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HEALTH LAW
Update

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# The 2009 Medicare Physician Fee Schedule (MPFS): Something Old, Something New, Something Borrowed, and Some Folks Blue

**December 9, 2008**

On November 19, 2008, the Centers for Medicare & Medicaid Services ("CMS") published the final 2009 Medicare Physician Fee Schedule ("2009 MPFS") in the Federal Register. The 2009 MPFS covers a number of significant payment and regulatory topics, including (1) revisions to the so-called "anti-markup rule," which has already gone through a number of rulemaking cycles ("something old"), (2) new Medicare enrollment procedures that could limit the ability of providers and suppliers to bill retrospectively once their enrollment applications are accepted ("something new"), (3) CMS commentary on a Stark law exception for incentive payments and shared savings programs, an area highlighted in recent years by a number of favorable OIG advisory opinions under the federal anti-kickback statute ("something borrowed"), and (4) new IDTF enrollment requirements for certain suppliers of diagnostic imaging services ("some folks blue"). This Health Law Update will summarize these highlights of the 2009 MPFS.

## Anti-Markup Rule

CMS payment rules contain a longstanding prohibition on physician practices purchasing the technical component ("TC") of diagnostic tests for their patients and then billing the Medicare program for those tests at a higher rate. The rule, which is intended to address potential concerns about over-utilization of diagnostic tests by physicians, has gone through a number of changes in recent CMS rulemakings, including changes that expand the mark-up prohibition to the professional component ("PC") of diagnostic tests.

*Rulemaking Activity Prior to the 2009 MPFS*

In November 2007, CMS modified the anti-markup rule by, among other things, expanding the application of the rule to include the PC of diagnostic tests. However, most of these changes were

postponed until January 1, 2009. In June 2008, CMS proposed additional changes to the rule as described in more detail in a previous Health Law Update.[1]

*The Provisions of the 2009 MPFS*

The final 2009 MPFS adopts many of the earlier proposed changes, but includes modifications that will provide more flexibility to physician groups providing diagnostic tests. The final rule is effective as of January 1, 2009.

When the anti-markup rule applies, payment for the TC and the PC is limited to the lowest of: (a) the performing supplier's net charge to the billing physician; (b) the billing physician or other supplier's actual charge; or (c) the fee schedule amount. "Net charge" may not take overhead into account. Therefore, when the anti-markup rule applies, physicians could be performing the diagnostic tests at a loss.

The anti-mark-up rule applies when a physician or other supplier bills for the TC or PC of a diagnostic test that (1) was ordered by the physician or other supplier (or by a party related to the billing physician or other supplier by common ownership or control), and (2) was performed by a physician who does not "share a practice" with the billing physician or other supplier (note that the "performing" physician is the supervising physician in the case of the TC and the physician who actually read the image or performed the professional interpretation in the case of the PC).

Thus, physician groups and other billing suppliers can avoid the application of the anti-markup rule by ensuring that the performing physician "shares a practice" with them. CMS provides two alternate ways to meet the "shares a practice" requirement, one related to volume of services ("Alternative 1") and the other related to location of the services ("Alternative 2"). If *either* alternative can be met, then the anti-markup rule does *not* apply.

*Alternative 1*

Under Alternative 1, if the performing physician (that is, the physician who supervises the TC or performs the PC, or both) performs substantially all (at least 75%) of his or her professional services "through" the billing physician or other supplier, the anti-markup rule will not apply.[2] CMS does not define what it means for the performing physician to perform his or her professional services "through" the billing physician, which suggests that a group practice could measure the 75% in a variety of ways, e.g., by the dollar amount of charges or collections generated for the group or by time spent on patient care services for patients of the group practice.

Although CMS does not define what it means to perform professional services "through" a group, CMS does indicate in the preamble commentary that it intends the "substantially all" test in the anti-markup rule to be consistent with a similar test in the Stark law definition of a group practice (i.e.,

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[1] See Health Law Update entitled "Still on the Radar Screen: CMS Proposed Further Restrictions for Physician Groups Providing Diagnostic Imaging," dated August 28, 2008, available at www.bassberry.com.

[2] The 75% test may be met by looking either backward or forward, i.e., it can be met based on the levels of services provided during the 12 months *prior to* and including the month in which the test was performed, or by looking *forward* to the physician's expected service levels in the following 12 months, including the month the test was provided. The billing physician has to have a "reasonable belief" that the 75% threshold is/was met in one of these two ways.

the test as to whether "substantially all," that is at least 75 percent, of the total patient care services of the group practice members must be furnished through the group and be billed under a billing number assigned to the group, and the amounts received must be treated as receipts of the group). The Stark law definition specifies that one acceptable way to measure "substantially all" is to look at total time spent on patient care services, but other measures may also be used if they are reasonable, fixed in advance of the performance of the services being measured, uniformly applied over time, verifiable, and documented. Group practices that have historically used total time spent on patient care services to meet the Stark law test may be inclined to continue to use this standard for purposes of the anti-markup rule.

Both the TC and the PC should be analyzed separately. It is possible that the TC, but not the PC, may be subject to the anti-markup rule in a given circumstance, or vice versa. To meet the 75% threshold for the TC, the physician does not have to physically perform the TC, but only has to provide supervision. The level of supervision needed (general, direct, or personal) depends on applicable Medicare rules, and nothing in the anti-markup rule changes the required supervision level.

*Alternative 2*

If an arrangement cannot meet the requirements of Alternative 1, it can still avoid the anti-markup rule by meeting the requirements of Alternative 2 on a case by case basis.[3] Under Alternative 2, if the TC is conducted and supervised *in the office of the billing physician or other supplier*, then the anti-markup rule will not apply to the TC. Likewise, if the PC is performed *in the office of the billing physician or other supplier*, the anti-markup rule will not apply to the PC.

The "office of the billing physician or other supplier" is defined in two different ways: one general definition; and another that is applicable to physician organizations.[4] Generally, the "office of the billing physician or other supplier" is any medical office space, regardless of the number of locations, in which the *ordering* physician or other ordering supplier regularly furnishes patient care. If the billing physician or other supplier is a *physician organization*, then the "office of the billing physician or other supplier" is space in which the ordering physician provides *substantially the full range* of patient care services that the ordering physician provides generally. These definitions include space located in the same building[5] in which the ordering physician or other ordering supplier regularly furnishes patient care or, in the case of a physician organization, in which the ordering physician provides substantially the full range of, patient care that the ordering physician provides generally. Thus, space that meets the "same building" standard under the in-office ancillary exception in the Stark law will qualify under Alternative 2, but not "centralized buildings."[6] As a

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[3] In the preamble to the 2009 MPFS, CMS stated that arrangements should be analyzed *first* under Alternative 1. If the performing physician does not meet the "substantially all" services requirement of Alternative 1, an analysis under the Alternative 2 requirements may then be applied on a test by test basis.

[4] A "physician organization" is a physician, physician practice, or a group practice that complies with the requirements of the federal Stark law "group practice" provisions set forth at 42 C.F.R. § 411.352.

[5] The "same building" means a structure with, or a combination of structures that share a single street address, as assigned by the U.S. Postal Service, excluding all exterior spaces (e.g. lawns, courtyards, driveways, parking lots) interior loading docks, or parking garages. For purposes of this section, the "same building" does not include a mobile vehicle, van, or trailer.

[6] The "office of the billing physician" does *not* include diagnostic testing space that would qualify as a "centralized building" under the federal Stark law due to CMS's concern about potential "overbreadth of that definition with respect to such arrangements."

result, Alternative 2 will not be available for off-site diagnostic testing centers operated by physician practices or for so-called "pod labs."

The physician who supervises or performs the test under Alternative 2 may be an owner, employee, or independent contractor of the billing physician. For purposes of meeting Alternative 2, the 75% rule from Alternative 1 does not apply.

**Independent Diagnostic Testing Facilities**

An anti-markup rule analysis cannot be conducted in a vacuum. Frequently anti-markup rules may intersect with other important rules such as the federal Stark law (especially the in-office ancillary services exception, as was just explained)[7] and rules applicable to Independent Diagnostic Testing Facilities ("IDTFs").

In the 2009 *Proposed* MPFS, CMS contemplated expanding the standards applicable to IDTFs to physicians and non-physician practitioner organizations performing diagnostic testing. This proposed change would have required some physician offices to comply with a number of quality and performance standards that were previously only applicable to IDTFs. However, under the final 2009 MPFS, CMS declined to impose this requirement (except with respect to "mobile" entities, as will be explained). Instead, CMS indicated that it is deferring the requirement to further review comments and may consider finalizing this provision in a future rulemaking. CMS also may wait for implementation of section 135 of the Medicare Improvements for Patients and Providers Act of 2008 ("MIPPA") which requires the establishment of an accreditation process for entities furnishing advanced diagnostic testing procedures by January 1, 2012.

However, the final 2009 MPFS *does* require mobile diagnostic testing entities to enroll in Medicare as IDTFs and to directly bill – unless the services are furnished "under arrangements" to a hospital (in which case the mobile entity does not have to directly bill the test, but still has to enroll as an IDTF). This requirement has already created challenges and raised some unanswered questions for certain business models. For example, are diagnostic testing entities that possess portable equipment and that exclusively engage in leasing equipment and technicians to fixed site physician practices, with the tests being supervised by the physician practice, "mobile" entities that must enroll? These entities may very well be required under the new rules to enroll as IDTFs and to bill for the test directly, but other Medicare rules would restrict the ability of mobile entities to bill for the test because they did not provide the supervision.[8]

As another example, the exception for "under arrangements" services provided to hospitals was not explicitly extended to other providers such as skilled nursing facilities (SNFs), which are subject to consolidated billing rules and which contract for "under arrangements" services. This gap in drafting, whether intended or not, may complicate the ability of SNFs to contract with mobile diagnostic testing entities.

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[7] For example, the fact that "centralized" buildings may be perfectly acceptable under the Stark in-office ancillary exception does not mean that they will avoid application of the anti-markup rule.

[8] In such an event, these entities would have to consider purchasing the interpretation from the physician practice and to analyze whether compliance with all of the rules surrounding purchased interpretations is possible or feasible.

**Medicare Enrollment and Information Updates**

In the 2009 MPFS, CMS also announced new Medicare enrollment rules for physicians, nonphysician practitioners ("NPPs"), and physician and NPP organizations (collectively "physicians and NPPs"). In the past, CMS has permitted physicians and NPPs to retrospectively bill Medicare for services that were furnished up to 27 months prior to being enrolled as a Medicare supplier. However, in the proposed version of the 2009 MPFS, CMS expressed concern that retrospective billing might allow physicians and NPPs to bill Medicare for services provided prior to the time that they were meeting Medicare program requirements.

Under the new rule announced by CMS in the 2009 MPFS, the effective date of billing for physicians and NPPs is *the later of*:

> (1) the date of filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor; or
> (2) the date a physician or NPP first started furnishing services at its new practice location.

The "date of filing" will be the date that a contractor receives an application that the contractor ultimately processes (or, for electronically filed applications, the date the contractor has received the signed certification statement, electronic version of the application, and signature page of an application that is processed to approval). Contractors will continue to provide notice to applicants of any application deficiencies and to allow at least 30 days to correct those deficiencies. Furthermore, contractors will be required to deny, not reject, an enrollment application if the applicant fails to cure any deficiencies in the application. This change from CMS' earlier final rule[9] affords physicians and NPPs appeal rights that will preserve the original date of application filing. However, if the applicant does not submit a corrective action plan or appeal within the designated timeframe, then the applicant would not preserve the right to bill Medicare for services furnished from the initial application filing date or the date the physician or NPP first furnished services at the new practice location.

CMS has also finalized a provision that allows physicians and NPPs to retrospectively bill for services up to 30 days prior to their effective date of billing (90 days for a Presidentially-declared disaster) when the physicians or NPPs met all program requirements (including state licensure requirements), services were furnished at the practice location prior to the date of filing, and circumstances precluded enrollment in advance of providing services to Medicare beneficiaries.

To facilitate more efficient processing of Medicare enrollment applications, CMS will be rolling out an internet-based enrollment process through its Provider Enrollment, Chain and Ownership System ("PECOS"). CMS expects that PECOS enrollment will be more streamlined and efficient than the traditional paper-application enrollment method by reducing common application errors and the time necessary to enroll and make changes to enrollment. Accordingly, CMS anticipates that most contractors will fully process enrollment applications within 30-45 days, down from the current 60-90 days. Electronic enrollment via PECOS was made available for physicians and NPPs in 15 states

[9] "Medicare Program; Requirements for Providers and Suppliers to Establish and Maintain Medicare Enrollment," 71 Fed. Reg. 20754 (April 21, 2006).

plus the District of Columbia on December 1, 2008, and CMS expects to make it available to physicians and NPPs in all states within two months.[10]

CMS also emphasizes its desire for providers and suppliers to voluntarily revalidate their Medicare enrollment. All physicians, suppliers, and providers should update their enrollment records when a reportable change occurs, and absent a reportable change, revalidate their enrollment at least every five years. If an enrollment application has not been submitted or revalidated within the last five years and is initiated at CMS' request, providers and suppliers will be required to complete the revalidation process within 60 days or may lose their Medicare billing privileges.

**Stark Changes**

*Incentive Payment and Shared Savings Programs*

In the proposed 2009 MPFS, issued on June 30, 2008, CMS proposed to add a single new exception to the Stark law that would include pay-for-performance, shared savings (including gainsharing), and similar programs that provide incentives for physicians to offer high quality and cost-effective care. CMS did not finalize a proposed exception to the Stark law for incentive payment and shared savings programs in the 2009 MPFS; instead, it chose to reopen the public comment period for additional input from stakeholders.

Most of the comments submitted in response to the proposed rule support the establishment of either one or two additional exceptions to the Stark law for incentive payment and shared savings programs. However, commenters urged substantial modifications to CMS' proposal, which was viewed by many as too narrow, and CMS now seeks additional views on how to formulate an exception or exceptions that would be as broad as possible without creating a risk of program or patient abuse. Accordingly, CMS has requested comments that "address the best ways in an exception or exceptions for incentive payment or shared savings programs to achieve transparency and accountability, ensure quality of care, and prevent disguised payments for referrals."[11] A 90-day public comment period began on November 19, 2008.

Specifically, CMS has requested comments directed at a laundry list of 55 specific, enumerated issues related to a potential Stark exception. These 55 issues are organized into five main categories: (i) distinguishing between "incentive payment" and "shared savings programs;" (ii) risk of program or patient abuse; (iii) design of the program; (iv) structure of the arrangement between the hospital sponsoring the program and the physicians participating in the program; and (v) the availability of other physician self-referral exceptions. For example, within the first category, CMS asks for comments on six specific points, including (1) how to define the terms "incentive payment program" and "shared savings programs," (2) whether different terminology would better describe the range of nonabusive programs CMS intends to cover, and (3) which (and why) specific conditions of the exception set forth in the proposed rule should be made applicable to incentive payment programs in the event that separate Stark exceptions are adopted.

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[10] For more information about electronic enrollment, please refer to our March 27, 2008 Health Law Update, *Brave New E-World: Accessing, Updating, and Submitting Medicare Provider Information Online*, available at www.bassberry.com.

[11] 73 Fed. Reg. 69794 (November 19, 2008).

Within the fifth category, CMS requests comments on whether it is necessary to have a "stand-alone" exception(s) to the Stark law for incentive payment and shared savings programs. In the alternative, CMS suggests that it might be preferable to modify aspects of existing exceptions to protect a broader range of incentive payment and shared savings programs. According to a statement made by a presenter during a recent ABA teleconference, Congressman Pete Stark opposes the gainsharing aspect of the proposed Stark exception, but not necessarily the aspects relating to incentive pay for quality.[12]

CMS requests that commenters respond with specificity and include detailed, practical examples to the extent possible. While CMS numbers the 55 individual issues for comment and asks that commenters specifically identify which of the 55 issues they are addressing, CMS also encourages commenters to submit comments on other issues relevant to development of an exception(s). CMS had indicated that it does not believe that it should delay issuance of a final Stark exception until completion of the gainsharing demonstrations authorized by the Social Security Act and Deficit Reduction Act.

*Speech Language Pathology Services*

CMS updated the Stark regulations, effective July 1, 2009, to comply with statutory changes regarding speech-language pathologists implemented by MIPPA. Section 143 of MIPPA provided authority for CMS to enroll speech-language pathologists as suppliers of Medicare services and allows speech-language pathologists to bill Medicare for services furnished in private practice, beginning July 1, 2009. MIPPA also amended the Stark law to include "outpatient speech-language pathology services" in the list of designated health services ("DHS") (under the Phase I final rule, speech-language pathology services were included in the DHS category of physical therapy services). Accordingly, CMS revised the regulatory definition of "designated health services" to conform to MIPPA by adding the word "outpatient" before the phrase "speech-language pathology services," revised the definition of "physical therapy, occupational therapy, and speech-language pathology services," and added a new definition of "outpatient speech-language pathology services."

## Conclusion

The 2009 MPFS continues CMS's recent trend of grafting significant regulatory changes onto annual payment updates. If you have any questions about any of the topics covered in this Health Law Update, please contact one of the attorneys in our Healthcare Industry Practice Area listed below.

[12] "The Final 2009 Physician Fee Schedule – Are Revised Anti-Markup, IDTF, and Stark Gainsharing Rules in Store?" presented by The American Bar Association Health Law Section and the ABA Center for Continuing Legal Education (November 12, 2008).

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