



Medicare Proposes Changes To The Anti-Markup Rule

On June 30, the Centers for Medicare & Medicaid Services ("CMS") issued proposed changes to the Medicare Physician Fee Schedule for 2009 ("2009 PFS Proposed Rule"), which contains, among other provisions, the anti-markup provision. CMS will accept comments on the proposed rule until August 29, 2008, and will respond to those comments in a final rule to be issued by November 1, 2008. The revised policies and payment rates will become effective January 1, 2009.

I. BACKGROUND

The 2008 Physician Fee Schedule Final Rule¹ amended the anti-markup provision contained in 42 C.F.R. §414.50 for certain diagnostic tests ("Revised Anti-Markup Rule"). The Revised Anti-Markup Rules apply to the technical component ("TC") and/or professional component ("PC") of certain diagnostic tests. Specifically, it applies only to those diagnostic tests that are ordered by the billing physician or other supplier (or ordered by a party related by common ownership or control to such physician or other supplier), when the TC and/or PC is (a) outright purchased, or (b) when the TC and/or PC is not performed in the office of the billing physician or other supplier. If the Revised Anti-Markup Rule applies, the payment to the billing physician or other supplier (less the applicable deductibles and coinsurance paid by the beneficiary or on behalf of the beneficiary) for the TC or PC of the diagnostic test may not exceed the lowest of the following amounts:

- The performing supplier's net charge to the billing physician or other supplier;
- The billing physician or other supplier's actual charge; or
- The fee schedule amount for the test that would be allowed if the performing supplier billed directly.

Subsequent to the publication of the 2008 Physician Fee Schedule Final Rule, CMS issued another final rule² to delay the effective date of the Revised Anti-Markup Rule until January 1, 2009 (except for when the TC purchased from an outside supplier, which has been a longstanding rule, and anatomic pathology diagnostic testing furnished in a certain kind of space) largely due to the industry's concern about the Revised Anti-Markup Rules' definition of "office of the billing physician or other supplier," and that it did not appear to be satisfied under the Stark Law's definition of "same building" in 42 C.F.R. § 411.355(b)(2)(i) for purposes of the in-office ancillary services exception.

The Revised Anti-Markup Rules define the "office of the billing physician or other supplier" as medical office space where the physician or other supplier regularly furnishes patient care. For a billing physician or other supplier that is a physician organization, the "office of the billing physician or other

¹ 72 Fed. Reg. 66222, 66306 (Nov. 27, 2007).

² 73 Fed. Reg. 404 (Jan. 3, 2008).

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supplier” is space in which the physician organization provides substantially the full range of patient care services that the physician organization provides generally.³

II. PROPOSED CHANGES

In the 2009 PFS Proposed Rule, CMS has proposed two alternative approaches for amending the Revised Anti-Markup Rules:

A. First Proposal

Under the first proposal, CMS proposes to amend the Revised Anti-Markup Rules in §414.50 to apply in all cases where the TC or PC of a diagnostic testing service is either: (i) purchased from an outside supplier, or (ii) performed or supervised by a physician who does not share a practice with the billing physician or physician organization. In other words, the anti-markup prohibition would not apply if it is not outright purchased or if the TC or PC is performed or supervised by a physician who “shares a practice” with the billing physician or physician organization.

CMS noted that it would consider a physician who is employed by or contracts with a single (i.e., only one) physician organization or physician (regardless of whether it is on a full-time or part-time basis) to share a practice with that physician organization or physician. In contrast, a physician who is an employee of, or independent contractor with, more than one billing physician or physician organization would not be deemed to share a practice with any of the physicians or physician organizations with which he or she is affiliated, and therefore the TC or PC would be subject to the anti-markup rules.⁴ CMS has, however, recognized that circumstances may exist under which it is beneficial for a physician to provide diagnostic testing services to more than one physician practice (i.e., contracting to provide physician services on a locum tenens basis to another practice while a physician in that practice is on vacation or maternity leave) and is seeking comments regarding whether and, if so, how it could permit a physician to provide occasional services outside of his or her physician organization without the secondary arrangement precluding the physician from “sharing a practice” with his or her physician organization.

This first proposal removes any site-of-service requirement, thus alleviating concerns that the definition of “office of the billing physician or other supplier” contained in the Revised Anti-Markup Rules was more restrictive than the “same building” test under the Stark Law’s in-office ancillary services exception.

B. Second Proposal

Alternatively, CMS proposes to maintain most of the text of the Revised Anti-Markup Rules and its “site-of-service” approach, with some changes or clarification. In other words, CMS would apply the anti-markup provision to the TC and PC of non-purchased tests that are performed outside the “office of the billing physician or other supplier.” CMS proposes changes and clarifications to the Revised Anti-Markup Rules under this second proposal, including the following:

(1) **Definition of the “Office of the Billing Physician or Other Supplier.”** CMS proposes to clarify the definition of “the office of the billing physician or supplier” to: (i) include

³ For purposes of the anti-markup provision, the office of a billing physician or other supplier has its common meaning – that is, it is space in which the physician or other supplier regularly furnishes patient care services, and does not include a “centralized building” as defined at §411.351.

⁴ CMS does not consider providing services at a free clinic or moonlighting in a hospital emergency department or as a hospitalist to be “sharing a practice” and such activities would not require the application of the anti-markup provisions with respect to the services the physician provides for his or her physician organization.

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space that is in the “same building” (as defined at §411.351 for purposes of the Stark Law) as where the ordering physician or other ordering supplier regularly furnishes patient care, and for physician organizations in the same building as where the ordering physician provides substantially the full range of patient care services that the ordering physician provides generally; (ii) clarify in the definition that a physician or supplier may have more than one location where it regularly furnishes patient care; and (iii) address concerns raised by multi-specialty groups that may not provide substantially its full range of services at any one location by amending the definition to provide that the “office of the billing physician or other supplier” is medical office space where the ordering physician provides substantially the full range of patient care services that the ordering physician generally provides.

(2) **Performed at a Site Other Than the Office of the Billing Physician or Other Supplier.** CMS proposes to clarify that, with respect to the TC, the anti-markup provision applies if the TC is either conducted or supervised outside of the office of the billing physician or other supplier. CMS takes the position that that “performance” of the TC includes both the technician’s work in conducting the test and the physician’s supervision of the technician.

(3) **Exception for Certain “Hub and Spoke” Arrangements.** CMS recognizes that, unlike the first proposal that eliminates the site-of-service requirement, the second proposal may adversely affect certain “hub and spoke” arrangements in which a physician providing services in a centralized diagnostic testing facility owned by and serving a multi-site group practice has a significant nexus to the physician organization that employs or contracts with the physician. To this end, CMS is proposing to provide an exception in §414.50(b) to the anti-markup provision that would be applicable to diagnostic tests ordered by a physician in a physician organization that does not have any owners who have the right to receive profit distributions. The exception would not apply to the TC purchased from an outside supplier.

C. Additional Proposed Amendments

In addition to the specific amendments noted above, which appear to be applicable only if CMS elects to maintain the Revised Anti-Markup Rule and its “site-of-service” approach (*i.e.*, CMS’s second proposal), the 2009 PFS Proposed Rule proposes two additional amendments that would appear to apply regardless of whether CMS adopts the first or second proposal in the 2009 PFS final rule. These proposed amendments are as follows:

(1) **Purchased from an Outside Supplier.** In response to questions regarding whether the TC of a diagnostic test would be purchased from an outside supplier if the technician conducting the TC is not an employee of the billing group but the physician supervising the technician is an employee or contractor of the billing group, CMS proposes to clarify that a TC of a diagnostic test is not purchased from an outside supplier if the TC is both conducted and supervised in the office of the billing physician or other supplier and the supervising physician is an employee or independent contractor of the billing physician or other supplier⁵

⁵ CMS also proposes two alternative proposals. First, if the TC is conducted by a technician who is a non-employee of the billing supplier, the TC is considered purchased from an outside supplier regardless of where the TC is conducted and regardless of the supervising physician’s employment status and where the supervision took place. Second, if the TC is conducted by a non-employee of the billing physician or other supplier and outside the office of the billing physician or other supplier, the TC nevertheless will not be a purchased test if the supervising physician is an employee or independent contractor of the billing physician or other supplier and performs the supervision in the office of the billing physician or other supplier.

(2) **The Performing Supplier's Net Charge.** Where the anti-markup provision applies, Medicare payment to the billing physician or other supplier is limited to the lowest of three specified amounts, one of which is "the performing supplier's net charge to the billing physician or other supplier." In response to questions regarding who is the supplier when a physician in a group practice supervises the performance of a TC but the group practice bills for the TC directly (e.g., without a reassignment from the supervising physician), CMS proposes to clarify that the "performing supplier" of the TC is the physician who supervised the TC, and the "performing supplier" of the PC is the physician who performed the PC. Therefore, where the anti-markup provision applies, the billing physician or other supplier would need to determine what it paid the physician for supervising the TC or for performing the PC.

Assuming the anti-markup provision applies, this proposed "clarification" of who is the performing supplier, in combination with the Revised Anti-Markup Rule's requirements for calculating net charge at 42 C.F.R. §414.50(a)92(ii), severely limits the amount of reimbursement the billing physician or supplier can collect from Medicare. If the amount that the purchaser can bill is limited to the amount that such purchaser paid the physician for supervising the TC or performing the PC, the purchaser would be unable to recoup payment for any other expenses related to the diagnostic test, such as the purchaser's overhead expenses related to the equipment, space, or personnel.

Due to commenters' concerns from the 2008 PFS Final Rule that the exclusion of overhead costs from the net charge would have a detrimental financial impact on their practice and ultimately to patient access to care, CMS is expressly soliciting comments on whether it should allow some overhead costs to be recovered. CMS is also specifically seeking comments on whether and how it should provide specific regulatory guidance for calculating the net charge for the PC when the anti-markup provision applies.

(3) **Other Comments Solicited by CMS.** In addition to the above proposed changes and clarifications, and requests for comments, CMS is seeking input on whether, in addition to or in lieu of, the anti-markup provision, reassignment should be prohibited in certain situations and require the physician supervising the TC or performing the PC to bill Medicare directly. CMS is also seeking guidance from the industry on whether the Revised Anti-Markup Rule, which was delayed until January 1, 2009, should go into effect on that date or whether some or all of the revisions should be further delayed past January 1, 2009.

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To the extent that you have any questions, please contact your regular GWT attorney.

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