In last year’s Medicare Physician Fee Schedule (MPFS) proposed rule, CMS described its concerns for the potential for fraud, waste and abuse of the Medicare program that may be caused by the growth of so-called “pod” or “condo” laboratories. “Pod” laboratories are laboratories that are located off-site from a physician’s office (sometimes even in another state) and operated entirely by an independent contractor physician pursuant to a reassignment arrangement for the purpose of performing pathology studies that will be billed globally by the ordering physician’s office. Typically the physician’s office pays the pod laboratory a fixed fee for a diagnostic test that is less than the global fee the physician is able to collect from the Medicare program when he/she bills for the test. Last year, CMS had proposed to amend its reassignment rules to include a new provision to attempt to take the profit from the arrangements. CMS decided to not act on last year’s proposals, but in this year’s MPFS rules, CMS has acted—and decisively so. The agency’s new rules affect pod labs, but also will have a significant impact on many imaging arrangements involving referring physicians.

The final rule effectively bars any IDTF from having part-time lease arrangements with referring physicians, and the new anti-markup rules may cause many deals to cease since CMS has removed any profit opportunity from even those lease agreements that meet the in-office ancillary services exception to Stark, unless the imaging service is performed on the premises of the physician’s group office.
where they provide the full range of their services.

**The IDTF Anti-Sharing Ban**
Fixed IDTFs that are located somewhere other than in a hospital building will be precluded from subleasing the IDTF’s office space or equipment to a referring physician practice to, even if the physician practice has an office in the same building as the imaging center. Recognizing that this new standard would require IDTFs currently engaged in a space sharing arrangement with physician groups to restructure those arrangements, CMS has delayed the implementation date for unwinding such space sharing arrangements for existing IDTFs until January 1, 2009, in order to provide IDTFs a full year to restructure. But any sublease agreement is barred after January 1, 2008.

**Anti-Markup Rule**
Under Medicare’s long-standing “purchased diagnostic test” rule, also referred to as the “anti-markup” rule, if a physician bills Medicare for the technical component of a diagnostic test performed by an outside supplier, the physician is prohibited from “marking up” the charges submitted to Medicare for the technical component services above what the physician paid to purchase the test from the outside supplier. But the anti-markup rule has had limited application and has not deterred many part-time, turn-key leasing arrangements. Nor has the existing rule applied to billings submitted for the professional component services.

CMS has expanded the anti-markup rule by: 1) applying the prohibition on marking up charges to professional component services and 2) clarifying that the anti-markup provisions apply to any technical or professional component the “ordering” physician either: i) obtains from an “outside supplier,” regardless of whether the component is obtained as a “purchased test” or via reassignment from the outside supplier or ii) the test is performed outside the physician group’s “office.” The “office of the billing physician” is defined as “the medical office space where the physician or other supplier regularly furnishes patient care.”

If the professional or technical component of a test is “performed at a site other than the office of the billing physician or supplier,” it will be subject to anti-markup prohibition. Thus, for example, if an orthopedic group has a full time office in the same building as a radiology group’s imaging center, and leased space, equipment, and personnel from the imaging center, the arrangement could permit no Medicare profits since it would be subject to the anti-markup rule, even when such lease qualifies under the same building requirements of the Stark in-office ancillary services exception—a major blow to most part-time leasing arrangements.
Proposed Stark Regulations
CMS declined to adopt as final the bulk of the other significant and controversial changes to the Stark rules it set forth in the proposed rule. CMS reported that it received approximately 1,100 comments in response to the proposed Stark changes. CMS apparently decided that, given the significance of the proposal and the volume of public comments it received, it was not prudent to finalize any of the other proposed changes to the Stark regulations. CMS noted, however, that because it received sufficient information both from the commenters and CMS's own independent research, CMS intends to finalize revisions to the Stark regulations without requesting or providing any additional public comment period.

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