THE 2009 MEDICARE PHYSICIAN FEE SCHEDULE: THE ANTI-MARKUP RULE AND IDTF DEVELOPMENTS IMPACTING DIAGNOSTIC TESTING SERVICES

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In recent years, the Centers for Medicare and Medicaid Services ("CMS") has heavily scrutinized the terms and conditions under which Medicare will pay for diagnostic testing services, resulting in heightened regulatory action targeting certain diagnostic testing arrangements (including imaging services). These initiatives include changes to the federal Stark law, proposed (and now final) expansions of the federal anti-markup prohibition, changes to the Independent Diagnostic Testing Facility ("IDTF") performance standards, and implementation of payment changes related to the way imaging services are paid under the physician fee schedule.[1] On November 19, 2008, CMS published the 2009 Final Physician Fee Schedule ("Final Rule").[2] This article will focus on two significant aspects of the Final Rule which will significantly impact diagnostic testing arrangements: (1) a final anti-markup rule and (2) IDTF enrollment requirements

Medicare's Final Anti-Markup Rule – Effective January 1, 2009

In the Final Rule, CMS adopts a flexible approach, using two alternative tests with respect to the application of the anti-markup rule to the provision diagnostic testing services.[3] Under the new finalized alternative test approach, CMS has moved away from its long-standing approach of focusing on whether the test was "purchased" from an "outside supplier," now offering two alternative tests that focus on the underlying principle that the anti-markup payment limitation will not apply if the performing or supervising physician "shares a practice" with the billing physician.[4] The final anti-markup rule went into effect January 1, 2009.[5]

The Evolution of the Anti-Markup Rule – A Brief History

By way of brief background, in the 2009 Medicare Proposed Physician Fee Schedule CMS revisited changes it had already enacted to its longstanding anti-markup rule,[6] which originally prohibited only the mark-up of the technical component ("TC") of certain diagnostic tests performed by outside suppliers and billed to Medicare by a different individual or entity.[7] Specifically, in its 2008 Medicare Final Physician Fee Schedule, CMS significantly expanded the scope of the long-standing anti-markup provision and applied it to the provision of both the TC and the professional component ("PC") of diagnostic tests ordered by a billing physician or other supplier (or related party) if: (1) the TC or PC is purchased outright or (2) if the TC or PC is performed at a site other than "the office of the billing physician or other supplier."[8]

After its earlier finalization of the anti-markup rule, CMS received an overwhelming number of comments from industry stakeholders who were concerned about the application of the expanded rule to common arrangements, and concerned about the clarity (or lack thereof) of the language setting forth the intent of the rule's provisions.[9] In response to these concerns, in the 2009 Medicare Proposed Physician Fee Schedule CMS proposed to apply the anti-markup provisions where the TC or the PC of a diagnostic testing service is either: (1) purchased from an outside supplier; or (2) performed or supervised by a physician who does not "share a practice" with the billing physician or other supplier. CMS proposed two alternative approaches to determining whether a physician "shares a practice" with the billing physician or other supplier. Under the first alternative, CMS proposed that a physician who is employed or contracts (whether full-time or part-time) with a single physician or physician organization "shares a practice" with that physician or physician organization. Under the second alternative, CMS proposed to maintain its "site of service" approach to determining whether a physician "shares a practice" with the billing physician or other supplier. Under this second alternative, a physician would "share a practice" with the billing physician or other supplier if the TC or PC of the test was performed in the "office of the billing physician". However, under the second alternative, CMS would expand the definition of "office of the billing physician" to include testing performed within the same building in which the billing physician regularly furnishes patient care (as opposed to its earlier approach of same office suite).[10]

Two Alternative Tests for Determining Whether the Performing Physician "Shares a Practice" with the Billing Physician or Other Supplier

After careful consideration of comments from industry stakeholders, in the Final Rule CMS adopted a relatively flexible approach that incorporates both of its earlier proposed alternatives, with some slight modification.[11] In particular, the final anti-markup payment limitation will not apply to a diagnostic testing arrangement if a physician or other supplier can meet either of the following two alternative tests:

1) Alternative 1 – "Substantially All Test." Arrangements should be analyzed first under Alternative 1, as follows: where the performing physician (i.e., the physician who supervises the TC or performs the PC, or both) performs substantially all (i.e., at least 75 percent) of his or her professional services for the billing physician or other supplier, the services will not be subject to the anti-markup rule payment limitation. If the performing physician does not meet the "substantially all" services requirement under Alternative 1, an analysis under Alternative 2 (below) may be applied on a test-by-test basis to determine whether the anti-markup payment limitation applies to an arrangement.[12]

2) Alternative 2 – "Site of Service Test." Under Alternative 2, only TCs conducted and supervised in, and PCs performed in, the "office of the billing physician" (which is expanded to include testing performed in the "same building" under Stark) by an employee, owner, or independent contractor physician will avoid application of the anti-markup payment limitation.[13]

Both the "substantially all" and "site of service" tests (identified above) measure whether a performing or supervising physician "shares a practice" with the billing physician or other supplier. With respect to the "site of service" test, CMS believes that the restrictions requiring the TC to be both conducted and supervised in the office of the billing physician or other supplier creates sufficient control and nexus to the individuals conducting and supervising the tests.[14] CMS also added some flexibility to the "substantially all" test by not requiring a physician to exclusively work for one physician practice and, rather, merely requiring him or her to "share a practice" with a particular physician or physician organization. To meet this standard, a physician must provide at least 75 percent of his or her professional services for that practice.[15] This change aligns certain provisions of the Stark group practice definition with the anti-markup provisions.[16]

The Final Rule provides that a billing physician or other supplier will satisfy the "substantially all" (Alternative 1) requirement if he or she has a reasonable belief, at the time he or she submits a claim, that: (1) the performing physician has furnished substantially all of his or her professional services through the billing physician or other supplier for the period of 12 months prior to and including the month in which the service was performed; or (2) the performing physician is expected to furnish substantially all of his or her professional services through the billing physician or other supplier during the following 12 months (including the month the service is performed).[17]

Further, under the Final Rule's Alternative 1 "substantially all" test, a physician can "share a practice" with a physician, physician organization, or other supplier and provide up to 25 percent of his or her professional services through other arrangements (including acting as a *locum tenens* physician).[18] With respect to *locum tenens* situations only, CMS is careful to clarify that whether an arrangement satisfies Alternative 1 depends upon whether the permanent physician (i.e., the physician for whom the *locum tenens* is substituting) performs "substantially all" (i.e., at least 75 percent) of his or her professional services through the billing physician or other supplier.[19]

With respect to the "site of service" approach utilized in Alternative 2, CMS aligns the location test with the Stark Law "same building" test and clarifies that a physician or other supplier may have more than one "office of the billing physician or other supplier" and such space is defined as space in which the ordering physician or other ordering supplier regularly furnishes patient care (and with respect to physician organizations or group practices, the definition refers to space in which the ordering physician performs substantially the full range of patient care services that the ordering physician provides generally).[20] Additionally, with respect to Alternative 2, CMS adds a requirement that the physician supervising the TC, or performing the PC, must be an owner, employee, or independent contractor of the billing physician or other supplier.[21]

As a practical matter, under the final anti-markup rule, CMS permits the use of shared space imaging arrangements between physicians that occur in the "same building", but, the agency notes, centralized building locations raise concerns for overutilization and are not permitted for the provision of diagnostic tests.[22] CMS, cautions, however, that despite its flexibility with the "same building" approach, it still has concerns with the present use of the in-office ancillary services exception under Stark and may issue proposed changes in the future.[23]

Of particular significance for those physicians providing diagnostic testing services in reliance upon Alternative 2, the TC must be both conducted and supervised in the "office of the billing physician or other supplier" ("Same Office Requirement"). Despite the fact that the Stark Law generally applies the Medicare coverage and payment regulations governing supervision of tests ("Medicare Coverage Requirements"), providers seeking to rely on Alternative 2 must meet the Same Office Requirement, whether or not this new supervision requirement is more stringent than the Medicare Coverage Requirements. CMS believes this final anti-markup rule requirement is necessary to minimize the potential for overutilization and program abuse.[24]

The Final Rule does not finalize a definition of "outside supplier" because CMS deletes the references to a "purchased" test or interpretation in the regulatory text, as the terms are unnecessary in light of CMS' "shares a practice" alternative test approach.[25] CMS notes that the Social Security Act only requires it to impose an anti-

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markup limitation on diagnostic tests that are performed or supervised by a physician who does not share a practice with the billing physician or other supplier, and it would be unduly complex and confusing to use separate bases for imposing an anti-markup payment limitation on "purchased" tests or interpretations from an outside supplier.[26]

In light of its two alternative tests approach, in the Final Rule CMS also declined to create a separate exception for diagnostic tests ordered by a physician in a physician organization that does not have any owners who have a right to receive profit distributions.[27]

Anti-Markup Payment Limitations – "Net Charge"

Diagnostic testing arrangements that fall within the ambit of the final anti-markup provisions are subject to restrictive payment limitations. That is, under the anti-markup provisions, payment to the billing entity will be limited to the lowest of: (1) the performing physician's or other 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 allowed if the performing physician or supplier billed directly.[28]

Of significant importance is that the "net charge" amount (identified in (1) above) must be determined without reference 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, notwithstanding that these are bona fide expenses incurred in connection with the diagnostic testing service.[29] Under the "net charge" approach, the billing physician or other supplier is limited to recovering costs for the salary and benefits it paid to the performing supplier of the TC or PC (i.e., the supervising physician or performing physician).[30] Notably, in the Final Rule, CMS declined to revise the meaning of "net charge" and indicates that the payment limitations are intended to be punitive.[31] As a practical matter, billing physicians or other suppliers that implicate the anti-markup rule likely will receive reimbursement that does not cover the costs of providing the diagnostic testing services.

Practical Application of the Anti-Markup Final Rule

Below are two examples of the final anti-markup provisions and their application to common diagnostic testing services arrangements:

1) **Group Practice Independent Contractor Radiologist Arrangement.** A physician in a multi-specialty group practice orders an x-ray and the part-time employed technician performs the x-ray in the group's office. The ordering physician works exclusively for the multi-specialty group and supervises the test in the group's office. A radiologist who is an independent contractor with the multi-specialty group practice performs the PC of the test in the group's office and reassigns his right to payment to the group. The independent contractor radiologist provides professional services to several groups and hospitals in the area. He performs approximately 20 percent of his professional services for the multi-specialty group practice. In this example, the anti-markup rule does not apply to the group's billing of the TC because the supervising physician (i.e., the performing physician) "shares a practice" with the billing group insofar as he performs at least 75 percent of his professional services for the group. With respect to the PC of the test, the independent contractor (i.e., the performing physician) does not perform substantially all of his professional services to the group (he performs approximately 20 percent). Thus, an analysis under Alternative 2 applies. Under the second alternative "site of service" test, the anti-markup rule does not apply because the performing radiologist provided the interpretation on-site in the group's office. As a practical matter, if the TC and the PC of the diagnostic testing are not subject to the anti-markup payment limitation, the payment made to the group will be the Medicare Part B fee schedule amount. If, however, the independent contractor physician were to have performed the PC off-site, the anti-markup payment limitations would apply to the group's billing of the PC of the test. In this situation, as a practical matter, the payment made to the group for the PC could not exceed the contracted radiologist's net charge (which cannot take into account any charge that is intended to reflect overhead of space leased to the radiologist by or through the billing group, if applicable). For example, if the radiologist charges the group $40 per professional interpretation, the group's payment from Medicare will be limited to $40 for the service (this assumes that the $40 fee is lower than the billing entity's actual charge or the fee schedule amount).
2) **IDTF Arrangement.** A physician orders a diagnostic test. A separate IDTF entity provides the test and bills globally for the test (TC and PC). The anti-markup rule does not apply because the IDTF did not order the test; rather, it was ordered by an outside physician. As a practical matter, in this arrangement, the payment made to the IDTF for the TC and the PC will be the Medicare Part B fee schedule amount.

The final anti-markup two alternative tests approach was effective January 1, 2009.[32] Attorneys providing guidance to physicians and other suppliers performing and billing for diagnostic testing services should analyze their clients' arrangements to ensure compliance with

the new provisions. Further, when analyzing these arrangements it is also important to be aware of the myriad of other applicable healthcare laws and regulations (e.g., Federal Stark Law, Federal Anti-Kickback Statute, and Medicare coverage regulations) that may apply to the arrangement

IDTF Performance and Enrollment Requirements

IDTF Performance Standards for Physician In-Office Testing – CMS Declines to Implement IDTF Quality Standards for In-Office Testing

In recent years, CMS established performance standards for suppliers enrolled in the Medicare program as an IDTF[33] The standards were established with a view towards improving the quality of care for diagnostic testing furnished to Medicare beneficiaries by Medicare-enrolled IDTFs.[34] In response to the standards, many industry stakeholders expressed concern that the IDTF performance standards (including prohibitions regarding the sharing of space) do not apply to physicians (and non-physician practitioners) who are furnishing diagnostic testing to patients and have enrolled in Medicare as a clinic, group practice, or physician's office[35] As a consequence, the standards for diagnostic testing services were not applied consistently to all providers[36] In an attempt to address these concerns, earlier this year CMS introduced a proposal that would require any physician or NPP (non-physician practitioner) furnishing diagnostic testing services (except diagnostic mammography) to enroll as an IDTF and be subject to most IDTF performance standards.[37] If adopted, this proposal would have eliminated the ability of physician practices to share diagnostic imaging and other testing equipment and facilities, even if the equipment and facility were located in the "same building" as the term is defined in the Stark Law in connection with the in-office ancillary services exception. As a practical matter, this proposal also would have resulted in a significant decline in the number of physician practices that furnish diagnostic testing services to their patients based on the difficulty for non-radiologist offices to secure properly qualified non-physician personnel, and numerous specialty practices likely would have been unable to satisfy the proficiency requirements for supervision of the tests.

Citing the enactment of Section 135 of the Medicare Improvements for Patients and Providers Act of 2008 ("MIPPA"),[38] in the Final Rule CMS declined to implement the IDTF enrollment proposals which were contained in the 2009 Medicare Proposed Physician Fee Schedule.[39] CMS, however, states that it will consider finalizing the IDTF enrollment requirements in a future rulemaking, if necessary.[40] For now, CMS' decision means that physicians who perform diagnostic testing services in their offices do not have to enroll as an IDTF, or be subject to the IDTF performance standards.

Mobile Entities – Enrollment and Direct Billing Requirements

Although CMS declined to implement its IDTF enrollment requirement for physician practices providing in-office diagnostic testing services, CMS did finalize its earlier proposal to require mobile entities to enroll and bill Medicare directly for the TC services that they provide.[41] CMS, however, is not requiring mobile testing entities to bill directly for their services when such services are furnished "under arrangements" with hospitals.[42]

According to the preamble commentary of the Final Rule, the implementation of this rule will prohibit many common arrangements in which mobile entities lease diagnostic testing equipment and technicians to physicians who conduct and bill for such tests in their offices.[43] Specifically, a commenter urged CMS to exclude from the definition of entities furnishing mobile diagnostic testing services those entities that lease equipment and provide technicians who conduct the tests in the office of the physician or physician organization, and furnish testing under the supervision of a physician who shares an office with the billing physician or physician organization. In response, CMS stated:

> "We disagree with the commenter. We maintain that a mobile entity providing diagnostic testing services must enroll for any diagnostic imaging services that it furnishes to a Medicare beneficiary, regardless of whether the service is furnished in a mobile or fixed base location so that CMS knows which entity is providing these diagnostic testing services."[44]

Notably, in complete contradiction to CMS' response in the Final Rule's commentary, on December 16, 2008, CMS posted a frequently asked question ("FAQ") on its website as follows:

Question:

> "My company leases/contracts diagnostic testing equipment and/or non-physician personnel described in 42 CFR 410.33 to an enrolled Medicare provider/supplier (e.g., medical group practice). Do I need to enroll as an Independent Diagnostic Testing Facility (IDTF)?"

Response:

> "Companies that lease or contract with a Medicare enrolled provider or supplier to provide: a) diagnostic testing equipment; b) non-physician personnel described in 42 CFR 410.33(c); or c) diagnostic testing equipment and non-physician personnel described in 42 CFR 410.33(c) are not required to enroll as an IDTF. Medicare continues to evaluate arrangements where both diagnostic testing equipment and non-physician personnel are contracted to a Medicare enrolled provider or supplier and where the Medicare enrolled provider or supplier is billing for the diagnostic service."[45]

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The CMS FAQ reflects that apparently CMS will distinguish a mobile leasing company that provides the equipment and non-physician personnel (i.e , does not have to enroll as an IDTF and bill directly) from a mobile company that also provides the physician supervision component of the service (i.e., must be an IDTF and bill directly)

Although the CMS FAQ is not binding authority, it appears that it may reflect the current view of the agency While it is not possible to ascertain with certainty the future action that CMS will take relative to the IDTF enrollment issue, the publication of the FAQ (which the authors understand to reflect the prevailing view within the agency), suggests that additional clarification to the Final Rule may be forthcoming

In summary, effective January 1, 2009, pursuant to the Final Rule, all mobile entities that furnish diagnostic testing services must enroll in the Medicare program and bill directly for the services, unless they are billing "under arrangements" with a hospital [46] The issue that appears to be open to forthcoming guidance or regulation is CMS' interpretation of a mobile entity furnishing diagnostic imaging services Thus, attorneys advising mobile entities and other providers of diagnostic imaging services must remain attentive to future developments in this area

Conclusion

Through a series of regulatory actions, CMS has been targeting diagnostic testing services arrangements Attorneys advising diagnostic testing services providers should stay tuned for future developments and rulemakings, which may significantly affect the structure of many current arrangements

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Endnotes

1 See, for example: (1) 73 Fed Reg 48688 (2008) for the 2009 Final Stark rules, which were contained in the 2009 Final Hospital Inpatient Payment Systems Rule; (2) 42 C F.R. Section 410 33, which contains the quality and performance standards applicable to IDTFs; (3) 42 C.F.R Section 414 50, 72 Fed. Reg. 66222 (2007), 73 Fed Reg 404 (2008), 73 Fed Reg 38544-38548, 38606 (2008), and 73 Fed Reg 69799-69817,69935 (2008) all of which address the amended anti-markup provisions applicable to diagnostic imaging tests; and (4) Section 5102 of the Deficit Reduction Act of 2005 ("DRA"), which was intended to level the playing field between physician offices and outpatient hospitals with respect to reimbursement for the technical component ("TC") of certain imaging services provided to Medicare beneficiaries

2 73 Fed Reg 69726 (2008). CMS originally displayed the Final Rule on October 30, 2008

3 42 C.F R Section 414 50, 73 Fed Reg 69935 (2008)

4 73 Fed. Reg 69799-69800 (2008)

5 73 Fed. Reg 69801 (2008)

6 73 Fed Reg 38502 (2008)

7 42 C.F R. Section 414 50 (2007).

8 72 Fed. Reg 66307-66308, 66401 (2007), 42 C.F R. Section 414 50.

9 73 Fed Reg. 38502 (2008)

10 73 Fed Reg 38544-38548, 38606 (2008)

11 73 Fed Reg 69800 (2008)

12 73 Fed Reg. 69800, 69803-69807, 69935 (2008), 42 CFR Section 414 50 (a) (2) (ii) (2008)

13 73 Fed Reg. 69800, 69807-69809, 69935 (2008), 42 CFR Section 414 50 (a) (2) (iii) (2008)

14 73 Fed Reg 69800 (2008)

15 73 Fed Reg. 69800, 69935 (2008), 42 CFR Section 414 50 (a) (2) (ii) (2008)

16 73 Fed Reg 69800 (2008)

17 73 Fed Reg 69800-69801, 69935 (2008), 42 CFR Section 414 50 (a) (2) (ii) (A) and (B) (2008)

18 73 Fed Reg 69804-69805 (2008)

19 73 Fed Reg 69805 (2008)

20 73 Fed. Reg 69800-69801,69809-69811, 69935 (2008), 42 CFR Section 414 50 (a) (2) (iii) (2008)

21 *Id*

22 73 Fed Reg 69808 (2008) Note that technically central locations are permitted but, from a practical perspective, they will be subject to severe payment limitations

23 73 Fed Reg 69808-69809 (2008)

24 73 Fed Reg 69800, 69810 (2008)

25 73 Fed Reg 69801, 69812-69813 (2008)

26 *Id*

27 73 Fed. Reg 69801,69809 (2008)

28 73 Fed. Reg 69935, 42 C.F.R. Section 414 50 (a) (1) (i), (ii), and (iii) (2008).

29 73 Fed Reg. 69935, 42 C.F R. Section 414.50 (a) (2) (i) (2008)

30 73 Fed Reg 69813-69814 (2008).

31 73 Fed. Reg 69801, 69813-69814 (2008)

32 73 Fed. Reg. 69801, 69815-69816 (2008).

33 71 Fed. Reg. 69695 (2006), and 72 Fed Reg 66285 (2007)

34 42 C F R Section 410 33

35 73 Fed Reg 69762-69763 (2008)

36 73 Fed Reg 69762-69763 (2008).

37 73 Fed. Reg. 38502 (2008).

38 MIPPA requires that the Secretary establish an accreditation process for those entities furnishing advanced diagnostic testing procedures which include diagnostic magnetic resonance imaging, computed tomography, and nuclear medicine by January 1, 2012.

39 The 2009 Medicare Proposed Fee Schedule proposals can be found at 73 Fed. Reg. 38502 (2008).

40 73 Fed. Reg. 69762-69763 (2008).

41 73 Fed. Reg. 69763-69765, 69933 (2008), 42 C.F.R. Section 410.33 (g) (16) and (17) (2008).

42 73 Fed. Reg. 69933 (2008), 42 C.F.R. Section 410.33 (g) (17) (2008).

43 73 Fed. Reg. 69764 (2008).

44 73 Fed. Reg. 69764 (2008).

45 The FAQ can be accessed at https://questions.cms.hhs.gov/cgi-in/cmshhs.cfg/php/enduser/std_adp.php?p_faqid=9511&p_created=1229355972&p_sid=C8KnSxlj&p_accessibility=0&p_redirect=&p_lva=&p_sp=cF9zcmNoPSZwX3NvcnRfYnk9JnBfZ3JpZHNvcnQ9NDoyJnBfcm93X2NudD0yMTE1LDIxMTUmcF9wcm9kcz0mcF9jYXRzPSZwX3B2PSZwX2N2PSZwX3NlYXJjaF90eXBlPWFuc3dlcnMmc2VhcmNoX25sJnBfcGFnZT0x&p_li=&p_topview=1 Last accessed on December 17, 2008.

46 73 Fed. Reg. 69933 (2008), 42 C.F.R. Section 410.33 (g) (16) and (17) (2009) Note that at the time of publication of this article, there appears to be a discrepancy between the comments made by CMS and the regulatory language as it relates to enrollment requirement for mobile entities Specifically, CMS' comments indicate that the new IDTF enrollment and billing requirements apply to mobile units providing diagnostic testing services but the regulatory language relating to enrollment contained in 42 C.F.R. Section 410.33 (g) (16) refers to diagnostic imaging (as opposed to testing) services It is anticipated that this discrepancy may be corrected in a future notice.

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