STARK ENFORCEMENT

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The Federal Physician's Self-referral or "Stark" law is a broad-based prohibition limiting a physician's ability to refer Medicare patients for selected services to entities with which the physician has a financial relationship. The law was intended to provide a bright line prohibition to discourage over-utilization prompted by financial motives. The breadth of the statute and its many ambiguities, however, have made it a labyrinth of complex definitions and picayune exceptions. The law invades the most basic financial relationships involving physicians and attempts to impose static rules on a dynamically evolving delivery system. Although many (including your author) can find much to criticize in the law, neither Congress nor the regulators appear dissuaded. Stark is a fact of life. Physicians and organizations who work with physicians must learn to weave their way through the intricacies of the law in order to survive.

This paper first reviews the evolution of the Stark law and the changes introduced in Phase I of the final Stark II regulations. Second, it summarizes Stark enforcement activities including case law interpreting the Stark law.

I. The Stark Law

In 1989 Congress passed "Stark I," a statute prohibiting a physician from referring Medicare patients to an entity for clinical laboratory services if the physician (or an immediate family member of the physician) has a financial relationship with that entity. In the Omnibus Reconciliation Act of 1993, Congress enacted "Stark II," which expands the federal self-referral ban to include certain designated health services provided to Medicare patients. Stark II also extended the referral prohibition to the Medicaid program by denying federal financial participation for certain Medicaid services provided pursuant to a tainted referral.

The designated health services identified in Stark II are:

- Clinical laboratory services;
- Physical therapy services;
- Occupational therapy services;
- Radiology services, including ultrasound, MRI and CT scans;
- Radiation therapy services;
- Durable medical equipment;
- Perenteral and enteral nutrients, equipment and supplies;
- Prosthetics, orthotics and prosthetic devices and supplies;
- Home health services;

- Outpatient prescription drugs;
- Inpatient and outpatient hospital services.

Sanctions for violating Stark include denial of payment, mandatory refunds, civil money penalties and/or exclusion from the Medicare program. Medicaid referrals that fall within the prohibition, however, are subject to only whatever sanctions the particular state has adopted.

In August of 1995, the Health Care Financing Administration (recently renamed the Centers for Medicare and Medicaid Services ("CMS")) published final regulations interpreting the Stark prohibition as applied to clinical laboratory services. In January 1998, CMS released proposed regulations interpreting Stark II. Three years later, CMS finally published a portion of the final Stark II regulations. By the end of 2002, the agency could potentially complete the task.

With each set of Stark regulations CMS's interpretation of the statute has evolved. This has resulted in considerable confusion concerning the scope of the referral prohibition and the various exceptions. Phase I of the final Stark II regulations attempts to address several of the ambiguities created by the language of the statute and its evolving administrative interpretations. Several ambiguities remain and it is anticipated that CMS will refine its position in Phase II of the final regulations.

II. Phase I Highlights

CMS issued "Phase I" of the final Stark II regulations on January 4, 2001. Phase I includes the agency's interpretation of the basic self-referral prohibition, the so-called global exceptions (including the in-office ancillary services and prepaid plan exceptions) and the statutory definitions. Selected compensation arrangement exceptions are also addressed. On January 5, 2002, almost all of the Phase I regulations went into effect[1].

Delays are inevitable when CMS attempts to decipher Stark and it is not known when the agency will issue Phase II of the final Stark II regulations. Eventually, Phase II of the final regulations will address the ownership and investment interest exceptions, the remaining compensation arrangement exceptions, reporting requirements and sanctions.

The bifurcation of the final Stark regulations has created some confusion and heightened the level of uncertainty concerning certain issues. CMS has indicated that Phase II of the final regulations will respond to the comments submitted on Phase I of the final regulations. Thus, these recently adopted regulations could be modified when Phase II is issued. That stated, Phase I of the final regulations includes a number of noteworthy developments that merit study. Some of the highlights are discussed below.

[1] CMS delayed implementation of the proposed definition of "set in advance," until July 7, 2003. The proposed definition was controversial because it limited an entity's ability to pay a physician based on a percentage of revenues, collections or other indeterminate metric.

Prohibition and Definitions

Stark prohibits a physician from making a referral to an entity for the furnishing of designated health services for which Medicare would otherwise pay, if the physician (or immediate family member) has a financial relationship with that entity. This basic Stark prohibition contains a number of terms requiring definition. Phase I of the Stark II final regulations modifies or clarifies several of these definitions.

Referral

The Stark Law defines *referral* very broadly to include the request by a physician for an item or service for which payment may be made under Medicare Part B or the establishment of a plan of care. The proposed Stark II regulations clarified that the statutory prohibition applies only to referrals for "designated health services," covered by Medicare. The final regulations further modify the definition of referral by excluding any designated health service personally performed or provided by the referring physician. Thus, a physician does not make a referral when he or she personally performs a service. However, the regulations indicate that a service is not personally performed if it is provided by any other person, including but not limited to, the referring physician's employees, independent contractors or group practice members.

Designated Health Services

The proposed Stark II regulations created considerable confusion concerning the definitions of the 11 *designated health services* listed in the statute. In Phase I of the final Stark II regulations, CMS attempts to clarify these definitions. Certain designated health services (clinical lab, physical therapy, occupational therapy, radiology, and radiation therapy services) are now defined by specifically identified procedure codes (CPT or HCPCS codes). With respect to other designated health services (durable medical equipment, parenteral and enteral nutrients equipment and supplies, prosthetics, orthotics and prosthetic devices, home health services, outpatient prescription drugs or in-patient out-patient hospital services) CMS revised the definitions in Phase I of the final regulations in an attempt to create "bright line" rules.

In another change from the proposed regulations, the final Stark II regulations provide that services that would otherwise constitute designated health services, but are paid by Medicare as part of a composite payment for a separate benefit are not designated health services. Thus, designated health services provided in an ASC and bundled into the ASC payment are **not** designated health services. Designated health services bundled and billed as a hospital or home health service, however, would still be designated health services because hospital services and home health services are themselves designated health services.

Financial Relationship

Stark prohibits referrals only if the physician has a *financial relationship* with the

entity to which the referral is made. A financial relationship may consist of either an ownership/investment interest or a compensation arrangement. The financial relationship does not need to involve designated health services or Medicare/Medicaid patients. A referral alone, however, does not create a financial relationship.

Indirect Ownership

An ownership interest or compensation arrangement can be direct or indirect. An indirect ownership interest may pierce through several "holding companies" or layers of ownership. The final regulations clarify, however, that an indirect ownership interest will trigger Stark sanctions only if the entity furnishing the designated health services has actual knowledge of or acts in reckless disregard or deliberate ignorance of the fact that the referring physician (or an immediate family member) has some ownership or investment interest in the entity.

Indirect Compensation

The final regulations also (1) articulate a test for determining when an indirect compensation arrangement will trigger the Stark referral prohibition; and (2) create a new exception for indirect compensation arrangements. The new exception may apply when the compensation received by the referring physician from an intermediate entity with which the physician has a direct financial relationship is consistent with fair market value and does not vary based on the volume or value of the physician's referrals to the entity providing designated health services. It is difficult to reconcile the definition of indirect compensation arrangement and the terms of this exception. It is anticipated that CMS will attempt to clarify these definitions in Phase II of the final regulations.

Group Practice and In-office Ancillary Services Exception

The final Stark II regulations clarify the criteria medical groups must satisfy to qualify as a "group practice" under Stark. In general, CMS has attempted to be more flexible in its approach. Nonetheless, groups must still meet specific operational and organizational standards relating to their level of integration, compensation systems and the provision of patient care services.

With respect to the in-office ancillary services exception, CMS has articulated more flexible standards for both the level of required physician supervision as well as who is eligible to supervise such services. More specifically, the final regulations interpret the requirement that in-office ancillaries be "directly supervised" to mean supervision sufficient to satisfy the requirements of the Medicare/Medicaid payment or coverage rules. The regulations further provide that supervision of in-office ancillaries can be provided by group practice owners, employees or independent contractors who qualify as "physicians in the group."

With respect to the locational requirements of the in-office ancillary services exception, CMS took a more restrictive approach. The final regulations preclude groups

from establishing part time remote locations for the "centralized" provision of designated health services. Thus, if a group were to rent an MRI facility one day per week, that location would not be considered a centralized location for designated health services.

CMS also took a dim view of mobile units, suggesting that these units could meet the locational requirements only if the unit is operated *exclusively* by the group practice (7 days a week, 24 hours a day for at least six months).

Other Exceptions

The final Stark II regulations also established new exceptions to the referral prohibition, including:

Risk Sharing Arrangements

Compensation pursuant to a risk sharing arrangement (including withholds, bonuses and risk pools) between a managed care organization and a physician for services provided to enrollees of a health plan will not trigger the referral prohibition provided the arrangement meets specific criteria and does not violate the anti-kickback statute or any law or regulation governing billing or claim submission.

Academic Medical Centers

Payments to physician members of a faculty practice plan from the components of an academic medical center may qualify for a new Stark exception so long as the payments support the institution's mission. This exception generally applies to physicians who provide substantial academic or clinical teaching services. The total compensation from all academic medical center components to the referring physician must be set in advance, not exceed fair market value and not be determined a manner that takes into account the volume or value of any referrals or other business generated by the referring physician within the academic medical center. The terms of this new exception are considered unduly restrictive by many involved in academic medicine. It is likely that CMS will adopt more flexible standards in Phase II of the final regulations.

Fair Market Value Compensation

The fair market value compensation exception, first articulated in the proposed Stark II regulations, is clarified in Phase I of the final regulations. This exception could eclipse some of the more specific compensation exceptions.

Medical Staff Incidental Benefits

Non-cash compensation from a hospital to a member of its medical staff will not trigger the referral prohibition if, *inter alia*, the compensation is offered to all members of the medical staff without regard to the volume or value of referrals, the compensation is provided by and used by the hospital's medical staff members only on the hospital's

campus and, the compensation is consistent with the benefits offered to medical staff members by other hospitals in the region.

III. Stark Enforcement

A. Background

As noted above, sanctions for violating Stark include denial of payment, mandatory refunds, civil money penalties and/or exclusion from the Medicare program. Medicaid referrals that fall within the prohibition are subject to whatever sanctions the particular state has adopted.

Due to the complexity of the statute, the lack of final regulations and agency inertia, there has been very little administrative enforcement. A few providers have disclosed Stark violations to the Office of the Inspector General (OIG) and CMS. It is unclear what administrative actions, if any, have been taken in response to these disclosures. At least one carrier has suspended payments to a provider based upon alleged Stark violations and other misdeeds.

With the issuance of the final Stark II regulations, both CMS and the OIG could begin enforcing the Stark referral prohibition. The nature and scope of these enforcement activities remains to be defined.

There is a process for seeking an advisory opinion from CMS interpreting the Stark law. CMS has issued only two such opinions and appears reluctant to provide additional guidance. It is possible, however, that the advisory opinion process will be resuscitated after Phase II of the Final Stark II regulations are issued.

Currently, the vast majority of the Stark enforcement actions have been in the context of claims asserted under the federal False Claims Act. 31 U.S.C. §3729 *et seq*. This type of Stark enforcement is particularly chilling for two reasons. First, the False Claims Act authorizes private "whistleblowers" to sue on behalf of the federal government and provides for a bounty or percentage of the recovery to be awarded to these individuals. Thus, under the FCA the government has abdicated its prosecutorial discretion to bounty hunters. A statute as technical and complex as the Stark law is a dangerous weapon in the hands of a financially motivated whistleblower. Second, penalties under the federal False Claims Act are draconian and include treble damages, attorneys' fees and civil penalties of $5,500 to $11,000 per claim. In the context of a Stark violation involving a physician and a hospital to which that physician regularly refers, the potential exposure under the False Claims Act is staggering.

B. Case Law

Set forth below is a summary of some of the published opinions interpreting the Stark law:

U.S. ex rel. Thompson v. HCA Healthcare Corp., 20 F.Supp.2d 1017 (S.D. Tex., 1998)

False Claim Act (FCA) whistleblower case based on HCA's relationships with physicians. Both Stark and anti-kickback allegations were cited as bases for the FCA claims. The initial 5th Circuit ruling affirmed that violations of Stark and anti-kickback statutes, by themselves, do not necessarily give rise to actionable false claims under the FCA. 5th Circuit also remanded to trial court issue of whether claims for services rendered in violation of Stark laws constitute false or fraudulent claims under the FCA.

On remand, District Court ruled that the Stark laws' express prohibition on payment for services rendered in violation of the referral prohibition makes such alleged violations actionable under the FCA. In other words, defendants' submissions for Medicare payments which they knew they were statutorily prohibited from receiving under Stark creates FCA liability. The **Thompson** case is still pending.

U.S. ex rel. Pogue v. Diabetes Treatment Centers of America, Inc., 2002 WL 31856364 (D.D.C., 2002)(mem. opinion).

Affirms **U.S. ex rel. Pogue v. American Healthcorp., Inc.**, 914 F.Supp. 1507 (M.D.Tenn., 1996) ruling that violations of anti-kickback and Stark laws can support a claim under the FCA.

U.S. ex. rel. Goodstein v. McLaren Regional Medical Center, 202 F.Supp.2d 671 (E.D. Mich. 2002).

False Claim Act *qui tam* action brought against medical center and individual physicians alleging that the parties violated the Stark law (and hence submitted false claims for hospital services referred by the physicians) by entering into a lease arrangement that was not commercially reasonable. The trial was bifurcated with the first phase focusing on whether the lease rate was fair market value. In ruling in favor of the defendants, the District Court judge focused on the acrimonious negotiations between the hospital and the physicians and concluded that the lease rate was fair market value.

American Lithotripsy Society v. Thompson, 215 F.Supp.2d 23 (D.C. D.C. 2002).

The American Lithotripsy Society and the Urology Society of American sued CMS contending that regulations indicating lithotripsy as a "designated health service" under the Stark law were unlawful. Based on the legislative history and statutory definitions the District Court agreed that lithotripsy should not be classified as a designated health service under Stark. The government has appealed this ruling.

U.S. v. Advocate Health Care, 211 F.Supp.2d 1045 (N.D. Ill. 2002).

False claim *qui tam* action brought against a hospital claiming that it illegally offered special benefits to physicians to induce them to refer patients. The District Court dismissed the claim on a 12(b)(6) motion noting that the term "set in advance" under the Stark law does not prohibit percentage payment arrangements but only requires that the payment methodology be fixed at the onset. The Court's ruling on this issue is at odds with the proposed definition of set in advance in Phase I of the final Stark II regulations.

C. Settlements

In addition to the cases referenced above, prosecutors have successfully negotiated settlements in FCA cases based on alleged Stark violations. For example, Pastor Medical Associates, a multispecialty group in Massachusetts, settled a False Claims Act lawsuit initiated by one of its former partners based on Stark law violations tied to its group practice compensation system. The group paid members a percentage of the income derived from lab tests the member physician ordered from the group's lab. Note that whether this compensation methodology violated the Stark group practice requirements is not clear, particularly in light of the fact that the allegations date from 1992.

In a more recent settlement out of South Dakota, Rapid City Regional Hospital and a local oncology group agreed to pay $6 million dollars to resolve a False Claims Act suit initiated by a whistleblower alleging that the hospital rented office space to the physician group at below market rent. Finally, in early 2002 St. Joseph's Hospital in North Dakota settled a *qui tam* FCA claim based on Stark violations for $5 million.

Conclusion

The Stark Law and final regulations affect the organization and operation of physician groups, hospital-physician relationships and a host of other arrangements. The law is daunting in its complexity and one should carefully analyze its implications when assessing existing or proposed financial arrangements with physicians.

Enforcement of the Stark law is in its infancy. The federal False Claims Act is both the most common and the most disturbing enforcement mechanism currently in use. The case law confirms the numerous ambiguities in the statute and suggests that the courts will play an increasingly important role in defining the Stark referral prohibition.

For more information about the Stark law or related issues, contact Bob Homchick at (206) 628-7676, email roberthomchick@dwt.com or your usual DWT attorney.