Ten Myths about the Stark Statute Debunked

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The Stark statute was enacted in 1995, but final regulations were not published until January 2001 and even then did not address all the Stark exceptions. Many people are confused about how to apply the exceptions and what the Stark statute means. This article identifies 10 of the most common myths about Stark and explains and corrects the misconceptions.

Key words: Stark statutes; anti-kickback statutes; Medicare regulations; safe harbors.

The Stark statute has loomed large on the landscape of medical practice management since its enactment in 1989 (Stark I), followed by amendments that went into effect January 1, 1995 (Stark II). The implications of the Stark statute for the organization, operation, and compensation within group practices are significant.

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Today, though, more than eight years after the law took effect, final regulations still address only part of the statutory provisions. Many common myths abound regarding this law. This article addresses 10 of the most common and clarifies the misperceptions they create.

Myth 1: The Stark statute and the anti-kickback statute are the same.

Actually, these two laws are not even in the same title of the Social Security Act. The *Stark statute* pertains exclusively to Medicare and Medicaid services and applies only to clinicians who are considered physicians under the Medicare program. This includes MDs, DOs, dentists, podiatrists, and chiropractors but does not include nurse practitioners, physician's assistants, clinical psychologists, clinical social workers, nurse midwives, or clinical nurse specialists, even when they are acting as substitutes for physicians.

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In addition, the Stark statute implicates only those referrals for specific "designated health services" that are enumerated by the CPT code in an updated list maintained by the Centers for Medicare and Medicaid Services (CMS).[1]

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In contrast, the anti-kickback statute is applicable to all parties who may conduct business within federal health-care programs, regardless of their licensure, and goes well beyond referrals to ordering, providing, leasing, furnishing, recommending, or arranging for a service, item, or good payable by a federal health-care program.

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The Stark statute provides an explicit prohibition: no physician or immediate family member may refer a Medicare or Medicaid patient to an entity with which he or she has a financial relationship unless the transaction meets one of the enumerated exceptions.

The anti-kickback statute offers safe-harbor regulations that describe those transactions that tend to induce referrals but will not be considered to violate the statute. Failure to comply with the anti-kickback safe-harbor regulations does not necessarily entail a violation of the

statute. Moreover, the safe-harbor regulations address only a limited range of transactions; so anything that does not comply with a safe harbor will be evaluated on a facts and circumstances basis by enforcers using prosecutorial discretion.

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It is always useful to analyze the Stark statute implications to an arrangement before the anti-kickback statute implications, since failure to comply with Stark precludes the necessity of even initiating an anti-kickback analysis.

Myth 2: The Stark statute has criminal penalties.

Violation of the Stark statute entails a $15,000 civil penalty for each improper referral and for each claim submitted pursuant to an improper referral. The services that are provided inappropriately are considered to be overpayments. Circumvention schemes are punishable by a $100,000 civil penalty. While improper Stark claims may be construed to be false, and a Stark violation may well entail an anti-kickback violation as well, the Stark statute itself does not provide for criminal penalties.

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In contrast, a violation of the anti-kickback statute is punishable by a $25,000 fine, up to five years in jail, or both, exclusion from the federal programs without any conviction and, since 1996, a civil penalty of $50,000 for each violating transaction. Both the Stark and anti-kickback statutes, however, are subject to whistleblower complaints.

Myth 3: The Stark statute cannot be enforced in the absence of regulations.

Stark II, which extended its reach beyond just clinical laboratory services, became effective January 1, 1995. Final regulations addressing any aspect of the law were not published until January 4, 2001, and are referred to as "Phase 1 final regulations." They still do not address all of the exceptions permissible under the Stark statute. For example, the following exceptions are not addressed in the final regulation:

- Leases.
- Rural providers.
- Hospital ownership.
- Personal services.
- Most of the exceptions that do not entail group-practice issues.

The Stark statute is being enforced today primarily in settlements of whistleblower cases. The legal ability of the enforcers to rely upon the statute is not restricted by the government's failure to interpret parts of the statute in regulation.

Myth 4: There is an exception for activities conducted within group practices.

There is no group-practice exception under the Stark statute. Rather, there are several exceptions, including those for referrals to another physician in a group, for in-office ancillary services, and where there is a contract with a hospital that predates December 19, 1989, and that can apply only if the entity conducting the activity meets the definition of a group practice.

There is no group-practice exception in the Stark statute.

The criteria that characterize a compliant group practice are set forth in the definition; these include provisions pertaining to compensation to the members of the group. Therefore, to be able to refer within the group for in-office ancillary services, the group must first meet all of the criteria for a group practice. This group-practice definition has been construed in the final regulations.

Myth 5: As long as a group bills under one number, that's all that counts.

Many people believe that the group-practice definition requires only that the group have a single billing number for all Medicare claims. Some consultants advise physician practices that "group practices without walls," virtual groups, and formerly independent entities that come together simply for the purpose of billing will qualify under the definition. *In fact, this is wrong.* Billing under one number recognized by Medicare for that purpose is only one of the criteria to meet the definition of a group practice. The criteria to qualify for a single number are the same as have traditionally applied under the Medicare reassignment rules.[2]

Another aspect of the definition is the "unified business test"—all the revenue, overhead, and expenses must be considered and treated as the revenue, overhead, and expenses of the business. This does not mean that there may not be locational expense accounting, nor that prior group practices cannot come together to form a new Stark-compliant group practice. Under the final regulations, however, where prior groups come together to form a new group, the prior groups may not continue to render medical services; rather, medical services must be provided through the new group.[3]

Substantially all of the services of the group must be provided through members of the group. This leads to the 75 percent test: the number of part-time physicians must balance the number of full-time physicians so that the average amount of time spent with the group is 75 percent. This does not mean that *each* physician working for the group must spend 75 percent of his or her time with the group. Rather, it means that the physician members of the group (excluding independent contractors) must be looked at individually to see what portion of practice time they spend with the group. These percentages are added and averaged. If the average is less than 75 percent, the group does not meet the definition. In addition, any physicians who work part-time must provide through the group substantially the full range of the services they provide elsewhere. As a result, a cardiology group that hires a part-time physician with a general cardiology practice elsewhere, but uses that physician solely for providing cardiac catheterization services, would not comply with this definition.

Myth 6: All diagnostic services are implicated under Stark.

When the statute was originally enacted, it *did* include all diagnostic services. This provision was amended in 1994 so that the Stark-covered diagnostic services are limited to imaging services including ultrasounds, MRI, and CT.

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Based on the designated health services list noted earlier, a range of diagnostic services—including electrocardiograms, Holter monitors, nuclear testing, evoked potentials, spirometries, and the like—that do not entail imaging, are not implicated by Stark. Arrangements involving these services still must be analyzed under the anti-kickback statute, however.

Myth 7: All ancillary service revenue must be shared equally by the physician shareholders.

The group-practice definition addresses permissible profit-sharing arrangements that must take into account a distribution of the profits of the overall practice. Profits from ancillary revenues may be shared in any way if they are not from "designated health services." In no event may a physician be given credit just for ordering designated health services.

Profit distributions may be based on location-specific profits, specialty-specific profits, or any other reasonable methodology as long as the distributions entail pods of no fewer than five physicians. Per-capita shareholder status, seniority in the group, and ownership of shares based on investment in the group are all potentially legitimate methodologies.

There is nothing that limits profit sharing to shareholders. Employees and independent contractors may share profits as set forth in their contracts.

Myth 8: Physicians cannot be given economic credit, dollar-for-dollar, for the studies they order.

This may be the single biggest myth about the Stark statute. The group-practice definition says that members of the group may be compensated in a manner that either gives them a share of the overall profits of the group or rewards them for their personal productivity, including services that are provided "incident-to" their services.

Profits from ancillary services may be shared in any way as long as they are not from designated health services.

The "incident-to" standard has long been in effect in the Medicare program.[4] These services are an incidental although integral part of the physician's personal professional services to the patient, and services may be claimed only when a physician of the group is present in the office suite. Claims are submitted as if the services were performed by the physician, when in fact they were performed by ancillary personnel whose identity is invisible on the claim form. The technical components of diagnostic services are incident-to the interpretation of the study. In addition, the administration of in-office drugs is incident-to the oncologist treating the patient.

Non-physicians in a practice may bill either as incident-to or on their own number. For example, when services of nurse practitioners, physician's assistants, clinical nurse specialists, and physical therapists are billed on their individual numbers, these are not incident-to services and no direct credit may be given for them to a treating or ordering physician. Those revenues would have to be shared as part of overall profits. If the very same clinician services are billed incident-to the physician services—which is permissible—then the treating physician can get credit for them. Incidentally, the treating physician need not be the supervising physician.

With respect to in-office ancillary services, the regulators interpreted the requirement that the services be provided by the referring physician, by another member of the group practice, or by an individual "directly supervised" by a member of the group practice to mean the level of supervision that otherwise pertains in the Medicare program. Many people believe that independent contractor

physicians may not supervise ancillary personnel. This myth was created primarily by the proposed regulations, which did not consider an independent contractor physician to be a member of the group practice. The final regulations, however, clearly state that independent contractor physicians not only may supervise ancillary personnel to meet the in-office ancillary services exception, but may also be paid for their own productivity, including on a percentage compensation basis.[5]

Diagnostic-testing-service supervision levels are set forth in Transmittal B-01-28 (April 19, 2001). For many services, no physician is required to be on premises, even though the tests are billed incident-to a physician service. So, physicians may not only be given dollar-for-dollar credit for diagnostic testing incident-to their interpretation, if the test is subject to general supervision only, they also may be given credit even when no physician is on premises.[6] The Stark statute does not direct that a profit or productivity approach be used, as long as payments conform with the regulations.

Myth 9: Per-click lease arrangements are forbidden.

Although the lease exception has not yet been addressed in the regulations, the Phase I final regulations have defined the ubiquitous "volume or value" standard. Virtually all the Stark statute exceptions state that the financial relationships may not take into account the volume or value of referrals between the parties.

Here, in contrast with the "anti-kickback" safe harbors, which require that the aggregate compensation under a lease arrangement be stated in advance irrespective of the volume or value of referrals, the Stark regulators have stated that per-click or per-time unit equipment lease arrangements will be legitimate, as long as no physician in the leasing group receives direct dollar-for-dollar credit for services that he/she *merely orders*.[7]

This permission is particularly relevant where physician practices lease diagnostic or other equipment—such as cardiac catheterization labs, lithotripters, or other expensive technologies—to a hospital at which they render services and therefore influence referrals.

Myth 10: Commercial reasonability and fair market value are the same thing.

Fair market value is a standard that applies to employment, personal services, and lease exceptions, among others. In addition, the final regulations created a separate exception for fair market value-based relationships that are in writing, incorporate the volume or value standard, are commercially reasonable, and comply with the anti-kickback statute.[8] "The parties may use the fair market value exception even if another exception potentially applies."[9]

The Stark statute contains exceptions for lease arrangements, whether for buildings or equipment, which include another provision in addition to the fair market value requirement: The transaction must be "commercially reasonable" in the absence of referrals between the parties. Consider the case where a diagnostic testing entity leases space in a physician practice. If the testing entity provides Stark-designated health services only to the landlord's patients, the transaction would not be commercially reasonable. Indeed, the diagnostic testing entity would have no reason to be at that location absent referrals from the landlord. This has not yet been interpreted in the regulations, however. It is possible that when Phase II final regulations are published, the regulators may rule that when a diagnostic testing entity is at that location to provide *non-Medicare* services, the transaction will be deemed commercially reasonable.

The statutory provision is unequivocal, but the interpretation of it is not yet known. Still, the "fair market value" exception may offer safe haven for some arrangements.

CONCLUSION

The Stark statute and regulations are detailed, sweeping, and complex for Medicare- and Medicaid-designated health services referrals. The Phase I final regulations have gone a long way toward clarifying matters that made no sense in the proposed regulations. Still, confusion remains about the law and regulations.

This article has addressed only the 10 most common myths we hear. There are others. The message is that Stark remains a challenge to physician practices and must be addressed whether there really are alligators in the sewers of New York—or not. ■

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