

Diagnostic testing and the anti-markup provisions

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On Nov. 1, 2007, CMS published the 2008 Physician Fee Schedule Rule (the Final Rule), which contains anti-markup provisions (the Anti-Markup Rule) that may significantly impact the ability of many physicians to provide certain diagnostic testing services to their Medicare patients.

The Anti-Markup Rule was to take effect Jan. 1, 2008, a mere eight weeks after the Final Rule was published. However, amid the frenzy to comply with the anti-markup provisions, and just three days prior to the Final Rule taking effect, CMS issued the Revised Rule. The latest rule postponed the effective date of the Anti-Markup Rule until Jan. 1, 2009, as to the professional component of purchased diagnostic tests, with one exception – the professional component of certain anatomic pathology diagnostic tests.

The Revised Rule, however, did not delay the applicability of the anti-markup provisions to the technical component of purchased diagnostic tests.

The Anti-Markup Rule prevents physicians, medical practices, group

practices, independent diagnostic testing facilities and any other supplier (the "billing entity") from marking-up the technical and professional components of ordered diagnostic tests that are purchased from an outside supplier or performed at a location other than the office of the billing entity. The technical and professional components of diagnostic tests, which are covered by Section 1861(s)(3) of the Social Security Act, are subject to the Anti-Markup Rule and are not allowed to exceed the lowest of the following amounts:

- (1) the performing supplier's net charge to the billing entity;
- (2) the billing entity's actual charge; or
- (3) the fee schedule amount for the test that would be permitted if the performing supplier billed for the test directly.

Interpretation

The easiest way to interpret the Anti-Markup Rule is to determine when the rule is not triggered – which is when the technical and professional components are ordered, billed and performed by the billing entity at an office space where the billing entity regularly furnishes patient care. If the diag-

nostic tests are performed within such office space, the diagnostic tests may be performed by a full-time or part-time employee or an independent contractor that reassigns his or her benefits to the billing entity. The Anti-Markup Rule will generally not be triggered when a diagnostic test is ordered by a physician but performed and billed by another physician, group practice or independent diagnostic testing facility.

Physicians around the country have expended considerable resources consulting with lawyers to restructure their medical practices and existing

manner that would prove economically viable. In most cases, the overriding result is dismal – if diagnostic tests are required to be performed in the office of the billing entity, providing diagnostic tests are not cost-effective for most physicians.

Physicians are concerned that if a profit cannot be earned from the professional component of diagnostic tests performed outside the office of the billing entity, it would be economically impractical to provide those diagnostic testing services to Medicare patients.

Opponents of the Anti-Markup Rule present strong arguments that,

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contractual relationships to comply with the Anti-Markup Rule. The problem is not mere compliance with the Anti-Markup Rule but, rather, restructuring the physicians' existing practices and contractual relationships in a

by requiring the diagnostic tests to be performed at the office of the billing entity, without carving out an additional exception for tests performed in

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the “same building” or a “centralized building,” CMS has vitiated the purpose behind the In-Office Ancillary Services Exception of the Stark Law. CMS has received countless inquiries regarding the impact of the Anti-Markup Rule on the in-office exception. CMS has confirmed that compliance with the exception does not obviate the need to comply with the Anti-Markup Rule.

Most physicians understand that CMS has a legitimate interest in preventing fraud and abuse in diagnostic testing. However, the potential impact of the Anti-Markup Rule has many concerned that CMS has overstepped its rule-making authority. It appears that the rule undermines Congress’ initial intent to allow a specific exception to the Stark Law for those compensation and ownership relationships that satisfy the In-Office Ancillary Services Exception.

Currently, if a neurology group practice owns an MRI facility that is

located on the first floor of a building, and the office where the group practice consults with patients is located on the second floor of the building, the group practice may profit from the diagnostic tests that it orders and are performed at its MRI facility.

If the Anti-Markup Rule takes effect next January, the group practice will not be allowed to mark-up the diagnostic tests performed at its MRI facility because the MRI facility is not located in its office on the second floor of the building—whether or not the group practice satisfies the in-office exception to Stark.

Another common complaint received by CMS relates to what constitutes the “office of the billing physician or other supplier.” CMS has not clearly defined “office of the billing physician or other supplier.” It has, however, delayed the enactment of the Anti-Markup Rule, at least in part to address this concern.

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