

CMS Continues Regulatory Crackdown on Self-Referral of Diagnostic Imaging Services

On July 7, 2008, CMS released its Proposed Medicare Physician Fee Schedule for Calendar Year 2009. Continuing a trend started with the Proposed MPFS for 2008, CMS included in the 2009 proposed fee schedule a number of proposed changes to the regulations that control the manner in which Medicare pays for diagnostic imaging services.

In particular, CMS proposed revisions to both the performance standards for Independent Diagnostic Testing Facilities (“IDTFs”) (42 C.F.R. §410.33) and the Anti Mark-Up Rule (42 C.F.R. §414.50) that could result in further limitations on the ability of physicians and medical groups to refer patients in need of diagnostic imaging services to diagnostic imaging facilities they own.

Mandatory IDTF Enrollment Will End Shared Diagnostic Imaging Facilities

CMS proposes to amend the performance standards for IDTFs to require each physician or medical group that furnishes diagnostic testing services (excluding diagnostic mammography services) to enroll as an IDTF for each practice location furnishing such services. As an IDTF, each such physician or medical group will be subject to the IDTF performance standards (with a couple of exceptions).

Most notable among these standards is a prohibition on an IDTF sharing, leasing, or subleasing its operation, practice location, and/or equipment with another Medicare-enrolled individual or organization. Thus, an IDTF must be the sole Medicare-enrolled individual or organization that uses its operations, practice location, and/or equipment.

If finalized, this change to the IDTF performance standards will effectively end the ability of physicians and medical groups to maintain and utilize a diagnostic imaging facility that is shared with other physicians and medical groups (a “Shared Facility”). This prohibition would apply even if the facility is located in the same building as their primary practice locations.

CMS is proposing that this revision to the IDTF performance standards become effective September 30, 2009.

CMS’ Indecision Thwarts Health Care Industry Preparations as Anti Mark-Up Rule Effective Date Looms

In the 2008 Medicare Physician Fee Schedule, CMS expanded the Purchased Diagnostic Test Rule (the “PDT Rule”) in two (2) significant ways. First, CMS expanded the PDT Rule to apply to both the technical component of a diagnostic test and the professional component of a diagnostic test.

Second, CMS expanded the PDT Rule to cover both (a) the technical component or professional component of a diagnostic test that is purchased by the billing physician or medical group from an outside supplier (referred to in the rule as the “Outside Supplier”), and (b) the technical component or professional component of a diagnostic test that is performed by the billing physician or medical group at a location other than the office where the billing physician or medical group regularly furnishes the full range of patient care services that the billing physician or medical group provides generally (identified in the rule as the “Office of the Billing Physician or Other Supplier”). As expanded, the PDT Rule is now known as the Anti Mark-Up Rule (the “Anti Mark-Up Rule”).

CMS had intended that the Anti Mark-Up Rule go into effect on January 1, 2008. Due to concerns expressed by the health care industry regarding the types of arrangements that would be subject to the Anti Mark-Up Rule, the impact the Anti Mark-Up Rule would have on patient access to diagnostic tests and the fact the full Anti Mark-Up Rule was only released to the health care industry

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35 days before its intended implementation date, CMS announced that it would delay the implementation of the Anti Mark-Up Rule until January 1, 2009.

During this time period, CMS stated that it would issue clarifying guidance regarding the types of arrangements that would be subject to the Anti Mark-Up Rule. In particular, it was thought that CMS would provide a clearer definition of the terms “Outside Supplier” and “Office of the Billing Physician or Other Supplier.” It was also hoped that CMS would provide a narrower definition of “Outside Supplier” and a broader definition of “Office of the Billing Physician or Other Supplier,” in each case to allow greater flexibility for physicians and medical groups to provide diagnostic tests as a part of their practices.

Unfortunately, despite the intervening six (6) months, CMS seems no closer to meeting these goals/hopes than it was on January 1, 2008. In the 2009 proposed fee schedule, CMS attempts to clarify its intentions regarding the Anti Mark-Up Rule. As the discussion in the 2009 fee schedule reflects, CMS is still not clear on how to do so.

For example, instead of offering a clearer definition of the term “Outside Supplier,” CMS discusses three (3) alternative definitions it is currently considering. Worse still, each of these definitions conflicts in some significant manner with other definitions being considered. Thus, to the frustration of healthcare providers and the attorneys who advise them, there is no way to anticipate how CMS will eventually elect to define this term.

Further, instead of offering a clearer definition of the term “Office of the Billing Physician or Other Supplier,” CMS offers two (2) alternative approaches to this aspect of the Anti Mark-Up Rule. In the first alternative, CMS proposes to scrap the concept of the “Office of the Billing Physician or Other Supplier” in favor of a concept focused on the nature/structure of the contractual arrangement between the billing physician or medical group and the performing physician or medical group.

In the second alternative, CMS retains the “Office of the Billing Physician or Other Supplier” concept and provides some clarification regarding the meaning of that term. At the same time, CMS admits that further clarifications of the term are necessary and seeks input from the health care industry on such clarifications.

Although it is clear from the 2009 proposed fee schedule that CMS is trying to provide clearer guidance on the Anti Mark-Up Rule, it is equally clear that CMS has not yet decided how best to do so. Further, the health care industry is now less than six (6) months from the proposed implementation date of the Anti Mark-Up Rule.

If the 2008 fee schedule is any indication, it is likely that CMS will not release the final MPFS for 2009 until mid to late November. Thus, it is likely that the health care industry will have less than sixty (60) days to prepare for the impact of the Anti Mark-Up Rule before it goes into effect on January 1, 2009. Needless to say, this is not sufficient time for the health care industry to make the changes that may be necessitated by the final version of the Anti Mark-Up Rule.

The 2009 proposed fee schedule remains open for public comment until August 29, 2008. If you desire additional information concerning the proposed rule or assistance in preparing comments for submission to CMS, please contact your Lathrop & Gage attorney or any of the following members of our Health Law Department.

**If you have questions about this Legal Alert, please contact your
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