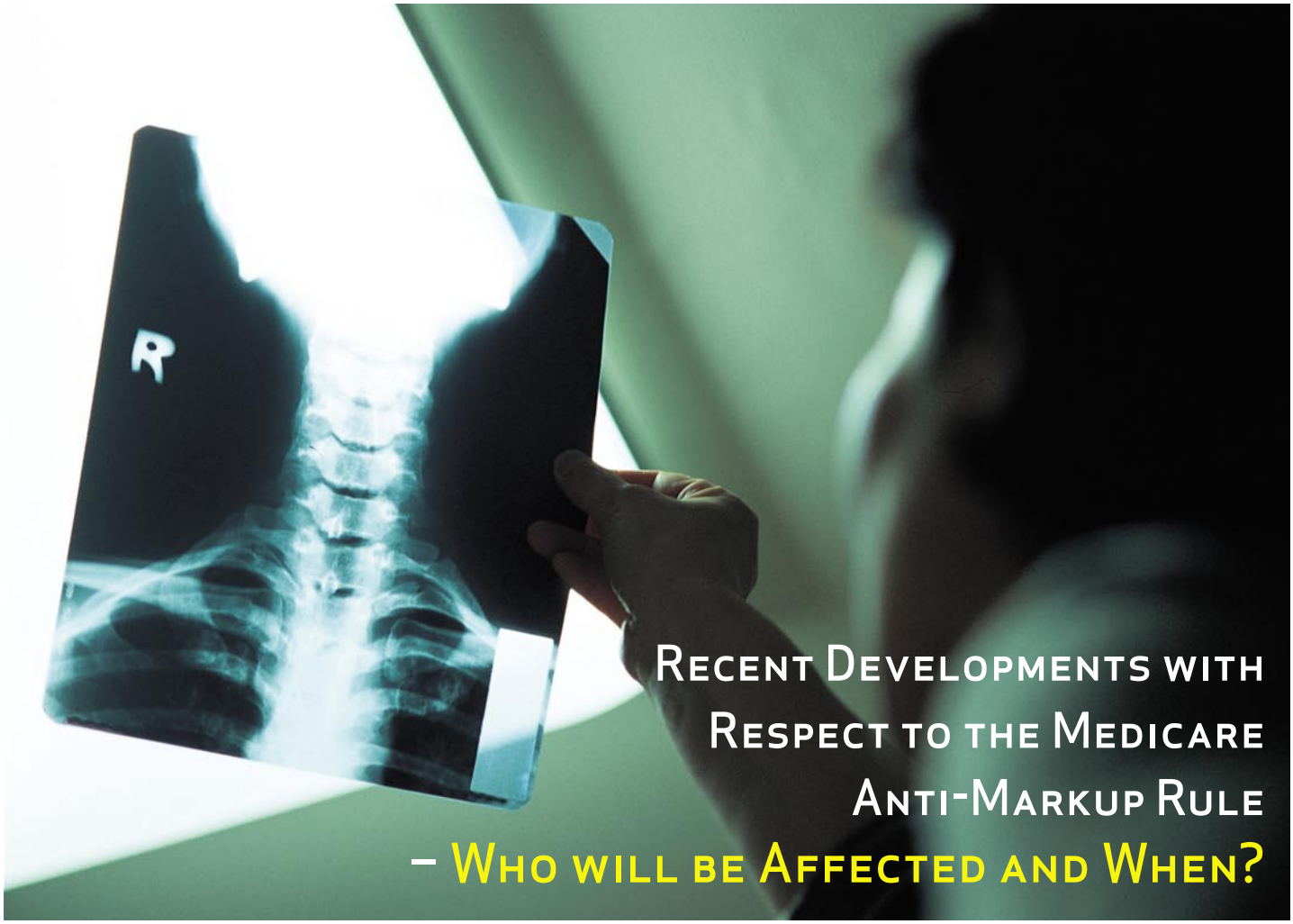

Recent Developments with Respect to the Medicare Anti-Markup Rule – Who will be Affected and When?

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In the 2008 Medicare Physician Fee Schedule released on November 1, 2007, and published in the Federal Register on November 27, 2007, the Centers for Medicare and Medicaid Services ("CMS") recently revised the longstanding Medicare anti-markup rule, which previously applied only to billing for the technical component of diagnostic tests. The newly revised rule will have a potentially dramatic effect on the ways that physicians and other suppliers provide and bill for diagnostic tests.

Evolution of the New Rule

The Medicare anti-markup rule is found at 42 C.F.R. §414.50. Prior to the publication of the 2008 Medicare Physician Fee Schedule, the rule limited the amount that could be billed by a physician or group practice for the technical component of diagnostic tests (excluding clinical diagnostic tests performed by clinical laboratories) that were performed by an outside supplier.

CMS originally proposed revisions to the anti-markup rule, as well as the rules for purchased interpretations, in the 2007 Medicare Physician Fee Schedule, but did not finalize the revisions at that time. The revisions contained in the 2007 Medicare Physician Fee Schedule proposed to extend the anti-markup prohibition applicable to the purchase of the technical component of diagnostic tests to the purchase of the professional component as well. The proposed revisions focused in large part on the employment status of the person performing either the technical or professional component of the diagnostic test; specifically, whether such person was a full-time employee of the billing entity, as opposed to an independent contractor or part-time employee.

Based on comments received in response to the proposed revisions contained in the 2007 Medicare Physician Fee Schedule, CMS decided to move forward in the 2008 Medicare Physician Fee Schedule with the concept of extending the anti-markup prohibition to both the technical and professional components of diagnostic tests. In doing so,

CMS expressed as its rationale the concern that certain arrangements which were structured so as to comply with the technical requirements of the in-office ancillary services exception to the federal Stark law, which permits physician groups to bill for certain services referred by group physicians and furnished by a contractor physician in a "centralized building", were not within the intended purpose of such exception. CMS also expressed the concern that allowing physicians or other suppliers to purchase diagnostic testing services and then to profit from them when billing Medicare may lead to program and patient abuse in the form of overutilization of services and ultimately result in increased costs to the Medicare program.

Although many of the revisions contained in the 2008 Medicare Physician Fee Schedule marked a significant departure from the proposed rules set forth in the 2007 Medicare Physician Fee Schedule for which comments were solicited and received, the revised anti-markup rule contained in the 2008 Medicare Physician Fee Schedule was published in final form and was initially scheduled to go into effect on January 1, 2008. As discussed below, on January 3, 2008, CMS delayed the effective date of certain of the more controversial aspects of the newly revised rule, pending further clarification and/or rulemaking on the part of CMS.

How and When Does the New Rule Apply?

The newly revised anti-markup rule contained in the 2008 Medicare Physician Fee Schedule eliminates the distinction surrounding whether the person performing either the technical or the professional component of the diagnostic test is a full-time employee of the billing group versus an independent contractor or part-time employee. Instead, the newly revised rule focuses on whether the technical or professional component of the diagnostic test is purchased from an outside supplier or whether it is performed at a site other than the "office of the billing physician or other supplier".

Specifically, the newly revised anti-markup rule applies if a physician or other supplier bills Medicare for the technical or professional component of a diagnostic test that was ordered by the physician or other supplier (or a party related to the physician or supplier by common ownership or control), and the diagnostic test is either: (a) purchased from an outside supplier, or (b) performed at a site other than the office of the billing physician or other supplier. In cases where the anti-markup rule applies, the rule limits payment to the billing entity to the lowest of the following amounts:

(1) the outside supplier's net charge to the billing entity;
(2) the billing entity's actual charge; or
(3) the fee schedule amount that would be allowed if the outside supplier billed Medicare directly. (42 CFR §414.50(a)(1))

One of the more controversial aspects of the newly revised rule is the new definition that CMS created in 42 CFR §414.50(a)(2)(iii) for the "office of the billing physician or other supplier". This definition is seemingly at odds with the definitions of "same building" and "centralized building" that are used in the Stark in-office ancillary services exception. The term "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". With regard to a physician organization, the term is further defined as the space where the physician organization provides "substantially the full range of patient care services that the physician organization provides generally". This definition is problematic in that the Stark in-office ancillary services exception permits the furnishing of certain designated health services that are ancillary to a referring physician's practice where certain requirements relating to location, supervision and billing are met. Specifically, with regard to the location requirements, the exception permits designated health services to be performed in either the same building (but not necessarily the same space) as where the physician or group practice provides some non-designated health services or in a "centralized building" in which all or part of the building is owned or leased on a full-time basis by the physician or group practice and is used exclusively by the physician or group practice.

THE ANTI-MARKUP PROHIBITION ARGUABLY APPLIES TO DIAGNOSTIC TESTS PERFORMED IN THE SAME BUILDING BUT NOT IN THE SAME OFFICE SPACE

Under the newly revised rule, the anti-markup prohibition arguably applies to diagnostic tests performed in the same building but not in the same office space. For instance, a group practice's main office location where it regularly provides patient care services is located on the second floor of a medical office building. The practice leases space on the first floor of the building where it has located an MRI machine. This arrangement is structured so as to comply with the "same building" requirements of the Stark in-office ancillary services exception. If the newly revised anti-markup rule were to go into effect as currently drafted, any MRI test performed by the group would be subject to the anti-markup prohibition because it was not provided in the same space where the group provides "substantially the full range of patient care services." In another example, a group locates a diagnostic imaging center across the street from its main office location. The group uses the center on a full-time exclusive basis but does not also provide other patient care services there. This arrangement will arguably also be subject to the anti-markup prohibition, even though it is structured so as to comply with the "centralized building" approach

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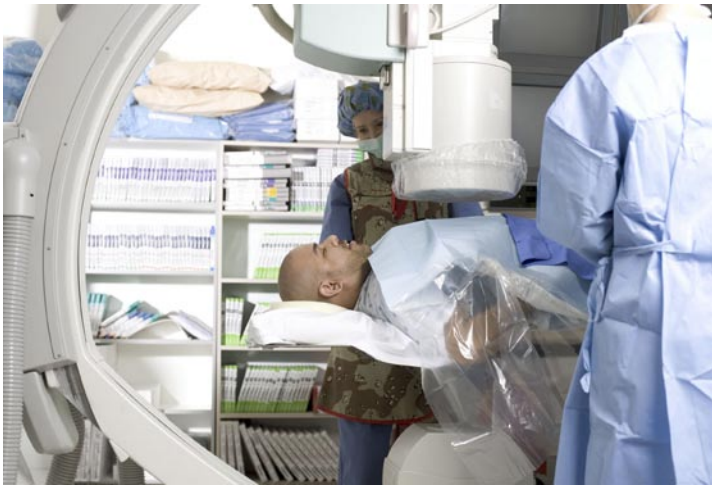
to the Stark in-office ancillary services exception, because the space is not routinely used to provide substantially the full range of the group's patient care services.

Another controversial aspect of the newly revised rule is the concept of limiting the amount of payment to the outside supplier's "net charge" to the billing entity. In the 2008 Medicare Physician Fee Schedule, CMS stated that in order to prevent "gaming", a situation where, according to CMS, the outside supplier's net charge to the billing entity is inflated to cover the cost of equipment or space that is leased by the billing entity to the outside supplier, CMS defined "net charge" as exclusive of any amount that takes into effect such costs. The effect of this provision is that a billing entity can no longer factor into its fee schedule certain costs to the entity in providing the technical or professional components of diagnostic tests. For instance, where the diagnostic test is performed at a location other than the billing entity's office, the billing entity will no longer be able to recoup its overhead expenses, nor will it be able to recoup its costs for the equipment and supplies needed to perform the tests. As a practical matter, then, it may no longer be economically feasible for physicians and groups to perform diagnostic tests in locations outside of their normal patient care locations.

It should be noted that the newly revised anti-markup rule does not apply to a diagnostic test performed by an independent lab or independent diagnostic testing facility ("IDTF") where the lab or IDTF purchases the professional component of the test and bills for both the technical and professional components provided that the lab or IDTF does not order the test.



"...physician groups are questioning the applicability of the newly revised anti-markup rule to arrangements..."

So Where Do We Stand Now?

On January 3, 2008, CMS announced in a final rule that it would delay, with some exceptions, the effective date of the newly revised anti-markup rule until January 1, 2009.

CMS stated in the final rule that the reason for the delay is due to the fact that the application of the revised anti-markup rule is "unclear with respect to whether certain types of space arrangements meet the definition of 'office of the billing physician or other supplier'". According to the January 3, 2008 final rule, physician groups are questioning the applicability of the newly revised anti-markup rule to arrangements, which have otherwise been structured so as to comply with the federal Stark in-office ancillary services exception. CMS stated that it had received comments in response to the 2008 Medicare Physician Fee Schedule that warn that patient access to diagnostic services could be significantly disrupted due to the inability of physician groups to render services in a cost-effective manner if medical office space that complies with "same building" or "centralized building" tests under the Stark in-office ancillary services exception becomes subject to the new anti-markup provisions contained in revised 42 CFR §414.50. Further, according to CMS, commenters also expressed concerns that if limited to billing Medicare for the amount of the "net charge" imposed by the outside supplier, physician practices would not only fail to realize a profit, but would fail to recoup their overhead costs in providing diagnostic testing services, thereby limiting their ability to continue to provide such services to the same extent they are currently doing so.

CMS acknowledged in the January 3, 2008 final rule that the defined term "office of the billing physician or other supplier" may not be clear and could have unintended consequences. In order for CMS to study the issue further, it delayed the effective date of the revised anti-markup rule to January 1, 2009 except in certain instances.

CMS chose not to delay the effective date of the revised anti-markup rule with respect to anatomic pathology services (i.e., "pod labs") and the purchase of technical component services. Specifically, the revised anti-markup rule took effect as of January 1, 2008 for anatomic pathology testing services furnished in space that (a) is utilized by a physician group practice as a "centralized building" for purposes of complying with the Stark in-office ancillary services exception, and (b) does not qualify as a "same building" under that exception.

CMS indicated in the January 3, 2008 final rule that anatomic pathology diagnostic testing arrangements have been the focus of its concern and were, in fact, the original impetus for the revisions to the anti-markup rule.

CMS also indicated in the January 3, 2008 final rule that it intends to issue clarifying guidance between now and the end of 2008 as to what constitutes the "office of the billing physician or other supplier", or propose additional rulemaking, or both.

In light of the uncertainty surrounding the application of the revised Medicare anti-markup rule to arrangements, which comply with the Stark in-office ancillary services exception, providers of diagnostic testing services are advised to stay tuned for additional developments on this topic later in the year.

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