

Nuclear Medicine, Including PETT Scans, Included in Stark Self-Referral Prohibition

By Marguerite Massett



The Centers for Medicare and Medicaid Services (CMS) has reversed its long-standing position that diagnostic and therapeutic nuclear medicine is not subject to the “Stark” self-referral prohibition, and is giving physicians one year to terminate or revise business ventures that afford physicians an opportunity to refer patients to facilities in which they have a financial interest. The pronouncement, appearing in the Final Rule implementing the FY 2006 Physician Fee Schedule (*Federal Register* Vol. 70, No. 223, November 21, 2005, pages 70283-70289), may cause the dismantling, or at least restructuring, of physician investment ventures and leasing arrangements, which had been touted by some consultants as a legally defensible method for referring physicians to take advantage of the CMS exclusion of nuclear medicine from the broad federal self-referral prohibition. This about-face has sent shockwaves through the physician community, not only for its substantive content, but also because it highlights that CMS can and will reverse long-standing guidance if it determines that arrangements crafted specifically — and lucratively — to exploit loopholes caused by previous regulatory directives pose a risk of abuse (that is, over utilization of services based on financial incentives). In commentary that accompanied both the proposed rule last August (*Federal Register*, Vol. 70, No. 151, pages 45854–45856) and the recent final rule, CMS cited a variety of factors that led to its decision. CMS noted that consultants had actively marketed joint ventures involving nuclear medicine as a way for physicians to capture a portion of the revenue associated with patients they refer for nuclear medicine services. In addition, CMS referred to data indicating that there had been a substantial increase in nonhospital-based nuclear medicine service sites owned by physicians, accompanied by an 85 percent increase in the number of, and revenue generated by, such services between 1999 and 2003. Citing studies from the early 1990s, showing that referrals for other radiology services were cut in half after physicians were precluded from holding financial interests in testing facilities, CMS stated that it believes a similar drop in “over-utilization” of nuclear medicine services will result from its new position. In response to an outcry of criticism, CMS has announced that it will delay the effective date for the new prohibition until January 1, 2007, to permit physicians and others to restructure, divest or dissolve ownership and investment arrangements to comply with the new rules. Participants in affected arrangements can look to other Stark exceptions, such as the in-office ancillary services exception and the rural provider exception, as possibilities for bringing ventures

into compliance with the applicable law. However, over the last year, other guidance has been issued regarding various Stark exceptions, and any restructuring plan must be crafted carefully to be consistent with such new guidance.

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