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Anti-Markup and Stark Law Changes as Part of the 2009 Medicare Physician Fee Schedule Final Rule

On October 30, 2008, the Centers for Medicare & Medicaid Services (CMS) released the final rule regarding the 2009 physician fee schedule and other Medicare Part B payment policies (PFS Final Rule). Two notable aspects of the PFS Final Rule are the revisions to the Medicare anti-markup rule (AM Rule) and the request for additional comments regarding a new exception to the Stark Law for incentive payment programs (IPP) and shared savings programs (SSP). Publication of the PFS Final Rule in the *Federal Register* is scheduled for November 19, 2008.

AM Rule and Diagnostic Testing Services

Prior to release of the PFS Final Rule, the AM Rule imposed limits on payments to billing physicians or suppliers for diagnostic tests "purchased from an outside supplier or performed at a site other than the office of the billing physician or supplier." CMS' prior interpretation of "office of the billing physician or supplier" was widely criticized as too narrow, pulling many legitimate arrangements under the AM Rule prohibitions. Under the PFS Final Rule, however, physicians must now consider two new "alternatives" to determine whether the AM Rule applies to claim payments for particular diagnostic testing services. If the arrangement satisfies one of these two alternatives, it is not subject to the AM Rule proscriptions. The two new alternatives become effective **January 1, 2009**.

Under the first alternative, the AM Rule will not apply to diagnostic testing services provided by a physician—whether supervising the technical component or performing the professional component of the services—who **shares a practice** with the billing physician or other supplier (Shared Practice Requirement). A performing or supervising physician may satisfy the Shared Practice Requirement

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based either: (1) on the amount of services provided by the physician to the billing physician or other supplier; or (2) on the location where the services are provided.

To meet the Shared Practice Requirement, the supervising or performing physician must perform "substantially all" of his or her professional services for the billing physician or supplier within the given 12-month period. Consistent with the Stark Law usage of the term, "substantially all" is defined to mean that the supervising or performing physicians provided at least 75 percent of the physician's professional services for the billing practice.¹ The substantially all test (rather than an exclusivity test) allows billing practices to avoid the AM Rule limitations even when engaging supervising or performing physicians who also provide physician services under unrelated locum tenens, part-time or on-call arrangements.

If the supervising or performing physician cannot meet the substantially all test, a billing physician or other supplier may avoid the AM Rule limitations by meeting the requirements of the second alternative (Site-of-Service Requirement).

Under the Site-of-Service Requirement, the AM Rule will not apply to the technical component (or the corresponding professional component) conducted and supervised in **the office of the billing physician or other supplier**. Per the definition contained in the 2008 changes to the AM Rule, the "office of the billing physician or other supplier" means the space in which services are regularly furnished to patients. In other words, the ordering physician or supplier will meet the Site-of-Service Requirement if he or she regularly furnished patient services in the office of the billing practice, including the services related to the supervision or performance of diagnostic tests.

CMS designed the Site-of-Service Requirement to ensure that the billing physician retains a "proper nexus" to the individuals conducting and supervising the diagnostic tests. In addition to meeting the location portion of the Site-of-Service Requirement, the supervising or performing physician must also be an owner, employee or independent contractor of the billing physician or other supplier. Having a defined relationship with the billing physician or other supplier provides further evidence of a "proper nexus" between the parties.

Additional Comments Requested for Proposed IPP and SSP Exceptions

CMS solicited comments in the proposed PFS Rule regarding a proposed Stark Law exception for IPP and SSP.² The proposal was aimed at encouraging innovative gainsharing or other cost-saving programs, while protecting Medicare and its beneficiaries from abuse. Despite receiving comments to the initial proposal, CMS did not receive sufficient information or agreement to finalize the proposed rule. As a result, an additional comment period will be open until February 19, 2009.

One question requiring clarification is whether one or two new exceptions will be necessary to cover IPP and SSP arrangements. While the distinction may be subtle, IPP generally create financial incentives for patient-focused, high-value care and are tied to achieving certain performance goals, such as adopting new technology, furnishing preventative care services, achieving patient satisfaction, and improving patient health indicators. SSP, on the other hand, promote waste reduction and efficiency by offering physicians payment of a share of the hospitals' variable cost savings attributable to the physicians' efforts in controlling patient care expenditures.

Regardless of the type of incentive program employed, the relationships between the sponsoring hospitals and the participating physicians create financial relationships that implicate the Stark Law. While CMS notes that existing Stark Law exceptions may cover some gainsharing arrangements, more information is needed to determine whether existing exceptions should be modified or new exceptions should be created specifically for IPP and SSP arrangements.

Specifically, the PFS Final Rule sets out 55 additional inquiries that CMS hopes will be addressed following its publication. These inquiries include CMS' seeking of comments regarding incentive program safeguards, quality measures and independent review, physician participation and compensation, documentation, and the availability of existing Stark Law exceptions for application to IPP and SSP arrangements. According to CMS, the goal of the additional comment period is to obtain sufficient information to assist in crafting an exception or exceptions for arrangements that will be able to achieve "transparency and accountability, ensure quality of care, and prevent disguised payments for referrals."

Summary

Physician practices and suppliers should take time to evaluate their current diagnostic testing and billing practices in light of the new changes to the AM Rule. Additionally, health care providers should watch for updates in the coming year regarding potential additions or modifications to the Stark Law exceptions, especially as they relate to incentive compensation programs

¹ See 42 C.F.R. 411.352(d) (2004); 42 C.F.R. 411.356(c)(1) (2004).

² See Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; and Revisions to the Amendment of the E-Prescribing Exemption for Computer Generated Facsimile Transmissions; Proposed Rule, 73 Fed. Reg. 38502, 38544 (July 7, 2008).

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