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The New 2009 Physician Fee Schedule: Key Changes in Connection With Furnishing, Billing for Diagnostic Tests But No Stark Gainsharing Exception

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Introduction

On Nov. 19, the 2009 final Medicare Physician Fee Schedule (MPFS) was published in the *Federal Register*.¹ Among its many provisions are significant revisions to the anti-markup rule, which limits the amount of reimbursement Medicare will pay for certain diagnostic tests. Although the final MPFS regulations generally will provide more flexibility than the current version of the anti-markup rule, health care organizations involved in the provision of diagnostic tests need to respond quickly to ensure that they are in compliance by Jan. 1, 2009, when the MPFS goes into effect.

In another key development, the MPFS contains important modifications to the Independent Diagnostic Testing Facility (IDTF) rules, and now requires mobile entities to enroll and satisfy IDTF standards.

Many in the industry had expected that significant changes to the Stark regulations² might be proposed and finalized in the MPFS, because various modifica-

tions had been proposed in several prior physician fee schedules.³ However, the MPFS proposed only one provision directly related to the Stark Law, and the final rule did not contain a Stark regulatory exception for incentive payment and/or shared savings programs, but rather reopened the comment period for 90 days following MPFS publication.

What does this mean for hospitals, physicians and other health care providers? Hospitals generally will be exempt from the revised anti-markup provisions (unless they own a group practice). The new IDTF requirements for mobile entities should have little direct impact on hospitals because of a specific exemption for mobile entities providing services to hospitals "under arrangements."

Hospitals interested in developing incentive payment or shared savings programs (sometimes collectively referred to below as "gainsharing" arrangements) may be disappointed that no specific exception was created to eliminate the risk of Stark exposure that such arrangements potentially can create. Nevertheless, because the MPFS preamble suggests that incentive payment and shared savings programs can be structured to comply with other Stark Law exceptions, hospitals, as well as physicians, may show renewed interest in such "gainsharing" arrangements.

The MPFS regulations provide a certain reprieve for certain physicians and group practices. Many physicians/groups will be able to structure or restructure their arrangements so that they are not subject to

¹ 73 Fed. Reg. 69726.

² 42 C.F.R. § 411.351 et seq.

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³ The FY 2009 inpatient hospital payment system rule also proposed and finalized significant changes to the Stark regulations. See 73 Fed. Reg. 48434 (Aug. 19, 2008). Some of these changes took effect Oct. 1, 2008, but several other key changes will go into effect Oct. 1, 2009.

the anti-markup payment limitations. Further, CMS did not finalize its proposal to require all physician offices that furnish diagnostic tests to enroll as an IDTF and satisfy most of the IDTF regulatory standards. However, CMS states in the MPFS preamble that several regulatory options remain under consideration so the “reprieve” may well be temporary.

Nevertheless, mobile testing entities face significant challenges under the new regulations, because they will be required to enroll as IDTFs, and they will also be required to bill directly (except where the service is furnished to a hospital “under arrangements”). The new enrollment and billing requirements impose new operational standards and may well change the way a mobile entity can do business with certain types of providers. For example, it is unclear how these new regulations will impact skilled nursing facilities (SNFs) that have been obtaining diagnostic testing services from mobile entities.⁴ Moreover, as described in more detail below, certain practical issues may make compliance difficult by Jan. 1, 2009.

With respect to “gainsharing” arrangements, hospitals and physicians have two primary options. Although they can wait to see if CMS finalizes a Stark exception, any exception likely will take months, if not years, and there is no guarantee that such a specific exception ever will be promulgated. Alternatively, the parties could proceed with a “gainsharing” arrangement by relying on an existing Stark exception (assuming they meet other legal requirements).

However, the Stark Law is a strict liability statute, and enforcement, whether initiated by the government or by a whistleblower under False Claims Act litigation, appears to be on the increase. Therefore, proceeding by using an existing Stark exception will necessitate careful planning and expert guidance.

This article will provide a brief discussion of some of the significant developments related to the MPFS issues summarized above.

The Anti-Markup Statutory Requirement

The Medicare statute places a limitation (commonly known as the anti-markup rule) on payment for most diagnostic tests unless the test has been personally performed or supervised by the billing physician or by another physician who shares a practice with the billing physician/group.⁵ When applicable, the anti-markup rule means that Medicare will reimburse the billing physician or other supplier the lowest of the following amounts: (1) the performing supplier’s “net charge;” (2) the billing physician’s or other supplier’s “actual charge;” or (3) the Medicare Physician Fee Schedule amount.

As a practical matter, the first amount (the “net charge”) typically is the amount paid. In the past, this statutory requirement (which was not originally associated with the Stark Law or regulations) frequently was referred to as the “purchased diagnostic test” rule because CMS applied the anti-markup payment limitation

to the technical component of diagnostic tests “purchased” from an “outside supplier.”⁶

Perceived Abuse of the Anti-Markup Rule and Initial CMS

Response. Over the past few years, CMS has noted potential abuses arising under the Stark Law’s in-office ancillary services exception, e.g., where a group practice provided and billed for diagnostic tests performed by an independent contractor physician in a “centralized building,” separate and apart from the site where the group provided its physician services.

Often, CMS noted, there was little interaction between the independent contractor physician, the provision of the diagnostic tests, and the group practice. Nevertheless, the purchased diagnostic test rule, as it was implemented in the past, did not apply. Using the in-office ancillary services exception to comply with Stark, the group was able to treat the diagnostic test as an ancillary service of the group and “mark up” the amount charged by the independent contractor physician, thereby making a profit from the group’s referrals for such diagnostic tests.

Over the past few years, CMS proposed or made various regulatory modifications in an effort to address these perceived abuses. For example, in last year’s (2008) MPFS final rule, CMS extended the anti-markup payment limitation to the technical component (TC) and professional component (PC) of diagnostic tests performed outside the “office of the billing physician or other supplier,” using a new, site-of-service approach.

CMS received many questions concerning these revised anti-markup provisions, including what constituted the “office of the billing physician or other supplier,” and as a result, delayed until Jan. 1, 2009, much of the anti-markup provisions.⁷

In the 2009 MPFS proposed rule, CMS re-proposed its site-of-service approach, with the clarification that diagnostic testing arrangements taking place in the same building in which the physician ordering the test sees patients would not be subject to the anti-markup payment limitation. In addition, and as an alternative to the site-of-service approach, CMS proposed that the anti-markup payment limitation would not apply if the performing physician worked exclusively (either part-time or full time) for the billing physician or other supplier.

The New Anti-Markup Requirements. The MPFS final rule creates a new methodology to determine if the physician performing the diagnostic test has sufficient nexus with the billing physician/supplier so as to share a practice with it. If sufficient nexus exists, the anti-markup rule will not apply. Toward this end, CMS finalized a two-pronged approach, by adopting both proposed alternatives (with some modification), which ultimately should provide greater flexibility than the originally proposed regulations.

As of Jan. 1, 2009, the anti-markup payment limitation will apply if a physician/supplier bills for the TC or PC of a diagnostic test, ordered by that physician/supplier (or a party related to them through common ownership or control) and the test is performed by a physician

⁴ As discussed below, the new IDTF regulations require the mobile entity to bill for the services it furnishes to Medicare beneficiaries, but other regulations impose a consolidated billing requirement on Medicare SNFs.

⁵ Section 1842(n)(1) of the Social Security Act (42 U.S.C. § 1395u(n)(1)).

⁶ 42 C.F.R. § 414.50.

⁷ 73 Fed. Reg. 404 (Jan. 3, 2008). CMS did not delay past January 1, 2008 arrangements involving anatomic pathology testing that was not performed in the same building as the office of the billing physician or other supplier.

who does not “share a practice” with the billing physician/supplier.⁸

Under the two-pronged approach, the performing physician will “share a practice” with the billing physician/supplier, and the anti-markup limitation will not apply, if the testing arrangement fits *either* the “substantially all” or the “site-of-service” approach. It is important to note that parties can rely on one approach to avoid the anti-markup payment limitation for the TC, and utilize the other approach, if need be, to avoid the anti-markup payment limitation for the PC.

The ‘Substantially All’ Approach. Under the “substantially all” approach, the performing physician (the physician who supervises the TC or performs the PC) must furnish “substantially all” (at least 75 percent) of his or her professional services through the billing physician/supplier. In most cases, this will be the easier of the two approaches to satisfy.⁹ However, even if the arrangement does not fit the “substantially all” approach, it will not be subject to the anti-markup payment limitation if it satisfies the site-of-service approach (as modified by the 2009 MPFS).

The ‘Site of Service’ Approach. If the performing physician is an owner, employee or independent contractor of the billing physician/supplier, and the TC and/or PC is performed in the office of the billing physician/supplier, the anti-markup payment limitations will not apply to the TC and/or PC. The office of the billing physician/supplier is defined in the regulations as medical office space where the ordering physician/supplier regularly furnishes patient care, including space in the “same building” where the ordering physician/supplier regularly furnishes patient care.¹⁰

Thus, diagnostic testing arrangements that take place in the same building as where the ordering physician regularly furnishes patient care are protected. However, the TC must be both conducted and supervised in the office of the billing physician/supplier for the TC to fit the site-of-service approach (irrespective of whether the supervision regulation would otherwise permit off-site supervision for coverage purposes¹¹).

Stringent ‘Net Charge’ Requirements Remain Unchanged; Other Features of Note. In the proposed rule, CMS solicited comments as to whether it should revise the meaning of “net charge” under the anti-markup rule, but ultimately declined to do so. Accordingly, overhead, such as the cost of space or equipment leased to the performing supplier by or through the billing physician/supplier, cannot be included in the “net charge,” and thus will not be reimbursed.

CMS also declined to impose a direct billing requirement (rather than permitting reassignment) but noted that it may propose to do so in a future notice of proposed rulemaking. Even more open-ended, CMS states that it is aware of commenters’ concerns about abuse of the Stark Law’s in-office ancillary services exception as

it relates to diagnostic testing, and may propose future rulemaking on this issue in the future as well.

Finally, under the new rules, CMS has discarded the prior concept of imposing the anti-markup rule on tests “purchased from an outside supplier” as unnecessary and potentially confusing.

Coming Into Compliance. Under the 2009 MPFS final rule, many physicians/suppliers may be able to avoid the anti-markup payment limitation by structuring (or restructuring) their arrangements so to fit one of the alternatives, most likely the “substantially all” approach.

In particular, multi-specialty hub-and-spoke arrangements (where a multi-specialty group practice has several patient care offices and performs its diagnostic testing in a separate, centralized building), that were subject to the anti-markup restrictions under the prior site-of-service approach, can avoid the payment limitation if the performing physician furnishes at least 75 percent of his or her professional services through the billing group. As discussed in some detail in the MPFS preamble, various *locum tenens* arrangements also should not trigger the anti-markup restrictions. Hospitals that own physician groups will need to be cognizant of these new regulations and structure their arrangements accordingly.

IDTFs

Heightened Standards for Provision of Diagnostic Tests by IDTFs. In the 2007 and 2008 MPFS final rules, CMS established performance standards for all suppliers that enrolled in the Medicare program as an IDTF.¹² The standards were established to improve the quality of care for diagnostic testing furnished to Medicare beneficiaries and to improve CMS’s ability to verify that IDTFs meet minimum criteria to enroll or maintain enrollment in the Medicare program.

Efforts to Impose ‘IDTF’ Standards on Physicians Who Provide Diagnostic Testing are Abandoned (or Delayed). The 2009 proposed MPFS contained a proposal that would have required physician and non-physician practitioner organizations that furnish diagnostic testing services (other than diagnostic mammography) to enroll each practice location furnishing these services as an IDTF, and to comply with the IDTF standards (with some exceptions). Had such a provision been enacted, it would have had major implications for numerous entities.

However, in the final MPFS, CMS stated that it was deferring implementation of these proposals in light of the enactment of the Medicare Improvements for Patients and Providers Act (MIPPA), which mandates an accreditation process for entities that furnish certain “advanced” diagnostic testing.¹³ However, CMS noted that it would continue to review the public comments it

¹² 42 C.F.R. § 410.33.

¹³ Section 135 of 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 (including positron emission tomography), and other such diagnostic testing procedures described in section 1848(b)(4)(B) of the Act (excluding X-ray, ultrasound, and fluoroscopy) by January 1, 2012. The accreditation organizations must have criteria to evaluate medical personnel, medi-

⁸ See new 42 C.F.R. § 414.50.

⁹ Note that the regulations require the billing physician/supplier to have a reasonable belief that the performing physician meets the “substantially all” test for a specified period of time.

¹⁰ The regulations make clear that the Stark regulation’s definition of “same building,” at 42 C.F.R. 411.351, applies in the anti-markup context.

¹¹ See 42 C.F.R. § 410.32(b)(3).

had received on these issues and would consider finalizing its proposals in a future rulemaking.

Most Mobile Entities that Provide Diagnostic Tests Now Must Enroll as an IDTF. Nevertheless, CMS did finalize a proposal to require that each entity that furnishes mobile diagnostic services must enroll in Medicare as an IDTF and bill directly for its mobile diagnostic services, regardless of where the services are furnished. The regulations create one exception in the case of diagnostic services furnished to a hospital “under arrangements,” i.e., the hospital is allowed to bill for such services (although the mobile entity is still required to enroll as an IDTF).

A Temporary Reprieve for Group Practices? For now, physician practices that provide diagnostic testing do not have to enroll and meet the regulatory standards for IDTFs. Whether CMS will revisit this issue or whether it will simply accept the more limited MIPPA regulation of certain diagnostic tests or take some other course of action remains to be seen.

New Concerns for Mobile Entities. The new MPFS revisions raise several practical questions of immediate importance for mobile entities and the physician practices and providers that they serve. First, although mobile entities are required as of Jan. 1, 2009, to enroll with Medicare as IDTFs and bill directly, current backlogs in processing enrollment applications may delay enrollment for some mobile entities well beyond that date.

Second, although the final rule provides an exception in the case of services furnished to hospital patients, so that the hospital, rather than the mobile entity, may bill “under arrangements” for such services, other providers, such as SNFs, also are allowed to bill Medicare for services furnished “under arrangements,” and it is not clear why the exception does not apply to these non-hospital providers as well. Moreover, in light of the consolidated billing rules applicable to SNFs,¹⁴ it is unclear whether the new IDTF requirements effectively will prevent SNFs from contracting with mobile entities to furnish diagnostic testing to SNF residents.

Third, it appears that mobile suppliers that travel to a physician’s office and lease equipment and technician to the physician (with the supervision of the technician provided by the physician) will be required by the new MPFS rule to enroll and directly bill for the test. However, under other Medicare rules, the mobile entity is not able to bill for the test because it did not perform the supervision.

As a practical matter, this may mean that mobile entities will have to restructure their arrangements in order to purchase the test (supervision) from the physician so the mobile entity can bill for it. However, these types of arrangements may not be cost effective, particularly when “low tech” imaging services (e.g., ultrasound) are involved.

cal directors, supervising physicians, equipment, safety procedures, and quality assurance programs.

¹⁴ SNFs generally are required to furnish all services to their patients directly, or indirectly through “under arrangements” and to bill for the services. See 42 C.F.R. § 411.15(p).

Incentive Payment and Shared Savings Programs

In the 2009 IPFS proposed rule, CMS solicited comments on whether it should invoke its statutory authority to create an exception¹⁵ to the general prohibition against physician self-referral, for certain “gainsharing” arrangements.¹⁶ This solicitation of comments was quickly replaced in the 2009 MPFS proposed rule with a proposed Stark exception that would have covered two types of programs: those for incentive payments (quality improvement) and those for shared savings (gainsharing). The proposal was self-described as “narrow,” and included numerous detailed criteria that tracked features that the OIG has approved in its advisory opinions on gainsharing.¹⁷ For example, programs would have been required to have independent medical review of their impact on the quality of patient care services, and patient care quality measures would have been required to derive from CMS’s Specifications Manual for National Hospital Quality Measures.

No Stark Exception for Shared Savings or Incentive Payment Programs was Finalized. CMS received many detailed comments on the proposal. Numerous commenters believed that the proposed exception was too narrow and cumbersome to be of much use, whereas others objected that any exception allowing gainsharing would necessarily pose a risk of program or patient abuse.

Although CMS did not finalize an exception in the MPFS, it restated its commitment to publish an exception for both incentive payment and shared savings plans, and requested comments on 55 specific issues, including how to differentiate between the two types of programs and the requirements that should be applicable to each. More specifically, it sought comments on: how to avoid allowing hospitals to make payments based on sham measures (or measures that did not reflect objective quality standards) that instead could be vehicles to reward referrals; possible alternatives to requiring independent medical review; and whether payments per physician should be capped in amount and/or duration.

Future Prospects for ‘Gainsharing.’ Although CMS signaled an intention to proceed with finalizing a Stark exception for programs that foster high quality, cost effective care, it is not likely to do so anytime soon. Crafting such an exception would be daunting under the best of circumstances. Further, the Medicare statute requires that any such exception must pose no risk of program

¹⁵ Under section 1877(b)(4) of the Social Security Act (42 U.S.C. § 1395n(b)(4)), CMS may create a new exception, or modify an existing exception, only if doing so would create no risk of program or patient abuse.

¹⁶ The term “gainsharing” typically refers to an arrangement under which a hospital gives a physician a share of the reduction in the hospital’s costs (that is, the hospital’s cost savings) attributable in part to the physician’s efforts.

¹⁷ To date, the OIG has issued 12 favorable advisory opinions on proposed gainsharing arrangements, finding that although at least some aspects of each of the proposed arrangements would violate the Civil Monetary Penalty (CMP) statute, 42 U.S.C. § 1320a-7a(b), and could implicate the anti-kickback statute, 42 U.S.C. § 1320a-7b(b), it would not impose sanctions under either authority because the arrangements contained “sufficient safeguards” against abuse.

or patient abuse. Moreover, personnel changes in the CMS division responsible for drafting the Stark regulations may make it more difficult, at least in the near future, for CMS to finalize any exception. However, to the extent that CMS is willing to issue separate exceptions, that is, one for incentive payment programs and one for shared savings programs, it may be possible to expedite the process to some extent.¹⁸

Under these circumstances, and given the arduous task of responding to CMS's voluminous solicitation of comments, a fair question is whether hospitals and phy-

¹⁸ In either case, the parties still must address the CMP provision that is potentially implicated by such arrangements, because satisfying a new Stark exception would guarantee compliance only with the Stark Law (and likely the anti-kickback statute, given that when CMS has added new Stark exceptions, by regulation, it explicitly has required compliance with the anti-kickback statute).

sicians will be willing to invest the time and effort to submit comments, or whether they will explore other alternatives for the time being. In this regard, CMS has stated that "properly structured arrangements involving physician participation in an incentive payment or shared savings program may meet the requirements of one or more of the existing [Stark] exceptions for compensation arrangements."¹⁹

In light of the current economic crisis and the financial benefits possible through aligning hospital and physician incentives, there likely will be substantial interest in developing "gainsharing" programs. The question is how health care entities can safely implement such programs in the context of a strict liability statute.²⁰

¹⁹ 73 Fed. Reg. at 69798.

²⁰ The information contained in this article is for informational purposes only, and is not intended to provide legal advice.