Recent Developments and Key Legal Issues Impacting Diagnostic Imaging Services, Part 2

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EXECUTIVE SUMMARY

- Medicare's recently finalized anti-markup rule provides a flexible 2 alternative approach to determining whether or not a diagnostic testing arrangement is subject to the anti-markup payment limitation. Both tests measure whether a performing or supervising physician "shares a practice" with the billing physician or other supplier.
- Although in the 2009 Medicare Final Physician Fee Schedule CMS declined to implement the IDTF enrollment proposals, which would have required any physician or non-physician practitioner furnishing diagnostic testing services to enroll as an IDTF and be subject to most IDTF performance standards, CMS did finalize its earlier proposal to require mobile IDTFs to enroll and bill Medicare directly for the technical component services that they provide.
- Imaging services providers should be prepared for heightened Medicare auditing activity, as CMS has made permanent and is expanding its Recovery Audit Contractors program.

This article is the second part of a 2 part series addressing recent federal regulatory action targeting diagnostic imaging arrangements. Part 1 (published in the January/February 2009 issue of *Radiology Management*) focused solely on some of the more significant changes to the federal Stark regulations. Part 2 will summarize some of the significant regulatory actions contained in the 2009 Medicare Final Physician Fee Schedule addressing the Medicare anti-markup provisions and issues relating to independent diagnostic testing facilities (IDTFs). Additionally, this article will address anticipated Medicare audit activity for diagnostic imaging providers in connection with the Medicare Recovery Audit Contractor Program. Industry stakeholders should anticipate, and be attentive to, further regulatory action addressing imaging arrangements. On October 30, 2008, CMS displayed the 2009 Medicare Final Physician Fee Schedule (2009 MFPFS).* This article summarizes the anti-markup provisions and the IDTF enrollment requirements contained in the 2009 MFPFS.

*CMS put the 2009 MFPFS on display on October 30, 2008 (CMS-14030-FC). It was scheduled to be published in the Federal Register on November 19, 2008. All references to the 2009 MFPFS in this article will cite page numbers associated with the displayed version (CMS-14030-FC).

Medicare's Anti-Markup Rule

In a move not anticipated by the provider community, in the 2009 MFPFS, CMS adopted a flexible approach, using 2 alternative tests, with respect to the application of the anti-markup rule to the provision of certain diagnostic testing services. The final anti-markup rule is effective January 1, 2009.[1]

The Evolution of the Anti-Markup Provisions

By way of brief background, in its 2009 Medicare Proposed Fee Schedule, CMS revisited changes it had already enacted to its longstanding anti-markup rule,[2] 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.[3] 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

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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."[3,4]

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 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.[2] In response to these concerns, in the 2009 Medicare Proposed 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 2 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).[5]

The Final Anti-Markup Rule

After careful consideration of comments from industry stakeholders, in the 2009 MFPFS, CMS adopted a relatively flexible approach that incorporates both of its earlier proposed alternatives, with some slight modifications.[1] In particular, under the 2009 MFPFS final anti-markup provisions, the following principles apply to determine whether a diagnostic testing arrangement is subject to the anti-markup payment limitation:

1. **Alternative 1: "Substantially All Test."** Arrangements should be analyzed first under Alternative 1 as follows: where the performing physician (ie, the physician who supervises the TC or performs the PC, or both) performs substantially all (at least 75%) 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 limitations. If the performing physician does not meet the "substantially all" services requirement under Alternative 1, an analysis under Alternative 2 (below) may be applied.
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 or independent contractor physician will avoid application of the anti-markup payment limitation.

Both the "substantially all" and "site of service" tests measure whether a performing or supervising physician "shares a practice" with the billing physician or other supplier. 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.[6] CMS also added some flexibility to the tests 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% of his or her professional services for that practice. This change aligns certain provisions of the Stark group practice definition with the anti-markup provisions.

Additionally, the 2009 MFPFS provides that a billing physician or other supplier will satisfy the "substantially all" requirement if he or she has a reasonable belief, at the time he or she submits a claim, that:

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(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).[7]

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 1 "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).[8] Additionally, with respect to Alternative 2, CMS adds a requirement that the physician supervising the TC must be an owner, employee, or independent contractor of the billing physician or other supplier. Further, under Alternative 2, with respect to the PC, the performing physician must be an employee or independent contractor of the billing physician or other supplier.[8]

As a practical matter, under the final anti-markup provisions, 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 over-utilization and are not permitted for the provision of diagnostic tests.* CMS cautions, however, that despite its flexibility with the "same building" approach, it still has concerns with the present use of the IOAS exception under Stark and may issue proposed changes in the future.[9]

Of particular significance for those physicians providing imaging services in reliance on Alternative 2, the TC must be both conducted and supervised in the "office of the billing physician or other supplier" ("the Same Office Requirement"). While 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.[10]

Arrangements that fall within the ambit of the 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.[11]

Of significant importance is that the net charge amount 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 service.[12] 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 (ie, the supervising physician or performing physician).[12] Notably, CMS declined to revise the meaning of "net charge" in the 2009 MFPFS and indicates that the payment limitations are intended to be punitive.[13] As a practical matter, billing physicians or other suppliers that implicate the anti-markup rule likely will receive reimbursement that does not even cover the costs of providing the services.

Below are 2 examples of the final anti-markup provisions and their application to common imaging services arrangements:

1. **Group Practice Independent Radiologist Arrangement.** A physician in a multi-specialty group practice orders an x-ray and the part time employed technologist 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

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*Please note that technically central locations are permitted but they will be subject to severe payment limitations.

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the area. He performs approximately 20% 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 (ie, the performing physician) "shares a practice" with the billing group insofar as he performs at least 75% of his professional services for the group. With respect to the PC of the test, the independent contractor (ie, the performing physician) does not perform substantially all of his professional services to the group (he performs approximately 20%). Thus, an analysis under Alternative 2 applies. Under the "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 from an IDTF. The IDTF 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.

Notably, a provider that fails to comply with the anti-markup provisions could be subject to potential false claims liability and/or revocation of its billing privileges.

IDTF Performance Standards for Physician In-Office Testing

In recent years, CMS established performance standards for suppliers enrolled in the Medicare program as an IDTF.[14,15] The standards were established with a view towards improving the quality of care for diagnostic testing furnished to Medicare beneficiaries by Medicare enrolled IDTFs.[16] In response to the standards, however, many industry stakeholders expressed concern to CMS that the IDTF performance standards (including prohibitions regarding the sharing of space) do not apply to physicians (and non-physician practitioners [NPPs]) who are furnishing diagnostic testing to patients and have enrolled in Medicare as a clinic, group practice, or physician's office. As a consequence, the standards for imaging services were not applied consistently to all imaging providers.[17] In an attempt to address these concerns, earlier this year CMS introduced a proposal (which was viewed favorably by many in the imaging services industry) that would require any physician or NPP furnishing diagnostic testing services (except diagnostic mammography) to enroll as an IDTF and be subject to most IDTF performance standards.[2] If adopted, this proposal would have eliminated the ability of physician practices to share diagnostic imaging 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 IOAS exception. As a practical matter, this proposal also would have resulted in a significant decline in the number of physician practices that furnish diagnostic imaging 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.

In a development not anticipated by the industry in light of the recent scrutiny of in-office imaging arrangements, citing the enactment of Section 135 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA),* CMS declined to implement the IDTF enrollment proposals in the 2009 MFPFS. CMS, however, states that it will consider finalizing the IDTF enrollment requirements in a future rulemaking, if necessary.[18] For now, CMS's decision means that physicians who

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*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.

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Although CMS declined to implement its IDTF enrollment requirement for physician practices providing in-office imaging services, CMS did finalize its earlier proposal to require mobile IDTFs to enroll and bill Medicare directly for the TC services that they provide.[19] CMS, however, is not requiring mobile testing entities to bill directly for their services when such services are furnished "under arrangements" with hospitals.[20] According to CMS preamble commentary, the implementation of this rule will prohibit many common arrangements in which mobile entities lease diagnostic testing equipment and technologists to physicians who conduct and bill for such tests in their offices.[21] Specifically, a commenter urged CMS to exclude from the definition of entities furnishing mobile diagnostic testing services those entities that lease equipment and provide technologists 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[21]:

> 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.

Notably, in complete contradiction to CMS's response, on December 16, 2008, CMS posted an FAQ on its Web site as follows[22]:

> 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)?
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> 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.

The CMS FAQ reflects that apparently CMS will distinguish a mobile leasing company that provides the equipment and non-physician personnel (ie, 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 (ie, must be an IDTF and bill directly).

Although the CMS FAQ is not a 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 suggests that additional clarification to the Final Rule may be forthcoming.

In summary, effective January 1, 2009, 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.[23] The issue that appears to be open to forthcoming guidance or regulation is CMS's interpretation of a mobile entity furnishing diagnostic imaging services.*

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Medicare Recovery Audit Contractors (RACs)

Although CMS may have demonstrated some measure of flexibility with respect to imaging services arrangements in its recent release of the 2009 MFPFS, imaging services providers should be prepared for heightened Medicare auditing activity. The CMS Recovery Audit Contractor

*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's 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. Sect. 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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(RAC) program has been made permanent and is expanding nationwide, beginning this year. Claim denials and overpayment determinations made by RACs are subject to the Medicare appeals process.

Section 306 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), directed HHS to conduct a 3 year demonstration program using RACs. The demonstration began in 2005 in the 3 states with the highest Medicare expenditures: California, Florida, and New York. The purpose of the demonstration program was to determine whether the use of RACs would be a cost-effective way to identify and correct improper payments in the Medicare fee-for-service program. The RAC demonstration program yielded a favorable return on investment for CMS. In fact, over the course of the 3 year demonstration project, the RACs identified and collected more than $1.03 billion in improper payments. According to CMS, factoring in the underpayments returned to providers and suppliers, the claims overturned on appeal, and the operating costs of the demonstration project, the RAC demonstration program returned $693.6 million to the Medicare Trust Fund.[24]

Section 302 of the Tax Relief and Health Care Act of 2006 makes the RAC program permanent, and requires the expansion of the RAC program nationwide by no later than 2010. CMS is aggressively moving forward with this expansion. According to its most recently published "Expansion Schedule," CMS planned to expand to 19 states by October 1, 2008, 4 more states by March 1, 2009, and the remaining states by August 1, 2009 or later.[25] As a result, imaging services providers and suppliers can expect anticipated RAC auditing activity to commence, and then likely intensify, in the very near future, and are well advised to keep apprised of new rules and regulations to ensure that their relationships and billing protocols remain in compliance.[25]

Conclusion

Through a series of regulatory actions, CMS has been targeting diagnostic imaging services arrangements. Although CMS exercised some flexibility in its recent approach to the IDTF physician enrollment requirements and its alternative final anti-markup provision approach, the diagnostic imaging industry should be attentive to future rulemakings, which likely will affect the structure of common imaging arrangements. Providers are well advised to incorporate mechanisms into their contractual arrangements that will permit the arrangements to comply with the ever changing regulatory framework.

References

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[2]73 *Federal Register* 38502 (2008).

[3]Physician or other supplier billing for diagnostic tests performed or interpreted by a physician who does not share a practice with the billing physician or other supplier, 42 C.F.R. Sect. 414.50 (2007).
[4]72 *Federal Register* 66307–66308, 66401 (2007).
[5]73 *Federal Register* 38544–38548, 38606 (2008).
[6]Physician Fee Schedule Federal Regulation Notice, CMS-14030-FC 423 (October 30, 2008).
[7]Physician Fee Schedule Federal Regulation Notice, CMS-14030-FC 425 (October 30, 2008).
[8]Physician Fee Schedule Federal Regulation Notice, CMS-14030-FC 427 (October 30, 2008).
[9]Physician Fee Schedule Federal Regulation Notice CMS-14030-FC 470 (October 30, 2008).
[10]Physician Fee Schedule Federal Regulation Notice, CMS-14030-FC 491 (October 30, 2008).
[11]Physician or other supplier billing for diagnostic tests performed or interpreted by a physician who does not share a practice with the billing physician or other supplier, 42 C.F.R. Sect. 414.50 (a) (1) (i), (ii), and (iii).
[12]Physician or other supplier billing for diagnostic tests performed or interpreted by a physician who does not share a practice with the billing physician or other supplier, 42 C.F.R. Sect. 414.50 (a) (2) (i).
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[14]71 *Federal Register* 69695 (2006).
[15]72 *Federal Register* 66285 (2007).
[16]Independent diagnostic testing facility, 42 C.F.R. Sect. 410.33.
[17]Physician Fee Schedule Federal Regulation Notice, CMS-14030-FC 205 (October 30, 2008).
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