PHYSICIAN PRACTICES IN A STARK WORLD

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I. OVERVIEW OF THE STARK LAW

A. The Statutory Prohibition (Social Security Act § 1877; 42 U.S.C. § 1395nn)

The federal physician self-referral statute prohibits physicians from ordering "designated health services" for Medicare (and to some extent Medicaid) patients from entities with which the physician (or an immediate family member) has a "financial relationship."

Often, the federal self-referral law is referred to as the "Stark Law" after Congressman Pete Stark, the Congressman who introduced and strongly supported the statute. The first version of the Stark Law, which prohibited physicians from ordering only clinical laboratory services for Medicare patients from an entity with which the physician had a financial relationship, is often referred to as "Stark I." The expansion of the Stark Law to the other designated health services is often referred to as "Stark II."

In addition to applying to the Medicare program, certain aspects of the Stark Law apply to the states' Medicaid programs. Specifically, the Social Security Act denies federal financial participation payment under a Medicaid program to a state for services that would have been prohibited by Medicare under the Stark Law if Medicare covered the services to the same extent as under the state's Medicaid plan. Under the "Stark II Proposed Regulations" (discussed below), the Centers for Medicare and Medicaid Services ("CMS") articulated its proposed position that individuals and entities are not precluded from referring Medicaid patients or from billing for designated health services that otherwise would be prohibited under the Medicare Stark Law prohibition. Instead, CMS took the position that, in these circumstances, the state Medicaid programs may pay for these services even though

the states will not be eligible to receive federal financial participation dollar for these services.

B. Regulations (42 C.F.R. 411.350 et seq.)

On August 14, 1995, CMS published final regulations implementing the Stark Law's prohibition against the ordering of clinical laboratory services from an entity with which a physician has a financial relationship (the "Stark I Regulations"). The Stark I Regulations became effective on September 13, 1995.

On January 9, 1998, CMS published proposed regulations implementing the statutory prohibitions under Stark II (the "Stark II Proposed Regulations"). See 63 Fed. Reg. 1659 (Jan. 9, 1998).

On January 4, 2001, almost three years to the day after the Proposed Stark II regulations were issued, CMS published in the Federal Register "Phase I" of the Final Stark II regulations (the "Phase I Regulations"). 66 Fed. Reg. 856. Although the majority of the Phase I regulations became effective January 2002, the effective date of one sentence of the regulation (concerning percentage based arrangements) was continuously delayed.

On March 26, 2004, CMS published in the Federal Register "Phase II" of the Final Stark II regulations (the "Phase II Regulations") as an interim final rule with comment period. 69 Fed. Reg. 16054. The comment period ended on June 24, 2004 and the Phase II Regulations became effective July 26, 2004.

On August 8, 2006, CMS issued final regulations creating an exception for non-monetary remuneration that is used solely to receive and transmit electronic prescription drug information as well as exceptions for electronic health records software and directly related training services. 71 Fed. Reg. 45140.

On September 5, 2007, CMS issued the long-awaited Phase III Final Regulations ("Phase III Regulations"). 72 Fed. Reg. 51,012.

While traditionally CMS issued stand-alone Stark regulations, CMS has begun including extensive changes to the Stark regulations in other regulatory issuances such as the Medicare Physician Fee Schedule (MPFS) or the Hospital Inpatient Prospective Payment Systems (IPPS). For example, final Stark regulations can be found in the FY 2008 IPPS Final Rule, the CY 2008 MPFS Final Rule, the FY 2009 IPPS Final Rule, and the CY 2009 MPFS Final Rule.

C. Definitions

The term "financial relationship" is defined in the Stark Law to include both compensation arrangements and investment and ownership interests.

The term "referral" under the Stark Law is defined more broadly than merely recommending a vendor of designated health services to a patient. Instead, the term "referral" means, for Medicare Part B services, "the request by a physician for the item or service" and, for all other Medicare and Medicaid services, "the request or establishment of a plan of care by a physician which includes the provision of the designated health service."

Under the Stark Law, certain referral relationships are deemed not to constitute a referral if the services are furnished by (or under the supervision of) a specialist pursuant to a consultation. Specifically, the Stark Law excludes from the term "referral": 1) a request by a pathologist for clinical diagnostic laboratory tests and pathological examination services; 2) a request by a radiologist for diagnostic radiology services; and 3) a request by a radiation oncologist for radiation therapy, if such services are furnished by or under the supervision of the pathologist, radiologist or radiation oncologist.

The term "designated health services" ("DHS") includes the following:

- clinical laboratory services;
- physical therapy, occupational therapy, and speech language pathology services;

- radiology and certain other imaging services;
- radiation therapy services and supplies;
- durable medical equipment and supplies;
- parenteral and enteral nutrients, equipment, and supplies;
- prosthetics, orthotics, and prosthetic devices;
- home health services and supplies;
- outpatient prescription drugs; and
- inpatient and outpatient hospital services.

However, excluded from the definition of the term "DHS" are services that are reimbursed by Medicare as part of a composite, except for the services listed above that are themselves payable through a composite rate (e.g., home health, outpatient hospital services).

C. Penalties

The Stark Law provides significant civil sanctions for violations of this proscription, including denial of payment, refunds of amounts collected in violation of the statute, a civil money penalty of up to $15,000 for each bill or claim for a service a person knows or should know is for a service for which payment may not be made and three times the amount of the improper payment the DHS entity received from the Medicare program, and a civil money penalty of up to $100,000 for each arrangement or scheme which the physician or entity knows or should know has a principal purpose of assuring referrals which, if directly made, would be in violation of the proscription.

However, in the Phase II Regulations, CMS provided an exception to when the government will impose penalties if an arrangement involves "temporary noncompliance". Specifically CMS provides that a violation has not occurred if an arrangement met an exception for at least 180 consecutive calendar days preceding the date when the agreement was no longer in compliance, the financial relationship

fell out of compliance for reasons beyond the control of the entity and the arrangement does not violate the anti-kickback statute.

In the 2009 IPPS Final Rule, CMS adopted a provision that allows an entity under certain circumstances to submit a claim for a DHS if the compensation arrangement between the entity and a referring physician fully complied with an applicable exception except with regard to the signature requirement. More specifically, if the failure to comply with the signature requirement was "inadvertent" and the parties obtain the required signature(s) within 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant, the arrangement qualifies for the exception, without regard to whether any referrals occur or compensation is paid within the 90 day period. If the failure to comply was "not inadvertent," the parties must obtain the required signature(s) within 30 consecutive calendar days following the date on which the compensation arrangement became noncompliant to enjoy the protection of the exception. 42 C.F.R. § 353(g); See also 73 Fed. Reg. at 48,705 – 48,709. An entity may use the provision for alternative method for compliance with signatures only once every three years with respect to the same referring physician. CMS specifically declines to extend relief to failures to satisfy other prescribed procedural or "form" criteria of an exception such as the amount of compensation or the description of the services.

In addition, alleged violations of the Stark Law have been boot strapped into allegations of violation of the Federal False Claims Act. In addition, alleged violations of the Stark Law have been boot strapped into allegations of violation of the Federal False Claims Act.

D. Reporting Requirements

In the Phase II Regulations, CMS waived all reporting requirements for DHS entities providing less than twenty Part A and B services during a calendar year. Moreover, CMS decided not to require regular submission of information, but instead only require information to be submitted upon request by CMS.

However, as part of the Deficit Reduction Act of 2005, Congress required the Secretary of the Department of Health and Human Services to develop a strategic and implementing plan to address certain issues relating to physician-owned specialty hospitals. In preparing its report, CMS sent a voluntary survey to 130 specialty hospitals and 220 competitor hospitals which sought information regarding, among other things, the hospitals' ownership and investment relationships and their compensation arrangements with physicians. Then, in August 2008, CMS issued its Final Report to Congress and that it would require all hospitals to provide information on a periodic basis concerning the investment interests and compensation arrangements with physicians. See http://www.cms.hhs.gov/PhysicianSelfReferral/06a_DRA_Reports.asp#TopOfPage.

As a result, in 2007, CMS began its initiative to implement a survey to investigate the investment/ownership and compensation arrangements between physicians and hospitals to determine whether they are in compliance with the Stark Law and implementing regulations. This survey – entitled the "Disclosure of Financial Relationships Report" ("DFRR") – was designed to be a mandatory survey for 500 hospitals selected by CMS. The extensive worksheet contains 8 worksheets and covers direct and indirect physician investment and ownership in hospital, payments to the hospital by physician ownerships, a listing of each rental, personal service and recruitment arrangement between a hospital and physicians, and a series of questions targeting information on other types of compensation arrangements, including non-monetary compensation or medical staff incidental benefits that exceeded published limits and charitable donations by a physician to a hospital. Although CMS had previously introduced (and then withdrew) a proposed DFRR, CMS re-introduced the DFRR as part of the FY 2009 IPPS Proposed Rule, and CMS subsequently solicited comments on the DFRR that were to be sent to the Office of Management Budget. The results of the notice and comment period have not yet been published.

II. IN-OFFICE ANCILLARY SERVICES EXCEPTION

The in-office ancillary services exception relates to designated health services furnished by a physician in his or her office except for durable medical equipment (excluding infusion pumps) and parenteral and enteral nutrients, equipment, and supplies. See 42 C.F.R. § 411.355(b). However, CMS has expressly provided that certain forms of DME can be provided in the office: crutches, canes, walkers, folding manual wheelchairs and blood glucose monitors, provided that certain requirements are satisfied.

In order to qualify for the in-office ancillary services exception, the referring physician, or another physician who is a member of the same group practice, must personally furnish the services, or if other individuals, such as technicians, perform the services, they must be directly supervised by the referring physician or another physician in the group practice.

To be exempt, in-office ancillary services also must be furnished either (i) in a "centralized" building used by the group practice for the provision of some or all of the group's clinical laboratory services, or for the centralized provision of the group's designated health services (other than clinical laboratory services; or (ii) in the "same building" in which

- The referring physician or group practice has an office that is normally open to their patients at least 35 hours per week, and the referring physician or group members regularly practices medicine and furnishes physician services to patients in that office at least 30 hours per week;

- The referring physician or group practice has an office that is normally open to patients at least 8 hours per week and the referring physician regularly practices medicine and furnishes physician services to patients in that office at least 6 hours per week; or

- The referring physician or group has an office that is normally open 8 hours per week, and the referring physician or group member regularly practices medicine and furnishes physician services to patients at least 6 hours per week in that office (including "some" services that are unrelated to DHS) and referring physician must be present and **order the DHS in connection with a patient** visit during the time

the office is open or the referring physician or a group practice member is present while the DHS is furnished during the time the office is open.In addition, the services must be billed by the physician performing or supervising the services, by a group practice of which the physician is a member, or by an entity that is wholly owned by such physician or group practice.

III. DEFINITION OF A GROUP PRACTICE

Despite the misnomer used widely in the health care industry that there is a "group practice exception," the group practice requirements are not, themselves, an exception to the Stark Law. Instead, the group practice requirements are merely a definitional prerequisite for compliance with relevant exceptions, such as the exceptions for physicians' services and in-office ancillary services.

There are both structural and operational requirements for qualifying as a group practice. These requirements are important because group practices have greater flexibility in paying physicians incentive-based compensation under the Stark Law than do other physician organizations that fall short of group practice qualification. Phase I of the Stark II Final Regulations provides the following nine conditions that must be met to satisfy the definition of "group practice." See 42 C.F.R. § 411.352.

A. Single Legal Entity

A group practice must be structured as a "single legal entity" which is formed "primarily" for the purpose of being a physician group practice in any organizational form recognized by the state in which the group practice achieves its legal status. The single legal entity comprising the group practice may be organized by any party or parties, including, but not limited to, physicians, health care facilities, or other persons or entities (including, but not limited to, physicians individually incorporated as professional corporations). Hospital-owned medical groups can qualify as group practices under the Stark Law, provided the hospital-owned group meets the remaining requirements of the group practice definition. While separate entities are required in states that prohibit the

corporate practice of medicine, hospitals should be permitted to operate group practices directly in states where such structures are allowed.

There are several other important caveats to this structural requirement for group practices. The single legal entity comprising the group practice may not be organized or owned (in whole or in part) by another medical practice that is an operating physician practice, regardless of whether the other medical practice qualifies as a group practice. Also, the single legal entity requirement does not include informal affiliations of physicians formed substantially to share profits from referrals, or separate group practices under common ownership or control through a physician practice management company, hospital, health system, or other entity or organization. CMS has not been willing to extend protection to more loosely affiliated groups or conglomerations of groups that it feels are not practicing as "true" groups.

B. "Two or More" Physicians

The group practice definition requires that there be at least two physicians who are "members of the group," whether as employees or direct or indirect owners. This definition is a change from the proposed regulation's implicit restriction against groups consisting of one physician owner and one physician employee. However, independent contractors to a group will not qualify under this standard. Consequently, the Final Regulations do not recognize groups having one physician owner and multiple physician contractors.

C. Full Range of Care

Each physician who is a "member of the group" must furnish "substantially the full range of patient care services that the physician routinely furnishes, including medical care, consultation, diagnosis, and treatment, through the joint use of shared office space, facilities, equipment, and personnel." This requirement suggests that each member of a group practice must provide services using space, facilities and equipment that are leased or owned by the group, and with staff provided by the group. It is not entirely clear, however, the extent to which "joint use" by the physicians is actually required. This is a significant issue for multi-

state, geographically diverse group practices, where all the physicians practicing at a particular site may jointly use space, equipment and personnel, but may not use these resources of other group sites.

D. Services furnished by Group Practice Members

Substantially all of the patient care services of the physicians who are "members of the group" must be furnished through the group and billed under a billing number assigned to the group, and the amounts received must be treated as receipts from the group. To properly analyze this requirement, several key terms must be discussed in further detail.

An ongoing source of Stark Law controversy has been the definition of a "member of the group" – in particular, whether independent contractors qualify as members of the group. It is important to identify who fits into the definition of a member of the group for purposes of "counting" for the various "substantially all" tests in the group practice definition, and also had been important for purposes of the ability of the group to pay incentive compensation to independent contractors beyond personally performed services. The proposed Stark II regulations did not include independent contractors as members of the group. Additionally, under the Stark II proposed regulations, CMS had taken the restrictive position that only members of the group could "supervise" in-office ancillary services.

Under the Final Regulations, a "member of the group" means a direct or indirect physician owner of a group practice (including a physician whose interest is held by his or her individual professional corporation or by another entity), a physician employee of the group practice (including a physician employed by his or her individual professional corporation that has an equity interest in the group practice), a locum tenens physician (as defined) or an on-call physician while the physician is providing on-call services for members of the group practice. A physician is a member of the group during the time he or she furnishes "patient care services" to the group. The Final Regulations state that an independent contractor or a leased employee is not a member of the group.

“Physician in a group practice” means a member of the group practice, as well as an independent contractor physician during the time the independent contractor is furnishing patient care services (as defined in the Final Regulations) to the group practice under a contractual arrangement with the group practice to provide services to the group practice's patients in the group practice's facilities. The contract must contain the same restrictions on compensation that apply to members of the group practice under the “volume or value” requirement or the contract must fit within the Stark Law personal services exception, and the independent contractor's arrangement with the group practice must comply with the Medicare Program’s reassignment rules.

“Patient care services” means any tasks performed by a physician in the group practice that address the medical needs of specific patients or patients in general, regardless of whether they involve direct patient encounters; or generally benefit a particular practice. Patient care services can include the services of physicians who do not directly treat patients, such as time spent by a physician consulting with other physicians or reviewing laboratory tests, or time spent training staff members, arranging for equipment, or performing administrative or management tasks.

The “substantially all” test has been defined as at least 75 percent of the total patient care services of the group practice members. For purposes of compliance with the 75 percent test, the Final Regulations make clear that “patient care services” must be measured by one of the following: (i) the total time each member spends on patient care services documented by any reasonable means, including, but not limited to, time cards, appointment schedules, or personal diaries (*e.g.*, if a physician practices 40 hours a week and spends 30 hours on patient care services for a group practice, the physician has spent 75 percent of his or her time providing patient care services for the group), or (ii) any alternative measure that is reasonable, fixed in advance of the performance of the services being measured, uniformly applied over time, verifiable, and documented.

E. Distribution of Expenses and Income

All overhead expenses and income from the practice must be distributed according to methods that are determined before receiving payment for these services. The Final Regulations make clear that this provision does not prevent a group practice from adjusting its compensation methodology prospectively, subject to restrictions on the distribution of revenue from designated health services discussed in the section regarding the special rule for productivity bonuses and profit shares. This requirement is not specifically limited to profit shares or productivity bonuses paid to "members" of the group.

F. Unified Business

Although not a requirement in the statute, CMS has adopted a requirement in the Final Regulations that the group practice be a "unified business." In order to satisfy this condition, the physician practice must have a centralized decision-making body that maintains effective control over the group's assets and liabilities (including, but not limited to, budgets, compensation, and salaries); consolidated billing, accounting, and financial reporting; and centralized utilization review. This element could have implications for the operations of groups that were formed through the acquisition or merger of several previously independent medical groups, which joined together but desired to maintain a certain degree of independence at their various practice sites, despite their corporate integration.

G. Volume or Value of Referrals

This condition, which comes from the statute, prohibits any physician who is a member of a group practice directly or indirectly from receiving compensation based on the volume or value of referrals by the physician, except as specifically authorized under the special rule for productivity bonuses and profit shares. Although this requirement does not expressly apply to physicians who fall outside the definition of "members of the group" (such as independent contractors), compensation to a group's independent contractors is still important when independent contractor physicians supervise ancillary services and when groups bill for designated health services provided by independent contractors. In such

circumstances, the group's arrangement with an independent contractor is required to satisfy the group practice "volume or value" requirement or otherwise comply with the more narrow Stark Law personal services exception.

H. Physician-Patient Encounters

Members of the group must personally conduct no less than 75% of the physician-patient encounters of the group practice. This requirement comes from the statute and was set forth in the proposed Stark II regulations, except to the extent that the Final Regulations provides a more detailed definition of who qualifies as a "member of the group," discussed above. Independent contractors can supervise in-office ancillary services and be paid incentive compensation, but not be counted for the "substantially all" tests. This is the only standard where a group having a large number of independent contractors could be detrimentally affected because independent contractors are not "members of the group." The end result is that a group practice can have as many independent contractors as it wishes so long as physician "members of the group" conduct at least 75% of the group's physician-patient encounters.

I. Special Rule for Productivity Bonuses and Profit Shares

Finally, the Final Regulations provide that a physician in a group practice may be paid a share of "overall profits" of the group, or a "productivity" bonus based on services that he or she has personally performed (including services "incident to" those personally performed services), provided that the share or bonus is not determined in any manner that is directly related to the volume or value of referrals of designated health services by the physician. Under the Final Regulations, "overall profits" means the group's entire profits derived from designated health services payable by Medicare or Medicaid, or the profits derived from designated health services payable by Medicare or Medicaid of any component of the group practice that consists of at least five physicians. The sharing of profits from a subset of physicians practicing within a larger group ("pooling" arrangements) should be allowed, so long as the subset is comprised of five or more physicians, the distribution is not based directly on any physician's

referrals or orders for designated health services within the group, and the remaining requirements of the group practice rules are met.

The Final Regulations offer specific examples of profit distribution methodologies that will not be deemed to relate directly to the volume or value of referrals (and therefore will not constitute violations the Stark Law) including: dividing profits per capita; distributing revenues derived from designated health services based on the distribution of the group practice's revenues attributed to services that are not designated health services payable by any Federal health care program or private payer; with revenues derived from designated health services that constitute less than five percent of the group practice's total revenues, allocate a portion of those revenues to each physician in the group practice that constitutes 5 percent or less of his or her total compensation from the group; or divide overall profits in a reasonable and verifiable manner that is not directly related to the volume or value of the physician's referrals of designated health services.

In addition to profit distributions, a productivity bonus for personally performed services also may be paid within a group practice, provided such productivity bonus does not relate directly to the volume or value of a physicians' referrals for designated health services within the group. Such productivity bonuses can include services "incident to" a physician's personally performed services. Productivity bonus arrangements that meet the one of following conditions will be deemed not to relate directly to the volume or value of referrals of designated health services: (i) bonus is based on the physician's total patient encounters or relative value units (RVUs); (ii) bonus is based on the allocation of the physician's compensation attributable to services that are not designated health services payable by any Federal health care program or private payer; (iii) revenues derived from designated health services are less than 5 percent of the group practice's total revenues, and the allocated portion of those revenues to each physician in the group practice constitutes 5 percent or less of his or her total compensation from the group practice; or (iv) bonus is calculated in a reasonable and verifiable manner that is not directly related to the volume or value of the physician's referrals of designated health services.

The rules for profit shares and productivity bonuses apply to all physicians in a group, and are not limited only to the physician-members of a group. These new group practice rules regarding profit distributions and productivity bonuses give physician groups specific examples of profit distribution methodologies that are lawful under the Stark Law. They also provide a helpful 5% de minimis exception that did not previously exist, and confirm that groups can use non-designated health services performance as a proxy for measuring "indirect" designated health services distribution.

IV. SHARED FACILITIES

Although some in the industry believe that physicians in separate practices can not share a laboratory or office space in order to furnish designated health services, CMS has, in fact, confirmed that physicians who are not part of the same group practice can establish a laboratory (or other type of designated health service) that is separate from the physicians' various group practices while sharing in the costs of the operation. However, in order to satisfy the in-office ancillary services exception and not otherwise violate the Stark Law, the laboratory and any items and services that qualify as a designated health service must be located in the same building that each of the physician's practice medicine, the items and services must be billed by each physician's practice individually (i.e., not by a separate entity) and each physician must personally supervise the personnel who are performing the services for the physicians' patients.

V. UNDER ARRANGEMENTS

A. Pre-October 2009

In the Phase I Stark II Final Regulations, CMS adopted the definition of the term "entity" as "the person or entity to which CMS makes payment for the DHS." 42 C.F.R. § 411.351; *see* 66 Fed. Reg. at 943. Therefore, prior to 2009, one common structure for certain "designated health services" arrangements between hospitals and physicians was for there to be an entity that will provide a host of items and services to the hospital under either a "management services joint venture" or

pursuant to an "under arrangements" relationship. Under these arrangements, physicians, either with or without participation by a hospital, will establish an entity (e.g., a limited liability company) for the purpose of providing various items and administrative, leasing and/or management services (e.g., property leasing, equipment leasing, information systems, billing services, non-clinical personnel, as well as overall management of the delivery of the particular health care service in question) for which the hospital would bill third party payors as a being furnished as a provider-based service. The range of services provided by the entity could vary. The hospital would then compensate the entity for the fair market value of the services provided.

B. Post-October 1, 2009

In 2007, as part of the CY 2008 MPFS Proposed Rule, CMS proposed to revise the definition of the term "entity" to include not only the person or entity that bills for the DHS but also any person or entity that "performs" the DHS as well as any person or entity that "presented a claim or caused a claim to be presented" to Medicare for the DHS.

Although CMS did not finalize its proposal in the CY 2008 MPFS Final Rule, CMS did adopt a modified definition in the FY 2009 IPPS Final Rule so as to include any person or entity that "has performed services that are billed as DHS." By changing the definition of "entity" to include persons and entities that "perform" DHS, CMS specifically stated in the preamble to the regulations that it intended to include within the scope of the Stark Law those physician groups and other organizations that provide inpatient and/or outpatient services to a hospital "under arrangements." Consequently, any physician who maintains a financial relationship with the "under arrangement" organization/DHS entity can only make DHS referrals to the organization if that financial relationship meets a Stark Law exception. While it may be possible to structure a physician's *compensation* arrangement with such an "under arrangement" organization to satisfy a compensation arrangement exception, only under very limited circumstances will

a physician be able to maintain an *ownership* or investment interest in an "under arrangement" organization after October 1, 2009.

In the FY 2009 IPPS Final Rule, CMS specifically addressed two sets of services that, in many instances, are provided to hospitals by physician organizations under arrangements: lithotripsy services and cardiac catheterization services. With respect to lithotripsy and as a result of the District of Columbia District Court decision in 2002 finding that lithotripsy is not a DHS, CMS stated in the FY 2009 IPPS Final Rule that that lithotripsy services will not be subject to these principles. 73 Fed. Reg. at 48,730; *see also Lithotripsy Society v. Thompson*, 215 F. Supp. 2d 23 (D.C. 2002).

With respect to cardiac catheterization services, CMS states that the final rule does not prohibit physicians from furnishing services, in part because "[w]here a group practice or other physician organization provides the service and bills for it, the service is not DHS and the physician self-referral statute will not apply." Yet, this statement ignores the practical reality of cardiac catheterization practices as Medicare billing rules provide that cardiac catheterization services generally must be billed by a hospital. As a result of this position, a group of physicians and physician-owned entities that provide cardiac catheterization services ("Cath Labs") across Colorado brought a lawsuit to overturn CMS's position. *Colorado Heart Institute v. Johnson*, 609 F. Supp. 2d 30 (D.D.C. 2009).

To stop the definitional change prior to its October 1, 2009 effective date, plaintiffs sought a declaration that the expanded definition "'is contrary to clear congressional intent, based on an impermissible construction of the Stark Law, arbitrary and capricious, and exceeds the agency's authority,' in contravention of the Administrative Procedure Act . . . ." The district judge's interpretation of the definitional change recognized that "absent an applicable exception, the Stark Law will prohibit the individual physician Plaintiffs from making referrals to their own Cath Labs." However, the court never reached a decision on the merits. The court ultimately dismissed the case for lack of subject matter jurisdiction, reasoning in its Memorandum Opinion that even though the Cath Labs were not

entitled to HHS administrative review because they do not bill or receive payments from Medicare, their contracting hospitals could bring such a challenge.

VI. PHYSICIAN RECRUITMENT AND RETENTION

The Stark Law now includes both physician recruitment and physician retention exceptions.

The physician recruitment exemption protects payments made by a hospital to a physician to induce the physician to relocate to the geographic area served by the hospital and to become a medical staff member. See 42 C.F.R. § 411.357(e). In order to qualify for this exemption, the physician cannot be required to refer patients to the hospital, and the amount of the payment cannot be determined in a manner that takes into account, directly or indirectly, the volume or value of any referrals by the referring physician. In the Phase II Regulations, CMS provides that a hospital can make payments to an existing group in order to assist the group in recruiting the physician as long as the remuneration is passed directly through to and remain with the recruited physician, except for actual recruitment expenses. In the case of an income guarantee, the costs allocated by the physician or group practice to the recruited physician may not exceed the actual additional incremental costs attributable to the recruited physician.

As part of the exception, the recruited physician must relocate his/her medical practice to the geographic area served by the hospital (the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 75 percent of its inpatients) as evidenced by the physician moving his/her medical practice at least 25 miles; or the physician deriving 75% of his/her revenues from professional services furnished to patients not previously seen by the physician during the prior 3 years.

In addition, in the Phase II Regulations, CMS added an exception for retention payments made ***directly*** to a physician if the payment is to retain the physician's medical practice in the geographic area served by the hospital that is either a HPSA or is an area with a demonstrated need for the physician as determined through a Stark advisory opinion. See 42 C.F.R. § 411.357(t). This exception also requires that the physician have a *bona fide*

firm, written recruitment offer from an unrelated hospital that specifies the remuneration being offered and requires the physician to move his or her practice at least 25 miles *and* outside of the geographic area served by the hospital. Moreover the retention payment is limited to the *lower of* the amount obtained by subtracting (i) the physician's current income from physician and related services from (ii) the income the physician would receive from comparable services in the *bona fide*.

VII. INTERSECTION BETWEEN STARK AND ANTI-KICKBACK

There is often substantial confusion over the distinction between the Stark Law and the federal health care anti-kickback statute, and how and when to apply each of these laws. However, one of the most significant differences between these laws is that under the Stark Law, if a physician has a financial relationship with an entity to which the physician refers Medicare or Medicaid patients for designated health services, then this financial relationship must fall within an exception. Failure to meet a Stark Law exception means the referral is strictly prohibited. In contrast, the safe harbors and exceptions under the federal health care anti-kickback statute are *optional* exceptions that can be used by providers to avoid anti-kickback liability. Specifically, the safe harbors were written to delineate those financial arrangements that will not be viewed as violative of the federal health care anti-kickback statute. Consequently, safe harbor conformity is purely voluntary, and failure to conform to one of the safe harbor provisions does not mean that the financial arrangement is illegal.

This dichotomy can create confusion as to what rules to follow when analyzing physician financial arrangements. However, if a financial relationship is not permitted under the Stark Law, for purposes of making referrals, it is irrelevant whether the arrangement fits within a safe harbor to the federal health care anti-kickback statute. For example, a joint venture may qualify for safe harbor protection if it meets the requirements of the small entity investment safe harbor. However, depending upon the nature of the joint venture, there may not be an exception under the self-referral ban that would permit physician-investors to refer patients to the joint venture. In fact, until the recent implementation of the advisory opinion process under the Anti-Kickback Statute, providers had to operate with uncertainty as to whether the government would view conduct as violating the Anti-Kickback Statute or satisfying a safe

harbor. Now, providers rightfully may choose whether or not to qualify for a safe harbor, or seek an advisory opinion, or otherwise to proceed with an arrangement under a business judgment of risk under a “facts and circumstances” analysis. There also may be arrangements falling outside of the safe harbors that the OIG would not “bless” with a favorable advisory opinion because the facts are not yet sufficiently developed (e.g. newly operational joint ventures), or for other reasons.

On the other hand, even if an arrangement is permitted under the self-referral ban, the arrangement still must be examined under the federal health care anti-kickback statute to determine whether the arrangement qualifies for safe harbor protection, or otherwise potentially implicates the federal health care anti-kickback statute. For example, an arrangement may fit within the personal services exception of the self-referral ban, but may not meet the safe harbor criteria for personal services contracts unless the aggregate compensation is set in advance. Of course, as the federal health care anti-kickback statute is intent-based, an arrangement's qualification for a self-referral exception might, in the appropriate circumstances, provide an argument regarding the parties' lack of intent to violate the federal health care anti-kickback statute.