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Proposed Policy Changes in The 2009 Medicare Physician Fee Schedule

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On July 7th, the Centers for Medicare & Medicaid Services (“CMS”) published proposed changes to the Medicare Physician Fee Schedule for 2009 (“2009 PFS Proposed Rule”) in the *Federal Register*. As in previous years, the 2009 PFS Proposed Rule includes significant proposed changes to Medicare payment policies, including proposed changes to the anti-markup rule for purchased diagnostic tests. In addition to proposing changes to payment policies, CMS has also used the 2009 PFS Proposed Rule to propose amendments to the Stark Law regulations and provider enrollment requirements. This article will address these proposed amendments.

The anti-markup rule set forth at 42 C.F.R. §414.50 historically prohibited a physician who orders a diagnostic test, but who “purchases” the technical component (“TC”) of the test from a third-party supplier, from “marking up” the price the physician bills Medicare for the TC. This means that if the amount paid by the physician is less than the applicable fee schedule amount, the physician could only bill Medicare the lower amount. The rule was expanded in the 2008 Physician Fee

Schedule Final Rule to apply, not only to the TC of a test purchased from an outside supplier, but also to (i) the professional component (“PC”) of such a purchased test, as well as (ii) both the professional and technical components if done outside the physician’s office — whether “purchased” or not. Specifically, as revised, the rule applied to those diagnostic tests that were ordered (the rule does not apply when the “order” comes from outside the billing physician’s practice) by the billing physician or other supplier (or ordered by a party related by common ownership or control to such physician or other supplier), when the TC and/or PC is (a) outright purchased, or (b) when the TC and/or PC is not performed in the office of the billing physician or other supplier.

Subsequent to the publication of the 2008 Physician Fee Schedule Final Rule, CMS issued another final rule to delay the effective date of the revised anti-markup rule until January 1, 2009 (except for when the TC is purchased from an outside supplier, which has been a longstanding rule, and for anatomic pathology diagnostic testing furnished in a space that did not meet various listed regulatory requirements), largely due to the industry’s concern that the revised anti-markup rule’s definition of “office of the billing physician or other supplier” did not appear to be satisfied under the Stark Law’s definition of “same building” for purposes of the in-office ancillary services exception.

The revised anti-markup rule defines the “office of the billing physician or other supplier” as medical office space where the physician or other supplier regularly furnishes patient care. For a billing physician or other supplier that is a physician organization, the “office of the billing physician or other supplier” is space in which the physician organization provides substantially the full range of patient care services that the physician organization provides generally. Given space limitations, this could have affected many practices that utilized different office space in the same building, even where the structures were specifically compliant with an existing Stark Law provisions.

In the 2009 PFS Proposed Rule, CMS offers two alternative proposals to clarify the industry’s concerns about the anti-markup rule. Under the first proposal, CMS would remove any site-of-service requirement, thus alleviating concerns that the definition of “office of the billing physician or other supplier” was more restrictive than the Stark Law’s “same building” test under the in-office ancillary services exception. Under this proposal, the anti-markup rule would apply in all cases where the TC or PC of a diagnostic testing service is either (i) purchased from an outside supplier, or (ii) performed or supervised by a physician who does not share a practice with the billing physician or physician organization. A physician will be considered to “share a practice” with the billing physician or physician organization if he or she is employed by or contracts only with that physician organization or physician (regardless of whether it is on a full-time or part-time basis). In contrast, a physician who is an employee

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of, or independent contractor with, more than one billing physician or physician organization would not be deemed to share a practice with any of the physicians or physician organizations with which he or she is affiliated, and therefore the TC or PC would be subject to the anti-markup rules.

Under the second proposal, CMS would keep the site-of-service requirement, but the definition of "office of the billing physician" would be revised to conform certain aspects of the rule to the Stark Law by including diagnostic services furnished in the same building as the "ordering" physician's office, even if services are furnished on different floors (provided that applicable supervision requirements are met). CMS also proposes to clarify that, with respect to the TC, the anti-markup provision applies if the TC is either conducted or supervised outside of the office of the billing physician or other supplier. CMS takes the position that the "performance" of the TC includes both the technician's work in conducting the test and the physician's supervision of the technician.

CMS also proposes to clarify that the TC of a diagnostic test should not be considered purchased from an outside supplier if the TC is both conducted and supervised in the office of the billing physician or other supplier and the supervising physician is an employee or independent contractor of the billing physician or other supplier. Thus, the emphasis is on the physician supervising the test, not the technician's employment relationship with the billing physician or supplier.

Lastly, CMS proposes to clarify that the "performing supplier" of the TC is the physician who supervised the TC, and the "performing supplier" of the PC is the physician who performed the PC. Therefore, where the anti-markup provision applies, the billing physician or other supplier would need to determine what it paid the physician for supervising the TC or for performing the PC. This proposed "clarification" in combination with the anti-markup rule's requirements for calculating net charges severely limits the amount of reimbursement the billing physician or supplier can collect from Medicare where

the anti-markup rule applies. If the amount that the purchaser can bill is limited to the amount that such purchaser paid the physician for supervising the TC or performing the PC, the purchaser would be unable to recoup payment for any other expenses related to the diagnostic test, such as the purchaser's overhead expenses related to the equipment, space, or personnel. It remains unclear what other costs will be allocated under the final rule.

In the 2009 PFS Proposed Rule, CMS proposes a new exception to the Stark Law for certain gainsharing, pay-for-performance ("P4P"), and other incentive payment and shared savings programs offered to physicians by hospitals. The Department of Health and Human Services, Office of Inspector General ("OIG") has commented on numerous occasions about gainsharing arrangements in advisory opinions and in a Special Advisory Bulletin. However, CMS has, heretofore, offered little guidance on the use of gainsharing or P4P programs under the Stark Law. This new proposed exception constitutes CMS's first effort at directly addressing the acceptableness of these programs under the Stark Law. The conditions set out in CMS's proposal reflect many of the attributes found in the gainsharing programs that the OIG has concluded do not pose a material risk of abuse under the fraud and abuse laws.

Under the new exception, as proposed, only programs offered by hospitals are covered. It does not apply to gainsharing or other P4P programs offered by other Medicare providers or suppliers. In addition, these programs can only be offered to physicians or "qualified physician organization[s]," which is defined as a physician organization comprised entirely of physicians participating in the same incentive payment or shared savings program.

While there are numerous requirements to satisfying the proposed exception, there are four main categories under which the requirements fall: (1) design of the program; (2) performance measures and benchmarks; (3) payments; and (4) physician participation. In addition to these categories, there are certain standard provisions, including that the remuneration be set in advance, not

vary during the term of the arrangement, and not be determined in a manner that takes into account the volume or value of referrals or other business generated between the parties. Lastly, the exception only applies to cash or cash equivalent forms of payment, and does not cover nonmonetary remuneration.

CMS proposes a fundamental change in how it will regulate who can perform diagnostic imaging services. Specifically, CMS proposes that all physician and nonphysician practitioner ("NPP") organizations (defined as any physician or NPP entity that enrolls in the Medicare program as a sole proprietorship or organizational entity such as a clinic or group practice) who perform and/or interpret diagnostic exams in their office — regardless of their specialty — to enroll as an independent diagnostic testing facility ("IDTF") for each practice location providing these services. Under the proposal, the IDTF performance standards set forth at 42 C.F.R. § 410.33 (including prohibitions regarding the sharing of space and leasing/sharing arrangements) would apply to physicians and NPPs who are performing diagnostic testing services for Medicare beneficiaries, and who have enrolled in the Medicare program as a clinic, group practice or physician office. CMS does propose, however, exceptions to certain established performance standards in cases where the physician organizations already meet or exceed some of these standards, or where CMS believes that compliance with the standards will be costly and burdensome and possibly limit beneficiary access.

CMS also proposes a new performance standard for mobile units. CMS believes that entities providing mobile diagnostic services to Medicare beneficiaries must be enrolled in the Medicare program, comply with the IDTF performance standards, and directly bill Medicare for services they provide.

The comment period on the 2009 PFS Proposed Rule was scheduled to close on August 29th. CMS will respond to those comments in a final rule to be issued by November 1st. The revised policies and payment rates, absent variation by CMS, are to become effective January 1, 2009. ■