

Health Law & Business Series

Fraud and Abuse

Portfolio 2400: Federal Self-Referral Law

Detailed Analysis

11. ANTI-MARKUP RULE FOR PHYSICIAN BILLING FOR DIAGNOSTIC TESTS

A. Background: The Statute and Brief History of the Anti-Markup Rule

The statutory limitation on the ability of physicians to purchase diagnostic services performed by other entities and bill for those services at marked-up prices, traditionally known as Medicare's "purchased diagnostic services" rule, originates in a statute that is not part of the Stark law, but is closely related in purpose.¹

¹ Social Security Act § 1842(n), 42 U.S.C. § 1395u(n).

The anti-markup statute does not speak of "purchased" tests, but instead addresses tests neither personally performed nor supervised by the billing physician or another physician with whom the billing physician shares a practice. In its implementing regulations and manuals, CMS historically referred to such tests as "purchased," but struggled for years to define that term. At one time CMS considered a technical component (TC) to be purchased unless it was performed by the billing physician's employees. CMS later liberalized its standard to accommodate the reality of leased employees and independent contractors supervised by the billing physician or another physician in the practice. CMS's manual continued, however, to suggest that leased or contracted technicians might not be considered the physicians' "personnel," resulting in the TC being considered purchased. See CMS Pub. 100-04, Claims Processing Manual, Chap. 13, § 20.2.4, before and after amendment by Transmittal 135 (Apr. 2, 2004). As discussed below, CMS ultimately eliminated the concept of "purchased" tests from the anti-markup provision in the rule adopted in the calendar year 2009 Medicare physician fee schedule rulemaking.

The trend towards "in-sourcing" of diagnostic testing had generally been encouraged, or at least facilitated, by the Stark law's in-office ancillary services (IOAS) exception. When pushed to its outer margins, however, the IOAS exception led to the creation of various types of "pod" businesses, most notably anatomic pathology laboratories, which CMS believes encourage overutilization and are abusive.²

² For a description of a "pod" laboratory arrangement, see the summary of Health & Human Services Office of Inspector General Advisory Opinion No. 04-17 at W. Bradley Tully, *Federal Anti-Kickback Law* (BNA's Health L. & Bus. Series No. 1500) Working Papers, Doc. 9E. As indicated in Adv. Op. No. 04-17, the OIG believes pod businesses are abusive "contractual joint ventures." For additional analysis of the OIG's position on contractual joint ventures, see § 1500.06.A.12., discussing the OIG's Special Advisory Bulletin: Contractual Joint Ventures, 68 Fed. Reg. 23148 (Apr. 30, 2003), reproduced at Portfolio 1500 Doc. 5B.

CMS therefore began to propose expansions of the anti-markup prohibition to diagnostic services that are not purchased, including certain arrangements for performing diagnostic testing in physicians' own offices. The anti-markup rule thus intertwines itself with the Stark law's IOAS exception, and CMS has addressed regulatory proposals under both statutes together as "physician self-referral issues" in its rulemakings.

Also, in order to coordinate with the anti-markup provision, the Stark regulations exclude from the definition of "entity" a physician practice that bills Medicare for a diagnostic test to which the anti-markup rule applies.³ The effect of this exclusion is that a physician practice may bill Medicare for the test (but may not realize a profit, or as is discussed below, will almost certainly realize a loss) without regard to whether an exception from the Stark prohibition is otherwise available.

³ 42 C.F.R. § 411.351 (subsection(3) of the "entity" definition).

Comment: It is important to keep in mind that the Stark and anti-markup regulatory schemes, which implement different statutes, are not coextensive in the services to which they apply. The anti-markup rule potentially applies only to diagnostic tests described in § 1861(s)(3) of the Social Security Act,⁴ which are reimbursed under 42 C.F.R. Chap. 414, other than clinical diagnostic laboratory tests.⁵ Although many diagnostic tests are also DHS subject to the Stark law (e.g., radiology and other imaging), some diagnostic services covered by the anti-markup rule are not DHS (e.g., EKGs and EEGs). In addition, the anti-markup rule obviously does not apply to the many nondiagnostic services that constitute DHS subject to the Stark law.

⁴ SSA § 1861(s)(3), 42 U.S.C. § 1395x(s)(3).

⁵ See 42 C.F.R. § 414.50(a)(1). The anti-markup rule does not apply to tests reimbursed under the clinical laboratory services fee schedule, which, under 42 U.S.C. § 1395l(h)(5)(A), physicians may not bill for unless they perform or supervise the tests. By contrast, application of the anti-markup prohibition to anatomic pathology services, consisting of slide preparation or "histology" services and the physician's interpretation of slides, which are reimbursed under the physician fee schedule, has been a major focus of CMS in the expansion of the anti-markup rule. CMS views the histology services performed by the technician, which do not in themselves produce clinically relevant information, not as laboratory tests, but as technical components of physician services. Ironically, however, in the CY 2009 PFS final rule, CMS may have (presumably inadvertently) excluded anatomic pathology testing from the anti-markup rule. See *infra* at § 2400.11.C.3.

The purchased technical components (TCs) of diagnostic tests (e.g., conducting x-rays, preparing pathology slides) are typically performed by nonphysician technicians. The professional components (PCs) (i.e., physicians' interpretations of TCs), however, are performed by physicians and were not traditionally subject to the anti-markup prohibitions. By its terms, the anti-markup statute applies to "diagnostic tests" reimbursed under a statutory benefit section separate from that for physician services,⁶ and the legislative history can be read to suggest that the anti-markup rule was not intended to apply to PCs.⁷ CMS respected this distinction for many years, but then proposed to apply the anti-markup limitations to PCs through the calendar year 2008 Medicare physician fee schedule rulemaking.⁸

⁶ Like other physician services, PCs of diagnostic tests are reimbursed under SSA § 1861(s)(1), 42 U.S.C. § 1395x(s)(1), whereas, as noted above, TCs are reimbursed under SSA § 1861(s)(3).

⁷ H.R. Rep. No. 100-495 (Conf. Rep. on H.R. 3545, Budget Reconciliation Act of 1987), at Joint Explanatory Statement of the Committee of Conference, Provisions Relating to Medicare, I.C.6., as reprinted in 133 Cong. Rec. H. 12103 (Dec. 21, 1987).

⁸ 72 Fed. Reg. 38122 (July 12, 2007)[hereinafter CY 2008 PFS final rule].

CMS's proposed expansion of the anti-markup rule to include PCs⁹ and nonpurchased tests proved to be a lightning rod for controversy, complexity, and change. The CY 2008 PFS proposal was substantially modified in the CY 2008 final rule,¹⁰ the application of which CMS generally delayed on the eve of its effective date.¹¹ In the CY 2009 PFS rulemaking, CMS made significant changes to the 2008 rule before it became generally effective.

⁹ CMS rejected arguments that it lacked authority to extend the anti-markup rule to PCs in both the CY 2008 and the CY 2009 rulemakings. See CY 2009 PFS Final Rule Preamble § II.N.2.b., 73 Fed. Reg. 69726, 69802 (Nov. 19, 2008).

¹⁰ In the CY 2008 PFS rulemaking, CMS initially proposed to extend the anti-markup prohibition to all TCs and PCs of tests performed by any party other than a full-time employee of the billing physician or medical group. See Proposed 42 C.F.R. § 414.50, Physician billing for purchased diagnostic tests; Preamble to the proposed rule, 72 Fed. Reg. 38122, 38179-38180 (July 12, 2007). That proposal was met with a great deal of opposition, since it would have affected the ability of physician practices to perform diagnostic tests using the services of part-time employees or independent contractors.

¹¹ Soon after adopting the CY 2008 PFS final rule in Nov. 2007, CMS acknowledged the disruption it was causing and generally delayed for one year (until Jan. 1, 2009) the expansion of the anti-markup rule to PCs and to nonpurchased TCs performed outside the medical practice office. CMS explained that it imposed the delay in response to informal comments from stakeholders and that it was concerned the definition of "office of the billing physician or other supplier" may not be entirely clear and could have unintended consequences. However, because anatomic pathology testing arrangements precipitated CMS's revision of the anti-markup provisions and remained its core concern, CMS did not delay the scheduled Jan. 1, 2008, effective date of the provisions, reproduced *infra* Doc. 10B, with respect to any anatomic pathology diagnostic testing services (apparently including both PCs and TCs) furnished in space that: (1) is utilized by a physician group practice as a "centralized building" (as defined in 42 C.F.R. § 411.351) for purposes of complying with Stark, and (2) does not qualify as a "same building" under 42 C.F.R. § 411.355(b)(2)(i). See 73 Fed. Reg. 404 (Jan. 3, 2008).

The revised anti-markup rule and CMS's decision to apply it to the PCs and TCs of anatomic pathology diagnostic testing services not performed in the "same building" during the one-year delay applicable to other diagnostic tests survived challenge in *Atlantic Urological Assocs. v. Leavitt*, 549 F. Supp. 2d 20 (D.D.C. 2008) (granting motion to dismiss on administrative procedural grounds).

In light of the interrelationship between the anti-markup rule and the Stark law, CMS's expansion of the anti-markup limitations, which culminated (at least for now) with the calendar year 2009 Medicare Physician Fee Schedule final rule,¹² is discussed below at § 2400.11.B.

¹² 73 Fed. Reg. 69726 (Nov. 19, 2008)[hereinafter CY 2009 PFS final rule], reproduced *infra* Working Papers, Doc. 20. Like most provisions of the final rule, the changes to the anti-markup rule are effective Jan. 1, 2009.

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B. Provisions of the Final Anti-Markup Rule (CY 2009 PFS Final Rule)

1. General rule

a. Application

In the CY 2009 PFS final rulemaking, CMS adopted final amendments to the expanded anti-markup rule, effective January 1, 2009. Under the final rule, the anti-markup limitations apply to a TC or PC of a diagnostic test¹³ (other than a clinical diagnostic laboratory test) that:

¹³ For a description of the “diagnostic tests” potentially subject to the anti-markup rule, see § 2400.11.A, above.

- was ordered by the billing physician or other supplier (or by a party related to the billing physician or other supplier through common ownership or control as described in 42 C.F.R. § 413.17); and
- is performed by a physician who does not “share a practice” with the billing physician or other supplier.¹⁴

¹⁴ 42 C.F.R. § 414.50(a)(1), as modified by the CY 2009 PFS final rule. 73 Fed. Reg. at 69935. Unless otherwise indicated, all citations below to the anti-markup regulation refer to the CY 2009 final version, *reproduced infra*, Doc. 10A. CMS amended the provisions in Pub. 100-08, Medicare Program Integrity Manual and Pub. 100-04, Medicare Claims Processing, to reflect the regulation changes in Transmittals 326 and 1931 (both dated Mar. 12, 2010, effective June 14, 2010). For links to full text of the CMS manuals, see *Roadmaps to CMS Medicare Program Integrity & Other Manuals*.

These two predicates for application of the anti-markup provisions to a diagnostic test are discussed below at § 2400.11.B.2. and 2400.11.B.3.

Note: The CY 2009 PFS final rule eliminated a diagnostic test being “purchased from an outside supplier” as an explicit basis for imposing the anti-markup limitations.¹⁵

¹⁵ Although it is ironic that the traditionally described “purchased services rule” no longer explicitly applies to purchased tests, the irony is welcome, as CMS continued through the CY 2009 PFS proposal to struggle in its attempts to provide clear rules for determining when a test is “purchased.” See 73 Fed. Reg. 38502, 38547 (July 7, 2008), *reproduced infra* Doc. 19.

b. Limitation on reimbursement

If the anti-markup rule applies to the TC or PC of a test, the Medicare payment to the billing physician or other supplier (including applicable deductibles and coinsurance paid by or on behalf of the beneficiary) is the lowest of:

- the performing supplier's net charge to the billing physician or other supplier;
- the billing physician or other supplier's actual charge; or
- the fee schedule amount for the test that would be allowed if the performing supplier billed directly.¹⁶

¹⁶ 42 C.F.R. § 414.50(a)(1)(i)-(iii). The billing physician or other supplier must identify the performing supplier and indicate the performing supplier's net charge for the test. If the billing physician or other supplier fails to provide this information, Medicare makes no payment to the billing physician or other supplier, and the billing physician or other supplier may not bill the beneficiary. 42 C.F.R. § 414.50(b)(1). A physician may be excluded from Medicare or subjected to civil monetary penalties for "knowingly and willfully in repeated cases" billing Medicare beneficiaries in violation of the anti-markup rule. 42 U.S.C. § 1395u(n)(3).

Typically, the performing supplier's net charge will be the relevant reimbursement limit, hence the provision being known as the "anti-markup" rule. Under a provision first proposed in the CY 2009 PFS proposed rule "with respect to the TC, the performing supplier is the physician who supervised the TC, and with respect to the PC, the performing supplier is the physician who performed the PC."¹⁷

¹⁷ 42 C.F.R. § 414.50(a)(1)(i).

2. Is test "ordered by the billing physician or other supplier" (or a related party)?

To be covered under Medicare, diagnostic tests generally must be ordered by physicians.¹⁸ Yet most tests are not billed by the individual ordering physicians, but by physician practice entities and other suppliers, such as independent diagnostic testing facilities (IDTFs) and laboratories. With CMS's extension of the anti-markup rule to all suppliers in the CY 2008 final rule,¹⁹ whether a billing "other supplier" is deemed to order a test actually ordered by a physician is thus critical to application of the rule. Presumably a physician practice will be deemed to order any test ordered by its owning, employed, or contracted physicians, although this result does not necessarily follow from the text of the rule.

¹⁸ 42 C.F.R. § 410.32(a).

¹⁹ The anti-markup statute applies only to "a physician's bill or a request for payment for services billed by a physician" (SSA § 1842(n), 42 U.S.C. § 1395u(n)), and 42 C.F.R. § 414.50, as proposed to be amended

by the CY 2008 PFS proposed rule, similarly would have applied only to a billing “physician or medical group.” In the CY 2008 final rule, however, “the anti-markup provisions are applicable to all types of suppliers.” 72 Fed. Reg. at 66310.

As to other types of suppliers, CMS indicated in the CY 2008 final rule that IDTFs and laboratories may “order” tests, but the standards for making this determination are cryptic at best.²⁰ Perhaps CMS applies an agency theory and attributes to the other supplier tests ordered by an employed physician, but not an independent contractor physician.²¹ The reference in the rule to a party related to a *physician* under the rules of 42 C.F.R. § 413.17 appears to be meaningless, because such rules attribute relationship to *organizations* through *common* ownership or control and thus would not appear to apply between an organization and a physician or group of physicians that owns or controls it.

²⁰ See 72 Fed. Reg. at 66310-66311.

²¹ See CY 2009 PFS Final Rule Preamble § II.N.2.g., 73 Fed. Reg. at 69812 (concluding that where a (presumably independent contractor) cardiologist reassigns the right to payment for a PC to a hospital, the anti-markup rule does not apply because “the hospital did not order the PC”).

Pathologists and radiologists are not normally subject to the anti-markup limitations because they do not typically order tests. If they do order tests (e.g., follow-up studies), however, then they are treated under the rule the same as other ordering physicians.²²

²² See CY 2009 PFS Final Rule Preamble § II.N.2.c., 73 Fed. Reg. at 69806; 72 Fed. Reg. at 66310-11.

3. Does performing physician “share a practice” with the billing supplier?

In a significant relaxation of the anti-markup rule as drafted in the CY 2008 final and CY 2009 proposed rulemakings, CMS in the CY 2009 PFS final rulemaking provided that the performing physician will “share a practice” with the billing physician or other supplier (and the anti-markup limitations will not apply) if **either** of the following alternative standards is satisfied:

- the performing physician furnishes “substantially all” (i.e., at least 75%) of his or her professional services through the billing physician or other supplier (which CMS in the commentary termed “Alternative 1”); or
 - the performing physician is an owner, employee, or independent contractor of the billing physician or other supplier and the TC or PC is performed in the “office of the billing physician or other supplier” (“Alternative 2”).²³
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²³ The CY 2009 proposed rule would have required the performing physician to work *solely* for the billing supplier under the first alternative. More significantly, CMS indicated in the proposal that it was considering

finalizing only one of the alternatives, not that it would allow parties to avoid the anti-markup limitations by satisfying either standard. See 73 Fed. Reg. at 38545. In its explanation of the final rule, CMS stated that allowing billing physicians and other suppliers to satisfy either alternative would afford parties “flexibility while addressing our concerns regarding the ordering of unnecessary diagnostic tests.” CY 2009 PFS Final Rule Preamble § II.N.2., 73 Fed. Reg. at 69800.

a. Alternative 1 (“substantially all” professional services)

The regulation provides that the “substantially all” standard is satisfied if, at the time the billing physician or other supplier (hereinafter sometimes collectively referred to as the “billing supplier”) submits a claim for a test furnished by the performing physician, the billing supplier has a reasonable belief that:

- for the 12 months prior to and including the month in which the service was performed, the performing physician furnished at least 75% of his or her professional services through the billing supplier; or
- the performing physician will furnish at least 75% of his or her professional services through the billing supplier for the next 12 months (including the month in which the service is performed).

CMS stated that the Alternative 1 standard should be applied first, and if the performing physician satisfies it, then none of the TCs or PCs he or she supervises or performs will be subject to the anti-markup rule.²⁴

²⁴ See CY 2009 PFS Final Rule Preamble § II.N.2., 73 Fed. Reg. at 69800.

The Alternative 1, “substantially all” rule allows the performing physician to provide up to 25% of his or her professional services under a locum tenens or other part-time arrangement for parties other than the billing supplier.²⁵ In what CMS termed the “flip side” of this issue, it stated that *with respect to locum tenens situations only*, the “substantially all” test will be applied by examining the professional services of the permanent physician for whom the locum tenens physician is substituting.²⁶ Thus, consistent with most other Medicare rules, the locum tenens physician is effectively treated as if he or she were the permanent physician for whom he or she substitutes.

²⁵ See CY 2009 PFS Final Rule Preamble § II.N.2.c., 73 Fed. Reg. at 69804.

²⁶ See CY 2009 PFS Final Rule Preamble § II.N.2.c., 73 Fed. Reg. at 69805.

Example: Locum tenens Physician A contracts with Group Practice C to render services in the place of Physician B, who is on vacation. Physician B performs at least 75% of her professional services through Group Practice C. The arrangement meets the “substantially all” test, because Physician B, the permanent physician, performs at least 75% of her professional services through Group Practice C. The extent to which locum tenens Physician A furnishes professional services for Group Practice C is irrelevant.²⁷

²⁷ See CY 2009 PFS Final Rule Preamble § II.N.2.c., 73 Fed. Reg. at 69805.

Comment: The Alternative 1, “substantially all” test will remove from the anti-markup limitations TCs supervised and PCs performed by full-time employees or contractors of physician practices, regardless of where the tests are performed or supervised. This provision could be of particular benefit to large group practices that utilize “outside” specialists (e.g., radiologists) to supervise or interpret tests, if the referring group's business constitutes at least 75% of the contracted physician's professional services.

Note: CMS did not define “professional services” in the final rule. Given that the definition of “substantially all” is consistent with the Stark regulations,²⁸ it is notable that CMS did not adopt the term “patient care services” (as defined in 42 C.F.R. § 411.351) or “physician-patient encounters,” both of which are used in the 75% tests for “group practice” status under 42 C.F.R. § 411.352. The anti-markup standard requiring that substantially all of the professional services be furnished “through” the billing supplier may suggest a test based on charges or collections.

²⁸ See CY 2009 PFS Final Rule Preamble § II.N.2., 73 Fed. Reg. at 69800.

b. Alternative 2 (“office of billing physician or other supplier”)

If the Alternative 1, “substantially all” standard for the performing physician to be considered “sharing a practice” with the billing supplier is not satisfied, then the Alternative 2, site-of-service standard is applied on a test-by-test basis.²⁹ Under Alternative 2, the performing physician will be deemed to share a practice with the billing supplier if:

²⁹ See CY 2009 PFS Final Rule Preamble § II.N.2., 73 Fed. Reg. at 69800.

- the performing physician is an owner, employee, or independent contractor of the billing supplier, and
- the TC or PC is performed in the “office of the billing physician or other supplier.”

As under the 2009 proposed rule, “office of the billing physician or other supplier” is defined as:

any medical office space, regardless of number of locations, in which the ordering physician or other ordering supplier regularly furnishes patient care, and includes space where the billing physician or other supplier furnishes diagnostic testing, if this space is located in the same building (as defined in § 411.351) in which the ordering physician or other ordering supplier regularly furnishes patient care. With respect to a billing physician or other supplier that is a physician organization (as defined in § 411.351 of this chapter), 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.³⁰

³⁰ 42 C.F.R. § 414.50(a)(2)(iii).

It appears clear from CMS's explanation that the "same building" language at the end of the first sentence quoted above also applies to the second quoted sentence, which defines "office of the billing physician or other supplier" with respect to physician organizations.³¹ Thus, this site-of-service standard is satisfied by the TC or PC being performed in space in the "same building" in which the ordering physician provides substantially his or her full range of patient care services, notwithstanding that the testing space is, e.g., located on a separate floor of that building. CMS noted in the commentary that a "same building" as defined under 42 C.F.R. § 411.351 (i.e., the interior spaces of a structure or combination of structures that share a single street address) need not satisfy the additional requirements (e.g., hours for which the office is open) necessary for DHS furnished in a "same building" to satisfy the IOAS exception under 42 C.F.R. § 411.355(b)(2).³²

³¹ See CY 2009 PFS Final Rule Preamble § II.N.2.d., 73 Fed. Reg. at 69807-08.

³² See CY 2009 PFS Final Rule Preamble § II.N.2.d., 73 Fed. Reg. at 69808.

Note: A physician performing PCs or supervising TCs in a building that is not a "same building" under the Stark regulations will not satisfy the Alternative 2, site-of-service standard. For such tests to avoid the anti-markup limitations, they must therefore be performed or supervised by a physician who meets the Alternative 1, "substantially all" professional services standard.

Comment: In focusing on the "ordering physician," the above standard, which CMS included in the CY 2009 PFS proposed rulemaking, allows multispecialty practices to provide testing in multiple offices, even if all specialty services are not furnished in any particular office. Although the rule thus cures a problem inherent in the CY 2008 final rule, the 2009 rule creates a potentially bigger problem: The anti-markup limitations will apply (assuming the performing physician does not satisfy Alternative 1) if a group physician who practices in a particular office orders a test that is performed in another office (and building) in which the ordering physician does not perform "substantially the full range of patient care services" that he or she provides generally. The "site of service" standard is applied at the level of the individual ordering physician, not of the physician organization as a whole, a significant distinction which CMS glossed over in a preamble example in the proposed rule, but confirmed in the CY 2009 final rule.³³

³³ See CY 2009 PFS Final Rule Preamble § II.N.2.f., 73 Fed. Reg. at 69809. CMS declined to define "full range of patient care services" because "this would vary greatly based on factors such as the specialty of the ordering physician, the types of services within the physician's specialty, and the focus of services at the specified practice." 73 Fed. Reg. at 69810.

For purposes of the Alternative 2, site-of-service standard, the performance of the TC includes both the conducting of the TC by the technician as well as the supervision of the TC by the physician.³⁴ Thus, for this standard to be satisfied, the activities of both the technician and the supervising physician must be performed within the "office of the billing physician or other supplier." This provision appears to be the sole instance in which the technician is relevant under the final rule.

³⁴ 42 C.F.R. § 414.50(a)(2)(iii).

Note: Alternative 2 requires that the supervising physician be physically present in the “office” when the technician conducts the TC, even if the TC is only subject to general supervision (and therefore would not require such presence of the supervising physician for coverage purposes).³⁵ CMS recognized that properly structured “block-time” sharing arrangements may satisfy this standard.³⁶

³⁵ See CY 2009 PFS Final Rule Preamble § II.N.2.f., 73 Fed. Reg. at 69810; CY 2009 PFS Final Rule Preamble § II.N.2.g., 73 Fed. Reg. at 69812. A similar issue is presented by the Stark regulations considering an independent contractor to be a “physician in the group practice” only during the time he or she performs services in the group practice's facilities. See the Phase III rule preamble, 72 Fed. Reg. at 51012, 51035 (Sept. 5, 2007).

³⁶ See CY 2009 PFS Final Rule Preamble § II.N.2.d. CMS said that shared space arrangements “can promote efficiency without raising the same concerns for overutilization or other abuse as arrangements that involve centralized buildings for diagnostic testing,” but also (in one of several similar statements regarding the Stark IOAS exception) “that we continue to have concerns with the present use of the in-office ancillary services exception and that we may issue a proposed rulemaking at a future date to address these concerns.” 73 Fed. Reg. at 69808.

CMS stated that it did not define “conducting and supervising the TC,” because it believes that the terms are clear on their face: “[T]hat is, the term ‘conducting the TC’ refers to the technician's (or physician's) performance of the test For a service to be covered by Medicare, the regulations at § 410.32 define and specify various levels of supervision.”³⁷ Moreover, it is noteworthy that the anti-markup regulation text in no manner defines supervision, whether by reference to 42 C.F.R. § 410.32 or otherwise.

³⁷ CY 2009 PFS Final Rule Preamble § II.N.2.f., 73 Fed. Reg. at 69810. At present, Medicare does not typically impose any training or specialization requirements with respect to physicians who supervise tests performed in medical practice offices (as distinct from IDTFs and laboratories). For MRI, CT, and other “advanced” imaging, however, the accreditation standards to be implemented under § 135 of the Medicare Improvements for Patients and Providers Act of 2008, Pub. L. No. 110-275, which become effective Jan. 1, 2012, as well as standards now being implemented by some private payors, will provide specific standards for supervising physicians.

Although, as noted above, CMS eliminated a diagnostic test being “purchased from an outside supplier” as a separate basis for imposing the anti-markup limitations, a vestige of the “purchased” concept remains. To satisfy the Alternative 2, site-of-service standard, the physician performing the PC or supervising the TC must be an owner, employee, or independent contractor of the billing physician or other supplier.³⁸ Somewhat analogously to independent contractor “physicians in the group practice” under the Stark regulations, this rule would appear to require that the performing or supervising physician (whether employee or independent contractor) contract directly with the billing supplier. However, the employment or contractual status of the technician, whether direct or indirect, should be irrelevant under this standard.

³⁸ See CY 2009 PFS Final Rule Preamble § II.N.2.d., 73 Fed. Reg. at 69809; CY 2009 PFS Final Rule Preamble § II.N.2.h., 73 Fed. Reg. at 69813.

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C. Implications of the Final Rule

1. General

Some practical implications of the final rule are reasonably clear. By adopting two alternative means for the performing physician to “share a practice” with the billing physician or supplier (essentially, examining the billing supplier’s relationship with the performing physician, and failing that standard, examining the site-of-service of individual diagnostic tests) the CY 2009 PFS final rule significantly reduces the number of diagnostic testing arrangements subject to the anti-markup limitations in comparison to the CY PFS 2008 final rule and the CY 2009 PFS proposed rule.

Diagnostic testing arrangements that remain subject to the anti-markup provisions under the 2009 rule, however, will continue to face the potentially draconian charge limitation, discussed in more detail below.

Also, the general elimination of “purchased” tests from the anti-markup rule appears to allow physician practices to bill without restriction for part-time testing arrangements through which mobile companies provide the equipment and technician, under the supervision of a physician in the billing practice.³⁹ Demonstrating that a practice physician in fact performs all required supervision under such mobile arrangements may be difficult, however, particularly with respect to “general” supervision.^{39a}

³⁹ CMS also finalized in the CY 2009 PFS rulemaking a regulation purporting to require providers of mobile testing services to enroll as IDTFs and bill Medicare directly. See 42 C.F.R. § 410.33(g)(16), (17); CY 2009 PFS Final Rule Preamble § II.I.2, 73 Fed. Reg. at 69764. Before this regulation became effective, however, CMS issued FAQ 9511 (last modified June 16, 2010), which appears effectively to override the regulation and allow physician practices to bill under such mobile arrangements.

CMS did not finalize its proposal to require physician and nonphysician practitioner entities that provide diagnostic tests to enroll as IDTFs. See CY 2009 PFS Final Rule Preamble § II.I.1., 73 Fed. Reg. at 69763.

^{39a} 42 C.F.R. § 410.32(b)(3) generally provides that all diagnostic tests are subject to “general” physician supervision. 42 C.F.R. § 410.32(b)(3)(i) states: “Under general supervision, the training of the nonphysician personnel who actually perform the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the physician.”

Finally, the final rule’s definition of the “performing supplier” in the case of the TC is conceptually flawed and yields results (discussed immediately below) that either are excessively punitive or frustrate CMS’s core concern in expanding the anti-markup rule. For this reason, the 2009 final rule may not be the last of the anti-markup rulemakings.

2. Performing supplier's net charge

The definition of “performing supplier” as the physician performing the PC or supervising the TC means

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that, where the anti-markup provision applies, the billing physician practice or other supplier's Medicare reimbursement is limited to the amount it paid the performing or supervising physician. As under the CY 2008 PFS final rule, the net charge "must be determined without regard to any charge that is intended to reflect the cost of equipment or space leased to the performing supplier by or through the billing physician or other supplier."⁴⁰

⁴⁰ 42 C.F.R. § 414.50(a)(2)(i).

Although application of the limiting charge provision to the PC is not particularly problematic, its application to the TC is extremely so. This provision limits the "net charge" to a single element—the compensation paid the supervising physician—without considering the compensation paid to the technician⁴¹ or the other *direct costs* in providing the test, such as the costs of space, equipment, supplies, and billing.⁴² It is curious that CMS effectively assumes the supervising physician is the sole element of cost in furnishing the TC. The oddness of this assumption is illustrated by a TC subject only to general supervision. It is very unlikely a billing physician practice will be able to identify any specific compensation that is paid to a physician who performs such general supervision (unless the physician is specifically contracted to supervise).

⁴¹ The CY 2008 PFS final rule effectively treated the *technician* as the performing supplier of the TC, in limiting the net charge for the TC to amounts paid to the technician (or outside supplier for whom the technician worked). See 72 Fed. Reg. at 66318. Although it suffered from the same flaws as the 2009 final rule in not allowing recovery of other costs, the 2008 rule appears conceptually superior to limiting the net charge for the TC to the amount paid the supervising physician.

⁴² See CY 2009 PFS Final Rule Preamble § II.N.2.i.(1) Like prior preamble statements, the CY 2009 final rule provides that the billing supplier bears the responsibility of accurately computing the net charge for the TC or PC "in any reasonable manner" and must maintain contemporaneous documentation of the methodology and information used in the computation. 73 Fed. Reg. at 69814.

Moreover, although the explanation in the CY 2009 PFS proposed rule preamble might suggest that treating the physician as the performing supplier for purposes of determining the net charge should be limited to situations where the group practice provides the TC, or at least supervises it, directly⁴³ (i.e., not through a purchased or other turnkey arrangement with an outside entity), the text of the regulation (both proposed and final) and the preamble to the final rule do not. The regulation would thus appear to limit the net charge to the amount the outside entity pays its supervising physician.

⁴³ See 73 Fed. Reg. at 38547-38548.

3. Unexpected implications for anatomic pathology

Ironically (to put it mildly), CMS's definition of the performing supplier of the TC as the physician who supervises the TC results in the anti-markup rule on its face not applying to anatomic pathology tests. In the final regulation text and preamble, CMS thus appears to have reopened the door to precisely the

arrangements targeted by its expansion of the anti-markup rule—offsite anatomic pathology laboratories run by part-time contracted pathologists (including the infamous “pods”).

Under the general rule of 42 C.F.R. § 414.50(a)(1), the anti-markup limitations do not apply unless “the diagnostic test is performed by a physician who does not share a practice” with the billing supplier. As previously noted, 42 C.F.R. § 414.50(a)(1)(i) further states that, for purposes of subsection (a)(1), “with respect to the TC, the performing supplier is the physician who supervised the TC.” Thus, TCs that are not subject to physician supervision literally are not “performed by a physician,” and therefore are not subject to the anti-markup rule.

CMS explicitly so states in the final rule preamble: “If the TC does not require physician supervision under our rules, the anti-markup provisions are inapplicable.”⁴⁴ For example, CMS “recognize[d] that where audiologist services are performed by an audiologist, no physician supervision is necessary, and therefore the anti-markup provisions do not apply (because § 414.50 applies to tests performed by a physician).”⁴⁵ As noted above, CMS stated that the relevant supervision rules for purposes of the anti-markup provisions are “the regulations at § 410.32.”⁴⁶ CMS presumably relied upon this regulation in concluding that tests performed by an audiologist are not subject to the anti-markup rule, as 42 C.F.R. § 410.32(b)(2)(ii) provides that diagnostic tests personally furnished by a qualified audiologist are excluded from the supervision rules.

⁴⁴ CY 2009 PFS Final Rule Preamble § II.N.2.h., 73 Fed. Reg. at 69813.

⁴⁵ CY 2009 PFS Final Rule Preamble § II.N.2.g., 73 Fed. Reg. at 69812.

⁴⁶ CY 2009 PFS Final Rule Preamble § II.N.2.f., 73 Fed. Reg. at 69810.

Importantly, however, 42 C.F.R. § 410.32(b)(2)(vi) similarly provides that pathology and laboratory procedures listed in the 80000 CPT series are excepted from the supervision requirements. Thus, the final anti-markup regulation and CMS’s explanation rather clearly provide that anatomic pathology tests are not subject to the anti-markup limitations.

It is equally clear, however, that CMS intended that the anti-markup rule would apply to anatomic pathology.⁴⁷ CMS refused to defer application of the CY 2008 final rule to anatomic pathology TCs and PCs not furnished in a “same-building,” because such tests were CMS’s “core concern” in expanding the anti-markup rule.⁴⁸ Moreover, the CY 2009 PFS Final Rule Preamble, like each of the prior preambles, indicates that CMS believes the anti-markup rule applies to anatomic pathology tests, particularly under “pod” laboratory arrangements.⁴⁹

⁴⁷ The Deputy Director, CMS Division of Technical Payment Policy (Lisa Ohrin) emphatically confirmed this intent in remarks at the ABA Health Law Section Washington Healthcare Summit (Nov. 17, 2008), stating there is no anatomic pathology carve-out..

⁴⁸ See 73 Fed. Reg. 404 (Jan. 3, 2008).

⁴⁹ See, e.g., CY 2009 PFS Final Rule Preamble § II.N.2.c., 73 Fed. Reg. at 69805-06; § II.N.2.d., 73 Fed. Reg. at 69807-08; § II.N.2.f., 73 Fed. Reg. at 69810; § II.N.2.i. and § II.N.2.j., 73 Fed. Reg. at 69815-16.

One must thus assume that CMS and the enforcement agencies will vigorously attempt to apply the anti-markup limitations of the final rule to anatomic pathology. A potential means to this end might be to characterize a contracted pathologist or other laboratory director as the supervising physician. There are, however, at least two impediments to such characterization. First, in the final rule preamble, CMS explicitly declined to impose on supervising physicians the standards for laboratory directors under the Clinical Laboratory Improvements Act (CLIA), in concluding, "Section 410.32 establishes the level of supervision (general, direct, or personal) for diagnostic tests potentially subject to the anti-markup provisions."⁵⁰ Second, as can be confirmed by the list of CPT codes subject to CLIA that CMS maintains on its CLIA Web site, most of the pathology TCs performed by referring physician practices are surgical pathology codes that are not subject to CLIA.

⁵⁰ CY 2009 PFS Final Rule Preamble § II.N.2.d., 73 Fed. Reg. at 69808.

An additional basis for concluding that pathology TCs are not subject to the anti-markup rule is the argument that they are not covered as diagnostic services under SSA § 1861(s)(3) (after all, pathology TCs have no diagnostic value in their own right), but they are instead covered under SSA § 1861(s)(1) as TCs of professional services.

Note: Even if anatomic pathology TCs escape the anti-markup limitations, CMS will presumably attempt to apply the limitations to the PCs. Although there may be no physician performing (i.e., supervising) the TC, "with respect to the PC, the performing supplier is the physician who performed the PC."⁵¹ Thus, in contrast to the TC, for which, as discussed above, there is no "performing supplier" for purposes of the "sharing a practice" standard, the pathologist or other interpreting physician will be considered to perform the PC, and the anti-markup rule might appear to apply if he or she does not "share a practice" with the billing physician group.

⁵¹ 42 C.F.R. § 414.50(a)(1)(i).

On the other hand, if anatomic pathology TCs are not subject to the anti-markup rule, then arguably the PCs are also billable without limit. As discussed above at § 2400.11.A, the anti-markup statute by its terms potentially applies only to TCs, not PCs, of diagnostic tests. Although, commencing with the CY 2008 PFS rulemaking, CMS has extended the potential application of the anti-markup limitations to PCs, it appears from the text of the regulation that the anti-markup rule would only extend to PCs where the TC was subject to the anti-markup rule. In addition, it can be argued that PCs are not subject to the rule on the ground that Medicare does not cover them as diagnostic tests under SSA § 1861(s)(3), but instead covers them as professional services under SSA § 1861(s)(1).