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CMS Finalizes Changes to Medicare's Anti-Markup Rule That Will Have Substantial Implications For Physician / Supplier Practice Models

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On October 30, 2008, the Centers for Medicare & Medicaid Services ("**CMS**") filed with the Office of the Federal Register the final provisions to the 2009 Medicare Physician Fee Schedule (the "**Final Rule**"). Among the many changes in this Final Rule, CMS expanded the scope of the "anti-markup" rule, most notably, to prevent physicians (and other suppliers) from marking up either the technical or professional component (e.g., interpretations) of certain diagnostic tests, and CMS also published a new and more restrictive site-of-service limitation. The new anti-markup rule will upset the practicality of many otherwise permissible arrangements under the Federal physician self referral law's (the "**Stark Law's**") in-office ancillary services exception. Therefore, certain physician and supplier practice models, especially centralized building models, that are permissible today may become impractical and may need to be restructured or unwound in advance of the effective date of the Final Rule — January 1, 2009.

The History of the Anti-Markup Rule

Originally, the Medicare anti-markup rule prohibited physicians (and other suppliers) from marking up the technical component (TC) of certain diagnostic tests that outside suppliers performed but which the physician (or other supplier) billed to Medicare.[1]

In 2007, CMS proposed expanding the anti-markup rule to the professional component (PC) (e.g., interpretations) of diagnostic tests and adding a site-of-service requirement to the payment limitation. In summary, the 2007 proposed rule would have limited the payment for diagnostic tests that were either purchased from an outside supplier or performed at a site other than the "office of the billing physician or other supplier" (defined generally as the medical office space where the physician or other supplier regularly furnished patient services).

As described in Epstein Becker & Green's January 3, 2008 Client Alert titled "CMS Issues Final Rule Delaying Implementation of Anti-Markup Rules With Limited

Exceptions," in response to public concerns regarding the clarity and effects of the definition of "office of the billing physician or other supplier" CMS delayed the effective date of the final rule until January 1, 2009 to provide time for CMS to review and respond to comments in this area.

However, and as EBG noted in our January Client Alert, the application of the updated anti-markup rule was not delayed for anatomic pathology diagnostic testing arrangements. Specifically, CMS stated that: "Because anatomic pathology diagnostic testing arrangements precipitated [CMS'] proposal for revision of the anti-markup provisions and remain [CMS'] core concern, [CMS is] not delaying the date of applicability with respect to anatomic pathology diagnostic testing services furnished in space that: (1) is utilized by a physician group practice as a "centralized building" (as defined at §411.351 of this chapter) for purposes of complying with the physician self-referral rule; and (2) does not qualify as a "same building" under §411.355(b)(2)(i) of this chapter."[2] In late January 2008, various plaintiffs (including urology physician practices that owned and operated pathology laboratories), challenged in Federal court CMS's decision to not delay the final rule for anatomic pathology diagnostic testing arrangements. However, the plaintiff's litigation was dismissed in May of 2008 on procedural grounds.

How Has CMS Revised the Anti-Markup Rule?

The January 2009 revisions to the anti-markup rule broaden the scope of the rule and apply the provisions to both the technical and professional components of a diagnostic test that are not performed by a physician who "shares a practice" with the billing physician or other supplier. In the Final Rule, CMS implemented an approach that uses two alternative tests (the "substantially all" test and the "site-of-service" test) to determine whether a physician who performs the professional component or supervises the technical component (the "**Performing Physician**") "shares a practice" with the billing physician or other supplier (the "**Billing Physician**"). Numerous times in the preamble to the Final Rule, CMS states that if the "substantially all" test is not met, an analysis under the "site-of-service" approach may be utilized on a case-by-case basis to determine whether the anti-markup rule applies. The factors relevant to these two tests are described below.

Approach 1 – The "Substantially All" Test:

Under the "substantially all" professional services test, the anti-markup rule would not apply when the Performing Physician performs "substantially all" of his or her professional services for the Billing Physician. For the purposes of this approach, and consistent with the Stark rules, "substantially all" means at least 75 percent. That is, to avoid the application of the payment limitations under the anti-markup rule on grounds that the Performing Physician is determined to share a practice with the Billing Physician, the Performing Physician must provide at least 75 percent of his or her professional services to the Billing Physician —"even if the physician works for one or more billing physician groups or other health care entities."[3]

According to CMS, the "substantially all" approach adequately addresses a number of concerns raised in the public comments regarding locum tenens situations, as well as part-time physicians and other similar arrangements. In a situation where a Performing

Physician shares a practice with a Billing Physician while providing some services through other arrangements, the anti-markup rules do not apply if the "substantially all" test is met. Thus, as long as the Performing Physician is not providing more than 25 percent of his or her professional services as a locum tenens physician or other arrangements (i.e., part-time or moonlighting at a hospital) the anti-markup payment limitations will not apply. Conversely, CMS clarified that a Billing Physician may avoid application of the anti-markup payment limitations when a locum tenens physician is substituting for a permanent physician, if the permanent physician performs "substantially all" of his or her professional services through the Billing Physician. Likewise, with part-time Performing Physicians, a physician group may hire a part-time physician who "shares a practice" with the group as long as the part-time physician furnishes "substantially all" of his or her professional services through the group. Therefore, if the Performing Physician provides professional services a total of 20 hours a week and at least 15 hours per week are provided to the Billing Physician group, the anti-markup payment limitations will not apply.

Approach 2 – The Site-of-Service Test:

If the "substantially all" test is not satisfied, Billing Physicians have the option of satisfying the "site-of-service" test. In the "site-of-service" test, "TCs conducted and supervised and PCs performed in the "office of the billing physician or other supplier" by an employee or independent contractor physician will avoid application of the anti-markup payment limitation."[4] The "office of the billing physician or other supplier" is defined as any medical office space, regardless of number of locations, in which the ordering physician or other ordering supplier regularly furnishes patient care, and includes space where the billing physician or other supplier furnishes diagnostic testing, if the space is located in the "same building" (as defined by the Federal physician self-referral law) in which the ordering physician or other ordering supplier regularly furnishes patient care. With respect to physician organizations, the "office of the billing physician or other supplier" is the space in which the ordering physician performs substantially the full range of patient care services that the ordering physician provides generally. Therefore, the site-of-service test essentially becomes whether the diagnostic test is performed within in the same building (as defined by the Stark Law) where the physician or other ordering supplier regularly furnishes patient care.

With respect to the "same building" restriction, CMS stated: "[w]e believe that a site-of-service approach, employing the 'same building' test, is a reasonable means of determining whether a physician shares a practice and has a sufficient nexus with the billing physician or other supplier."[5] In response to comments that the "site-of-service" distinctions are irrelevant for determining the scope of the new anti-markup rule, CMS also stated that the Stark Law's centralized building approach creates the potential "for overutilization of diagnostic testing through arrangements involving a billing group and physicians who have little or no real connection to the billing group other than to serve as a point of referral to generate profits for the billing group."[6]

If the Anti-Markup Rule Applies, Then What Are The Billing Limitations?

If the anti-markup payment limitations apply, the payment to the Billing Physician for the TC or PC of the diagnostic test may not exceed the lowest of the following

amounts: (i) the Performing Physician's "net charge" to the Billing Physician, (ii) the Billing Physician's actual charge, or (iii) the fee schedule amount. It is important to note that "net charge" does not include the Billing Physician's overhead or "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 supplier."[7] Because the allowable billing amount consists only of the "net charge", these arrangements may no longer be practical.

In connection with various CMS proposals, concerns with the definition of "net charge" were raised by a number of commenters. For example, a number of commenters expressed concern that the term "net charge" did not permit practices to recoup their direct practice or overhead costs. CMS stated that: "[W]e are concerned that, allowing billing physicians and other suppliers to recoup costs such as overhead in situations in which the anti-markup provisions apply, would undermine a purpose of the anti-markup payment limitation because the incentive to overutilize (to recover capital outlays and other costs) would still be present."[8]

How Does the Anti-Markup Rule Relate to the Stark Law In-Office Ancillary Services Exception?

In several places in the preamble, CMS states that it distinguishes between the anti-markup rule and the Stark Law in-office ancillary services exception. According to CMS, "[t]he anti-markup provisions, when applied, limit only how much a physician or other supplier may bill Medicare, whereas the physician self-referral rules, when implicated and not satisfied, prevent a physician or other supplier (or provider) from billing Medicare (for any amount)."[9] Although, the anti-markup payment limitations do not make the in-office ancillary services exception illegal under the Stark Law, they do affect the practicality of these arrangements by limiting the payment to the Billing Physician. CMS states, "the fact that the physician self-referral law, as interpreted or implemented by us, does not prohibit a certain type of arrangement does not mean that we should not take measures, through an anti-markup approach, to address the potential for overutilization or other abuse that exists with certain arrangements that seek to take advantage of our definitions of "group practice" and "centralized building" that are used for the purposes of the physician self-referral exception for in-office ancillary services."[10] As a result, CMS appears to be limiting the practicality of the in-office ancillary exception without amending provisions related to the Stark Law. However, it should be noted, that CMS has indicated that they will continue to examine the use of the in-office ancillary exception and may propose future changes to the Stark Law.

What Are Some of the Practical Issues That Arise as a Result of the New Anti-Markup Rule?

Although not expressly stated in the rule, to avoid being adversely impacted by the anti-markup payment limitations, those group practices that meet the "centralized billing" test of the Stark Law in-office ancillary exception and who bill for diagnostic services that are performed in locations other than where the ordering physicians are located (i.e., not in the same building) must restructure or meet the "substantially all" professional services test (the 75% test). By way of example, assume that a group practice with multiple locations (e.g., Locations A, B & C) is setup in such a way that

each one of the group's physicians works at only one location and the group's diagnostic services are provided at only one of the locations (i.e., Location A). Moreover, assume that the group contracts with an independent contracting specialist (e.g., a radiologist or pathologist) on a part-time basis to supervise the technical component (TC) and perform the professional component (PC) (e.g., interpretations) of the diagnostic services under an arrangement whereby the group bills for both the TC and PC of the diagnostic services through an appropriate reassignment. In this situation, orders for diagnostic services from the group's physicians at Location A will not be subject to the new anti-markup rule so long as the ordering physicians regularly furnish patient care at Location A and the specialist also provides the PC and supervision for the TC of the diagnostic services at Location A. However, if the independent contracting specialist does not furnish "at least 75 percent" of his or her professional services through the billing group, orders from physicians in Locations B and C would be subject to the new anti-markup rule, since those ordering physicians will not be located in the same building as the building where the tests are supervised and approved. Therefore, the group will need to consider, for example, moving the location where diagnostic services are rendered, rearranging physician schedules so that all physicians "regularly furnish services" at Location A or contracting with the specialist to ensure that "at least 75 percent" of his or her professional services are furnished through the billing group. Needless to say, the new anti-markup rule will be disruptive for many groups that operate at multiple locations and have a centralized diagnostic services location.

What Is Next? What Initial Questions Should Physicians and Health Care Organizations Be Asking?

Given that these revised anti-markup provisions become effective January 1, 2009, and the possibility that arrangements will need to be restructured and/or unwound, it is important for health care providers to review their arrangements as soon as possible. As part of an initial review, health care providers should address the following preliminary questions:

1. Is my organization a physician or other supplier (e.g., a group practice)? If not, then the anti-markup rule does not apply. If yes, see Question 2.

2. Does our organization/do our physicians order diagnostic services? If no, then the anti-markup rule does not apply. If yes, see Question 3.

3. Does our organization bill for diagnostic services? If no, then the anti-markup rule does not apply. If yes, then your organization must analyze where the diagnostic services are performed and supervised and understand whether your organization may meet one of the anti-markup rule tests or whether restructuring or unwinding is warranted.

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Endnotes

[1] See 42 U.S.C. 1395u(n); 42 C.F.R. § 414.50.

[2] 73 Fed. Reg. 404, 405 (January 3, 2008).

[3] Page 425 of the Federal Register Display Copy of the Final Rule. In addition, CMS clarified that the billing physician (or other supplier) meets the "substantially all" test, if at the time the claim is submitted for the performing physician's service, the billing physician (or other supplier) has a "reasonable belief"

that (A) for the 12 months prior to and including the month in which the service was performed, the performing physician furnished substantially all of his or her professional services through the billing physician or other supplier; or (B) the performing physician will furnish substantially all of his or her professional services through the billing physician or other supplier for the next 12 months (including the month in which the service is performed).

[4] Page 423 of the Federal Register Display Copy of the Final Rule.

[5] Page 463 of the Federal Register Display Copy of the Final Rule.

[6] Page 463 of the Federal Register Display Copy of the Final Rule.

[7] Page 504 of the Federal Register Display Copy of the Final Rule.

[8] Page 504 of the Federal Register Display Copy of the Final Rule.

[9] Page 441 of the Federal Register Display Copy of the Final Rule.

[10] Page 441 of the Federal Register Display Copy of the Final Rule.