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Big Changes to Physician Diagnostic Testing Under 2008 Medicare Physician Fee Schedule

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The anti-markup provisions in the final 2008 Medicare Physician Fee Schedule Rule (Final Rule) is likely to produce major changes in the ways physicians provide diagnostic tests. The Centers for Medicare & Medicaid Services (CMS) published the Final Rule in the *Federal Register* on November 27, 2007. *See* 72 Fed. Reg. 66222, 66306-66321 (Nov. 27, 2007). The changes in the Final Rule took effect January 1, 2008. While the anti-markup provisions of the Final Rule are fairly straight-forward, the effect of these provisions on the ways in which physician practices provide diagnostic tests cannot be overstated.

Stark Changes

In July, CMS proposed a host of changes to the Stark physician self-referral regulations as part of the proposed 2008 Medicare Physician Fee Schedule Rule (Proposed Rule). *See* 72 Fed. Reg. 38122, 38179-38187 (July 12, 2007). With respect to many of the proposed Stark changes, CMS identified areas of concern and specifically requested comments. In some instances, CMS proposed very specific changes, and in other instances, CMS was more circumspect about its proposed fix. The Stark provisions in the Proposed Rule are different from (although somewhat related to) the changes in the Stark II, Phase III final rule (Phase II). *See* 72 Fed. Reg. 51,012 (Sept. 5, 2007). The Phase III changes are final and became effective December 4, 2007.

In the Final Rule, CMS announced that it was deferring action on the Stark provision in the Proposed Rule. CMS indicated that it would finalize the following proposed changes in a separate final rule:

- Burden of proof;
- Obstetrical malpractice insurance subsidies;
- Unit-of-service (per-click) payments in lease arrangements;
- Period of disallowance for noncompliant financial relationships;
- Ownership or investment interests in retirement plans;
- "Set in advance" and percentage-based compensation arrangements;
- "Stand in the shoes" provisions;
- Alternative criteria for satisfying certain exceptions; and
- Services furnished "under arrangements." ►

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In addition, CMS indicated that it would make any changes to the in-office ancillary services exception through a future notice-and-comment rulemaking, because the Proposed Rule did not contain a specific proposal but rather solicited comments regarding the scope and application of the exception. CMS was inundated with comments about the Stark changes in the Proposed Rule and did not have sufficient time to consider all of the comments in time to be included in the Final Rule. CMS did not provide any specific timeline for when it might move forward with any of the Stark changes.

Anti-markup Changes

Although CMS did not finalize the Stark proposals in the Final Rule, it did finalize changes to the Medicare reassignment and anti-markup rules (collectively referred to as the anti-markup rules). The anti-markup rules are separate from the Stark rules, but they are intertwined and CMS uses both to try to limit what CMS believes are fraudulent or unnecessary activities.

CMS originally proposed changes to the reassignment and anti-markup rules in the proposed 2007 Medicare Physician Fee Schedule Rule. CMS chose not to finalize the proposed changes to the anti-markup rules in the final 2007 Medicare Physician Fee Schedule Rule. Instead, based on comments CMS received on the 2007 proposed rule, CMS proposed modified changes to the anti-markup rules in Proposed Rule for 2008. Specifically, CMS proposed to impose an anti-markup limitation to the technical (TC) and professional (PC) components of diagnostic tests. CMS explained that it was concerned that certain arrangements that on their face meet the Stark in-office ancillary services exception are not within what CMS views as the intended purpose of that exception. CMS said it was troubled with services provided in "centralized buildings" and those where physician practices purchased or contracted for the provision of diagnostic tests. The basis for this concern appears to be the potential for a physician to realize a profit on the tests, which might then lead to overutilization resulting in higher costs to the Medicare program.

The Proposed Rule focused on whether the person performing either the TC or PC of the test was a full-time employee of the group practice, rather than a part-time employee or an independent contractor. The Final Rule eliminates that distinction. It imposes the anti-markup provision on the TC and PC of diagnostic tests that are ordered by a billing physician or other supplier (or a related party) *if* the TC or PC is purchased from an "outside supplier" or *if* it is performed at a site other than the office of the billing physician or other supplier. 42 C.F.R. § 414.50. An "outside supplier" is defined as someone who is not an employee and who has not furnished the TC or PC under a reassignment.

In the preamble to the Final Rule, CMS states that physicians can opt not to "take advantage of" the purchased diagnostic rules or the reassignment option and instead, bill and receive payments for tests they have personally performed. Unfortunately, this statement ignores the fact that every physician in a group reassigns the right to bill and collect to the group. One might speculate that CMS is suggesting that the anti-markup rules only apply when using the Stark in-office ancillary services exception, as opposed to the Stark exception for personally performed services. The anti-markup provisions, however, are separate and distinct from the Stark regulations.

In the anti-markup rules, CMS creates a new definition for an "office of the billing physician or other supplier" without any reference to the definition of "same building" under the Stark in-office ancillary services exception. The office of the billing physician or other supplier is defined as the "medical office space where the physician or other supplier regularly furnishes patient care." 42 C.F.R. § 414.50(a)(2)(iii). With respect to a billing physician or other supplier that is a "physician organization," the "office of the billing physician or other supplier" is only the space in which the physician organization provides "substantially the full range of patient care services that the physician organization provides generally." *Id.*

Prior to Phase II of the Stark regulations, the in-office ancillary services exception defined the "same building" to be where substantially the full range of services was provided. This terminology was stricken from the final Phase II Stark regulations and replaced with a test that looks at how many hours a week the practice is open and requires only "some" non-designated health services (DHS) to be provided at that location. By creating a new definition of "office," the *raison d'être* for the definition of "same building" under the Stark exception is made irrelevant for physician practices that perform diagnostic tests in their offices. In light of the Final Rule, such physician practices will need to meet the "substantially full range of services test" to avoid the anti-markup provisions. ►

The Final Rule applies the anti-markup provision to tests performed in the same building, but not in the same office space. For example, an orthopedic practice that structured its practice to provide MRI tests in compliance with the Stark in-office ancillary services exception utilizing the "same building" criteria, may have located the MRI machine on the first floor of an office building and its practice on the third floor of the same building. Under the Final Rule, MRI tests would be subject to the anti-markup provision because the MRI is not located in the office where the physician practice provides substantially the full range of services (even though it is the same building where the physician provides the full range of services).

Although CMS did not address such a situation in the preamble to the Final Rule, CMS's comments support the view that the anti-markup provisions apply to block leases. To be acceptable under Stark, a block lease must meet the in-office ancillary services exception. Under the in-office ancillary services exception, a block lease must meet the same building criteria — the centralized building criteria will not work, because a centralized building must be leased 24 hours per day, seven days per week. If the anti-markup provision applied only to "centralized buildings," but not the "same building," there would be no basis under the Final Rule for the anti-markup provisions to apply to block leases.

Therefore, while CMS never specifically states that diagnostic tests provided in the same building, albeit not the same office space, would be subject to the anti-markup provision, this is the practical effect of the Final Rule.

Similarly, through the anti-markup rules, CMS has vitiated the applicability of the definition of "centralized building" under the Stark in-office ancillary services exception for diagnostic tests, even though Congress expressly created a statutory exception under Stark for DHS services provided in centralized buildings. While CMS has said it is concerned about the use of centralized buildings for diagnostic testing where independent contractors or part-time employees perform the tests that provide services to many physician practices, CMS had not previously proposed subjecting all diagnostic tests performed in centralized locations to the anti-markup rules.

In the Final Rule, CMS states that physicians can continue to purchase, and bill for, diagnostic tests — they just cannot profit from such tests. However, the definition of "net charge" realistically precludes most diagnostic testing arrangements that fall within the anti-markup prohibition. Not only does CMS prohibit such physicians from profiting, it potentially prohibits them from fully recouping their costs.

Under the anti-markup rules, the amount a physician practice may bill Medicare for diagnostic tests may not exceed the lowest of the following amounts:

(i) The performing supplier's net charge to the billing physician or other supplier.

(ii) The billing physician or other supplier's actual charge.

(iii)The fee schedule amount for the test that would be allowed if the performing supplier billed directly.

42 C.F.R. § 414.50(a)(1). According to the Final Rule, the billed amount "must be determined without regard to 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." In addressing the calculation of the "net charge" where there is no "charge" per test (*e.g.*, physicians performing TC or technicians are paid at a fixed rate, at a time-based amount, or a salary), CMS deferred to the billing physicians to determine a "reasonable manner" to ascertain an accurate net charge. CMS also suggested physician practices retain contemporaneous documentation of both the methodology and the information used to calculate the net charge.

Even more troubling, CMS eliminates *any* costs to the physician practice in providing the TC and PC of the diagnostic test in calculating the net charge. CMS refuses to prohibit the performing supplier from taking the costs of equipment or services (such as insurance) obtained from the billing supplier into account when determining its net charge in one response. In another response, CMS states that practice administrative expenses, such as the costs of billing, could not be part of the net charge. Specifically, CMS stated that, although the anti-markup rules are not designed to prevent the physician practice from recouping overhead expenses, where a diagnostic test is performed at a location other than the physician office, ►

> the billing supplier will not be able to recoup the overhead…If billing suppliers were able to recoup overhead incurred for TCs and PCs that are performed at sites other than their offices, the effectiveness of the anti-markup provisions would be undermined, because there would be an incentive to overutilize to recover the overhead incurred for purchasing or leasing space.

In response to another comment requesting that CMS permit the inclusion of the costs of equipment and supplies utilized in performing the services in the net charge, CMS said doing so would be the equivalent of a "net charge plus" approach; a methodology CMS believes would defeat the purpose of the anti-markup provisions. The practical effect of the "net charge" provision is that physician practices cannot take into account the cost of equipment when billing for the TC or PC of a diagnostic test that is not performed in its offices.

Consequently, diagnostic tests not performed in a physician practice's office space may not be economically feasible. For example, if an orthopedic group owns (or leases from a manufacturer) an MRI that it locates in a "centralized building" or in the "same building," but not the same office space as the physician practice, the physician practice would not be able to include any costs related to the MRI equipment in its net charge to Medicare for the TC. Without receiving any reimbursement from Medicare for the equipment (or for the related overhead), it is unlikely that any physician practice could afford to provide such services.

Conclusion

While the provisions that CMS chose to finalize in the final 2008 Physician Fee Schedule Rule initially appear quite simple and limited to payment rules for purchased diagnostic tests, the application of these rules in ways that CMS did not suggest in the proposed rule, or discuss in the Final Rule, will lead to major changes in how physicians provide diagnostic tests. Recently, CMS has hinted that it recognizes that there have been some unintended consequences of its changes to the anti-markup rules. The extent and timing of any clarification to the anti-markup rules is unclear at this time. Unfortunately, without further action by CMS, the anti-markup rules became effective January 1, 2008. ▲

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