs to be included in the calculation and expressed its concern that to do so would undermine the purpose of the payment limitation.

In the Final Rule, CMS stated that where the billing physician or other supplier pays the performing supplier a fixed fee for the TC or the PC, the "net charge" is the fixed fee (exclusive of 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). Otherwise, the billing physician or other supplier is limited to the salary and benefits it paid to the performing supplier for the TC or PC. CMS, repeating comments that it made in the 2008 Physician Fee Schedule final rule, stated that it is the responsibility of the billing entity to determine the amount it paid for the TC or PC and the billing entity is required to maintain contemporaneous documentation of the

methodology and information used to calculate the net charge.

CMS also stated again that for purposes of determining the "performing supplier's net charge," the "performing supplier" with respect to the TC is the physician who supervised the test and the "performing supplier" with respect to the PC is the physician who performed the professional services. When the Anti-Markup Rule applies, the billing physician or other supplier may bill for the lesser of: (1) the performing supplier's net charge to the billing physician or other supplier; (2) the billing physician or other supplier's actual charge; or (3) the fee schedule amount for the test that would be allowed if the performing supplier billed directly.

Reassignment

In the Proposed Rule, CMS solicited comments on whether it should develop a provision prohibiting reassignment in certain situations and require the physician supervising the technical component or performing the professional component to bill Medicare directly. In the Final Rule, CMS declined to finalize either requirement but noted that it may do so in future rulemaking with comment period.

Exception for Incentive Payments and Shared Savings Plans

In the Final Rule, CMS did not finalize any exception under the Stark law for incentive payments or shared savings plans, but rather re-opened the comment period for an additional ninety (90) days and indicated specific issues for which CMS was seeking comments in order to have sufficient information to develop a final rule. While CMS maintains that it is a priority to issue a final exception, given the transition to the new Administration, it appears unlikely that such an exception will be finalized for some time.