The Continued Relevance of the Stark Law's IOASE: In-Office Imaging Arrangements Remain Viable

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Recent legislative initiatives to restrict (or eliminate) the Stark Law's In-Office Ancillary Services Exception (IOASE) are by no means a new phenomenon. Rather, over the last few years, the Centers for Medicare and Medicaid Services (CMS) has introduced several significant proposals targeting the provision of diagnostic imaging (and other ancillary services) in the physician office setting, through proposed changes to the Stark regulations, independent diagnostic testing facility (IDTF) regulations, and other Medicare reimbursement regulations (such as the Medicare Anti-Markup Rule [AMR]). Despite these proposals, however, the IOASE remains intact and the prospect of a near-term wholesale elimination of the IOASE appears remote. This article provides a brief overview of the IOASE and examines some recent CMS legislative initiatives directed at diagnostic imaging arrangements. Finally, this article discusses the current status of the IOASE, which permits (and, we expect, will continue to permit) appropriately structured diagnostic imaging arrangements in the physician office setting.

THE IOASE- A Brief History

The Federal Stark law prohibits physicians from referring Medicare patients to entities that provide designated health services (DHS) (including diagnostic imaging services) if the physician (or his immediate family member) has a financial relationship with that entity, unless a Stark exception applies. The IOASE is the statutory vehicle that permits physicians and group practices to furnish DHS, such as diagnostic imaging services, in the office, with the goal of balancing beneficiary convenience, efficiency of services, quality and continuity of care, on one hand, against the prevention of abusive sham arrangements that do not have a bona fide nexus to the physician's core medical practice, on the other hand. A substantial majority of office-based diagnostic imaging arrangements rely upon the IOASE to enable referring physicians to provide these services within their practices. Specifically, this exception protects diagnostic imaging arrangements if the services are provided or supervised by the referring physician or his group, billed by the performing physician/group (or the group's wholly-owned subsidiary), and provided either in the same building as the physician's/group's office or a centralized building cite operated exclusively by the group practice. Notably, the IOASE was contained in the original Stark statute adopted by Congress in order to preserve the long standing practice of physicians integrating within their practices those ancillary services that complement the professional physician services they furnish.

CMS' Earlier Proposals Targeting the IOASE

In recent years, CMS has introduced various legislative proposals which, in one form or another, effectively attempted to restrict (or eliminate) the IOASE. Most of these original proposals, however, were either never finalized or implemented in manner that did not substantially affect many common diagnostic imaging arrangements involving true in-office integration.

The 2008 Medicare Proposed Physician Fee Schedule, for example, contained commentary by CMS expressing concern that the IOASE was being inappropriately used for services that were not closely connected to the physician's practice. At that time, CMS solicited comments on potential changes to the IOASE, including whether certain DHS should be excluded from the exception, whether the location requirements of the exception should be tightened, and whether the exception should be available for specialized services involving equipment owned by non-specialists. CMS, however, to date, has not introduced a formal proposal to materially restrict the scope of the IOASE and any revisions to the IOASE will require a future notice of proposed rulemaking with provision for pub-

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lic comment. CMS has noted that any future rulemaking will present a coordinated, comprehensive approach to accomplishing the goals of minimizing the threat of program abuse while retaining sufficient flexibility to enable arrangements that satisfy the requirements and intent of Stark.

In a related matter, recently CMS took a relatively flexible position when it finalized the AMR (which applies to many common diagnostic imaging arrangements). Although the original AMR proposals would have placed restrictive payment limitations on a significant number of such arrangements, in the form the AMR was adopted, if a physician group is willing to exercise certain operational flexibility, substantially all of its diagnostic imaging arrangements that are structured to comply with the IOASE likewise can be structured in a manner that does not implicate the AMR's restrictive payment limitations. Further, under the AMR, CMS permits the use of shared space imaging arrangements between physicians that occur in the "same building." CMS did caution that it may issue proposed changes to the IOASE in the future, but expressly noted that it had been asked to consider, and rejected, a complete elimination of the IOASE.

Recently, CMS has also promulgated some significant federal Stark regulatory changes that impact diagnostic imaging arrangements, such as eliminating the use of "per-click" fee and percentage-based payments in space and or equipment leases when the payments reflect serviced provided to patients referred between the parties. Notably, however, these changes do not prohibit the overwhelming number of common diagnostic imagining arrangements that are structured to comply with the IOASE.

In yet another attempt to target certain IOASE diagnostic testing arrangements, in 2008, CMS introduced a proposal that would have required any physician furnishing in-office diagnostic testing services to enroll as an IDTF, with the result that these practices' diagnostic imaging operations would be subject to most IDTF performance standards. If adopted, this proposal would have eliminated physician practices' ability to share diagnostic imaging and other testing equipment and facilities, even if located in the "same building" as defined under Stark. As a practical matter, this proposal would have also resulted in a significant decline in the number of physician practices that furnish diagnostic testing services to their patients. Notably, CMS declined to implement this IDTF proposal.

Although CMS declined to implement its IDTF enrollment requirement for physician practices providing in-office diagnostic imaging services, CMS did finalize its earlier proposal to require mobile IDTFs to enroll and bill Medicare directly for the TC services that they provide. Importantly, although the implementation of this final rule appeared to prohibit many common arrangements in which mobile entities lease diagnostic testing equipment and technicians to physicians who furnish and bill for such tests in their offices, in a noteworthy development, CMS posted a frequently asked question (FAQ) on its Web site clarifying that companies that merely lease or contract with a Medicare provider for non-physician personnel and/or equipment (but do not provide physician supervision) are not required to enroll and directly bill for such services. CMS noted that it continues to evaluate these arrangements. Nonetheless, absent further guidance from CMS to the contrary, the common imaging paradigm whereby a physician leases equipment and non-physician personnel from a mobile leasing entity can continue to bill for these services, provided that the physician group supervises the service and otherwise complies with the IOASE.

The Current State of the IOASE

In recent years, through a serious of proposals, CMS has heightened its focus on certain diagnostic imaging arrangements, including arrangements structured in compliance with the IOASE. However, despite these proposals, the IOASE remains intact as the statutory vehicle that permits physicians to furnish diagnostic imaging services in their offices. Physicians furnishing in in-office diagnostic testing services should remain attentive to potential future regulatory changes that might further restrict the scope of the IOASE. As a result, parties to such arrangements should consider inclusion of well designed strategies to unwind or restructure these transactions if regulatory changes preclude physicians' participation in such arrangements. At this point, however, the prevailing thinking among industry insiders is that near-term elimination of the IOASE remains a remote prospect. ■