

HEALTH LAW

Update

NEWS FOR THE CLIENTS AND FRIENDS OF BASS, BERRY & SIMS PLC

The Surprising Anti-Markup Rule: CMS Ends a Busy Year With a Bang

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The last half of 2007 has seen an unusually large number of significant regulatory initiatives from the Centers for Medicare & Medicaid Services (CMS) that affect a variety of payment systems and healthcare financial relationships. First, we saw the final 2008 inpatient hospital prospective payment system (IPPS) rule, which ushered in a new severity-adjusted DRG payment system for hospitals.¹ Then, we saw the final 2008 hospital outpatient prospective payment system (HOPPS) rule, which instituted a new payment system for ambulatory surgery centers (ASCs).² And, of course, no one can forget the final Stark Phase III regulations,³ which, among other things, gave an entirely new meaning to the concept of standing in someone's shoes.

Last, but certainly not least, we have the final 2008 Medicare Physician Fee Schedule (MPFS) issued in November.⁴ Many had awaited this final rule with a mixture of anticipation and dread, because the rule in its proposed form⁵ had not only updated the physician fee schedule for 2008 but had also proposed several changes to the Stark regulations, some potentially much more significant than the proposed Phase III regulations. In fact, the proposed 2008 MPFS rule involved such sweeping guidance regarding the Stark Law that it received the nickname "Stark Phase 2.5," referring to its release in between the time of publication of the final Phase II and Phase III Stark regulations.

As it turns out, in the final 2008 MPFS rule, the vast majority of the proposed changes to the Stark regulations were deferred – not accepted but not rejected – to future rulemaking. The potentially significant changes to per click lease arrangements, percentage compensation arrangements, and "under arrangements" transactions, among other relationships, which we have addressed in previous

¹ 72 Fed. Reg. 47130 (August 22, 2007).

² See 72 Fed. Reg. 42470 (August 2, 2007) and 72 Fed. Reg. 66580 (November 27, 2007).

³ 72 Fed. Reg. 51012 (September 5, 2007).

⁴ 72 Fed. Reg. 66222 (November 27, 2007).

⁵ 72 Fed. Reg. 38122 (July 12, 2007).

Health Law Updates,⁶ will be tackled by CMS at an unspecified future point in time. In other words, instead of "Stark Phase 2.5," we can all wait for "Stark Phase IV."

The only major change from the proposed rule that was finalized in the 2008 MPFS, which will take effect January 1, 2008, was the anti-markup provision. But the language of this final provision is dramatically different than the proposed version and, as we will discuss in this Health Law Update, appears to render irrelevant for many purposes the widely used in-office ancillary services exception under Stark.

Substance of Final Anti-Markup Rule

The final anti-markup rule, codified at 42 C.F.R. § 414.50, applies if a physician or other supplier bills for the technical component *or professional component* of a diagnostic test that is covered by Section 1861(s)(3) of the Social Security Act⁷ and that:

(a) was ordered by the physician or other supplier, or by a party related to such physician or other supplier by "common ownership or control;"⁸ *and*

(b) is either purchased from an "outside supplier" or performed at a site other than the "office of the billing physician or other supplier" (the definitions of these terms will be discussed below).

Where applicable, the anti-markup provision limits the billing physician or other supplier to the lowest of: the performing supplier's "net charge" to the billing physician or supplier (without regard to any charge to the performing supplier by or through the billing physician or other supplier for the cost of equipment or leased space); the billing physician's or other supplier's actual charge; or the fee schedule amount for the test that would be allowed if the performing supplier billed Medicare directly.

Significance of the Final Anti-Markup Rule

The revisions to the anti-markup rule enacted as part of the final 2008 MPFS represent a significant expansion of the rule from the prior version that existed for many years. First, the revised rule explicitly applies to all "suppliers," not just to "physicians" and "physician groups." Second, the revised rule imposes a mark-up prohibition on the professional component of affected diagnostic tests, not just on the technical component.

The revised anti-markup rule applies only to situations where the physician or other supplier billing for the test has ordered it (either directly or through a related entity). However, where the rule is applicable, its reach extends beyond the prior rule's focus on "purchases" of tests that the physician or other billing

⁶ See Health Law Updates entitled "CMS Proposes Dramatic Changes to Stark Rules and Medicare Payment Rules," dated July 23, 2007, and "Stark Phase III Regulations: More Than Meets The Eye," dated October 12, 2007, available at www.bassberry.com.

⁷ There exists some uncertainty regarding the full scope of diagnostic tests that are covered by Section 1861(s)(3) of the Social Security Act. Some point to the 2001 CMS transmittal regarding physician supervision of diagnostic tests as the only reasonably available comprehensive listing, yet not all agree that it is comprehensive. See Transmittal B-01-28, Change Request 850 (April 19, 2001).

⁸ See 42 C.F.R. § 413.17(b)(3) for the definitions of "common ownership" and "control" used by CMS in this context.

entity has made from an "outside supplier"⁹ to situations in which the tests are performed at a site other than the "office of the billing physician or other supplier." Thus, the mark-up rule can apply to situations even where the billing physician group utilizes its own employed staff and equipment and is in no sense "purchasing" the technical component from an outside supplier.

The focus on location of the performance of the diagnostic test as a trigger for application of the final anti-markup rule surprised many because it was not the focus of the proposed version of the rule that appeared in the proposed 2008 MPFS. In the proposed version of the rule, the definition of "outside supplier" included everyone except for the full-time employees of the billing physician or physician group.¹⁰ Thus, the proposed rule focused on the employment status of the person performing the test, not the location of performance of the test. The final 2008 MPFS takes a completely different approach, not discussed in the proposed rule, and focuses on location, although employment status is still important for determining who is an "outside supplier."¹¹

Ambiguities in Interpreting the Final Rule

How to determine the "office of the billing physician or other supplier" – Eviscerating Effect on the Stark In-Office Ancillary Exception?

The "office of the billing physician or other supplier" is defined as the medical office space where the physician or other supplier regularly furnishes patient care.¹² In the case of a physician organization, it is the space where the physician organization provides substantially the full range of patient care services that the physician organization provides generally.¹³ CMS made clear in the commentary to the final 2008 MPFS rule that physician groups who provide imaging services in a "centralized building" that is off-site from the group's offices will not satisfy the same office test.¹⁴ Thus, physician groups who have structured arrangements to comply with the "centralized building" standard of the in-office ancillary services (IOAS) exception under Stark will find themselves faced with either restructuring these arrangements or potentially losing all profit margin from the tests performed at the centralized location.¹⁵

Since "centralized buildings" have been a regulatory concern vocalized by CMS in several recent contexts, the fact that the final anti-markup rule restricts the viability of centralized buildings is perhaps not surprising. What is surprising is that CMS may interpret the anti-markup rule to apply even to arrangements that otherwise comply with the "same building" standard under the IOAS exception. For the purposes of the IOAS exception, "same building" generally means any combination of structures that

⁹ An "outside supplier" is someone who is not an employee of the billing physician or other supplier and does not furnish the test or interpretation pursuant to a valid reassignment. 42 C.F.R. § 414.50(a)(2)(ii).

¹⁰ 72 Fed. Reg. 38225 (July 12, 2007).

¹¹ For example, an independent contractor who can't make a valid reassignment to the billing supplier would still, as a general rule, be considered an "outside supplier."

¹² 42 C.F.R. § 414.50(a)(2)(iii).

¹³ *Id.*

¹⁴ See, e.g., 72 Fed. Reg. 66308 (November 27, 2007).

¹⁵ The IOAS exception under Stark allows a physician group practice to provide designated health services (DHS) if certain criteria are met. These criteria include specific conditions regarding who performs the services, where they are performed, and how they are billed. The location requirements can be satisfied by providing the DHS in either in the "same building" where the group regularly provides physician services, as delineated in the standards contained in the regulations, or in a "centralized building" that is used by the physician or physician group for the provision for some or all of the group's DHS. See 42 C.F.R. § 411.355(b)(2).

share a single street address.¹⁶ Thus, a physician group that has its medical offices on the third floor of a building and a wholly-owned imaging center on the first floor could satisfy the "same building" requirement.

However, under the final anti-markup rule, a different floor of the "same building" may not necessarily qualify as the "same office" for purposes of determining whether the mark-up prohibition will apply. Such a result could conceivably apply even if the imaging operations on the different floor are functionally integrated with the medical offices, and even if the imaging operations are on the *same* floor as the medical offices but in a different suite. Representatives of CMS have indicated informally that CMS will issue guidance in the form of frequently asked questions (FAQs) posted to its website on this topic.

Hopefully CMS will also issue guidance on what the "full range of services" means for purposes of determining the "same office." For example, multi-specialty physician groups may have multiple different offices at which certain specialties practice exclusively, or at which some but not all specialties practice.

How to determine "net charge."

The anti-markup provision does not render a physician group unable to furnish and bill DHS, but it can severely limit the reimbursement that can be received for such services. Billing amounts allowed are the **lowest** of the performing physician's net charge, the billing physician/supplier's actual charge, or the fee schedule amount if the performing supplier billed directly.¹⁷ CMS states the net charge does not include overhead, rental of equipment or administrative costs involved in providing the diagnostic as part of the net charge.¹⁸

Essentially, CMS has said that billing suppliers can take into account only the salary and benefits of the technician or other person performing the test, even if the billing group owns the equipment and space in which the test is furnished and would otherwise expect, like any outside vendor, to factor these costs into net charges.¹⁹ Again, one would hope that CMS would include clarifications in this respect in FAQs posted to its website.²⁰

¹⁶ See 42 C.F.R. § 411.351.

¹⁷ 42 C.F.R. § 414.50(a)(1).

¹⁸ 72 Fed. Reg. 66307 (November 27, 2007).

¹⁹ In informal comments made in a recent American Health Lawyers Association (AHLA) teleconference, CMS officials reiterated this position. See "Who Moved My Same Building? The Practical Implications of the New Purchased Diagnostic Rule," AHLA teleconference held on December 12, 2007 (the "AHLA Teleconference").

²⁰ In one rather surprising informal comment made in the AHLA teleconference, *supra* note 17, a CMS representative suggested that, if the technical component of a test is supervised by a physician in the billing group, then the "billing" supplier may be deemed to be the same as the "performing" supplier and therefore the first payment limitation of the anti-markup rule, i.e., the "performing" supplier's net charge, would not apply. Instead, in these situations, the billing group would be limited to the lower of the billing group's actual charge or the fee schedule amount, which would in most cases mean the fee schedule amount. Since this result could largely eviscerate the "net charge" restriction in certain scenarios, it is unclear what the CMS representative meant by this informal comment. Hopefully, CMS will issue further clarification. We emphasize that comments made by CMS representatives during teleconferences are informal comments that do not necessarily reflect the official views of the agency.

Conclusion

The final anti-markup rule issued as part of the 2008 MPFS may dramatically change the landscape for physicians who have relied upon the IOAS exception under Stark in order to structure the delivery of ancillary services. If you have any questions about this Health Law Update, please contact any of the attorneys in our Healthcare Industry Practice Area, listed below.

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