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CMS Issues Final Anti-Markup Rule for Diagnostic Tests

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Background

On October 30, 2008, CMS issued the final anti-markup rule for diagnostic tests, after one year of uncertainty on the scope and application of the rule.

Historically, the "anti-markup rule" applied to the technical component (TC) of diagnostic tests that were ordered and billed by a physician, but purchased from another physician. The billing physician could not mark up the purchased test, which meant that the Medicare payment could not exceed the performing physician's net charge, the billing physician's actual charge, or the fee schedule amount — whichever was lowest. The term "net charge" was not defined.

In November 2007, to curb alleged abusive arrangements and overutilization, CMS expanded the anti-markup rule to apply when the TC was not performed in the office of the billing physician. CMS also extended the anti-markup payment limitation to the professional component (PC) of diagnostic tests ordered by a billing physician if the PC was purchased or not performed in the office of the billing physician. In addition, CMS defined “net charge.” The rule created considerable confusion, and CMS postponed its effective date except in the case of anatomic pathology tests performed in a group practice’s “centralized building” (as defined under the Stark law). In the interim, CMS sought to clarify the rule.

Final Rule

Under the final rule, if a physician (or other supplier) orders and bills for the TC or PC of a diagnostic test, and the diagnostic test is performed by a physician (or other supplier) who does not share a practice with the billing physician, the billing physician may not mark-up the TC or PC of the diagnostic test. This means that the billing physician (or other supplier) must bill Medicare the lowest of the following three amounts: (a) the performing physician's (or supplier’s) net charge; (b) the billing physician's (or other supplier’s) actual charge; or (c) the Medicare fee schedule amount. "Net charge" may not take into account the cost of equipment or space that the billing physician (or supplier) leases to the performing physician (or supplier). The anti-markup payment limitation also

applies if the diagnostic test is ordered by a party that is related to the billing physician through common ownership or control. For simplicity, we refer to "physicians and other suppliers" as "physicians" below.

A performing physician is deemed to "share a practice" with the billing physician — and the anti-markup payment limitation does not apply — if either of the following two approaches is satisfied:

(1) ***Substantially All Approach***. The performing physician furnishes substantially all (at least 75%) of his or her professional services to the billing physician (or his or her group practice). This approach is satisfied if at the time the billing physician (or practice) submits a claim for a service furnished by the performing physician, the billing physician (or practice) has a reasonable belief that (A) the performing physician has furnished at least 75% of his or her professional services to the billing physician (or practice) during the previous 12 months (including the current month), or (B) that the performing physician will furnish at least 75% of his or her professional services to the billing physician (or practice) for the next 12 months (including the current month). The performing physician may be an employee or independent contractor of the billing physician, as long at the 75% standard is met.

For example, if a physician group practice contracts with a radiologist to supervise and perform the professional interpretation of radiology procedures, the anti-markup payment limitation would not apply as long as the radiologist does not furnish more than 25% of his or her professional services elsewhere. If this approach is satisfied, any diagnostic tests that are billed by the group practice and furnished by the radiologist are exempt from the anti-markup payment limitation.

(2) ***Site of Service Approach.*** The performing physician is an owner, employee, or independent contractor of the billing physician practice, and the TC or PC is performed in the office of the billing physician (or group practice). The "office of the billing physician" is any medical office space where the ordering physician regularly furnishes patient care and includes space where the billing physician (or group practice) furnishes diagnostic testing if the diagnostic testing space is located in the same building where the ordering physician regularly furnishes patient care.

For physician solo or group practices, the "office of the billing physician" is space where the ordering physician provides substantially the full range of patient care services that he or she generally provides. The "performance" of the TC means both the conducting of the test and supervision of the test. The Site of Service approach is applied on a test-by-test basis — each diagnostic test must satisfy the requirements or the anti-markup payment limitation would apply. Note that this is not the same as the "same building" standard under the Stark law's prohibition on self-referrals. To take advantage of this Site of Service approach, the ordering physician (and not just a member of his or her group practice) must actually provide substantially the full range of patient care services in the same building as the performing physician.

Examples of how the Site of Service approach applies follow:

- *Example #1:* If a physician practice owns and operates a medical office ("Office A") and a pathology lab, both of which are located in the same building, a physician employee (or owner or independent contractor) of the practice who offices in Office A (and provides the full range of patient care services in Office A) may order a pathology test (and the physician practice may bill for the test) without application of the anti-markup payment limitation because the pathology lab is located in the same

building.

- *Example #2:* On the other hand, if the same physician practice has another medical office located 5 miles away ("Office B") and a physician employee (or owner or independent contractor) in Office B orders a pathology test to be performed by the pathologist in Office A, the test would be subject to the anti-markup payment limitation because the ordering physician does not regularly furnish patient care in the same building where the pathology lab is located. Thus, even though a group practice may refer patients and bill Medicare for diagnostic tests furnished in a "centralized building" under the Stark law or in the "same building" where only some of the group's physicians practice, the anti-markup rule may selectively apply to tests ordered by some physicians in the group practice depending on the location of the physician's office. CMS is aware of the impact that the rule will have on multi-site physician practices, but has commented that physician practices can avail themselves of the Substantially All approach if the Site of Service approach cannot be satisfied.

When analyzing arrangements for compliance with the final anti-markup rule, physicians and suppliers also must be aware of and comply with other applicable laws, regulations and standards. These include the Stark law, the federal anti-kickback law, and Medicare's physician supervision requirements, among others.

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