

November 13, 2007

## **Impact of the Anti-Markup Rule and IDTF Performance Standards Changes in the 2008 Physician Fee Schedule**

The 2008 Medicare Physician Fee Schedule, released November 1, 2007 and scheduled to be published in the Federal Register on November 27, 2007, contains a number of significant developments. This Health Care Alert focuses on two areas of particular relevance to imaging arrangements: (1) an expanded prohibition on “marking up” diagnostic tests (the “Anti-markup Rule”) and (2) changes in the performance standards for independent diagnostic testing facilities (“IDTFs”).

Because the new rules are generally effective January 1, 2008, health care providers should promptly review arrangements involving diagnostic services to determine whether they should be restructured to minimize the impact of these rules. Affected arrangements may include space leases, equipment leases, and arrangements for the services of physicians providing professional interpretations and/or of technicians.

Providers should also be mindful of the December 4, 2007 effective date of the Stark Law Phase III Rule. To ensure continuing compliance, providers will need to promptly review, and restructure if necessary, arrangements including the following:

Arrangements with physician groups, which will need to meet the requirements of a direct exception due to the new “stand in the shoes” attribution rule (prior to Phase III, such arrangements were treated as indirect and subject to less restrictive requirements).

- Arrangements whereby physician groups purchase items or services from hospitals and other designated health services providers. In general, these arrangements must now be structured to comply with the “fair market value” exception, which requires a written agreement meeting specified requirements. Prior to Phase III, such arrangements could meet the more lenient requirements of the “payments by a physician” exception.
- Office sharing arrangements, which will be evaluated under more restrictive rules regarding what can be treated as common areas.
- Physician recruitment agreements with physicians who did not relocate from outside the service area (other than residents) or who had medical staff privileges in any category when recruited.
- Group practice allocation formulas for net profits.

The definition of a physician practice will include tax-exempt hospital affiliates that are primarily operated as physician practices. However, on November 9, the Centers for Medicare & Medicaid Services announced that application of the rule to certain compensation arrangements involving physician organizations and academic medical centers or integrated tax-exempt health care systems will be deferred until December 4, 2008.

### **Anti-markup Rule**

Effective January 1, 2008, the Anti-markup Rule applies to both the technical component (“TC”) and the professional component (“PC”) of diagnostic tests covered under §1861(s)(3) of the Social Security Act (the “SSA”) (other than certain clinical laboratory tests) that are ordered by the billing physician or other supplier (or ordered by a party related by common ownership or control to such billing supplier) if the TC or PC is either (a)

purchased outright or (b) performed at a site other than the office of the billing physician or other supplier (the “Location Requirement”). The Anti-markup Rule does not apply if a billing physician did not order the test. The new rule is an expansion of an existing anti-markup rule applicable to purchases of the TC of diagnostic tests by a physician or a physician practice. Although CMS had proposed in July, 2007, basing the Anti-markup Rule on whether the technician performing the service was a full-time employee, part-time employee or independent contractor, the 2008 Physician Fee Schedule does not adopt that approach.

Under the Anti-markup Rule, payment to the billing entity will be limited to the lowest of (a) the performing physician’s or other supplier’s “net charge” to the billing entity, (b) the billing entity’s actual charge or (c) the fee schedule amount for the service that would be allowed if the physician or other supplier performing the service billed directly. The billing supplier has the responsibility for calculating the net charge for a test and must calculate the net charge in a reasonable manner.

The 2008 Physician Fee Schedule also revises the Stark Law definition of “entity” to exclude any physician’s practice when it bills Medicare for the TC or the PC of a diagnostic test for which the Anti-markup Rule is applicable under §414.50.

### **Tests to Which Anti-markup Rule Applies**

The Anti-markup Rule is not limited to tests that are designated health services for Stark Law purposes. It can apply to any diagnostic test covered under §1861(s)(3) of the SSA (other than clinical diagnostic laboratory tests paid under section 1833(a)(2)(D) of the SSA, which are subject to special billing rules set forth in section 1833(h)(5)(A) of the SSA). Tests subject to the Anti-markup Rule include diagnostic X-ray tests, diagnostic laboratory tests (other than the clinical laboratory tests noted above), and other diagnostic tests, including but not limited to diagnostic radiology, nuclear medicine, ultrasound, transcatheter procedures, transluminal atherectomy, cardiography, echocardiography, diagnostic cardiac catheterization, vascular studies, pulmonary tests, allergy tests, sleep lab tests, and audiologic function tests. (For a complete list please see CMS Memorandum B-01-28.)

### **Location Requirement**

The Location Requirement is new and may significantly impact the ability of physician practices and other suppliers to profit from diagnostic tests, depending on how strictly the phrase “office of the billing physician or other supplier” (meaning medical office space where the supplier “regularly furnishes patient care”) is interpreted. For physician organizations,<sup>1</sup> the phrase is defined as space in which the physician organization provides substantially the full range of patient care services that the physician organization provides generally. Thus, physician groups that provide diagnostic services at “centralized locations” outside their offices and not used to provide substantially the full range of patient care services will no longer be able to mark up those tests.

We understand that CMS is engaged in internal discussions as to how this term should be interpreted and may be providing further guidance.

### **Effect on Block Lease Arrangements**

Whether space being leased to a physician group on a blocked time basis will constitute an office of the physician group will depend on the configuration of the space, the types of services offered by the physician group, the types of services offered by the physician group in the block lease space and possibly the proximity of the space in relation to other offices of the group practice. Unless the leased space is in the “office of the billing physician or other supplier”, the Anti-markup Rule will apply.

<sup>1</sup> The term *physician organization* is defined as a physician (including a professional corporation of which the physician is the sole member), a physician practice or a group practice.

## Examples of Arrangements Impacted By the Anti-markup Rule

- Diagnostic testing block lease arrangements. A physician group enters into a block lease with a leasing organization under which it leases space and equipment in four-hour time blocks. The space is located in the same building as the group's office, but is not part of the group's office. The group employs a part-time technician to assist the group during its time block and pays the technician on an hourly basis. Unless the leased space is used by the group to perform substantially the same full range of patient care services that the group generally provides, any diagnostic testing ordered by the group's physicians will be subject to the Anti-markup Rule.
- Cath lab block lease arrangements. A cardiology group enters into a block lease with a leasing organization pursuant to which, during four-hour blocks of time, the leasing organization provides the space, equipment and personnel necessary to own and operate a cath lab. The cardiology group's physicians use the cath lab, which is not part of the group's office, to perform diagnostic cardiac catheters ordered by the physicians, and the cardiology group bills for these services. Unless the leased space is used by the group to perform substantially the same full range of patient care services that the group generally provides, the cath lab services will be subject to the Anti-markup Rule.
- Diagnostic testing facility in a "centralized building". A group practice maintains its diagnostic testing facilities in a "centralized building." The "centralized building" will not constitute "the office of the billing group practice", and accordingly the Anti-markup Rule will apply.
- Group practice – radiologist arrangement. A group practice enters into an independent contractor arrangement with a radiologist whereby the radiologist performs diagnostic test interpretations for a per-interpretation payment. The radiologist reassigns his or her right to bill for the interpretations to the group practice, which bills globally.
  - If the radiologist performs these interpretations in space that is considered to be "the office of the billing group practice," then the Anti-markup Rule will not apply.
  - If the radiologist performs these interpretations in space that is not considered to be "the office of the billing group practice," then the Anti-markup Rule applies to the interpretation. (Prior to the effective date of the Anti-markup Rule, the group practice is not allowed to bill for interpretations not performed on the group practice's premises.)
- IDTF – radiologist arrangement. An IDTF enters into an independent contractor arrangement with a radiologist whereby the radiologist performs diagnostic test interpretations for the IDTF for a per-interpretation payment. The radiologist reassigns his or her right to bill for the interpretation to the IDTF, which bills globally. If a group practice orders a test from the IDTF, the IDTF will not be subject to the Anti-markup Rule for either the TC or the PC of the test because the IDTF did not order the test.

## Sharing Restriction in New IDTF Performance Standards

The Physician Fee Schedule also contained a number of changes to the performance standards for IDTFs. Among these is a restriction on the sharing of space and equipment. CMS modified its July, 2007 IDTF performance standards proposals, which would have also prohibited shared staffing.

Under the finalized proposal, a fixed-based IDTF may not share a practice location with another Medicare-enrolled individual or organization, lease or sublease its operations or its practice location to another Medicare-enrolled individual or organization or share diagnostic testing equipment used in the initial diagnostic test with another Medicare-enrolled individual or organization. However, the sharing prohibition does not apply to IDTFs within hospitals or to mobile IDTFs.

CMS provides a one year transitional period for those IDTFs currently sharing a practice location with another Medicare-enrolled individual or organization. However, the transitional period does not apply to the sharing of diagnostic testing equipment.

The sharing provision does not prohibit the sharing of common areas (including hallways, waiting areas, parking lots and other common areas) or of nonclinical space and equipment.

The sharing prohibition will prevent a number of common arrangements, including:

- Arrangements whereby a physician practice leases a block of time from an imaging provider (such as an IDTF) or agrees to pay the provider a per-service fee to use its facility; and
- Arrangements where an IDTF that is not located within a hospital provides some services “under arrangements” to a hospital.

The prohibition is also likely to adversely impact non-radiologist physician clinics that provide a substantial volume of tests to patients of other physicians. Physician clinics that provide more than 30% of their tests to persons who are not their patients are supposed to do so as IDTFs. In order for this to be feasible, such clinics will generally need to provide all of their tests in their capacity as IDTFs and to do so in separate space.

CMS states that the sharing prohibition does not prohibit wholly-owned corporate subsidiaries and affiliated entities under common control from sharing equipment as long as the change in equipment location is timely reported and the IDTF’s practice location is separately distinguishable and not commingled with another Medicare provider or supplier. However, the regulatory language of the IDTF rules does not appear to allow such a sharing arrangement.

### **Additional Information**

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