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Anatomic Pathology and the Anti-Markup Rule—Redux

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Since publication of our article,[1] application of the 2009 Anti-Markup Rule[2] to anatomic pathology remains controversial. Somewhat surprisingly, the Centers for Medicare & Medicaid Services (CMS) has issued no further guidance on this issue, including in connection with its Manual changes to reflect the 2009 rule.[3] The legal case for Anti-Markup's inapplicability to pathology is thus unchanged, and we continue to believe that case is a strong one, based on CMS' own statements in the rulemaking that the Anti-Markup rule only applies to services which require physician supervision for coverage.

Given the ultimate legal uncertainty, however, there is merit to considering the Anti-Markup Rule's potential applicability in structuring practice-based pathology testing. Even assuming the Anti-Markup Rule applies to pathology technical components (TCs), the rule does not apply if the TCs are purchased by a pathologist who has not ordered them. In addition, avoiding the rule's billing limitations is relatively easy where the practice whose physician orders the testing employs or contracts with a pathologist to supervise the TCs and perform professional

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[1] W. Bradley Tully & Alan H. Rumph, *Unexpected Implications of the Final Anti-Markup Rule for Anatomic Pathology*, BNA Health L. Rep., Vol. 17, No. 48 (Dec. 11, 2008), which is *available at* www.healthlawyers.org/Members/PracticeGroups/PO/toolkits/Documents/Diagnostic_Testing_TOC/IVb2_Anti-Markup_Rule_for_Anatomic_Pathology.pdf and is hereinafter referred to as "Article."

[2] 42 C.F.R. § 414.50. The general operation of the anti-markup rule is discussed in the Physician In-Office Diagnostic Testing paper, which is *available at* www.healthlawyers.org/Members/PracticeGroups/PO/toolkits/Documents/Diagnostic_Testing_TOC/Physician_In-Office_Diagnostic_Testing_Paper.pdf

[3] Medicare Claims Processing Manual, Pub. 100-04, Chap. 1, §30.2.9.

components (PCs) on a substantially full-time basis. A number of legal and practical issues arise, however, where the pathologist performs less than 75% of his or her total professional services for the ordering and billing practice.[4] The discussion below assumes that the pathologist does not satisfy this 75%-of-services test and addresses the most salient of these issues.

The legal argument for Anti-Markup's inapplicability to pathology TCs is somewhat stronger for TCs that are excluded from the Clinical Laboratory Improvement Amendments (CLIA) than for those to which CLIA applies, because CLIA-excluded TCs are not subject to any federal supervision requirements whatsoever.[5] Referring practices may therefore wish to limit their Medicare testing to CLIA-excluded TCs. Significantly, the TCs of the most common surgical pathology tests provided in practice-based laboratories are excluded from CLIA.[6]

Notwithstanding the exclusion of surgical pathology and other specific TCs from CLIA, the PCs of such tests are subject to CLIA.[7] Moreover, based on the text of the Anti-Markup regulation, the argument that the rule does not apply to anatomic pathology is stronger for TCs generally than it is for PCs.[8] Conservative practices might therefore wish either to comply with the Anti-Markup Rule by arranging for the pathologist to perform Medicare PCs in a building satisfying Stark's "same" building standard and in which the ordering physician provides substantially the full range of his or her services[9] or to avoid the Anti-Markup Rule entirely by allowing the pathologist to bill separately for Medicare PCs.

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[4] TCs supervised and PCs performed by a physician who satisfies the 75%-of-services test of 42 C.F.R. § 414.50(a)(2)(ii) are not subject to the anti-markup limitations.

[5] *See* Article at p.3. Where CLIA applies, various supervision requirements referenced below are imposed. Although CLIA does not require that such supervision necessarily be provided by a pathologist or other physician, non-pathologists are subject to specific training standards. Clinical diagnostic laboratory tests, which are reimbursed under the clinical laboratory fee schedule, are categorically excluded from the anti-markup rule. *See* 42 C.F.R. § 414.50(a)(1). The anatomic pathology TCs in question, although sometimes subject to CLIA, are reimbursed under the Medicare physician fee schedule, and are therefore not excluded from anti-markup as being clinical diagnostic laboratory tests.

[6] The list of tests excluded from CLIA is *available at* https://www.cms.gov/CLIA/downloads/cpt4exc.pdf. Note the listing of TCs for CPT codes 88304 and 88305.

[7] The list of tests subject to CLIA is available at https://www.cms.gov/CLIA/downloads/Subject.to.CLIA.pdf. Both the PC (modifier "26") and the global for 88304 and 88305 are included.

[8] *See* Article at p.4.

[9] *See* 42 C.F.R. § 414.50(a)(2)(iii). For a practice that includes the referring physician to bill Medicare for PCs performed by an independent contractor pathologist—regardless of whether he or she satisfies anti-markup's 75%-of-services test—Stark's physician services exception in 42 C.F.R. § 411.355(a) and "physician in the group practice" definition in 42 C.F.R. § 411.351 will generally require that the

Having the pathologist interpret slides in the practice's laboratory will require CLIA certification for the laboratory, since the PCs are subject to CLIA. Even if the pathologist performs interpretations off site (and separately bills Medicare for them), CLIA ironically may apply to a practice laboratory performing excluded TCs. Specimen gross analysis (i.e., examining the specimen and recording its size, weight, and other description) is typically performed by the practice's histotechnologist before he or she prepares the slides. Yet such grossing—or at least a portion of it—may be part of the PC, not the TC.[10] Performance of this limited PC function in the practice's laboratory may thus necessitate that the practice obtain a CLIA certificate.

CLIA certification of the practice's laboratory will not impose any supervision requirement upon CLIA-excluded TCs. It could, however, raise the factual issue of who is actually supervising the TCs. CLIA does not mandate that a laboratory director be a pathologist (or even a physician). However, as a practical matter, the practice's regular (i.e., non-pathologist) physicians likely will not satisfy the requirements for serving as lab directors.[11] A pathologist therefore will typically be the practice's laboratory director under CLIA, whose responsibilities include overall supervision of the laboratory.[12] A practice having an "outside" pathologist laboratory director (or, indeed, any physician director) under CLIA thus raises the potential argument that the pathologist (or other physician director) is in fact "supervising" the TCs, notwithstanding the absence of any legal requirement for such supervision. Characterization of the pathologist (or another physician) as the de facto supervisor of the TCs might therefore result in the Anti-Markup Rule applying to them, unless the pathologist (or other supervising physician) is present when the TCs are performed in a "same" building (assuming that the Anti-Markup Rule could apply to the TCs as a legal matter).[13]

In light of the above, it is prudent to take steps to support characterization of one of the practice's regular physicians as the physician who "supervises" the TCs. Such steps might include his or her obtaining some basic knowledge of slide preparation so that he or she may

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pathologist perform the PCs in the practice's facilities, although not necessarily in a "same" or "centralized" building.

[10] The authors understand that CMS takes this position, although it is difficult to find specific authority on the issue. Perhaps most telling, if only indirectly so, is CPT 88300, which is specimen gross analysis only and includes a PC.

[11] *See* 42 C.F.R. § 493.1443.

[12] *See* 42 C.F.R. § 493.1445. Most regular practice physicians will not qualify as a laboratory Technical Supervisor under 42 C.F.R. § 493.1449 or General Supervisor under 42 C.F.R. § 493.1461.

[13] A similar argument might be made based on supervision requirements under applicable state law. Again, however, as stated in the Article, CMS commentary indicates that the anti-markup rule will only apply where physician supervision is *required* for Medicare coverage. Outside of that context, anti-markup apparently should not apply at all.

meaningfully interact with the histotechnologist, as well as actively monitoring both the histotechnologist's training, licensure, and certification and the maintenance of the pathology equipment.[14]

Beyond the Anti-Markup Rule, the Stark law does apply to anatomic pathology TCs and the supervision requirement of Stark's in-office ancillary services (IOAS) exception[15] also suggests that practices should take actions supporting characterization of a regular practice physician as the supervisor of TCs. Although the supervision standard under the IOAS exception is the same as that required for payment or coverage (meaning none in the case of CLIA-excluded TCs, and perhaps none in the case of CLIA-covered TCs, because supervision is then not necessarily that of a physician and is based on CLIA and not on Medicare's supervision requirements for diagnostic tests), the text of the regulation could be read to require some affirmative supervision ("[a]n individual who is supervised" by a "physician in the group practice").[16] In this regard, the Stark regulation appears similar to the Anti-Markup Statute—and more stringent than the Anti-Markup regulation text—in affirmatively requiring some, however minimal, physician supervision. In any event, the issue of who is in fact supervising the TCs would appear to arise equally under Stark as under Anti-Markup.

It should be noted that the above supervising physician issue is not limited to pathology TCs, but may arise with respect to other diagnostic tests under the Anti-Markup Rule or designated health services under Stark. For example, accreditation requirements, including those imposed on TCs of computed tomography, magnetic resonance imaging, and nuclear studies effective January 1, may result in a radiologist or other physician "outside" the practice being deemed to supervise the TCs, with potentially disastrous results. Until there is specific authority on the issue, affirmative steps accordingly should be taken to characterize an "in-practice" physician as the supervisor.

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[14] *Cf.* 42 C.F.R. § 410.32(b)(3)(i), prescribing such responsibilities for "general" supervision. Notwithstanding that anatomic pathology TCs are expressly excluded from this regulation, a practice physician's performing these functions supports the factual argument that he or she is "supervising" the TC.

[15] *See* 42 C.F.R. § 411.355(b)(1)(iii).

[16] *See* note 9, *supra*.