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Changes in Medicare Payment, Billing and Enrollment Policies in the Final 2009 Medicare Physician Fee Schedule

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Significant policy changes for physicians, nonphysician practitioners and other suppliers are contained in the 2009 Medicare Physician Fee Schedule final rule ("Final Rule"), which was displayed on October 30, 2008 and will be published in the *Federal Register* on November 19, 2008. This rule contains the final anti-markup provisions for diagnostic tests and new provider enrollment provisions. It also declines to extend the IDTF requirements to physicians and non-physician practitioners performing diagnostic tests in their offices, and makes many other policy pronouncements. The Final Rule was issued by CMS as a final rule with comments, and CMS has solicited comments on specific sections of the rule. Below are summaries of some of the issues addressed by the Final Rule.

The Anti-Mark Up Rules

In the Final Rule, CMS adopts what it deems to be a flexible approach to whether a diagnostic test can be "marked up" when billed to Medicare. In the proposed rule, CMS laid out two alternatives for determining whether a physician performing a diagnostic test "shares a practice" with the billing physician or other supplier and therefore would not be subject to the anti-mark up rule. In the Final Rule, CMS has chosen to adopt both alternatives with some modifications.

Under "Alternative 1" if the physician supervising the technical component (TC) or performing the professional component (PC) of a diagnostic test performs "substantially all" (at least 75%) of his/her professional services for the billing physician or supplier, the anti-markup rule does not apply. "Alternative 2" maintains a location approach. Under this alternative, TCs supervised and conducted in the same "office as the billing physician or other supplier" and PCs performed in the same "office as the billing physician or other supplier" will not be subject to the anti-markup rule. The "office of the billing physician or other supplier" is defined in the Final Rule as the same building where the ordering physician performs substantially the full range of patient care services that the ordering physician generally provides. The physician supervising the TC or PC must be an owner, employee, or independent contractor.

When determining whether an arrangement precludes a mark-up to Medicare, CMS has instructed providers to first analyze the arrangement under

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Alternative 1. If the performing physician does not meet the "substantially all" requirement, the arrangement should then be analyzed under the site of service requirement in Alternative 2.

The Final Rule also does away with the explicit application of the anti-markup rule to tests "purchased by an outside supplier." A test either falls under Alternative 1 or Alternative 2, or is subject to the anti-markup prohibition. Finally, CMS believes that because these alternatives are fairly liberal, they decided to make no change to the definition of "net charge."

Incentive Payment and Shared Savings Programs

In the proposed rule, CMS proposed a new exception to the Stark law for incentive payment and shared savings programs, such as gainsharing arrangements. CMS, however, declined to finalize this proposal, indicating that it did not have sufficient information or agreement among commenters to formulate an exception. CMS is now seeking comments to 55 different issues related to these programs. CMS stated that its goal is to formulate an exception that protects programs that have transparency, accountability, ensure quality of care, and prevent disguised payments for referrals. Comments are due within 90 days from the date of the Final Rule's publication in the Federal Register. If published on November 19, 2008, as scheduled, comments will be due February 17, 2009.

New DHS - Speech-Language Pathology

In 2008, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) amended the Stark statute to include "outpatient speech-language pathology services" in the definition of DHS by July 1, 2009. In the Final Rule, CMS made changes to the Stark regulations to reflect this statutory amendment as well as modified the list of CPT/HCPCS codes maintained by CMS that outlines the scope of DHS categories.

Independent Enrollment of Speech-Language Pathologists

CMS finalized a rule implementing section 143 of the MIPPA that permits speech-language pathologists to enroll as Medicare suppliers and to independently bill Medicare for outpatient speech-language pathologist services furnished in private practices. This provision is effective for services furnished on or after July 1, 2009.

Independent Diagnostic Testing Facilities (IDTFs)

In the proposed rule, CMS included a requirement that physicians or nonphysician practitioners (NPPs) furnishing diagnostic testing services enroll as IDTFs. Due to the enactment of MIPPA, which requires the establishment of an accreditation process for entities providing imaging services by January 1, 2012, and in consideration of comments received, CMS decided to defer finalization of this proposal.

Mobile Entity Billing Requirements

Contrary to its decision regarding physicians and NPPs, CMS finalized its proposal to require all mobile entities performing diagnostic testing to enroll as IDTFs. Such mobile entities must also bill Medicare directly for services furnished to Medicare beneficiaries, except when such services are provided "under arrangement" with a hospital. In response to comments, CMS stated that entities that, "lease equipment and provide technicians who conduct diagnostic tests in the office of the billing physician or physician organization; and furnish testing under the supervision of a physician who shares an office with the billing physician or physician organization" provide a service and, therefore, must enroll as an IDTF. Although not specifically stated in the Preamble to the Final Rule, it appears that this interpretation may prohibit block leases of equipment with a technician to a physician practice.

Physician and NPP Enrollment Issues

In the Final Rule CMS adopted changes to the enrollment and billing rules applicable to physicians and NPPs, both individual practitioners and organizations. Pursuant to the Final Rule, the effective date of physicians' and NPPs' billing privileges is the later of: (1) the date they first began furnishing services at a new practice location or (2) the date their Medicare enrollment application was filed (i.e., the date it was received by a Medicare Administrative Contractor "MAC"), provided such application was subsequently approved by

Medicare. Thirty (30) day retroactive billing and payment is permitted under circumstances that precluded a physician's or NPP's enrollment prior to treatment of Medicare patients, e.g., services provided in an emergency room. Ninety (90) days retroactive billing is permitted in the context of a Presidentially-declared disaster.

Under the Final Rule, CMS requires MACs to deny, as opposed to reject, Medicare billing privileges when they are not able to process an incomplete enrollment application submitted by a physician or NPP practitioner or organization. Unlike a rejection, a denial of billing privileges provides practitioners with appeal rights that preserve the initial application filing date.

DME CPAP Standards

CMS finalized its proposal to deny payment to a supplier of a continuous positive airway pressure device (CPAP) if they also perform the qualifying test. CPAPs are supplied to individuals diagnosed with obstructive sleep apnea, (OSA). OSA is diagnosed through the performance of a qualifying sleep test. Under the Final Rule, CMS prohibits payment for a CPAP device when the supplier is also the provider or interpreter of the sleep test used to diagnose a patient with obstructive sleep apnea (OSA), and therefore in need of the CPAP. An "affiliate" is a person or organization, directly or indirectly, related to the supplier through a compensation arrangement or some type of ownership. This payment prohibition does not apply when the sleep test performed by the supplier/provider is an attended facility-based polysomnography (PSG). Thus, as a practical matter, the prohibition only applies to home sleep tests (HST), which were just approved this year as qualifying tests for CPAP.

CMS believes that if a provider (individual or entity) of a sleep test has a financial interest in the outcome of such test, an incentive is created to test more frequently or less frequently than is medically necessary and to interpret the test results with bias. However, CMS recognized that attended facility-based PSGs are often incorporated into integrated sleep management programs. In addition, historically, such sleep management programs have not been significantly vulnerable to risk of overutilization and other abuse. Most importantly, CMS was concerned that this prohibition, if applied to attended facility-based PSGs, would disrupt this model of care and, as a result, harm some patients. Therefore, CMS included an exception for these tests to the finalized CPAP payment prohibition.