HEALTH CAPITAL Topics

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Anti-Markup Rule Provision Injunction

In November, 2007, CMS issued the *Physician Fee Schedule for CY 2008* final rule which expanded the scope of the "*Anti-Markup Rule*", a provision which prohibits billing physicians from *marking up*, or realizing a profit on, the technical component of a diagnostic test that was purchased from an outside supplier or performed at a site other than the office of the billing physician. "*Technical component*" refers to the cost of the test associated with the *actual performance* of the test. By contrast, "*professional component*" refers to that portion of the cost associated with the *interpretation* of the test results. The rule was expanded to apply not only to the technical component of certain diagnostic tests performed by outside pathology providers, but now also to the professional component of diagnostic testing. Significantly, the expanded rule applies to any test that is either purchased from an outside supplier or *"performed at a site other than the office of the billing physician or other supplier"*.[1] Under the expanded rule, a "*centralized building*", as defined under the Stark Law, used by a group practice solely for the purpose of providing pathology services, would no longer be considered as an "*office*" of the group, resulting in the *prohibition of marking up* the technical or professional components of any services rendered in such locations. Further, in order to comply with the *Anti-Markup Rule*, the billing physician cannot charge more than the lowest of either (1) the performing supplier's net charge to the billing physician; (2) the billing physician's actual charge; or, (3) the fee schedule amount for the test that would be allowed if the performing supplier billed directly.[1]

In January 2008, *"concerned that the definition of 'office of the billing physician or other supplier' may not be entirely clear and could have unintended consequences"*, CMS promulgated a new "final rule" which delayed the implementation of the new anti-markup provisions until January 1, 2009. The "*Delay Rule*" would apply in all but two circumstances: (1) in cases where anatomic pathology diagnostic testing is furnished in space that is utilized by a physician group practice as a "*centralized building*"; and, (2) anti-markup provisions would still apply to the technical component of purchased tests as this provision has existed since the inception of the *Anti-Markup Rule* in 1992, and prior to the recent expansion.[1] The *Delay Rule* was quickly challenged by a group of urologist plaintiffs who objected to CMS' decision to not delay the portion of the Delay Rule that applied to services performed in a "*centralized building*". Through their action (Atlanta Urological Associates, P.A., et al. v. Leavitt, D.D.C, No. 1:08-cv-00141), the plaintiffs were able to obtain a *preliminary injunction* which prohibited the Department of Health and Human Services (HHS) from applying the Anti-Markup Rule to services provided in a centralized building, based on the reasoning that HHS issued the Delay Rule without going through the formal notice and comment procedures, which made it "*arbitrary and capricious rulemaking*".[1]

HHS challenged the injunction, however, and obtained a *dismissal* of the plaintiffs' action on May 5, 2008. The court granted the agency's motion to dismiss and vacate the injunction on the grounds that the plaintiffs lacked standing because they could not show that they had suffered an injury that was likely to be redressed by a favorable decision and because the plaintiffs "*overstate[d] their case*", reasoning that the *Anti-Markup Rule* is merely a limit on Medicare reimbursement, and not a termination of participation.[1] Further, any challenge to the *Anti-Markup Rule* itself (as opposed to this challenge against the *Delay Rule*) by Medicare participants should be addressed through the administrative process before going to the courts.

Part of the reason HHS carved out the exception for pathology services performed in a "*centralized building*" is due to its growing concern over *"pod laboratories"*, which were defined by the judge in this case as *"a centralized collection of numerous small laboratories that are housed in adjacent cubicles (the 'pods') in a building subdivided and leased to several unrelated medical practices…[E]quipment in each pod is separately owned by each physician group practice that refers specimens to the centralized location. A single pathologist and staff then rotate among the various pods, performing pathology services which in each pod on the patient specimens referred by the physician group that owns the medical equipment."*[1] *Pod laboratories* were a response to the promulgation of the Stark self-referral laws which provide an exception for a physician practice that directly performs its own clinical laboratory services as part of its group practice. In essence, *pod laboratories* are an attempt by physician

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practices to fit into this Stark exception while still having a separate pathologist perform the testing. With this most recent decision on the challenges to HHS' *Anti-Markup rules*, pod laboratories may no longer be as appealing now that the billing physician has no control over what prices may be charged for the services provided.

However, just as all of these issues appeared to have been decided, CMS issued another proposed rule on June 30, 2008, in which it explores two alternatives to the original *Anti-Markup Rule* provisions promulgated in 2007. The first alternative, tests and services performed in a centralized building (or the same building, as defined under Stark law) would not be subject to *Anti-Markup Rule* provisions if they were performed by a physician who "*shares a practice*" with the billing physician or physician organization. However, if the physician performing the test provides services to more than one physician or physician organization, that physician would then not fall into the "*shares a practice*" exception. The second alternative proposes three amendments to the definition of the term "*office of the billing physician or other supplier*", whereby the definition would include: (1) space located in the "*same building*" in which the billing physician or other supplier regularly provides patient care; (2) more than one location where a physician regularly furnishes patient care; or (3) the office where the *ordering* physician provides most of his or her services in the context of a physician organization. Under the second alternative, the Anti-Markup Rule would apply to the technical component services conducted or supervised outside the office of the billing physician, and the technical component would not be purchased from an outside supplier if the technical component if it is supervised by someone in the office of the billing physician. The new proposed rule, with the new alternatives, is open for comment starting July 7, 2008 through August 29, 2008.

[1] "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Delay of the Date of Applicability of the Revised Anti-Markup Provisions for Certain Services Furnished in Certain Locations," Volume 73 Fed. Reg. 404 (Jan. 3, 2008).

[3] "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Delay of the Date of Applicability of the Revised Anti-Markup Provisions for Certain Services Furnished in Certain Locations," Volume 73 Fed. Reg. 404 (Jan. 3, 2008).

[3] "Court dismisses Urologists' Challenge to Anti-Markup Rule and Vacates Injunction," Sonnenschein, Nath, & Rosenthal, LLP, Health Care E-Alert, May 8, 2008, http://www.sonnenschein.com/practice_areas/healthcare2/pub_detail.aspx?id=44933&type=E-Alerts (accessed 6/16/2008).

[5] Atlanta Urological Associates, P.A., et al. v. Leavitt, Memorandum Opinion, Civil Action No. 08-141 (RMC), p. 8 (D.D.C. March 31, 2008).

[6] Atlanta Urological Associates, P.A., et al. v. Leavitt, Memorandum Opinion, Civil Action No. 08-141 (RMC), p. 13, 18 (D.D.C. May 5, 2008).

[7] Atlanta Urological Associates, P.A., et al. v. Leavitt, Memorandum Opinion, Civil Action No. 08-141 (RMC), p. 3-4, 18 (D.D.C. May 5, 2008).

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