January 14, 2008

CMS Announces One Year Delay for Portions of Anti-Markup Rule

Background

The final 2008 Medicare Physician Fee Schedule (the “Final MPFS”), which was published in the *Federal Register* on November 27, 2007 and is generally effective with respect to services provided on or after January 1, 2008, contained broad-sweeping changes to the anti-markup provisions in 42 CFR §414.50. As passed, the Final MPFS would prohibit mark-ups on diagnostic tests that are (i) purchased from an outside supplier, or (ii) performed at a site other than the “office of the billing physician or other supplier,” which the Centers for Medicare and Medicaid Services (“CMS”) defined to mean the medical office space where the physician or other supplier provides substantially the full range of their services.

The Delay

On Friday December 28, 2007, CMS issued a final rule which serves to delay, until January 1, 2009, the applicability of the anti-markup provisions in §414.50, except with respect to:

1. The technical component of a purchased diagnostic test; and

2. Any anatomic pathology diagnostic testing services furnished in space that:
   
   (i) Is utilized by a physician group practice as a “centralized building”; and

   (ii) Does not qualify as a “same building” (as such terms are defined under the Stark Law).

CMS stated that it was implementing the delay out of concern that “the definition of ‘office of the billing physician or other supplier’ may not be entirely clear and could have unintentional consequences,” such as significantly disrupting patient access for common diagnostic tests. CMS explained further that it was not delaying the effect of the revisions (i) with respect the technical component of purchased diagnostic tests, because the anti-markup prohibition for that component has already existed for a long time, and (ii) with respect to anatomic pathology diagnostic testing services furnished in a centralized building that is not a same building, because arrangements involving such services “precipitated [its] proposal for revision of the anti-markup rule and remain [its] core concern.”
CMS’ primary concern is with the perceived abuse of pod lab type arrangements under Medicare. Pod labs must meet the definition of a “centralized building” to be compliant with the Stark Law, but because they are located off-site, they do not meet the definition of “same building,” and thus are subject to the revised anti-markup rule. In-office laboratories, on the other hand, are of less concern to CMS and, because they generally meet the definition of the “same building,” are not subject to the anti-markup rule, at least for the time being.

**Action Steps**

CMS’ action provides a welcome delay for many physician organizations and offers CMS the opportunity to provide much needed clarification regarding the intent and impact of its definition of “office of the billing physician or other supplier.” Physician organizations that currently bill for anatomic pathology diagnostic testing services, however, must examine whether such services are being furnished in a centralized building that does not qualify as a same building. If so, the revisions to the anti-markup provision contained in the Final MPFS apply immediately and may necessitate restructuring such arrangements. For assistance in determining how the revised anti-markup provisions may affect your organization, please contact any member of the Honigman Health Care Department listed below.

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