



HEALTH LAW REPORTER



Reproduced with permission from BNA's Health Law Reporter, Vol. 17, No. 48, 12/11/2008. Copyright © 2008 by The Bureau of National Affairs, Inc. (800-372-1033) <http://www.bna.com>

Unexpected Implications of the Final Anti-Markup Rule for Anatomic Pathology

By W. BRADLEY TULLY
AND ALAN H. RUMPH

In its Medicare physician fee schedule (PFS) final rulemaking for the calendar year 2009, the Centers for Medicare and Medicaid Services (CMS) finalized amendments to the “anti-markup” rule codified at 42 C.F.R. § 414.50.¹ As the latest chapter of a regulation project marked by controversy and change, the 2009 final rule generally provided much needed clarity and flexibility for physicians and other suppliers that furnish diagnostic testing. Sources of continuing controversy, however, are the 2009 final rule’s excluding from application of the anti-markup provisions diagnostic tests that are not subject to physician supervision and the question of whether certain pathology technical components (TCs) and professional components (PCs)

are even diagnostic services. This article will advance arguments supporting the undoubtedly controversial conclusion that CMS has drafted a rule that fails, as a technical matter, to bring many, if not all, pathology TCs and PCs within its reach. If the authors’ readings are correct, this failure would open the door once again to the “pod” laboratory arrangements for anatomic pathology that were CMS’s principal motivation in revising the anti-markup rule.

After a brief history of the anti-markup rule and its application to anatomic pathology, the treatment of anatomic pathology TCs (e.g., histologists’ preparation of surgical pathology slides) and PCs (i.e., physicians’ interpretations of the TCs) under the revised anti-markup rule is discussed in detail.

History of the Anti-Markup Rule and Application to Anatomic Pathology

If applicable to a diagnostic test, the anti-markup rule limits a physician or other supplier’s reimbursement for the test to the net charge paid to the party deemed to perform the test. For years, CMS applied the anti-markup provisions only to “purchased” TCs of diagnostic tests. The underlying statute on which the rule is based,² however, speaks not in terms of purchased tests, but instead of tests neither performed nor supervised by the billing physician or another physician with whom the billing physician shares a practice. Perhaps for this reason, CMS never clearly defined “purchased” TCs,³ and some in the industry took the position that application of the rule was limited to arrangements

¹ The final rulemaking (hereinafter the “2009 final rule”) was displayed on CMS’s Web site on Oct. 30 and published at 73 Fed. Reg. 69726 on Nov. 19. 42 C.F.R. § 414.50(a), as amended, appears at 73 Fed. Reg. at 69935-36, and CMS’s explanation of the new provisions begins at 73 Fed. Reg. at 69799.

W. Brad Tully is a partner with Hooper, Lundy, & Bookman in Los Angeles and can be reached at btully@health-law.com or (310) 551-8160. Alan H. Rumph is of counsel at Smith, Hawkins, Hollingsworth & Reeves LLP, in Macon, Ga., and can be reached at alan@shhrlaw.com or (478) 743-4436. The authors are co-authors (along with David P. Henninger) of “Federal Self-Referral Law” (BNA’s Health L. & Bus. Series No. 2400) in BNA’s Health Law & Business Library .

² Social Security Act § 1842(n), 42 U.S.C. § 1395u(n).

³ See, e.g., CMS Pub. 100-04, Claims Processing Manual, Chap. 13, § 20.2.4, before and after amendment by Transmittal 135 (April 2, 2004).

structured as purchases of “finished” tests fully performed by enrolled suppliers. Under this interpretation, the anti-markup rule would not apply to arrangements under which the billing physician practice leased or otherwise contracted for the technician performing, and the space and equipment used in performing, the testing. Presumably because the anti-markup statute by its terms applies only to services described in Section 1861(s)(3) of the Social Security Act (SSA)⁴ and not to physician services under SSA Section 1861(s)(1), CMS traditionally did not apply the markup prohibitions to PCs of diagnostic tests.

The above limited application of the anti-markup rule, in combination with the Stark law’s in-office ancillary services (IOAS) exception⁵ allowing physician practices to furnish designated health services in a “centralized building,”⁶ facilitated the formation of “pod” arrangements for provision of diagnostic testing, most notably anatomic pathology. Under these arrangements, multiple physician group practices that order pathology tests could each contract on a turn-key basis for the tests to be performed in independent, self-contained “pod” laboratories in a single building, far removed from the various physician practice locations. As long as each “pod” was exclusively used in performing a single physician group’s pathology testing, the arrangement satisfied the letter of the “centralized” building definition and the IOAS exception allowed the physician groups to bill for and profit from the tests. The Department of Health and Human Services Office of Inspector General’s conclusion in Advisory Opinion 04-17 that such pod laboratory arrangements could generate illegal remuneration under the anti-kickback statute did not spell the end of pod laboratories.

In the PFS rulemaking for 2005, CMS noted its concerns with “pod” laboratories and stated that it might in the future amend the Stark self-referral regulations to address these arrangements.⁷ CMS discussed pod laboratories and the perceived abuses in detail in the 2007 PFS proposed rulemaking, in which it proposed both Stark regulation amendments, including minimum square footage requirements for certain space to constitute a “centralized” building, and amendments to the reassignment rules with respect to TCs and PCs of diagnostic tests. CMS did not, however, adopt these proposals in the final rulemaking.⁸

CMS’s 2008 PFS rulemaking marked its decision to combat pod laboratories and other testing arrangements it considered abusive not through amending the Stark regulations but instead by expanding the anti-markup rule. It initially proposed to subject to the anti-markup limitations all TCs and PCs performed by someone other than a full-time employee of the billing physician or medical group.⁹ In the 2008 PFS final rulemaking, CMS abandoned the full-time employment standard and amended 42 C.F.R. § 414.50 to subject to the anti-markup restrictions any TC or PC that was either “purchased” from an outside supplier or, in the case of a billing “physician organization” (as defined in

the Stark regulations), performed at a site other than “space” in which the physician organization provided substantially its full range of physician services.¹⁰

The 2008 PFS amendments to the anti-markup rule, which were scheduled to become effective on Jan. 1, 2008, met with substantial industry opposition, in large part because the site-of-service standard could be read to apply the anti-markup restrictions to testing performed in separate “space” in (e.g., on a separate floor of) the same building in which the physician organization maintained its core practice office. Concerned that it might be disrupting legitimate testing arrangements, CMS therefore generally delayed application of the final rule until Jan. 1, 2009, so that it might further study the issues. Because anatomic pathology testing arrangements precipitated CMS’s expansion of the anti-markup provisions and remained its “core concern,” however, CMS did not delay the Jan. 1, 2008 effective date of the amended rule with respect to anatomic pathology TCs and PCs furnished in space utilized by a physician group practice as a “centralized building,” as defined in the Stark regulations, that did not qualify as a “same building” under the IOAS exception.¹¹

In *Atlantic Urological Assocs. v. Leavitt*,¹² various participants in a pod laboratory arrangement challenged CMS’s decision to apply the anti-markup rule to anatomic pathology testing services not performed in a “same building” during the one-year delay applicable to other diagnostic tests. The court did not address the merits of the case, but granted the government’s motion to dismiss based on the plaintiffs lacking standing and failing to exhaust the administrative claims process.

Anatomic Pathology Testing under the 2009 Final Rule

Following its extensive regulatory history with pod laboratories and fresh off its victory in *Atlantic Urological*, CMS’s apparent treatment of anatomic pathology testing under the 2009 final rule amendments is puzzling. Effective Jan. 1, 2009, the anti-markup limitations will apply to TCs and PCs of diagnostic tests covered under SSA Section 1861(s)(3) and reimbursed under the physician fee schedule, if the tests are (1) ordered by the billing physician or other supplier (or a related party) and (2) “performed by a physician” who does not share a practice with the billing physician or other supplier.¹³ The second above element is critical for applica-

¹⁰ See 72 Fed. Reg. 66222, 66307-08 (Nov. 27, 2007).

¹¹ See 73 Fed. Reg. 404, 405 (Jan. 3, 2008).

¹² 549 F. Supp. 2d 20 (D.D.C. 2008).

¹³ 42 C.F.R. § 414.50(a)(1). A comprehensive analysis of the 2009 final rule amendments to the anti-markup provisions is beyond the scope of this article. Generally speaking, the final rule represented a substantial liberalization from prior rulemakings, in providing that the performing physician will be deemed to “share a practice” with the billing physician or other supplier (and the anti-markup rule will not apply) if either of two alternative tests is met: (1) the performing physician furnishes at least 75 percent of his/her professional services through the billing physician or other supplier, or (2) the performing physician is an owner, employee, or independent contractor of the billing supplier, and, in the case of a billing physician organization, the diagnostic test is performed in the same building in which the ordering physician provides substantially the full range of his/her physician services. A TC or PC being “purchased” is generally irrelevant to application of the anti-markup provisions under the 2009 final rule amend-

⁴ 42 U.S.C. § 1395x(s)(3).

⁵ See 42 C.F.R. § 411.355(b).

⁶ See 42 C.F.R. § 411.351.

⁷ See 69 Fed. Reg. 66236, 66316 (Nov. 15, 2004).

⁸ See 71 Fed. Reg. 48982, 49054-57 (Aug. 22, 2006) (proposed); 71 Fed. Reg. 69025, 69688 (Dec. 2, 2006) (final).

⁹ See 72 Fed. Reg. 38122, 38179-80 (July 12, 2007).

tion of the anti-markup rule to anatomic pathology tests.

1. Application of the Anti-Markup Rule to the TC

The 2009 final rule expanded a concept introduced in the 2009 proposed rule, in providing, “[W]ith respect to the TC, the performing supplier is the physician who supervised the TC.”¹⁴ Based upon this provision, if the technician’s performance of the TC is not subject to physician supervision, then the TC is not “performed by a physician,” and the anti-markup rule would appear to be inapplicable. As discussed below, pathology TCs most commonly furnished in (nonpathology) physician practices do not appear to be subject to any requirement of physician supervision, and it therefore seems, notwithstanding CMS’s obvious intent to the contrary, that the new anti-markup rule does not apply to them.

CMS explicitly affirmed in the preamble to the 2009 final rule the dramatic effect of the physician supervision requirements upon applicability of the anti-markup rule: “If the TC does not require physician supervision under our rules, the anti-markup provisions are inapplicable.”¹⁵ 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).”¹⁶

CMS further stated that the relevant supervision rules for purposes of the anti-markup provisions are “the regulations at § 410.32.”¹⁷ 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. 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 would appear to provide that anatomic pathology tests are not subject to the anti-markup limitations.

The purpose of the exception of pathology and laboratory procedures from the Section 410.32 supervision requirements is “that the decision as to the necessity of physician supervision in connection with these services should be made solely under the CLIA [Clinical Laboratory Improvements Act] regulations and not under both the CLIA regulations and the physician fee schedule

ments, a change that removed a long-standing source of uncertainty.

¹⁴ 42 C.F.R. § 414.50(a)(1)(i). Under the proposed rule, application of this “performing supplier” definition was limited to computation of the performing supplier’s net charge. Under the final rule, by contrast, the definition applies for all purposes of 42 C.F.R. § 414.50(a)(1). Although there may appear to be some confusion created by numbering changes in the final regulation compared to the proposed—subsection (a)(1) was merely the limiting charge provision in the proposed regulation—the final regulation’s use of “performed by a physician” in the initial language of (a)(1) and CMS’s preamble statements discussed in the text that follows make it clear that applicability of the “performing supplier” definition is not so limited under the final rule.

¹⁵ 73 Fed. Reg. at 69813.

¹⁶ 73 Fed. Reg. at 69812.

¹⁷ 73 Fed. Reg. at 69810.

regulations.”¹⁸ As CMS’s predecessor stated: “[T]he appropriate level of supervision of these pathology procedures (including the determination that there should be no physician supervision at all) should be determined under the CLIA regulations, and we would consider these matters beyond the scope of § 410.32.”¹⁹ However, while CLIA requires that laboratories be supervised by laboratory directors, those directors need not be physicians.²⁰

Moreover, most commonly performed surgical pathology TCs are not themselves even laboratory tests that are directly regulated by CLIA.²¹ Instead, such TCs consist simply of the slicing and staining of tissue and the affixing of the sliced and stained tissue onto a slide to make it possible for a pathologist to better examine the tissue visually. They are the conceptual equivalent of placing the tissue under a microscope and produce no information of any diagnostic value in themselves. Thus, for CLIA purposes, most surgical pathology TCs are considered to be “preanalytic” activities (in contrast to TCs such as histochemistry, which possess diagnostic value). Although a CLIA laboratory may be responsible for assuring the quality of these preanalytic TCs that its pathologists examine, no other requirements are imposed. Indeed, these TCs, as opposed to PCs, need not even be performed in CLIA regulated laboratories, and they are often performed in nonregulated histology laboratories.

This may explain why CMS, in the 2009 final rule, rejected a commenter’s request that it impose on anatomic pathology TCs the standards for laboratory directors under the CLIA regulations, in concluding, “Section 410.32 establishes the level of supervision (general, direct, or personal) for diagnostic tests potentially subject to the anti-markup provisions.”²² As noted above, this statement would suggest that the CLIA standards are irrelevant and that no anatomic pathology TCs are subject to the anti-markup rule, by virtue of their being excepted from Section 410.32. Therefore, at a minimum, CMS would appear to have excluded CLIA-exempt TCs from application of the anti-markup rule.

Perhaps CMS might contend that pathology TCs that are not subject to any physician supervision requirements, but are in fact supervised by a pathologist or other contracted physician, are “performed” by that physician and thus potentially subject to the anti-markup rule. Such an interpretation, however, would appear to be inconsistent with the preamble statements concerning physician supervision requirements, and could easily be avoided by the ordering/billing physicians characterizing themselves as providing such “supervision,” where there are no supervision standards.

An even more fundamental, if also more controversial, basis for contending that most surgical pathology

¹⁸ 64 Fed. Reg. at 59415 (Nov. 2, 1999) (2000 PFS final rule).

¹⁹ 64 Fed. Reg. at 39628 (July 22, 1999) (2000 PFS proposed rule).

²⁰ See 42 C.F.R. § 493.1443(b)(3).

²¹ Whether CLIA applies to a particular TC can be determined through the lists of CPT codes subject to and excluded from CLIA that CMS maintains on its CLIA Web site at www.cms.hhs.gov/CLIA/10_Categorization_of_Tests.asp. The general exclusion of surgical pathology TCs from CLIA was noted by some commenters in the 2009 final rule. 73 Fed. Reg. at 69807-08.

²² 73 Fed. Reg. at 69808.

TCs are not subject to the anti-markup rule is the argument that they are not covered as diagnostic services under SSA Section 1861(s)(3). As discussed above, these TCs have no diagnostic value in their own right, but merely are a step necessary to allow a pathologist to perform a service by examining the stained slide. The pathologist's professional service does not appear to be covered by Medicare as a diagnostic service under SSA Section 1861(s)(3), but instead is covered under SSA Section 1861(s)(1) as a physicians' service. Therefore, when viewed most naturally, it would appear that these pathology TCs, which are not themselves diagnostic services, are not covered under SSA Section 1861(s)(3). Instead, as they always are referred to, they are simply TCs of professional services and, as such, they would appear to be covered only as integral components of professional interpretations which are covered by SSA Section 1861(s)(1). If this view is correct, these pathology TCs could not be subject to the anti-markup rule, regardless of supervision.²³

2. Application to the PC

Even if anatomic pathology TCs escape the anti-markup limitations, the 2009 final rule as drafted does not on its face exclude anatomic pathology PCs, since "with respect to the PC, the performing supplier is the physician who performed the PC."²⁴ Thus, in contrast to the TC, for which there may be no "performing supplier," 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.²⁵

On the other hand, if an anatomic pathology TC is not potentially subject to the anti-markup rule, then arguably the associated PC should likewise be billable with-

²³ CMS almost certainly would not agree with this argument. Its longstanding position appears to be that all pathology TCs are SSA Section 1861(s)(3) services, as directly reflected in the current manual provisions on purchased TCs, see CMS Pub. 100-04, Claims Processing Manual, Chap. 13, § 20.2.4 (introductory paragraph), and indirectly reflected by its perceived need expressly to exclude pathology TCs from the 42 C.F.R. § 410.32 supervision rules applicable to most other Section 1861(s)(3) services.

²⁴ 42 C.F.R. § 414.50(a)(1)(i).

²⁵ See note 13 *supra* for a brief statement of the "sharing a practice" standards.

out limit. As noted above, the anti-markup statute by its terms applies only to SSA Section 1861(s)(3) services, which are TCs of diagnostic tests, and not to PCs, which are physician services under SSA Section 1861(s)(1). Commencing with the 2008 PFS rulemaking, CMS, in a controversial decision, extended application of the anti-markup limitations to PCs.²⁶ Yet the text of the regulation, like the statute, references Section 1861(s)(3) services. If pathology PCs are to be subject to the anti-markup rule, it would therefore appear to be only by virtue of reading the rule to apply to PCs of TCs that are potentially subject to the rule. This reading, however, is not supported by the text of the anti-markup statute, and it would appear that such an extension could only be justified under CMS's authority to restrict reassignments. Moreover, even under this expansive reading, pathology PCs would appear to escape the reach of the anti-markup rule if, for the reasons discussed above, the associated TCs are not potentially subject to the rule.

Conclusion

Given CMS's efforts to combat pod laboratories through the expanded anti-markup rule, which culminated in the *Atlantic Urological* case, it is inconceivable that CMS intended that the rule not apply to anatomic pathology PCs and TCs. Indeed, the 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.²⁷ Unless CMS again revisits the anti-markup rule, however, it may have eviscerated its "core concern" in expanding the rule.

²⁶ Although CMS rejected arguments that it lacked authority to extend the anti-markup rule to PCs in both the 2008 and the 2009 PFS rulemakings, see 73 Fed. Reg. at 69802-03, the legislative history of the anti-markup statute clearly indicates that application of the rule is limited to TCs. See 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).

²⁷ See, e.g., 73 Fed. Reg. at 69805-09, 69815-16. Lisa Ohrin, deputy director, CMS Division of Technical Payment Policy, confirmed the intent that the anti-markup rule apply to anatomic pathology in remarks at the Nov. 17 ABA Health Law Section Washington Healthcare Summit.