THE STARK LAW'S IN-OFFICE ANCILLARY SERVICES EXCEPTION: IN-OFFICE ANCILLARY ARRANGEMENTS REMAIN VIABLE FOR PAIN MANAGEMENT PRACTICES

Adrienne Dresevic, Esq.
Carey F. Kalmowitz, Esq.
The Health Law Partners, PC, Southfield, MI

Recent legislative initiatives to restrict (or eliminate) the Stark law's In-Office Ancillary Services Exception (the "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 certain ancillary services in the physician office setting, through proposed changes to the Stark regulations and other Medicare reimbursement and performance regulations. Despite these proposals, however, the IOASE remains intact and the prospect of a near-term wholesale elimination of the IOASE appears remote. Although for many pain management physicians the Stark ban on physician self-referral is not triggered (if the only ancillary services provided are certain invasive radiology procedures such as fluoroscopy), for many other pain management physicians who provide physical therapy ("PT") or other diagnostic testing in their offices, the Stark law remains a relevant consideration and they must stay attentive to potential changes to Stark's IOASE.

This article provides a brief overview of the IOASE, as it relates to pain management practices and discusses the current status of the IOASE, which

permits (and, we expect, will continue to permit) appropriately structured in-office PT and other ancillary service arrangements in the physician (including pain management practice) 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, for example, PT and diagnostic imaging services) if the physician (or his/her 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 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 ancillary service arrangements rely upon the IOASE to enable referring physicians to provide these services within their practices. Specifically, this exception

protects in-office ancillary arrangements if the services are provided or supervised by the referring physician or his/her 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 in-office ancillary service 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 core medical 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. Any revisions to the IOASE will require a future notice of proposed rulemaking with provision for public 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 Medicare Anti-Markup Rule (the "AMR") (which applies to many common diagnostic testing arrangements). Although the original AMR proposals would have placed restrictive payment limitations on a significant number of such arrangements, in the form the AMR initially was adopted, if a physician group is willing to exercise certain operational flexibility, substantially all of its diagnostic testing 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 diagnostic testing arrangements between physicians who furnish physician services, as well as the DHS that are the subject of the shared arrangement, 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 certain ancillary service 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

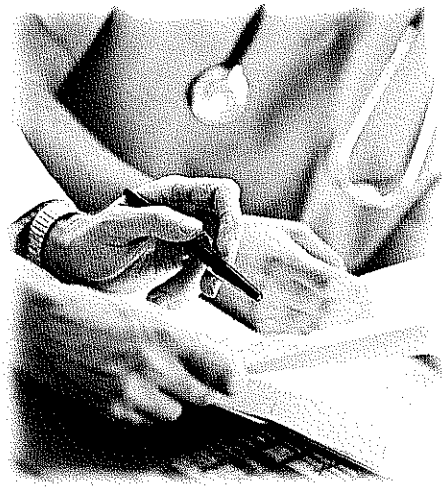
Continued on page 24

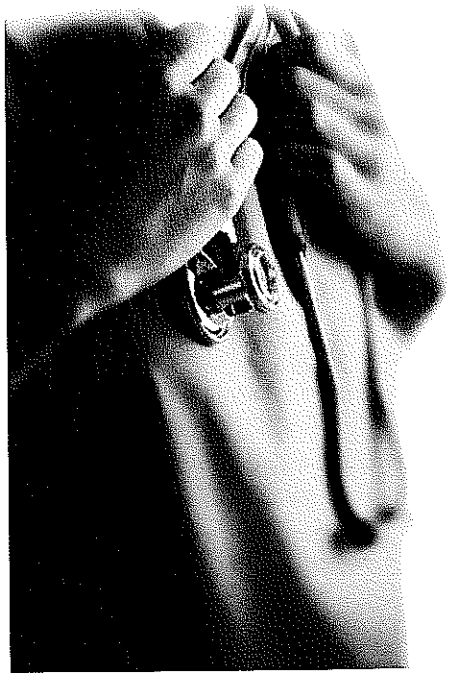
THE STARK LAW'S IN-OFFICE ANCILLARY SERVICES EXCEPTION: IN-OFFICE ANCILLARY ARRANGEMENTS REMAIN VIABLE FOR PAIN MANAGEMENT PRACTICES

Continued from page 23

in-office ancillary service arrangements that are structured to comply with the IOASE.

In yet another attempt to target certain IOASE arrangements, in 2008, CMS introduced a proposal that would have required any physician practice furnishing in-office diagnostic testing services (e.g., ultrasound, x-ray, CT, MRI, etc) to enroll as an independent diagnostic testing facility ("IDTF"), with the result that these practices' diagnostic testing services would be subject to the substantial majority of IDTF performance standards. If adopted, this proposal would have eliminated physician practices' ability to share diagnostic 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 pain management practices that furnish diagnostic testing services to their patients. Ultimately CMS declined to implement this IDTF proposal





THE CURRENT STATE OF THE IOASE

In recent years, through a series of proposals, CMS has heightened its focus on certain in-office ancillary service arrangements, including arrangements structured in compliance with the IOASE. However, despite these proposals, the IOASE remains intact as the statutory vehicle that permits pain management specialists to furnish both diagnostic testing services and PT services in their offices. Pain management specialists furnishing such in-office ancillary 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, it appears that a near-term elimination of the IOASE remains a remote prospect.

Adrienne Dresevic

Carey F. Kalmowitz

Adrienne Dresevic, Esq. is a founding member of The Health Law Partners, P.C. Ms. Dresevic practices in all areas of healthcare law and devotes a substantial portion of her practice to providing clients with counsel and analysis regarding Stark and fraud and abuse. Ms. Dresevic can be reached at adresevic@thehlp.com.

Carey F. Kalmowitz, Esq. is a founding member of The Health Law Partners, P.C. Mr. Kalmowitz practices in all areas of healthcare law, with specific concentration on the corporate and financial aspects of healthcare, including structuring transactions among physician group practices and other healthcare providers, development of diagnostic imaging and other ancillary services joint ventures, physician practice, IDTF and home health provider acquisitions, certificate of need, compliance investigations, and corporate fraud and abuse/Stark analyses. Mr. Kalmowitz can be reached at ckalmowitz@thehlp.com.