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CMS Goes After Self-Referral with a Focus on Diagnostic Tests

On July 2, 2007, the Centers for Medicare & Medicaid Services issued the proposed 2008 Medicare Physician Fee Schedule ("MPFS"). As usual, a vast majority of the proposed rules pertain to changes in the MPFS that will go into effect January 1, 2008. But in what has also become a recent trend, CMS took the opportunity to issue other Medicare-related proposals. In particular, the agency proposes significant rule changes to the Stark Law self-referral prohibition and to standards and rules that apply to independent diagnostic testing facilities (so-called "IDTFs"). In addition, CMS proposes a new "anti-markup" rule for the professional component (the so-called "PC") and the technical component (the so-called "TC") of most diagnostic tests.

The agency's stated rationale behind proposing many of these changes (consistent with some of its recent pronouncements) is to eliminate certain types of relationships that have developed over the years which are viewed by CMS as creating incentives to overutilize or as skirting the intent of the Stark Law (albeit in ways that are legal under current rules).

In summary, the most significant changes (and some open questions) are as follows:

Under Arrangement and Shared Service/Infrastructure Deals May be Non-Viable

CMS proposes to eliminate "under arrangement" and other "turn-key" deals by changing the definition of a DHS "entity," which currently is limited to the person or entity that bills Medicare for the DHS, to instead be the person or entity that "performs" the DHS as well as the person or entity that submits or causes claims to be submitted to Medicare for DHS. If this proposal stands, then the typical under arrangement deal, in which a hospital and referring physicians create a joint venture to provide hospital outpatient services under arrangement for the hospital, will no longer be viable.

Likewise, shared service/infrastructure ventures, in which referring physicians (and sometimes non-referring physicians like radiologists) create a joint venture to make infrastructure available on a turn-key basis to the referring physicians' groups for them to provide DHS on an in-office basis, also will no longer be viable.

The critical issue for each of these types of deals will be whether they are "performing" the DHS. CMS provided virtually no guidance on this issue. However, in the typical deal, in which the venture provides a turn-key solution to the hospital or the referring physicians' groups, it is likely that CMS will consider the venture to have performed the DHS, thereby creating a Stark Law violation if any physicians with direct or indirect ownership interests refer for the DHS.

"Per Click" Payments to Referring Physician Lessor No Longer Within Lease Exceptions

CMS proposes to modify the space and equipment lease exceptions under the Stark Law to prohibit the use of per unit of service rental payments when the lessor is the referring physician.

An open question is whether a per unit payment that is not made directly to the referring physician, but is instead made to an entity in which the physician is an owner (such as a physician group or an asset holding company), will be barred under the lease exceptions. CMS has also requested comments on whether it should bar per unit leasing arrangements when the referring physician is a lessee.

Percentage-Based Compensation No Longer Qualifies as “Set in Advance”

In a reversal of the de facto position it has taken for the past several years, CMS now says that percentage-based compensation, other than compensation based on revenues directly resulting from personally performed physician services, will no longer be considered to be “set in advance” for purposes of any Stark Law exceptions that contain the set in advance requirement. This is a key change for the space and equipment lease exceptions, as well as for the personal services exception and the fair market value exception (for the provision of items and services by physicians).

IDTFs Can No Longer “Share” Space, Equipment or Staff or Sublease Their Operations

In a reprise of the Program Integrity Manual changes that CMS issued (then withdrew) earlier this year, the agency proposes a new, 15th performance standard that states that an IDTF may not “share space, equipment, or staff or sublease its operations to another individual or organization.”

This proposed change means that a common model involving diagnostic imaging is non-viable, *i.e.*, an arrangement involving a per click turn-key lease from an IDTF to a physician group for the group to provide diagnostic imaging to its patients who are not beneficiaries of Medicare or other governmental programs. However, there are some unresolved questions. First and foremost, what does “share” mean in the eyes of CMS? Would a fixed schedule, fixed rental payment lease arrangement that satisfied all of the elements of the lease safe harbors under the Anti-Kickback Statute still constitute a sharing? If an IDTF leases the staff it uses, will that constitute a sharing? What if the leased employees spend 100% of their time working for the IDTF?

PC and TC of Diagnostic Tests Cannot be Marked-Up

Under a proposed change to the re-assignment rules, if a physician or physician group bills for the professional component (the so-called “PC”) or the technical component (the so-called “TC”) of most diagnostic tests, then the billing physician or group would not be able to mark up what they paid for the PC or the TC when they make claim to Medicare (unless the service was provided by a full-time employee of the billing physician or group).

This change was designed to eliminate financial incentives for self-referral. However, it could cause significant problems for certain specialties such as radiology. For example, if a radiology group accepts assignment from a part-time employed radiologist, and pays the person a per diem, how should the radiology group calculate the per procedure amount the radiology group is paying in order to assure compliance with the proposed anti-markup rules? Indeed, why should a radiology group even be subject to this new rule given that radiologists generally don’t refer?

Effective Date

Comments on the proposed rules are due on August 31, 2007. Unless delayed, the rules described above would likely go into effect on January 1, 2008.

Given the potential financial hardship that some of these rules may impose on segments of the health care industry, CMS may consider delaying the effective date. However, beware of counting on any delay. CMS did not mention any sort of “grandfathering” or other delay in its discussion of the new rules. Also, it is clear that CMS believes these changes are necessary to curb potential abuses, particular in diagnostic tests, so the agency may not be very receptive to comments advocating delays.

For Additional Information

Please contact one of the following Katten Muchin Rosenman LLP attorneys or your relationship partner if you would like to discuss the impact of the proposed 2008 Medicare Physician Fee Schedule.

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