11 Key Concepts from the Stark Law

Scott Becker, Partner
312.750.6016 | sbecker@mcguirewoods.com

Ji Hye Kim, Associate
312.849.8222 | jkim@mcguirewoods.com

Jessica L. Smith, Associate
312.849.3687 | jsmith@mcguirewoods.com

77 West Wacker Drive, Suite 4100
Chicago, Illinois 60601-1818
www.mcguirewoods.com
The Stark Law prohibits physicians from ordering designated health services (DHS) for Medicare patients from entities with which the physician, or a family member, has a financial relationship unless an exception applies. This article reviews 11 key concepts under the Stark Law, in the context of changes to the Stark Law made by the Centers for Medicare and Medicaid Services (CMS).

1. Agreements Between Providers and Referral Sources Must be in Writing

CMS has set forth numerous exceptions to the Stark Law. These exceptions permit certain financial relationships between providers of DHS and physician referral sources, so long as certain conditions are met. These exceptions almost uniformly require that the agreement between a provider of DHS and the physician referral source be in writing. For example, the following exceptions to the Stark Law require a written, signed agreement: office space and equipment rental, personal service arrangements, physician recruitment arrangements, group practice arrangements, and fair market value compensation arrangements. 42 C.F.R. 411.357.

CMS has indicated that the purpose of requiring a written agreement is “so that [the agreement] can be objectively verified, and meets the terms and conditions of [the exception.]” 66 F.R. 949 (Jan. 4, 2001). The inadvertent error of not placing an excepted financial relationship in writing generally means that the arrangement will not meet an exception, even if all other requirements of the given exception were satisfied.

The key excepted financial relationship that need not be in writing is for bona fide employment relationships. 42 C.F.R. 411.357(c).

2. Per Click Leasing Arrangements

As of Oct. 1, 2009, physician referral sources and providers of DHS will no longer be permitted to have per click relationships for office space and equipment leases. Four exceptions currently permit these types of arrangements: the office space exception, the equipment lease exception, the fair market value exception and the indirect compensation arrangement exception. 411 C.F.R. 411.357(a), (b), (l), and (p).

The 2009 Hospital Inpatient Prospective Payment System final rule (IPPS) modified these exceptions to explicitly exclude per click arrangements for lease of equipment or real estate. 73 F.R. 48343 (Aug. 19, 2008). CMS limited per click leasing arrangements in large part due to its concern that “such lease arrangements create the incentive for overutilization, because the more referrals the physician lessor makes, the more revenue he or she earns.” 73 F.R. 48715 (Aug. 19, 2008).

These changes that prohibit per click office space and equipment leasing arrangements will go into effect on Oct. 1, 2009. Any existing per click office space or equipment lease arrangement that relies on one of these exceptions will need to be restructured prior to the Oct. 1, 2009, compliance deadline.

3. Percentage-Based Arrangements

The revisions to Stark Law made by the IPPS do not extend to percentage-based compensation formulae outside of the office space and equipment lease context. Thus, “if a compensation formula for physician compensation for items or services—other than the rental of office space or equipment—was permissible prior to Oct. 1, 2009,…that formula would not be made impermissible by this final rule.” 73 F.R. 48712 (Aug. 19, 2008).

For example, percentage-based management and billing service relationships are still permissible, so long as they satisfy certain criteria set forth in the Stark Law and Anti-Kickback Statute.

CMS has indicated, however, that the prohibition on percentage-based compensation arrangements may be extended outside of the office space and equipment lease context: “although we are not extending, at this time, the prohibition on the use of percentage-based compensation formulae to arrangements for any non-professional service (such as management or billing services), we reiterate our intention to continue to monitor arrangements for nonprofessional services that are based on a percentage of revenue raised, earned, billed, collected, or otherwise attributable to a physician’s (or physician organization’s) professional services.” 73 F.R. 48710 (Aug. 19, 2008).
4. Lithotripsy Arrangements

As mentioned, the Stark Law prohibits physicians from ordering DHS for Medicare patients from entities with which the physician has a financial relationship. Lithotripsy services are not considered DHS. Am. Lithotripsy Soc. v. Thompson, 215 F. Supp. 2d 23 (D.D.C. 2002). The IPPS commentary confirms this analysis, suggesting that lithotripsy services are not DHS, regardless of whether the services are billed by the provider or a hospital. 73 F.R. 48730 (Aug. 19, 2008). As a result, the upcoming prohibition on per click leasing arrangements will not apply to lithotripsy lease arrangements or under arrangement agreements. CMS draws a very significant distinction between leases of equipment which can generally no longer be per click, and services agreements which include some equipment therein, and can be per click or per service. In the case of lithotripsy, the distinction is critical to whether urologists can make other DHS referrals to the hospital.

A urologist who leases a lithotripter to a hospital through a leasing agreement on a per click basis cannot make other referrals to that hospital (i.e., other referrals outside of lithotripsy). Per click leasing agreements, in short, will not meet an exception, and thus the urologist cannot make other referrals. A per click lithotripsy agreement, in contrast, that provides overall lithotripsy services (not just equipment) may be structured to fit into the fair market value exception. Thus, the urologist would be able to arguably make other referrals to the hospital.

In the case of a local urologist providing lithotripsy services to a hospital at which he or she generally practices, the key question will come down. Is the agreement a lease of equipment or a service agreement?

Key comments from CMS as to this issue are as follows:

a.) Currently, lithotripsy is not considered a designated health service for purpose of the physician self-referral law. Therefore, if the physician owners of the lithotripsy partnership make referrals to the hospital for lithotripsy services ONLY, the physician self-referral law would not be implicated, and a per-unit or percentage-based compensation formula for the compensation arrangement between the lithotripsy partnership and the hospital would be prohibited, even if the compensation arrangement is considered to be a lease of equipment (and other items or personnel).

b.) If the physician owners of the lithotripsy partnership refer Medicare patients to the contracting hospital for any designated health services (DHS), the compensation arrangement between the lithotripsy partnership and the hospital must comply with an applicable exception to the physician self-referral law. Where a compensation arrangement between the hospital and the physician-owned lithotripsy partnership is considered to be a lease of equipment, a per-unit or percentage-based compensation formula would fail to satisfy the requirements of any of the potentially applicable exceptions for the lease of equipment found in §411.357(b), §411.357(l) or §411.357(p).

5. Professional Courtesy

CMS recognized the long-standing tradition of extending professional courtesy to physicians and their family members in 2004, by promulgating an exception to the Stark Law for professional courtesy arrangements. 69 F.R. 16116 (March 26, 2004). The professional courtesy exception covers free or discount services provided to a physician or his or her immediate family members, so long as certain conditions are satisfied. 42 C.F.R. 411.351.

Specifically, the arrangement must be: (i) extended to all physicians on the medical staff or in the community; (ii) for items and services routinely provided by the entity; (iii) set forth in writing and approved by the provider’s governing body; (iv) unavailable to any physician or family member who is a federal health care program beneficiary; and (v) does not violate the Anti-Kickback Statute or any billing or claims submission laws. 42 C.F.R. 411.357(s).
6. Retention Payments

A hospital, federally qualified health center, or rural health clinic may make retention payments to physicians in order to induce them to stay in its geographic service area. Retention payments may be made when a physician has a bona fide offer or presents a written certification that he or she has a recruitment opportunity that would require the physician to relocate at least 25 miles outside of the entity’s geographic service area. 42 C.F.R. 411.357(t).

The Stark Law recently added more flexibility to the retention payments exception by widening the “geographic service area.” 72 F.R. 51065 (Sept. 5, 2007). The entity’s “geographic service area” not only encompasses a Health Professional Shortage Area, but also rural areas and an area with a demonstrated need for the physician, as determined by the Secretary of the Department of Health and Human Services. In addition, the geographic service area may include an area where at least 75% of the physician’s patients reside in a medically underserved area or are members of a medically underserved population.

7. Mission Support Payments

Many DHS entities make mission support payments to their affiliates in order to fulfill their missions of medical research, education, and health care services to the community.

The Stark Law provides a safe harbor for those DHS entities that meet the Academic Medical Centers (the AMC) exception. 42 C.F.R. 411.355(e). The AMC exception is as extensive as it is complicated. Each element of the exception must be satisfied when an academic medical center makes mission support payments to a faculty practice or other affiliates. The indirect compensation exception may also be available in those cases where the support arrangement constitutes an indirect compensation as defined by the Stark Law. Like the AMC exception, the indirect compensation exception entails a number of elements; each element of the indirect compensation definition and the exception must be satisfied. 42 C.F.R. 411.354(c)(2) and 411.357(p). An indirect compensation relationship may exist when at least one person or entity is interposed between the DHS entity and the referring physician. If the affiliate that is receiving the mission support payment is a physician organization and its physician employee has an ownership or investment interest in the organization, the physician owner is deemed to stand in the shoes of the organization. As a result, arrangements that were previously treated as indirect would now be direct, and one of the direct compensation exceptions must be satisfied. 42 C.F.R. 411.354(c)(1)(ii).

A DHS entity may avoid the Stark Law implications entirely, if it has no financial relationship with the physician employees of the affiliate. There is no financial relationship under the Stark Law if: i) a DHS entity provides mission support payments directly to its affiliate; ii) the affiliate is not owned by any of its physician employees; and iii) the affiliate’s compensation of its physician employees does not take into account the volume or value of referrals or other business generated by the physician employees to the DHS entity. If these three conditions are met, a DHS entity may make payments to its affiliate to keep it in good financial shape and accomplish its missions without implicating the Stark Law.

8. Publicly Traded Company Exception

The Stark Law excludes certain ownership interests in a DHS entity from the definition of the financial relationship, including ownership of investment securities that could be purchased on the open market when the DHS referral was made. These securities must either be listed for trading on the NASDAQ or a similar system, or traded under an automated dealer quotation system by the National Association of Securities Dealers. Further, the securities must be in a corporation that had stockholder equity exceeding $75 million either at the end of the corporation’s most recent fiscal year, or on average during the previous three fiscal years. 42 C.F.R. 411.356(a). Here, stockholder equity means the excess of the hospital’s net assets over its total liabilities.
9. Isolated Transactions

Physicians may engage in an isolated financial transaction with a DHS entity without violating the Stark Law only if the following conditions are met. First, the amount of remuneration must be based on fair market value and not take into account the volume or value of any referrals a physician makes to the DHS entity or any other business generated by the parties. Second, the arrangement must be commercially reasonable even if no referrals are made between the parties. Finally, no additional transactions, except ones specifically excepted from the Stark Law, may occur for six months after the isolated transaction. 42 C.F.R. 411.357(f). Installment payments may qualify as payment as part of an isolated transaction, if the total aggregate payment is: i) set before the first payment is made; ii) does not take into account, directly or indirectly, referrals or other business generated by the referring physician; and (iii) is secured. 72 F.R. 51055 (Sept. 5, 2007).

10. Non-Monetary Compensation Benefits

A physician may receive from a DHS entity non-monetary compensations up to $300 in the aggregate a year (i.e., meals, parking, training, etc.). (This amount is adjusted annually for inflation, the aggregate amount is $355 for 2009.) Non-monetary compensation cannot take into account the volume or value of any referrals or other business generated by the physician. Further, the physician must not have solicited such compensation. The compensation must also not violate the Anti-Kickback Statute or any federal or state law. 42 C.F.R. 411.357(k). CMS recommends that hospitals implement compliance systems, such as mechanisms to track and value the provision of gifts, complimentary items and other benefits for physicians, to ensure non-monetary compensation does not exceed the annual spending limit. 72 F.R. 51058 (Sept. 5, 2007).

The Stark Law does allow a hospital with a formal medical staff to throw a local staff appreciation event once a year without adhering to the spending cap. Any gifts or gratuities provided in connection with the event, however, are subject to the spending cap. 42 C.F.R. 411.357(k)(4). Finally, the recent revision to the Stark Law now allows an entity to stay below the spending cap when it inadvertently exceeds the cap by no more than 50% and the physician repays the excess within that calendar year or 180 consecutive days from receipt of the excess compensation, whichever is earlier. The entity and the physician may rely on the repayment provision no more than once every three years. 42 C.F.R. 411.357(k)(3).

11. Splitting Profits from Ancillary Services within a Practice

There are several ways to split profits from DHS within a group practice, so long as the given profit-splitting method is not related to the volume or value of referrals. Two profit sharing methods that are not prohibited by Stark include certain profit sharing arrangements between members of a group practice and certain productivity bonuses.

When a physician’s group meets the Stark Law’s definition of a “group practice,” its physicians may receive a share of the overall profits so long as the distribution is reasonable, verifiable and unrelated to the volume or value of referrals. The Stark Law deems certain methods of profit sharing as not relating directly to the volume or value of referrals. The profits, for example, may be divided per member of the group. The group may also distribute DHS revenues based on the distribution of the groups’ revenues attributed to services that are not DHS payable by any federal health care program or private payer. Finally, the Stark Law allows any method of profit sharing, if DHS revenues constitute less than 5% of the group practice’s total revenues and no physician’s share is more than 5% of the physician’s total compensation from the group practice. 42 C.F.R. 411.352(i)(1) & (2).

CMS has explicitly stated that “all physicians, whether employees, independent contractors, or academic medical center physicians, can be paid productivity bonuses based on work they personally perform.” 69 F.R. 16067 (March 26, 2004). A physician may be paid a productivity bonus based on work personally performed by that physician, so long as the productivity bonus is not calculated in a way that directly relates to the volume or value of a physician’s DHS referrals. One such method of calculating productivity bonuses is to base a physician’s bonus on his or her total patient encounters or relative value units. 42 C.F.R. 411.352(i)(3).