

Chapter 2210

Relationships Between Physicians and Hospitals

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Exh. 1 Relationships Between Physicians and Hospitals Checklist

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Chapter 2210

Relationships Between Physicians and Hospitals

Overview

Federal laws prohibit a wide range of financial dealings between physicians and the hospitals to which they refer. At the same time, financial relationships between these two providers are necessary and helpful to further legitimate business objectives. With federal enforcement continuing to increase in this area, providers must be diligent to ensure physician-hospital transactions are structured to comply with the law and do not generate illegal referrals or reimbursement claims.

This chapter discusses two major areas of concern related to financial relationships with physicians—the Stark law on “self-referrals” and the prohibition on “gainsharing.” For an overview of the Stark law, see *Chapter 2205, Key Concepts and Terms*. Stark law self-referral limitations in the context of physicians practicing together are discussed in *Chapter 2215, Group Practices*. The closely related anti-kickback law is discussed in *Chapter 1805, Hospital Incentives to Physicians*. Penalties for violations are outlined in *Chapter 210, Penalties*.

Stark Law. The federal physician self-referral law, or Stark law, seeks to remove incentives that could inappropriately tie a physician’s treatment decision to financial reward and result in overutilization of medical care. The original statute (Stark I) addressed physician referrals for clinical laboratory services. The law was expanded later (Stark II) to include many more services, referred to as “designated health services” (DHS). CMS has issued commentary and revised the Stark regulations in three principal phases.

The CMP Law and Gainsharing. The Civil Monetary Penalty provisions of the Social Security Act prohibit any hospital or critical access hospital from knowingly making a payment, directly or indirectly, as an inducement to reduce or limit services to a Medicare or Medicaid beneficiary under the physician’s direct care.¹ Gainsharing is an issue only for Medicare and Medicaid fee-for-service systems; the prohibition² does not apply to managed care plans (see *Chapter 2620, Underutilization and Quality of Care*, for treatment of capitated managed care organization physician incentive plans).

2210.10 The Stark Law

2210.10.10

General Prohibition and Key Terms

Overview. The Stark law prohibits a physician or immediate family member who has a “financial relationship” with an entity, such as a hospital—including psychiatric hospitals and rural primary care hospitals—from making “referrals” to that entity for “designated health services” (DHS) covered by Medicare, unless the financial relationship fits within an enumerated exception in the Stark law.³ It also prohibits the submission of reimbursement claims resulting from such referrals. A “financial relationship” under Stark can be a direct or indirect compensation arrangement or ownership interest.

The Scope of the Prohibition. Corresponding to the law’s broad definition⁴ of “remuneration,” which is not limited to relationships involving Medicare patients or relationships that provide DHS, the Stark prohibition

can reach a wide range of activities. Take the example of a physician who owns a small interest in a restaurant. If the development director of the local hospital regularly contracts to have the restaurant cater luncheons at the hospital, a financial relationship exists between the physician and the hospital that would need to be analyzed under the Stark law to ensure that the doctor is not prohibited from referring Medicare patients to the hospital. Under Stark, this financial relationship is indirect (the physician owns an interest in an intervening entity that contracts with the hospital). Because some of the links in the chain of relationships are ownership and some are compensation relationships, the final regulations would require one to analyze the situation under the “indirect compensation arrangement” definition and not as an indirect ownership. (See *Chapter 2220, Direct and Indirect Relationships*).

It is necessary to thoroughly analyze the facts surrounding any arrangement that might be subject to the

¹ Social Security Act § 1128A(b) [42 U.S.C. § 1320a-7a(b)].

² Office of Inspector Gen., U.S. Dep’t of Health & Human Servs., Advisory Op. No. 01-1 (Jan. 18, 2001).

³ Social Security Act § 1877 [42 U.S.C. § 1395nn].

⁴ Social Security Act § 1877(h)(1)(B)-(C) [42 U.S.C. § 1395nn(h)(1)(B)-(C)].

physician self-referral prohibition. If it is determined that the arrangement does not qualify as a financial relationship under the Stark law, it is not necessary for the arrangement to comply with a Stark exception (see, e.g., CMS advisory opinion at n.188, *infra*).

DHS. The Stark law lists categories of DHS that Congress identified as being subject to overuse or inappropriate use if provided by an entity in which a physician has a financial interest. These include the following items and services:

- clinical laboratory services;
- physical therapy services;
- occupational therapy services;
- radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services;
- radiation therapy services and supplies;
- durable medical equipment and supplies;
- parenteral and enteral nutrients, equipment, and supplies;
- prosthetics, orthotics, and prosthetic devices and supplies;
- home health services;
- outpatient prescription drugs;
- inpatient and outpatient hospital services; and
- outpatient speech-language pathology services.

Notably, lithotripsy is not considered DHS, as the result of a 2002 court decision.⁵

Definition of Entity. The definition of “entity” was recently expanded under Stark. Prior to October 1, 2009, “entity” was defined as the person or entity that bills for DHS. Effective October 1, 2009, the definition of “entity” has expanded to include the one performing the services that are billed as DHS.

As a result of the expanded definition of entity, a full-service, turnkey “under arrangements” service provider⁶ may now be considered to be a DHS entity. Accordingly, physicians’ ownership interests in such providers would be considered to be direct financial relationships requiring a Stark exception. Absent a situation involving providers residing in a rural area (who may be able to rely upon the rural provider ownership exception), there is no statutory or regulatory exception for ownership interests for the physician investors. Therefore, the “entity” definition may effectively eliminate referring physicians’ ability to own interests in “under arrangements” service providers, and many of

these arrangements have been restructured or unwound.

Exceptions. A number of exceptions to the general Stark law prohibition on referrals exist,⁷ including those applicable:

- to both ownership/investment interests and compensation arrangements;
- only to ownership and investment interests; and
- only to compensation arrangements.

The statutory and regulatory exceptions most relevant to referring physicians in financial relationships with hospitals include those covering:

- rental of space and equipment;
- bona fide employment arrangements;
- personal service arrangements;
- remuneration unrelated to DHS;
- physician recruitment arrangements;
- isolated transactions;
- academic medical centers;
- non-monetary compensation that is less than the amount set annually by CMS;
- fair market value compensation;
- incidental medical staff benefits;
- compliance training;
- indirect compensation arrangements;
- electronic prescribing systems;
- electronic health record items and services; and
- ownership interests in hospitals.

The exceptions most applicable to physicians referring within their group practices are the physician services and in-office ancillary services exceptions.

Stark and Managed Care Plans. The Stark law does not directly apply to services furnished by certain prepaid plans,⁸ including services furnished by managed care plans, such as health maintenance organizations (HMOs), to their enrollees and services furnished them by hospitals and others under contract to the HMO. Among the health plans exempted from Stark are Medicare Advantage (MA) “coordinated care plans,” demonstration project managed care organizations, health care prepayment plans, HMOs qualifying under the Public Health Service Act, and Medicaid managed care plans similar to the Medicare managed care plans already included in the exception.⁹

⁵ American Lithotripsy Society v. Thompson, No. 01-01812 (D.D.C., July 12, 2002); see also IPSS final rule FY 2009, 73 Fed. Reg. at 48719. CMS has noted, however, that regardless of whether lithotripsy is DHS, contractual relationships between hospitals and physicians or physician practices regarding lithotripsy can rise to the level of a “financial relationship” under Stark if the physician makes non-lithotripsy referrals to the hospital and that, unless the relationship falls into an exception, the physicians may not refer Medicare patients to the hospital for any

inpatient or outpatient services. Stark II final rule, Phase I, 66 Fed. Reg. at 940.

⁶ An “under-arrangements” service provider is a provider that furnishes a service for which the hospital bills.

⁷ Social Security Act § 1877(b)-(e) [42 U.S.C. § 1395nn(b)-(e)].

⁸ Excepted prepaid services are described in Social Security Act § 1877(b)(3) [42 U.S.C. § 1395nn(b)(3)].

⁹ 42 C.F.R. § 411.355(c).

2210.10.20**Relationship to Anti-Kickback Law**

Arrangements between hospitals (or other DHS entities) and referring physicians must comply with both the Stark and anti-kickback statutes (see *Chapter 1805, Hospital Incentives to Physicians*). However, only the anti-kickback law applies to referrals between other kinds of providers.

While many exceptions under the two statutes are similar, such as the exceptions for personal service arrangements and space and equipment rentals, their effect is quite different. The Stark law is a strict liability statute—a financial arrangement between a referring physician and a DHS entity is in violation of the Stark law unless an exception applies. Therefore, a financial arrangement between a physician and a DHS entity

that would otherwise result in a prohibited Stark referral must meet a Stark exception. However, the anti-kickback statute requires improper intent. Accordingly, failure to comply with a “safe harbor” under the anti-kickback statute does not render an arrangement illegal *per se*. Rather, a provider might be in compliance with the anti-kickback statute without meeting a safe harbor. The anti-kickback safe harbors do, however, afford automatic protection from prosecution.

Health reform legislation passed in 2010, clarifying that the element of “intent” under the anti-kickback statute does not require a showing of specific intent to violate the anti-kickback statute.¹⁰ The legislation also explicitly stated that a violation of the federal anti-kickback law is a false claim under the federal False Claims Act.¹¹

2210.20 Applicable Stark Exceptions

2210.20.10**Overview**

In ensuring physician/hospital relationships comply with the Stark law, compliance officers and counsel will find several statutory exceptions to be particularly pertinent including those for bona fide employment arrangements, personal services, remuneration unrelated to DHS, rental of space or equipment, physician recruitment, and isolated transactions. Each of these statutory exceptions has a similar exception set forth in the Stark regulations.

The regulations also contain a number of additional exceptions; for hospital/physician relationships, pertinent additional regulatory exceptions include those governing fair market value compensation, incidental medical staff benefits, academic medical centers, compliance training, indirect compensation arrangements, obstetrical malpractice insurance subsidies, retention payments in underserved areas, community-wide health information systems, and electronic health record items and services.

For physician referrals within group practices, the statutory and regulatory exceptions for physician services and in-office ancillary services are particularly relevant. For an explanation of what constitutes designated health services and the conditions under which “peripheral” services that otherwise would be classified as DHS lose that classification, see *Chapter 2205, Key Concepts and Terms*.

2210.20.20**Bona Fide Employment Arrangements**

Unlike the anti-kickback safe harbor for bona fide employment contracts, which exempts all remuneration resulting from such contracts regardless of the form of compensation, the Stark exception exempts only amounts paid under a contract that meets certain standards¹² (see *Chapter 1430, Marketing Practices*, § 1430.10.20.40).

Remuneration under the compensation arrangement must be:

- for identifiable services compensated at fair market value,
- determined in a manner that does not take into account (directly or indirectly) the volume or value of any referrals, and
- commercially reasonable even if no referrals are made to the employer.

Physicians can be paid a productivity bonus for personally performed services, including personally performed DHS.¹³ Also, unlike other Stark exceptions, a compensation arrangement with an employed physician, except in certain situations, does not have to be in writing.¹⁴

2210.20.30**Personal Services**

The exception for personal services—including professional services and excluding provision of items or equipment of any kind—is one of the more useful exceptions because it applies to such common situations as

¹⁰ 42 U.S.C. § 1320a-7b(b), as amended by the Patient Protection and Affordable Care Act (PPACA), Pub. L. No. 111-148, § 6402(f), effective for dates after March 22, 2010. The amended intent standard also applies to the other criminal violations enumerated in 42 U.S.C. § 1320a-7b.

¹¹ See also Tab 1400, Anti-Kickback—General Risk Areas.

¹² Social Security Act § 1877(e)(2) [42 U.S.C. § 1395nn(e)(2)]; 42 C.F.R. § 411.357(c).

¹³ 42 C.F.R. § 411.357(c)(4).

¹⁴ Stark contains a special rule that allows a employer to condition compensation on the physician’s referrals to a particular provider, provided that the compensation arrangement meets the specific requirements set forth at 42 C.F.R. § 411.354(d)(4).

hospital-based physician contracts or medical director agreements for the provision of administrative services.

To meet the exception, the arrangement must:¹⁵

- be in writing, be signed by the parties, and specify the services covered by the arrangement;
- be for a term of at least one year (if terminated during the first year, the parties may not enter into the same or substantially the same arrangement during the first year of the original term of the arrangement);
- cover all services the physician or immediate family member will furnish to the hospital (requirement is met if separate arrangements between the entity and the physician or any family members incorporate each other by reference or if they cross-reference a master list of contracts that is maintained and updated centrally);
- contract for aggregate services that do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement;
- be for services that do not involve the counseling or promotion of a business arrangement or other activity that violates state or federal law; and
- pay compensation that is set in advance, does not exceed fair market value (FMV), and, except in the case of a physician incentive plan, is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

Set in Advance. CMS considers compensation “set in advance” if the aggregate compensation, a time-based or per-unit-of-service-based amount (whether per-use or per-service), or a specific formula for calculating the compensation is agreed to by the parties and set out in writing before any items or services subject to the agreement are furnished.¹⁶ The agency said that the compensation formula satisfies the set-in-advance requirement if it 1) is set forth in such detail that it can be objectively verified and 2) is not changed or modified during the course of the agreement in any manner that reflects the volume or value of referrals or other business generated by the referring physician.¹⁷

Taking Into Account the Volume or Value of Referrals or Other Business Generated. Unit-based compensation is deemed not to take into account the volume or value of referrals if the compensation is fair market value for services or items actually provided and does not vary during the course of the compensation arrangement in any manner that takes into account referrals of DHS.¹⁸ Unit-based compensation is deemed not to take into account “other business generated between

the parties” if the compensation is fair market value for services or items actually provided and does not vary during the course of the compensation arrangement in any manner that takes into account referrals or other business generated by the referring physician, including private pay health care business.¹⁹

The statute allows compensation to be determined based on the volume or value of any referrals or other business only under certain physician incentive plans (PIP). To meet the PIP exception, no payments can be made to induce the reduction or limitation of medically necessary services (see *Chapter 2620, Underutilization and Quality of Care*, for a discussion of these incentive plans).

Fair Market Value. CMS at one point created a “safe harbor” provision in the definition of “fair market value” for hourly payments to physicians for their personal services.²⁰ The safe harbor consisted of two methodologies for calculating hourly rates that CMS would deem FMV for Stark law purposes. However, CMS later abandoned these safe harbor methodologies in response to complaints that they were impractical.²¹ To make clear that its action in not retaining the safe harbor within the FMV definition did not signal any agency laxity regarding the FMV requirement, CMS cautioned that it “will continue to scrutinize the fair market value of arrangements as fair market value is an essential element of many exceptions.”²²

Holdovers. CMS states that a personal service arrangement which continues in effect beyond its stated term (i.e., holdover) remains compliant with the personal service arrangements exception for a period of up to six months following the expiration of the agreement, provided that the immediately preceding agreement expired after a term of at least one year and the holdover arrangement is on the same terms and conditions as the original agreement.²³ After six months, the parties must enter into a new, signed personal services agreement or renew the original agreement in writing.

Personal services arrangements must be examined with the anti-kickback law also in mind (see *Chapter 1415, Personal Services and Management Agreements*).

2210.20.40

Remuneration Unrelated to DHS

The exception for remuneration that is not related to the provision of DHS²⁴ applies only to payments (i) to a physician and (ii) by a hospital;²⁵ it does not apply to remuneration from entities other than hospitals, nor to payments to a physician’s family members.

¹⁵ Social Security Act § 1877(e)(3)(A) [42 U.S.C. § 1395nn(e)(3)(a)]. 42 C.F.R. § 411.357(d).

¹⁶ 42 C.F.R. § 411.354(d)(1).

¹⁷ *Id.*

¹⁸ 42 C.F.R. § 411.354(d).

¹⁹ *Id.*

²⁰ See Stark II interim final rule, Phase II, 69 Fed. Reg. 16123.

²¹ Stark II final rule, Phase III, 72 Fed. Reg. at 51015; 42 C.F.R. § 411.354(d).

²² *Id.*

²³ 42 C.F.R. § 411.357(d)(1)(vii).

²⁴ Social Security Act § 1877(e)(4) [42 U.S.C. § 1395nn(e)(4)].

²⁵ 42 C.F.R. § 411.357(g).

To fall within the exception, remuneration must be “wholly unrelated” to the provision of DHS.²⁶ This is not the case if the DHS:

- is any item, service or cost that could be allocated in whole or in part to Medicare or Medicaid under applicable cost reporting principles;
- is given directly or indirectly, explicitly or implicitly, in a selective, targeted, preferential, or conditional manner to medical staff or other physicians who are in a position to make or influence referrals; or
- otherwise takes into account the volume or value of referrals or other business generated by the referring physician.

CMS has clarified that where there are no explicit cost reporting guidelines or requirements with respect to the allowability of a particular item, service, or cost so that a hospital does not know, and could not reasonably be expected to know, whether it can be allocated in whole or in part to Medicare or Medicaid, CMS will not consider the item, service, or cost to relate to the furnishing of DHS. CMS cautions, however, that the item, service, or cost still could be determined to be related to the furnishing of DHS if, for example, it is furnished in a selective, targeted, preferential, or conditional manner to medical staff.²⁷

A loan to a physician to finance the physician’s purchase of an interest in a limited partnership that owns the hospital would likely be construed as related to the provision of DHS as would payments for malpractice insurance, medical devices, and remuneration given to medical staff who are in a position to make referrals. Administrative and utilization review services would also not be considered unrelated to DHS.

Finally, despite recognizing that covenants not to compete are not necessarily equivalent to an obligation to make referrals, CMS said these agreements clearly relate to DHS and consequently, need to fall within another exception to be acceptable.²⁸

One commentator has reported “informal” interpretations by CMS representatives that, to fall within the exception, payments must be made to physicians who have neither medical staff membership nor clinical privileges at the hospital. Such a condition makes the exception practically useless, since it would apply only to the exceptional instance in which compensation is paid to a physician who is not on the hospital staff, the commentator said.²⁹

2210.20.50

Rental of Space or Equipment

The office space and equipment rental exceptions apply to rents paid pursuant to space and equipment

leases, meaning any kind of bona fide lease arrangement, including capital leases.³⁰ Like other compensation arrangements, the lease payments must:

- be consistent with fair market value;
- not take into account the volume or value of any referrals or other business between the physician and hospital (or other DHS entity);
- be commercially reasonable in the absence of referrals; and
- further the legitimate business purposes of the parties.

There must also be:

- a written lease for a term of at least one year that specifies the premises or equipment it covers;
- no sharing of the space or equipment by the lessee with the lessor or any person or entity related to the lessor; and
- rent that is set in advance.³¹

For space rentals, the space cannot exceed that which is reasonable and necessary for the legitimate business purposes of the lessee and must be used exclusively by the lessee on a full-time basis, or if a part-time lease, while in its use. The lessee may, however, jointly use space consisting of common areas if its rental payments do not exceed the lessee’s pro rata share of expenses for the space based on the ratio of the space used exclusively by the lessee to the total amount of space occupied by all persons using the common areas.

Termination of the lease with or without cause during the first year of the term does not cause the lease to fail the one-year term requirement, provided the parties do not enter into a new agreement during the original term.³² Holdovers that follow a lease agreement meeting all of the exception’s requirements are permitted for up to six months, provided the holdover rental is on the same terms and conditions as the immediately preceding lease.³³ Subleases also are permitted as long as the lessor does not share the rented equipment or space with the sublessee (meaning use them at the same time, or in lieu of the lessee).³⁴

Sharing Arrangements. Office and equipment sharing arrangements do not typically meet the exception, given the requirement that the lessee have “exclusive use” of the leased space or equipment. This limitation effectively requires that such leases be for set blocks of time (i.e., “block leases”).

Per Click Prohibition. The regulation governing rental of office space and equipment also prohibits rental charges determined using a formula based on 1) a percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space or

²⁶ *Id.*

²⁷ Stark II final rule, Phase III, 72 Fed. Reg. at 51057.

²⁸ 69 Fed. Reg. at 16094.

²⁹ W. Bradley Tully, Federal Self-Referral Law § 2400.06.G.2 (*BNA’s Health Law & Bus. Series*, No. 2400).

³⁰ Social Security Act § 1877(e)(1) [42 U.S.C. § 1395nn(e)(1)]; 42 C.F.R. §§ 411.357(a)-(b).

³¹ 42 C.F.R. §§ 411.357(a)-(b).

³² 42 C.F.R. § 411.357(a)(2).

³³ 42 C.F.R. § 411.357(a)(3).

³⁴ *Id.*

through the use of the equipment; or 2) per-unit-of-service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.³⁵ This limitation on per-click payments applies whether the lessor is a physician or an entity in which the referring physician has an ownership or investment interest. It also applies where the lessor is a DHS entity that refers patients to a physician or physician organization lessee (who refers patients to the DHS entity for other DHS).³⁶ CMS does not interpret the revisions as prohibiting a lessor from charging a lessee a pro rata share of expenses levied by a third party (e.g., property taxes or utilities).³⁷

Proving Market Value. A 2002 court decision in a False Claims Act case included a useful discussion of the factors courts consider when assessing evidence of the fair market value of leased space. The case concerned an orthopedic treatment facility's rental of office space in a building owned by a group of doctors who referred patients for such services. The court found the defendants' evidence on fair market value credible and dismissed the government's allegations of anti-kickback and Stark law violations.³⁸

In assessing the evidence, the court said the government expert unduly restricted the geographic area he considered in searching for comparable buildings and also failed to include any triple net leases (those under which the tenant pays taxes, insurance, and utilities) like the facility's at issue. Furthermore, he made no adjustments for the unusual way in which the facility's square footage was calculated (excluding common areas the facility used and measuring from the inside of exterior walls). As a result, the government evidence was unpersuasive, the court found.

The court also found that the orthopedic facility's demand for exclusivity and non-compete provisions, and a clause allowing it to break the lease if the physicians ever moved out of the building, did not indicate the lease rate was influenced by referrals. The purpose of the latter clause was to avoid the problems the facility had encountered with an off-site landlord at its previous leasehold, the court said. The court found the lease rate was determined at arms' length, with extensive negotiation of provisions over a long time, and that the facility even withheld lease payments at one point because of alleged poor maintenance. The court therefore concluded the government did not prove the health care facility paid a higher rental rate in order to receive Medicare patient referrals from the physician-owners.

2210.20.60

Physician Recruitment

The Stark law allows payments associated with physician recruitment under certain circumstances.³⁹

The exception is intended to allow hospitals, federally qualified health centers (FQHCs), and rural health clinics (RHCs)⁴⁰ to make payments intended to induce a physician to relocate his or her practice to the geographic area served by the hospital and to become a member of the hospital's medical staff. It also covers recruiting payments made directly or indirectly to physicians who are joining existing medical groups, provided certain stringent conditions are met.⁴¹

Generally, in the case of an income guarantee for a physician who is joining an existing practice, the practice may only allocate costs to the recruited physician that do not exceed the actual incremental costs attributed to the recruited physician. However, the regulations were recently revised to permit a group practice to allocate to the recruited physician a per capita allocation of the practice's aggregate overhead and other expenses, not to exceed 20 percent of the practice's aggregate costs, in certain limited situations in which the recruited physician is replacing a deceased, retiring, or relocating physician in a rural area or Health Professional Shortage Area.⁴²

The exception further prohibits a physician practice with whom a recruited physician is joining from imposing practice restrictions. In 2007, CMS also acknowledged the potential negative effect on hospitals' recruitment efforts if this provision categorically prohibited physician practices from imposing non-compete provisions on recruited physicians. The recruitment exception therefore now only prohibits practice restrictions that "unreasonably restrict" the recruited physician's ability to practice medicine in the geographic area served by the hospital.⁴³ According to CMS commentary, the following restrictions will not be viewed as "having a substantial effect on the recruited physician's ability to remain in the hospital's geographic service area"⁴⁴

- restrictions on moonlighting;
- prohibitions on soliciting patients and/or employees of the physician practice;
- requiring that a recruited physician treat Medicaid and indigent patients;
- requiring that a recruited physician not use confidential or proprietary information of the physician practice;

³⁵ IPSS final rule FY 2009, 73 Fed. Reg. at 48710.

³⁶ IPSS final rule FY 2009, 73 Fed. Reg. at 48710, 48713-13.

³⁷ *Id.* at 48710-48711.

³⁸ *United States ex rel. Goodstein v. McLaren Regional Medical Center*, No. 97-CV-72992-DT (E.D. Mich. Feb. 14, 2002); *Court Dismisses Facility Kickback Case, Finds Lease Not Above Fair Market Value*, 6 BNA's Health Care Fraud Rep. 189 (March 6, 2002).

³⁹ Social Security Act § 1877(e)(5) [42 U.S.C. § 1395nn(e)(5)].

⁴⁰ Stark II final rule, Phase III, 72 Fed. Reg. at 51048; 42 C.F.R. § 411.357(e)(6).

⁴¹ 42 C.F.R. § 411.357(e)(4).

⁴² 42 C.F.R. § 411.357(e)(4)(iii); Stark II final rule, Phase III, 72 Fed. Reg. at 51052.

⁴³ 42 C.F.R. § 411.357(e)(4)(vi).

⁴⁴ Stark II final rule, Phase III, 72 Fed. Reg. at 51053.

- requiring the recruited physician to repay losses of his/her practice that are absorbed by the physician practice in excess of any hospital recruitment payments; and

- requiring the recruited physician to pay a predetermined amount of reasonable damages (that is, liquidated damages) if the physician leaves the physician practice and remains in the community.

Any practice restrictions or conditions that do not comply with applicable state and local law “run a significant risk of being considered unreasonable” by CMS.⁴⁵

CMS also confirmed that the written agreement between the hospital and the recruited physician must be signed by the group practice if payments are being indirectly or directly made to a physician who joins an existing practice.⁴⁶ Counterpart signatures are permissible.⁴⁷ In addition, the recruitment exception does not prohibit a hospital from requiring a guaranty of the recruited physician’s repayment obligation from the practice. CMS has warned, however, against the practice of eliminating the physician’s obligation to reimburse the practice should the hospital draw upon the guaranty, potentially creating a financial relationship between the practice and the physician that would not meet a Stark law exception.⁴⁸

CMS has also clarified what kinds of expenses qualify as recruitment expenses and which may be included in the income guarantee. Depending on the circumstances, recruitment costs incurred could include:

- the actual costs of headhunter fees;
- airfare, hotel, meals, and other costs associated with visits by the recruited physician and his or her family to the relevant geographic area;
- moving expenses;
- telephone calls; and
- tail malpractice insurance covering the physician’s prior practice.⁴⁹

The recruitment exception also requires the physician to relocate his or her medical practice to the hospital’s geographic service area to become a member of the hospital’s medical staff. CMS has stated in commentary that a hospital that has granted a physician courtesy privileges to a physician may not rely on the recruitment exception with respect to that physician.⁵⁰

The physician recruitment exception requires that the recruited physician relocate his/her medical prac-

tice from outside to inside the “geographic area served by the hospital.”⁵¹ A recruited physician must relocate his or her medical practice from outside the geographic area into the area, and must also either (i) move the site of his or her practice a minimum of 25 miles; or (ii) derive at least 75 percent of his or her practice’s revenues from services provided by the physician to new patients (i.e., patients not seen at the physician’s former practice).⁵²

During the initial start up year of the recruited physician’s practice, the numerical requirement for new patients will be satisfied if there is a reasonable expectation that the start up practice will derive at least 75 percent of its revenues for the year from professional services to patients not treated by the physician at the physician’s prior medical practice location during the preceding three years.⁵³

There is no explicit requirement in the physician recruitment exception that the recruited physician spend 100 percent of his or her medical practice time in the geographic area served by the hospital. CMS approved an arrangement whereby a physician would spend 10 percent to 20 percent of his or her time providing medical services at a medical office not located in the hospital’s geographic service area. It cautioned, however, that it might reach a different conclusion if the recruited physician spent more practice time outside the hospital service area.⁵⁴

A hospital located in a rural area may determine its geographic service area using noncontiguous ZIP codes if the hospital draws fewer than 90 percent of its inpatients from all of the contiguous ZIP codes from which it draws inpatients. For hospitals not located in rural areas, a hospital’s geographic service area still must be comprised of the lowest number of contiguous ZIP codes from which the hospital draws 75 percent of its inpatients.⁵⁵

CMS has advised that a hospital should look at its inpatient data to determine where patients live and then calculate the lowest number of ZIP codes that touch at least one other ZIP code in which the inpatients reside. Recruited physicians may relocate a medical practice into a “hole” ZIP code area (i.e., a ZIP code area in which no inpatients reside) if that “hole” ZIP code area is surrounded by contiguous ZIP code areas from which the hospital derives 75 percent of its inpatients.⁵⁶

It is possible for physicians to take advantage of the recruitment exception without meeting the relocation

⁴⁵ Stark II final rule, Phase III, 72 Fed. Reg. at 51054.

⁴⁶ 42 C.F.R. § 411.357(e)(4)(i).

⁴⁷ 72 Fed. Reg. at 51051.

⁴⁸ *Id.* CMS has ruled that while the Stark law may not require the use of an excess receipts provision (i.e. the repayment of recruitment dollars above a certain collection threshold), a contract containing one cannot be amended to remove one since that might lead to additional compensation for the already recruited physician. Centers for Medicare & Medicaid Servs., U.S. Dep’t of

Health & Human Servs., Advisory Op. No. CMS-AO-2007-01 (September 2007).

⁴⁹ 72 Fed. Reg. at 51052.

⁵⁰ 72 Fed. Reg. at 51048.

⁵¹ 42 C.F.R. § 411.357(e)(2).

⁵² 42 C.F.R. § 411.357(e)(2)(iv).

⁵³ *Id.*

⁵⁴ Centers for Medicare & Medicaid Servs., U.S. Dep’t of Health & Human Servs., Advisory Op. No. CMS-AO-2006-01 (Nov. 6, 2006).

⁵⁵ 42 C.F.R. § 411.357(e)(2)(i).

⁵⁶ Stark II final rule, Phase III, 72 Fed. Reg. at 51050-51051.

requirement in a few limited circumstances. As long as the recruited physician establishes his or her medical practice in the geographic area served by the hospital, the relocation requirement will not apply if, for at least two years immediately prior to the recruitment arrangement, the recruited physician was employed on a full-time basis by:

- a federal or state bureau of prisons or similar entity (operating correctional facilities) to serve exclusively a prison population;
- the Department of Defense or Department of Veterans Affairs to serve active or veteran military personnel and their families; or
- facilities of the Indian Health Service to serve patients who receive medical care exclusively through the Indian Health Service.⁵⁷

The physician may not maintain an independent private practice for a two-year period while employed by one of the above entities. For example, CMS has said the relocation requirement should apply in the case of a physician who left private practice in the hospital's geographic service area to become a full-time employee of the Indian Health Service for one year only.⁵⁸ In addition, CMS commentary has indicated that there may be other "rare" instances in which a hospital should be permitted to provide recruitment assistance to a physician whose practice cannot be relocated for some other reason. Therefore, a recruited physician who establishes a medical practice in the hospital's geographic service area will not be subject to the relocation provision if the Secretary has deemed in an advisory opinion that the physician does not have an established medical practice that serves or could serve a significant number of patients who are or could become patients of the recruiting hospital.⁵⁹

The recruitment exception excludes from the relocation requirement medical residents and physicians who have been in medical practice for less than one year. A residency includes all training, including post-residency fellowships.⁶⁰ Residents and physicians who have been in medical practice less than one year will not be considered to have an established practice and therefore will be eligible under the physician recruitment exception regardless of whether or not the physician actually moves his or her practice location.⁶¹

The recruitment exception does not protect the recruitment of mid-level non-physician practitioners. CMS has warned that under the "stand in the shoes" doctrine, payments by a hospital to subsidize a group practice's costs of recruiting and employing a non-physician

practitioner would create a direct compensation arrangement between the hospital and the group practice "for which no exception would apply."⁶²

Physicians receiving recruitment assistance must be allowed to establish staff privileges at other hospitals and to refer to other entities, except as such referrals may be restricted under an employment agreement or Stark compliant services agreement.⁶³ However, reasonable credentialing restrictions on physicians becoming competitors of a hospital are permissible, so long as they do not take into account the volume or value of referrals.⁶⁴

Additionally, each arrangement must be set forth in writing and signed by the parties.⁶⁵ The arrangement must not be conditioned on the physician's referrals to the hospital, nor can the hospital determine the amount of remuneration to the physician based on the volume or value of actual or anticipated referrals by the physician or other business generated between the parties.⁶⁶ Finally, while documentation of community need is not required under this exception, such documentation may be required by the Internal Revenue Service for tax-exempt hospitals and it is also considered important for compliance with the Medicare anti-kickback statute.

2210.20.70

Isolated Transactions

The isolated transaction exception covers one-time business deals such as a property or practice sale between a physician and a hospital to which the physician makes referrals. Transactions giving rise to any type of financial relationship, not only those involving DHS, are affected.⁶⁷ Such isolated transactions will not be considered compensation arrangements under Stark if certain conditions are met.⁶⁸

To qualify for the exception, the amount of remuneration under the transaction must:⁶⁹

- be consistent with fair market value;
- not be determined in a manner that takes into account (directly or indirectly) the volume or value of referrals by the physician or other business generated between the parties; and
- be commercially reasonable even if no referrals are to be made by the physician.

Additionally, no other transactions (except transactions specifically excepted under another exception) can occur between the DHS entity and physician for six months after an isolated transaction, except for commercially reasonable post-closing adjustments that do

⁵⁷ 42 C.F.R. § 411.357(e)(3).

⁵⁸ 72 Fed. Reg. at 51048.

⁵⁹ 42 C.F.R. § 411.357(e)(3)(iii).

⁶⁰ 72 Fed. Reg. at 51051.

⁶¹ 42 C.F.R. § 411.357(e)(3).

⁶² 72 Fed. Reg. at 51049.

⁶³ 42 C.F.R. § 411.357(e)(1)(iv).

⁶⁴ Stark II interim final rule, Phase II, 69 Fed. Reg. at 16095; 72 Fed. Reg. at 51049.

⁶⁵ 42 C.F.R. § 411.357(e)(1)(i).

⁶⁶ 42 C.F.R. § 411.357(e)(1)(ii), (iii).

⁶⁷ Social Security Act § 1877(e)(6) [42 U.S.C. § 1395nn(e)(6)]; 42 C.F.R. § 411.357(f).

⁶⁸ Stark II, Phase II, 69 Fed. Reg. at 16098.

⁶⁹ Social Security Act § 1877(e)(6) [42 U.S.C. § 1395nn(e)(6)], see also 42 C.F.R. § 411.357(f).

not take into account (directly or indirectly) the volume or value of referrals.

Despite industry criticism of the six-month limit on post-closing adjustments, CMS states that post-closing adjustments occurring after six months of closing will be treated as new transactions that would have to satisfy the requirements of an exception. Adjustments based on breach of warranty are part of the original transaction and may occur at any time, according to CMS; they are not considered either post-closing adjustments or new transactions.⁷⁰

With respect to separate transactions involving related parties (e.g., a hospital's purchase of both a medical group practice and an office building owned by some of the physicians in the group), CMS views these as two separate transactions involving different parties, each of which independently would have to meet the requirements of the isolated transactions exception.⁷¹

Transactions involving long-term or installment payments qualify for the exception if:

- the installment payment relates to a single transaction;
- the total aggregate payment is fixed before the first installment payment is made;
- the total aggregate payment does not reflect the volume or value of Medicare DHS referrals or other business generated by the physician for the DHS entity; and
- the payments are either immediately negotiable, guaranteed by a third party, secured by a negotiable promissory note, or subject to a similar mechanism, to assure payment even in the event of default by the purchaser or obligated party.⁷²

With regard to the “immediately negotiable” note requirement for installment payments, CMS has noted that there are several options to meet the critical requirement that a mechanism be in place to ensure payment in the event of default. If state law does not provide for a “negotiable” promissory note, the parties are free to choose from the other options.⁷³

2210.20.80

In-Office Ancillary Services

The Stark law allows physicians in group practices⁷⁴ to refer within their practice for certain types of services that are a common part of a physician's normal practice.⁷⁵ This “in-office ancillary services” exception sets out specific requirements for performance of the service, for the location where the service is performed, and for billing the service.⁷⁶ Generally, the services must be performed or supervised by the referring phy-

sician or a “physician in the group practice,” provided in the physician's or group's office, and billed by the physician or the group.

The exception generally does not protect the provision of durable medical equipment (DME), but does cover specified infusion pumps and canes, crutches, walkers, folding manual wheelchairs, and blood glucose monitors that meet listed conditions. An arrangement for listed DME also must comply with the anti-kickback statute.

Performance. Under the regulations, the services must be performed personally by:⁷⁷

- the referring physician;
- a physician who is a member of the same group practice as the referring physician; or
- individuals who are supervised by the referring physician or by another physician in the same group practice. Supervision must comply with the level of supervision required under Medicare payment and coverage rules applicable to the particular service.

Location. A service is “furnished” in the location where the service is actually performed or where an item is dispensed. The regulations also stipulate that the services must be furnished in one of the following:

- the “same building” (as defined in 42 C.F.R. § 411.351) in which the referring physician, or another member of the same group practice, furnishes services that meet one of three alternative tests;⁷⁸
- a “centralized building” that is used by the group practice for the provision of all or some of the group's clinical laboratory services; or
- a centralized building that is used by the group practice for the provision of some or all of the group's DHS (other than clinical laboratory services).

Billing. The service must be billed by:⁷⁹

- the physician performing or supervising the service;
- the group practice of which the performing or supervising physician is a member; under a billing number assigned to the group practice;
- the group practice if the supervising physician is “a physician in the group practice” under a billing number assigned to the group practice;
- an entity that is wholly owned by the physician or the physician's group practice under the entity's own billing number or a number assigned to the physician or group practice; or
- an independent third party billing company acting as the group practice, physician, or entity agent, provided the arrangement meets certain requirements.

⁷⁰ Stark II final rule, Phase III, 72 Fed. Reg. at 51055.

⁷¹ *Id.*

⁷² 42 C.F.R. § 411.351.

⁷³ Stark II final rule, Phase III, 72 Fed. Reg. at 51055.

⁷⁴ “Group practice” is defined in the statute at Social Security Act § 1877(h)(4) [42 U.S.C. § 1395nn(h)(4)]. See also 42 C.F.R. § 411.352. See *Chapter 2215, Group Practices*.

⁷⁵ Social Security Act § 1877(b)(2) [42 U.S.C. § 1395nn(b)(2)].

⁷⁶ 42 C.F.R. § 411.355(b).

⁷⁷ 42 C.F.R. § 411.355(b)(1).

⁷⁸ 42 C.F.R. § 411.355(b)(2)(i).

⁷⁹ 42 C.F.R. § 411.355(b)(3).

A special rule for physicians who primarily treat patients in their private homes allows these physicians, who do not actually practice in a building, to meet the exception's building requirement.⁸⁰

According to CMS, the exception does not alter an individual's or entity's obligations under the rules regarding reassignment of claims, purchased diagnostic tests, payment for services and supplies incident to a physician's professional services, or any other applicable Medicare laws, rules, or regulations.⁸¹

Disclosure to Patients. Under provisions of the Patient Protection and Affordable Care Act (PPACA) passed March 23, 2010, and effective that date, physicians relying on the in-office ancillary exception are required to provide their patients, at the time of the referral, with a written statement that the patient may obtain the prescribed service from another physician or supplier outside of that physician's group practice.⁸² This disclosure requirement applies only to the following advanced imaging services: MRI, CT, and PET. Among other requirements, the physician must provide a list of five suppliers that are located within 25 miles of the physician's office (or all the suppliers, if there are fewer than five in a rural area).⁸³ In commentary to the final rule, CMS clarified that the disclosure to the patient does not have to include the distance from the physician's office; the physician does not have to keep a signed patient acknowledgement on file (though CMS noted that as a general compliance matter some sort of documentation should probably be maintained); mailing or emailing the disclosure is acceptable, if verbal notification has occurred; and the physician is not prohibited from including language stating that its list of other suppliers is not an endorsement or recommendation of those suppliers.⁸⁴

The key guidelines for the disclosure are that it must be reasonably understood by all patients; be given at the time of referral; include the name, address and phone number of the other suppliers; list suppliers who are able to perform the needed test, based on the physician's "reasonable effort" to compile the list; and be updated once a year. CMS clarified that the disclosure must be given at the time of each referral, not just for the initial service for the patient.⁸⁵

For more information on the in-office ancillary services exception, see *Chapter 2215, Group Practices*, § 2215.20.40.

2210.20.90

Academic Medical Centers

The academic medical center (AMC) exception protects referrals for services provided by an academic

medical center when specified conditions are met.⁸⁶ The referring physician must:

- be a bona fide employee, on a full-time or substantial part-time basis, of a "component" of the academic medical center;
- be licensed to practice medicine in the state, and have a bona fide faculty appointment at the affiliated medical school or "accredited academic hospital."⁸⁷
- provide either substantial academic or substantial clinical teaching services for which the physician is paid as part of the employment relationship.

"Component" of an academic medical center means an affiliated medical school, faculty practice plan, hospital, teaching facility, institution of higher education, departmental professional corporation, or nonprofit support organization whose primary purpose is supporting the teaching mission of the AMC. The components need not be separate legal entities.

Physician compensation must meet the following requirements:⁸⁸

- the total compensation paid by each AMC component to the referring physician must be set in advance;
- the aggregate compensation paid by all AMC components to the faculty physician does not exceed fair market value for the services provided; and
- the total compensation paid by each AMC component to the faculty physician must not be determined in a manner that takes into account the volume or value of any referrals or other business generated by the referring physician within the AMC.

For purposes of this exception, the compensation paid by each individual AMC component to a faculty physician need not be consistent with fair market value. (For other regulatory purposes, the component may want to ensure that such compensation reflects fair market value.) The aggregate compensation paid by all AMC components to that faculty physician must, however, be consistent with fair market value.⁸⁹

Finally, the academic medical center must meet the following conditions:⁹⁰

- all transfers of money between components of the AMC must directly or indirectly support the missions of teaching, indigent care, research, or community service;
- relationships of the components must be set forth in written agreements or other written documents that have been adopted by the governing body of each component (if the AMC is one legal entity, this requirement will be satisfied if transfers of funds between components of the AMC are reflected in the routine financial reports covering the components);

⁸⁰ 42 C.F.R. § 411.355(b)(6).

⁸¹ Stark II final rule, Phase III, 72 Fed. Reg. at 51032-51035.

⁸² Social Security Act 1877(b)(2)[42 U.S.C. § 1395nn(b)(2)].

⁸³ 42 C.F.R. § 411.355(b)(7).

⁸⁴ 75 Fed. Reg. 73169, 73443-47 (Nov. 29, 2010).

⁸⁵ *Id.*

⁸⁶ Stark II final rule, Phase I, 66 Fed. Reg. at 915; 42 C.F.R. § 411.355(e).

⁸⁷ *Defined at* 42 C.F.R. § 411.355(e)(2).

⁸⁸ 42 C.F.R. § 411.355(e)(1)(ii).

⁸⁹ Stark II final rule, Phase III, 72 Fed. Reg. at 51037.

⁹⁰ 42 C.F.R. § 411.355(e)(1)(iii).

- all money paid to a referring physician for research must be used solely to support bona fide research and must be consistent with the terms and conditions of the grant; and

- the referring physician's compensation arrangement must comply with the anti-kickback statute and all laws and regulations governing billing and claims submission.

The academic medical center, for purposes of the Stark exceptions, consists of:

- an accredited medical school, including a university or an accredited academic hospital when appropriate;

- one or more faculty practice plans affiliated with the medical school, the affiliated hospital(s), or the accredited academic hospital; and

- one or more affiliated hospitals in which both a majority of the medical staff consist of faculty physicians, and a majority of all hospital admissions are made by faculty physicians.⁹¹

The regulation provides that any faculty member may be counted, including courtesy and volunteer faculty, in determining whether the majority tests are met.⁹² However, payments to such volunteer faculty are not permitted under this exception, given the requirement that the referring physician be a bona fide employee (at least on a substantial part-time basis) of a component of the AMC. Such payments must qualify under another exception.

An affiliated hospital may exclude a particular class of privileges when determining whether it satisfies the test as to whether a majority of the medical staff consists of faculty physicians, but in doing so, it must exclude all individual physicians with the same class of privileges. In other words, if the hospital wishes to exclude certain members of its courtesy staff, then it must exclude all members of the courtesy staff for purposes of the calculation.⁹³

Regulations no longer require AMCs to have an accredited medical school to be a component of the AMC. Rather, a teaching hospital may be the only component of the AMC to provide teaching and education if it meets the requirements of an "accredited academic hospital," that is, a hospital or health system that sponsors four or more approved medical education programs.⁹⁴

Only one case to date has construed the Stark academic medical center exception.⁹⁵ In that case, the government alleged that an arrangement in which a hospital made payments to referring pediatric cardiologists through their university employer did not satisfy the AMC exception to Stark. The court adopted a "goal and

purpose-oriented perspective rather than a hyper-technical one" and found that the applicable party complied with the AMC exception.

2210.20.100

Non-Monetary Compensation

An exception for certain forms of non-monetary compensation might cover situations in which physicians or their immediate family members receive compensation from a hospital that is not part of a formal, written agreement.⁹⁶ For example, a physician might receive free training sessions for his or her staff before performing services for hospital patients, or training sessions that are not considered part of an existing agreement for services. A hospital also might furnish the physician with free coffee mugs or note pads. The exception allows the receipt of such compensation, provided that:

- the compensation received is in the form of non-cash items or services and does not include cash equivalents, such as gift certificates, stocks or bonds, or airline frequent flier miles;

- the gifts are valued in the aggregate at no more than the amount set annually by CMS;⁹⁷ and

- the compensation is not determined in a way that takes into account the volume or value of the physician's referrals or other business generated by the referring physician; and

- the compensation was not solicited by the physician or the physician's practice (including employees or staff members).

Finally, this compensation likewise must not violate the anti-kickback statute or any laws or regulations governing billing or claims submission.

Notably, this exception protects gifts to individual physicians only, and not gifts given to a group practice. For example, it does not apply to gifts such as holiday parties or office equipment, even if such gifts, in the aggregate, are not greater than the allowed amount per physician in the group, multiplied by the number of physicians in the group.⁹⁸ Because of this exception, hospitals may give small gifts and benefits, such as meals or gift baskets, to referring physicians. Hospitals should, however, also track these free items and services to ensure that they do not, in the aggregate, exceed the allowable amount per physician.

When a hospital has inadvertently exceeded the non-monetary compensation limit by no more than 50 percent, physicians can repay certain excess nonmonetary compensation within the same calendar year to preserve compliance with the Stark law. The physician who receives the compensation must return the excess

⁹¹ 42 C.F.R. § 411.355(e)(2)(iii).

⁹² *Id.*

⁹³ 42 C.F.R. § 411.355(e)(2)(iii). Stark II final rule, Phase III, 72 Fed. Reg. at 51037.

⁹⁴ 42 C.F.R. § 411.357(e)(3).

⁹⁵ *United States ex rel. Villafane v. Solinger*, 543 F. Supp. 2d 678 (W.D. Ky. 2008).

⁹⁶ 42 C.F.R. § 411.357(k).

⁹⁷ For CY 2012, for example, this value is set at \$373. See the Consumer Price Index-Urban All Item table promulgated by CMS.

⁹⁸ Stark II final rule, Phase I, 66 Fed. Reg. at 921.

amount by the earlier of (i) the end of the calendar year in which he or she receives it, or (ii) 180 consecutive calendar days from receipt. This provision can only be used by a hospital once every three years with respect to the same referring physician.⁹⁹ Finally, the exception also allows entities, without regard to the dollar limitation in 42 C.F.R. § 411.357(k)(1), to provide one medical staff appreciation function (such as a holiday party) for the entire medical staff per year. Any gifts or gratuities provided in connection with the event must, however, fall within the noncompensation monetary limits.

2210.20.110

Fair Market Value Compensation

The regulatory fair market value (FMV) compensation exception, provides that compensation resulting from an arrangement between an entity and a physician or group of physicians for the provision of items or services (other than the rental of office space) will not constitute a financial relationship if the arrangement is set forth in an agreement that meets the following conditions:¹⁰⁰

- is for identifiable items or services that are specified in a written agreement signed by the parties;
- specifies the time frame for the arrangement, which can be for any period of time and contain a termination clause, provided the parties enter into only one arrangement for the same items or services during the course of a year (an arrangement made for less than a year may be renewed any number of times if the terms of the arrangement and the compensation for the same items or services do not change);
- specifies the compensation under the arrangement (compensation must be set in advance; be consistent with fair market value; not be determined in a manner that takes into account the volume or value of any referrals or any other business generated by the referring physician;
 - involves an arrangement that is commercially reasonable and furthers the legitimate business purposes of the parties;
 - does not violate the anti-kickback statute, and
 - is for services that do not involve the counseling or promotion of a business arrangement or other activity that violates a state or federal law.

The FMV exception may be used in certain instances when another exception, such as the personal services exception, also applies.¹⁰¹ Because the personal services arrangements exception requires that agreements be for a term of at least a year, the FMV exception gives parties greater flexibility in structuring arrangements. Notably, however, under either exception, compensation

cannot be changed during the first year for the same items and services.

The FMV exception explicitly does not apply, however, to the rental of office space.¹⁰²

Although this exception previously applied only to payments by an entity to a referring physician or a group of physicians for items and services, it was recently expanded to cover payments by a physician or a group of physicians to an entity for items and services.¹⁰³

This expansion has the side effect of potentially vastly narrowing a different Stark law exception—the “payments by a physician” exception. The “payments by a physician” exception requires only that the compensation paid by the physician (or his or her immediate family member) to an entity be at a price consistent with FMV. The “payments-by-a-physician” exception, however, only protects payments for items or services “not specifically excepted by another” Stark law exception.¹⁰⁴

2210.20.120

Incidental Medical Staff Benefits

Stark contains an exception for certain incidental benefits of low value provided by hospitals to their medical staffs.¹⁰⁵ The exception was created to permit the types of customary industry business practices that benefit both hospitals and their patients. For example, a hospital might provide free Internet access to physicians to facilitate access to hospital medical records or information.

The exception covers compensation in the form of items or services, not including cash or cash equivalents, from a hospital (or other DHS entity with a bona fide medical staff)¹⁰⁶ to its medical staff, provided the compensation arrangement does not violate the anti-kickback statute and the compensation is:

- offered by a hospital to all members of the medical staff in the same specialty without regard to the volume or value of referrals or other business generated between the parties;
- except with respect to identification of medical staff on a hospital website or in hospital advertising, the compensation is provided only during periods when the medical staff members are making rounds or performing other duties that benefit the hospital or its patients;
- provided by the hospital and used by the medical staff members only on the hospital’s campus (Internet access, pagers, and two-way radios, used away from the campus only to access the hospital are considered to meet the “on campus” requirement);

⁹⁹ Stark II final rule, Phase III, 72 Fed. Reg. at 51058-51059; 42 C.F.R. § 411.357(k)(3).

¹⁰⁰ 42 C.F.R. § 411.357(l).

¹⁰¹ Stark II final rule, Phase I, 66 Fed. Reg. at 919.

¹⁰² Stark II final rule, Phase III, 72 Fed. Reg. at 51059.

¹⁰³ Stark II final rule, Phase III, 72 Fed. Reg. at 51057.

¹⁰⁴ 42 C.F.R. § 411.357(i)(2).

¹⁰⁵ 42 C.F.R. § 411.357(m).

¹⁰⁶ 42 C.F.R. § 411.357(m)(8).

- reasonably related to the provision of, or designed to facilitate directly or indirectly the delivery of, medical services at the hospital;
- of low value¹⁰⁷ (adjusted for inflation annually) with respect to each occurrence of the benefit; and
- not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties.

CMS explicitly said that medical transcription services, a commonly provided service at many hospitals, do not meet the exception's requirements.¹⁰⁸

Incidental benefits must be used exclusively on the hospital's campus as noted above or for patients on the hospital's campus. For example, a hospital may provide a physician with a device used to access patients and personnel on the hospital's campus, even if the physician is not on the campus, but the device may not be used to access patients or personnel in other locations. According to CMS, a hospital campus consists of "all facilities operated by a hospital except for facilities that have been leased for non-hospital purposes and are not used exclusively by the hospital."¹⁰⁹

2210.20.130

Physician Compliance Training

The Stark regulations also contain an exception for compliance training provided by a hospital (or other DHS entity) to a physician (or his or her immediate family member or office staff) if the physician practices in the hospital's local community or service area, provided the training is held in that same local community or service area.¹¹⁰ "Compliance training" is training regarding the basic elements of a compliance program—for example, establishing policies and procedures, staff training, and internal monitoring—or specific training regarding the requirements of federal health care programs—billing, coding, documentation, etc. See *Chapter 207, Compliance Program Basics*. The rule does not limit training to hospital-related services, and could allow hospital-funded compliance training relating to private physician practice, as well. It specifically allows compliance training for any federal, state, or local law, regulation, or rule that in any way governs the conduct of the party receiving training and is not limited to training for government benefits programs.¹¹¹

The exclusion also covers compliance programs that qualify as Continuing Medical Education as long as compliance training predominates. CMS has clearly

stated, however, that the primary purpose of the program must be to provide compliance training and that "traditional CME content under the guise of 'compliance training'" will not be protected under this exception.¹¹² While perhaps a minor change, this provision appears to indicate that CMS understands that the slight increased risk of program abuse is outweighed by the possibility of increased attendance and improved educational opportunities for compliance programs under this revised exception.

2210.20.140

Indirect Compensation Arrangements

If an indirect compensation arrangement is found to exist (see *Chapter 2220, Direct and Indirect Relationships*), DHS referrals are prohibited unless the arrangement fits within a compensation exception that protects such relationships. The indirect compensation exception will most frequently be applied for this purpose. The exception has three elements:¹¹³

- the compensation received by the physician or immediate family member is fair market value for services or items actually provided, not taking into account the value or volume of referrals or other business generated by the referring physician for the entity furnishing DHS;

- The agreement is set out in writing, signed by the parties,¹¹⁴ and specifies the services covered by the arrangement, except in the case of a bona fide employment arrangement between an employer and an employee, in which case the arrangement need not be written, but must be for identifiable services and must be commercially reasonable, even if no referrals are made to the employer.

- The compensation arrangement does not violate the anti-kickback statute or any laws or regulations governing billing or claims submission.

Effective Oct. 1, 2009, lease payments for office space or equipment may not be based on either a percentage of revenue raised, earned, billed, collected or otherwise attributable to the services performed or business generated in the space or through use of the equipment, or per-unit rental charges, to the extent that such charges reflect services for patients referred by the lessor to the lessee.

"*Stand in the Shoes*" Doctrine. Amendments to the definition of "compensation arrangement" in 2007 and 2008 substantially changed the analysis and determina-

¹⁰⁷ For CY 2012, for example, this value was set at \$31. See the Consumer Price Index-Urban All Item table promulgated by CMS.

¹⁰⁸ Stark II final rule, Phase I, 66 Fed. Reg. at 921.

¹⁰⁹ Stark II final rule, Phase III, 72 Fed. Reg. at 51060.

¹¹⁰ 42 C.F.R. § 411.357(o).

¹¹¹ *Id.*

¹¹² Stark II final rule, Phase III, 72 Fed. Reg. at 51061.

¹¹³ 42 C.F.R. § 411.357(p).

¹¹⁴ All physicians in a physician organization need not sign. See n.152 - n.156 *infra*. CMS will consider a physician who is standing in the shoes of his or her physician organization to have signed a written agreement memorializing a compensation arrangement when the authorized signatory of the physician organization has signed the agreement. This rule applies to all compensation exceptions. Centers for Medicare & Medicaid Servs., U.S. Dep't of Health & Human Servs., Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2010, 74 Fed. Reg. 61738 (Nov. 25, 2009) (final rule with comment period).

tion as to whether a financial relationship between an entity and a referring physician is direct or indirect.¹¹⁵

Under revised 42 C.F.R. § 411.354(c), effective since October 1, 2008, a physician “stands in the shoes” (SITS) of his or her physician organization and is deemed to have a direct financial arrangement with the DHS entity, if (i) the only intervening entity between the physician and entity furnishing DHS is his or her physician organization and (ii) he or she has a non-titular ownership interest in the physician organization.

A “physician organization” is defined as a physician (including a professional corporation of which the physician is the sole owner), a physician practice, or a group practice as defined under Stark.¹¹⁶ A titular ownership or investment interest is one that excludes the ability or right to receive the financial benefits of ownership or investment, including, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment.

If SITS applies, the physician is deemed to have a direct relationship with the DHS entity on the same terms as the arrangement between the physician organization and the DHS entity. In other words, his or her physician organization is no longer considered to be an “intervening entity” and many arrangements that were previously analyzed as indirect are now deemed to be direct compensation arrangements. Therefore, such arrangements must meet a direct exception; they are no longer analyzed under the three-part indirect compensation relationship definition or by the indirect compensation exception. There was, however, a limited grandfathering clause for the original term or current renewal term of any arrangement that met the requirements of the indirect compensation exception as of September 5, 2007.¹¹⁷

Notably, for the time period between December 4, 2007 and October 1, 2008, the SITS rules applied to a larger category of physicians, as they also covered referring physicians who were employees or independent contractors of their physician organizations (not just physicians who were non-titular owners). Accordingly, referring physician owners, employees, and independent contractors were all required to “stand in the shoes” of their physician organizations for that period of time. Accordingly, almost all arrangements between referring physicians affiliated with physician organizations and hospitals became direct for that period of time. The grandfathering provision for the original or current renewal term of any arrangement meeting the indirect compensation exception as of September 5,

2007, however, covered a number of these arrangements.

Furthermore, CMS delayed the effective date of these “stand in the shoes” provisions until December 4, 2008 for compensation arrangements between a faculty practice plan and another component of the same academic medical center, as defined by Stark, and for compensation arrangements between an affiliated DHS entity and an affiliated physician practice in the same integrated 501(c)(3) health care system. Accordingly, these arrangements were not subject to the SITS rules between December 4, 2007 and October 1, 2008.¹¹⁸

2210.20.150

Risk-Sharing Arrangements

CMS created the risk-sharing compensation exception in 2004 to avoid having Stark disrupt the various kinds of physician arrangements with managed care organizations that treat Medicare beneficiaries; the existing statutory prepaid plan exception did not previously protect many of these financial arrangements.¹¹⁹

The risk-sharing compensation exception protects commercial and employer-provided managed care arrangements using incentive compensation such as withholds, bonuses, and risk pools that would not be protected by either the employment or personal services exceptions.

The exception states that compensation for services provided to enrollees of a health plan pursuant to such risk-sharing arrangements does not constitute a financial relationship for purposes of Stark, provided the arrangement does not violate the anti-kickback statute or any law or regulation governing billing or the submission of claims.¹²⁰

CMS defines “health plan” in the same manner as the anti-kickback safe harbor,¹²¹ The regulation does not define “risk-sharing,” however CMS’s commentary¹²² makes clear that, for Stark purposes, the agency interprets the term more broadly than it does for purposes of the anti-kickback risk-sharing safe harbors.¹²³ CMS has said that this exception covers all risk-sharing compensation paid to physicians by any downstream entity, as long as the terms of the exception are met.¹²⁴

2210.20.160

Professional Courtesy/Intra-Family Rural Referrals

This compensation exception exempts free or discounted health care items or services (“professional courtesy”) offered by an entity to a referring physician or a physician’s immediate family member or office

¹¹⁵ Stark II final rule, Phase III, 72 Fed. Reg. at 51027-51028.

¹¹⁶ See 42 C.F.R. § 411.351.

¹¹⁷ 42 C.F.R. § 411.354(c)(3)(ii).

¹¹⁸ Delay of the Date of Applicability for Certain Provisions of Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships (Phase III), 72 Fed. Reg. 64161 (Nov. 15, 2007).

¹¹⁹ The Stark II interim final rule, Phase II, amended the prepaid plans exception at 42 C.F.R. § 411.356(c) to cover Medicaid managed care plans. See, 69 Fed. Reg. at 16056.

¹²⁰ 42 C.F.R. § 411.357(n).

¹²¹ 42 C.F.R. § 1001.952(1)(2).

¹²² Stark II final rule, Phase I, 66 Fed. Reg. at 912.

¹²³ *Id.*

¹²⁴ Stark II interim final rule, Phase II, 69 Fed. Reg. at 16114.

staff. This common and long-standing practice, whereby the DHS entity furnishes medical services at no or reduced cost, is permitted where:

- the courtesy is offered to all physicians on the entity's bona fide medical staff or in such entity's local community or service area without regard to the volume or value of referrals or other business generated between the parties;
- the health care items and services provided are of a type routinely provided by the DHS entity;
- the entity has a professional courtesy policy that is set out in writing and approved in advance by the entity's governing body;
- the professional courtesy is not offered to a physician (or immediate family member) who is a federal health care program beneficiary, unless there has been a good faith showing of financial need; and
- the arrangement does not violate the anti-kickback statute or any federal or state law or regulation governing billing or claims submission.¹²⁵

The exception does not protect professional courtesy provided by suppliers, such as laboratories or DME suppliers, but only that by hospitals and other providers with a formal medical staff. An entity is no longer required under Stark to notify an insurer when the professional courtesy involves a reduction of any coinsurance obligation (insurers may require such notification).

Intra-Family Rural Referrals. A regulatory exception permits physicians to refer patients living in a rural area to his or her immediate family member or an entity in which his or her immediate family member has either an ownership or compensation interest, provided the following requirements are met: (i) the patient who is referred lives in a rural area as defined by Stark, (ii) there is no other person or entity available to furnish the services in a timely manner within 25 miles or 45 transportation minutes of the patient's home, and (iii) in the case of services furnished to patients where they reside (for example, home health services or DME), no other person or entity is available to furnish the services in a timely manner considering the patient's condition. The referring physician or the immediate family member must make reasonable inquiries as to the availability of other persons or entities to furnish DHS within 25 miles or 45 transportation minutes of the patient's home.¹²⁶

In theory, a referring physician could avail him- or herself of the exception even if the physician and the DHS entity were both located in an urban area.¹²⁷ Unlike other location-based exceptions, this exception is

based on where the patient resides, rather than the location of either the referring physician or the DHS entity.¹²⁸

Since this provision is the only one that excepts some, but not all, patients referred to an entity by a particular physician, providers who use this exception should clearly distinguish between patients who qualify for the exception and those who do not. They should also track their patients' rural or urban geographical classification, and stay abreast of any regulatory changes to definitions of urban and rural boundaries. CMS has clarified that Micropolitan Statistical Areas, not being considered urban, are rural areas.¹²⁹

To the extent that the only person or entity that can furnish DHS to the beneficiary within 25 miles or 45 minutes transportation time from the patient's residence does not participate in Medicare, such an entity "should be treated as if it does not exist," CMS said.¹³⁰

2210.20.170

Physician Services

The physician services statutory exception requires that physician services be provided either personally by another physician group member or physician in the same group practice, or under the supervision of another group member physician or physician in the group practice.¹³¹ The exception applies only to physician services and to "incident to" services that qualify as physician services.

2210.20.180

Referral Services/Malpractice Insurance

Remuneration resulting from any arrangement that meets all the conditions set forth in the anti-kickback safe harbor for referral services,¹³² or the safe harbor for obstetrical malpractice insurance subsidies,¹³³ is excepted from the self-referral prohibition.¹³⁴

Effective October 1, 2008, CMS has also provided an alternative set of requirements for the obstetrical malpractice insurance subsidy exception. The new requirements were set forth in response to criticisms that, under the prior rule, even an agreement that received a favorable advisory opinion from the OIG as to the anti-kickback statute, despite not fitting within the anti-kickback safe harbor, would fail to satisfy the Stark requirement to meet all the conditions set forth in the safe harbor. The new requirements allow hospitals, federally qualified health centers, and rural health clinics to provide an obstetrical malpractice insurance subsidy to a physician who regularly engages in obstetrical practice as a routine part of a medical practice that is (i)

¹²⁵ 42 C.F.R. § 411.357(s).

¹²⁶ 42 C.F.R. § 411.353(j).

¹²⁷ Thomas S. Crane, Esq., Mintz, Levin, Cohn, Ferris, Glovsky and Popeo P.C., *et. al.*, *Stark Phase II Final Rule: Summary and Analysis* (Mintz, Levin Analysis), 8 BNA's Health Care Fraud Rep. 320 (April 14, 2004).

¹²⁸ Stark II interim final rule, Phase II, 69 Fed. Reg. at 16084.

¹²⁹ Stark II final rule, Phase III, 72 Fed. Reg. at 51040, *citing* 65 Fed. Reg. 82228-82233 (Dec. 27, 2000).

¹³⁰ Stark II final rule, Phase III, 72 Fed. Reg. at 51040.

¹³¹ Social Security Act § 1877(b)(1) [42 U.S.C. § 1395nn(b)(1)]. *See also*, Stark II final rule, Phase I, 66 Fed. Reg. at 879; 42 C.F.R. § 411.355(a).

¹³² 42 C.F.R. § 1001.952(f).

¹³³ 42 C.F.R. § 1001.952(o).

¹³⁴ 42 C.F.R. §§ 411.357(q) and 411.357(r), respectively.

located in a primary care health professional shortage area, rural area, or area with a demonstrated need, as determined by HHS in an advisory opinion; or (ii) is comprised of patients at least 75 percent of whom reside in a medically underserved area or are part of a medically underserved population.¹³⁵

The arrangement must be set out in writing, signed, and specify the payments to be made. The arrangement cannot be conditioned on the physician's referral of patients to the entity providing the payment, and the payment cannot be determined, directly or indirectly, based on the volume or value of actual or anticipated referrals by the physician or other business generated by the parties. The physician must be allowed to establish staff privileges at any entity and to refer business to any other entities (unless a directed referral requirement complies with 42 C.F.R. § 411.354(d)(4)). The physician must treat obstetrical patients in a nondiscriminatory manner, and payments must be made to a person or organization providing the malpractice insurance. The insurance must be a bona fide malpractice insurance policy or program and the premium calculated based on a bona fide assessment of the liability risk under the insurance. There are additional requirements regarding the patients treated under the policy or program.¹³⁶

2210.20.190

Retention Payments (Underserved Areas)

Money paid to a physician in order to retain the physician in a hospital or FQHC service area are excepted from the self-referral prohibition if several conditions are met.¹³⁷ Unlike the recruitment exception, the retention exception does not permit payments to be made to a physician indirectly through a medical group practice.

Retention payments may only be made to a physician if either (i) 75 percent of the physician's patients reside in a medically underserved area or are members of a medically underserved population, or (ii) if the physician's current medical practice is located in a rural area, a health professional shortage area (HPSA), regardless of physician specialty, or an area with a demonstrated need for the physician (as determined in an advisory opinion). Furthermore, the hospital can only enter into one retention arrangement with a particular referring physician every 5 years. The amount and terms of the arrangement cannot take into account the volume or value of referrals, or other business generated by the physician.¹³⁸

The following conditions must also be met:

- the physician has a firm written recruitment or employment offer,¹³⁹ from another hospital, academic medical center, physician organization, or FQHC inde-

pendent of the entity seeking to retain the physician, which would require the physician to move his or her practice at least 25 miles and out of the current hospital's service area (CMS may waive, through an advisory opinion, the relocation requirement for a physician practicing in a HPSA or other underserved area);

- the amount of the retention payment is limited to the lower of (i) the difference between the physician's current income from physician and related services and the income being offered in the recruitment or employment proposal, with each calculated over no more than a 24-month period using the same methodology, or (ii) the reasonable costs the hospital or FQHC must expend to recruit a replacement physician.

In addition, in certain circumstances, retention payments are permitted to be made to a physician who does not have a bona fide written recruitment or employment offer. The physician must certify that he or she has a bona fide opportunity for future employment that would require the physician to relocate his or her medical practice at least 25 miles and outside of the geographic area served by the hospital or FQHC (which is the same requirement applicable to a written recruitment or employment offer). Payment in this case is limited to the lower of either the reasonable costs the hospital or FQHC must expend to recruit a replacement physician or 25 percent of the physician's current income (measured over no more than a 24 month period).¹⁴⁰

2210.20.200

Community-Wide Health Information Systems

A hospital or other DHS entity may furnish physicians with information technology as part of a community-wide health information system without creating a financial relationship under the Stark law.¹⁴¹ The following requirements must be met:

- the items or services are provided and utilized primarily to allow access to a community-wide network of health information such as medical records, complementary drug information systems, general health information, medical alerts, and related patient treatment information;

- provision of the information system does not take into account the volume or value of referrals or violate the anti-kickback statute; and

- the system is available to all providers, practitioners, and residents of the community who wish to participate.

2210.20.210

Electronic Prescribing Systems

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) added a new Part D to the Social Security Act establishing a prescription

¹³⁵ 42 C.F.R. § 411.357(r)(2).

¹³⁶ 42 C.F.R. § 411.357(r)(2)(ix).

¹³⁷ 42 C.F.R. § 411.357(t).

¹³⁸ 42 C.F.R. § 411.357(t)(3).

¹³⁹ Such offers must specify the remuneration being offered. See 42 C.F.R. § 411.357(t).

¹⁴⁰ 42 C.F.R. § 411.357(t)(2).

¹⁴¹ 42 C.F.R. § 411.357(u).

drug benefit in the Medicare program.¹⁴² As part of the new legislation, Congress directed the secretary of the Department of Health and Human Services to create a Stark law exception to protect arrangements involving the provision of non-monetary remuneration (items and services in the form of hardware, software, or information technology and training services) necessary and used solely to receive and transmit electronic prescription drug information in accordance with electronic prescribing standards adopted by HHS.

In 2006, CMS published regulations laying out the rules for this exception.¹⁴³ At the same time, the HHS Office of Inspector General (OIG) issued a comparable safe harbor under the anti-kickback statute (see *Chapter 1805, Hospital Incentives to Physicians*, § 1805.20.50). Both the exception and the safe harbor are effective Oct. 10, 2006. A similar exception, which may have more utility, promulgated at the same time covers electronic health records (see § 2210.20.220.)

The regulations provide that electronic prescribing technology is excepted from the self-referral prohibition if several conditions are met:¹⁴⁴

- the items and services are provided 1) by a hospital to a physician who is a member of its medical staff, 2) by a group practice¹⁴⁵ to a prescribing health care professional who is a member¹⁴⁶ of the group practice; or 3) by a prescription drug plan sponsor or Medicare Advantage organization to pharmacists and pharmacies participating in the network of such sponsor or organization and to prescribing health care professionals;
- the items and services are part of, or are used to access, an electronic prescription drug program that meets standards under Medicare Part D applicable at the time the items and services are provided;
- the donor (or any person on the donor's behalf) takes no action to limit or restrict the use or compatibility of the items or services with other electronic prescribing or electronic health records systems;
- for items or services that are of the type that can be used for any patient without regard to payer status, the donor does not restrict, or take any action to limit, the recipient's right or ability to use the items or services for any patient;
- neither the physician nor the physician's practice (including employees and staff members) makes the receipt of items or services, or the amount or nature of

the items or services, a condition of doing business with the donor;

- neither the eligibility of a recipient for the items or services, nor the amount or nature of the items or services, is determined in a manner that takes into account the volume or value of referrals or other business generated between the parties;
- the arrangement is set forth in a written agreement that (i) is signed by the parties, (ii) specifies the items and services being provided and the donor's cost of the items and services, and (iii) covers all of the electronic prescribing items and services to be provided by the donor (or affiliated parties),¹⁴⁷ and
- the donor does not have actual knowledge of, and does not act in reckless disregard or deliberate ignorance of, the fact that the recipient possesses or has obtained items or services equivalent to those provided by the donor.

2210.20.220

Electronic Health Records Technology

Concurrent with its regulations to implement a Stark electronic prescribing exception (see *Electronic Prescribing Systems*, § 2210.20.210), CMS promulgated 42 C.F.R. § 411.357(w),¹⁴⁸ excepting from the self-referral prohibition certain arrangements involving the provision of interoperable¹⁴⁹ software and directly related training services necessary and used predominantly to create, receive, transmit, and maintain patients' electronic health records (EHR).

The exception protects items and services provided by an entity, as defined at 42 C.F.R. § 411.351, to a physician.¹⁵⁰ Like the exception for electronic prescribing arrangements, the EHR exception requires the donated items and services to be "necessary" and does not protect the provision of items or services technically and functionally equivalent to items and services the physician already owns or uses.¹⁵¹

The EHR exception also prohibits donor-imposed limitations on a physician's right to use the items for any patient¹⁵² as well as any actions to disable or limit the interoperability of any software component or impose any other barriers to compatibility.¹⁵³ Also, neither the physician nor the physician's practice (including employees and staff members) may make the receipt of items or services, or the amount or nature of the items

¹⁴² Pub. L. No. 108-173, § 101, establishing Social Security Act § 1860D-2.

¹⁴³ Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements, 71 Fed. Reg. 45140 (Aug. 8, 2006) (final rule).

¹⁴⁴ 42 C.F.R. § 411.357(v).

¹⁴⁵ "Group practice" is defined at 42 C.F.R. § 411.352.

¹⁴⁶ "Member" is defined at 42 C.F.R. § 411.351.

¹⁴⁷ This requirement is met if all separate agreements between the donor (and affiliated parties) and the recipient incorporate each other by reference or if they cross-reference a master list of agreements that is maintained and updated centrally and is avail-

able for review by HHS upon request. The master list must be maintained in a manner that preserves the historical record of agreements. 42 C.F.R. § 411.357(v)(7)(iii).

¹⁴⁸ Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements, 71 Fed. Reg. 45140.

¹⁴⁹ 42 C.F.R. § 411.357(w)(2). Software is deemed to be interoperable if a certifying body recognized by HHS has certified the software no more than 12 months prior to the date it is provided to the physician.

¹⁵⁰ 42 C.F.R. § 411.357(w)(1).

¹⁵¹ 42 C.F.R. § 411.357(w)(8).

¹⁵² 42 C.F.R. § 411.357(w)(9).

¹⁵³ 42 C.F.R. § 411.357(w)(3).

or services, a condition of doing business with the donor.¹⁵⁴

In selecting software recipients and determining the amount or nature of the items and services they are to receive, criteria may not include the volume or value of the recipient's referrals to the donor or other business generated between the parties.¹⁵⁵ A selection is deemed not to take directly into account the volume or value of referrals or other business generated between the parties if it is based on:

- the total number of prescriptions written by the physician (but not the volume or value of prescriptions dispensed or paid by the donor or billed to the program);
- the size of the physician's medical practice (for example, total patients, total patient encounters, or total relative value units);
- the total number of hours that the physician practices medicine;
- the physician's overall use of automated technology in his or her medical practice (without specific reference to the use of technology in connection with referrals made to the donor);
- whether the physician is a member of the donor's medical staff, if the donor has a formal medical staff;
- the level of uncompensated care provided by the physician; or
- any other reasonable and verifiable manner that does not directly take into account the volume or value of referrals or other business generated between the parties.

The following additional conditions must be met:

- the arrangement must be set forth in a written agreement signed by the parties that specifies the items and services being provided and the donor's cost of the items and services, and that covers all of the electronic health records items and services to be provided by the donor;¹⁵⁶
- before receipt of the items and services, the physician must pay a minimum of 15 percent of the donor's cost for the items and services¹⁵⁷ —the donor (or any party related to the donor) may not finance the physician's payment or loan funds to be used by the physician to pay for the items and services;
- the items and services may not include staffing of physician offices or be used primarily to conduct personal business or business unrelated to the physician's medical practice;¹⁵⁸
- the EHR software must contain electronic prescribing capability, either through an electronic prescribing component or the ability to interface with an

existing electronic prescribing system that meets the applicable standards under Medicare Part D at the time the items and services are provided;¹⁵⁹ and

- the arrangement may not violate the anti-kickback law or regulations governing billing or claims submissions.¹⁶⁰

Finally, the transfer of the items or services must occur and all requirements of the exception must be satisfied on or before the sunset date for the regulation, Dec. 31, 2013.¹⁶¹ This date was selected to be consistent with President George W. Bush's Health Information Technology Plan, announced April 26, 2004, which included the goal of having EHR technology adopted by 2014. Nothing, however, prevents CMS from extending the exception pursuant to notice and comment rulemaking.

The Stark Law provides that “[t]he provision of items, devices, or supplies that are used solely . . . to order or communicate the results of tests or procedures for such entity” do not qualify as remuneration needing an exception.¹⁶² In a 2008 Advisory Opinion, CMS reviewed a hospital system's plans to contract with a software vendor to develop custom computer interfaces to communicate with staff physicians' existing EHR systems in their practices, and concluded that it was not a Stark compensation arrangement in need of an exception.¹⁶³

According to CMS, the hospital already had developed a proprietary health care software information system that allowed staff physicians to view patient data, order tests, and communicate lab test results. Furthermore, the physicians already could view lab reports over a protected Internet connection to the hospital's system. CMS said that, according to the hospital system, the interface: 1) would be used only to order or communicate the results of tests and procedures furnished by the hospital; 2) could not be modified to perform an alternate function; and 3) could not be resold, transferred, or assigned by an affiliated physician practice.

As a result, CMS found the proposed arrangement did not meet the Stark law definition of “compensation arrangement” and therefore neither compliance with the EHR nor other Stark exception was needed to proceed with the arrangement.

CMS stated that its analysis was limited to the use of the physician practice interface to order or communicate results of hospital tests and procedures and might not be valid if the hospital system or the physicians were to use the interface for other purposes.

¹⁵⁴ 42 C.F.R. § 411.357(w)(5).

¹⁵⁵ 42 C.F.R. § 411.357(w)(6).

¹⁵⁶ 42 C.F.R. § 411.357(w)(7).

¹⁵⁷ 42 C.F.R. § 411.357(w)(4).

¹⁵⁸ 42 C.F.R. § 411.357(w)(10).

¹⁵⁹ 42 C.F.R. § 411.357(w)(11).

¹⁶⁰ 42 C.F.R. § 411.357(w)(12).

¹⁶¹ 42 C.F.R. § 411.357(w)(13).

¹⁶² 42 C.F.R. § 411.351.

¹⁶³ Centers for Medicare & Medicaid Servs. Advisory Op. No. AO-2008-01 (May 20, 2008).

2210.20.230**Ownership Interest in Entire Hospitals**

An ownership interest held by a referring physician (or his or her immediate family member) in a whole hospital (except hospitals located in Puerto Rico, which have their own unlimited exception) can be excepted from the self-referral prohibition if certain conditions are met. Most notably, the hospital must have had physician ownership and a Medicare provider agreement as of December 31, 2010, and the physician's ownership must be in the entire hospital itself and not in a subdivision of the hospital.¹⁶⁴

CMS also takes the position that a physician can maintain an ownership or investment interest in a hospital by holding an interest in an organization that owns a chain of hospitals, such as a health system, because the statute does not require that the physician have a direct interest in the hospital. To qualify for the exception, however, the physician must have privileges at the specific hospital in the chain to which he or she is referring.¹⁶⁵

Scope of Excepted Referrals. The exception covers any DHS the hospital provides. Referrals by the referring physician to the hospital entity are, however, the only DHS excepted; referrals to any other entity, such as a home health care agency or skilled nursing facility, even if owned by the hospital, are not protected by the "whole hospital" exception.¹⁶⁶ Therefore, a physician can refer to a hospital in which he or she had an investment interest, but cannot refer to a skilled nursing facility separately owned by that same hospital.

The limited scope of referrals excepted creates a situation in which a physician may refer to a laboratory in a hospital if the lab is a division of the hospital, but not if the lab is a separate legal entity, even if the hospital is its sole owner. It also means that, based on CMS's interpretation, the prohibition on referrals applies with full force to a hospital subsidiary in which a physician has an indirect financial relationship, even though the physician's direct ownership interest in the hospital accepts the physician's referrals to the hospital itself.

Restrictions on New Physician-Owned Hospitals and Expansions. PPACA banned the creation of new physician-owned hospitals after Dec. 31, 2010. Physician-owned hospitals with a Medicare provider agreement in effect at that time were grandfathered, although PPACA froze aggregate physician ownership in such existing physician-owned hospitals at its level as of March 23, 2010.¹⁶⁷

Physician-owned hospitals are also banned from expanding their facility capacity, except in very limited circumstances as prescribed by new regulations. Such hospitals cannot increase the number of operating rooms, procedure rooms, and beds beyond that for which the hospital was licensed on March 23, 2010 (or, for a hospital that did not have a provider agreement on that date, but did have one in effect as of December 31, 2010), unless the Secretary grants an exception.

An "applicable hospital" or high Medicaid facility may request an exception to the expansion limitation once every 2 years from the date of a CMS decision on the hospital's most recent request. The regulations at 42 C.F.R. § 411.362(c)(4) outline the procedure for submitting a request. A permitted increase in facility capacity may only occur on the hospital's main campus and may not result in the number of operating rooms, procedure rooms, and beds for which the hospital is licensed exceeding 200 percent of the hospital's baseline number of such rooms and beds.

An "applicable hospital" is one that:

- is located in a county whose population increase is at least 50 percent more than that of the hospital's entire state during the most recent 5-year period for which data are available;
- has an annual percent of total Medicaid inpatient admissions equal to or greater than the average percent of Medicaid admissions for all hospitals in the same county during the most recent fiscal year for which data are available;
- does not discriminate against beneficiaries of federal health care programs and does not permit physicians practicing at hospital to do so;
- is located in a state with a lower average bed capacity than the average bed capacity nationwide during the most recent fiscal year for which data are available; and
- has an average bed occupancy greater than the average bed occupancy statewide during the most recent fiscal year for which data are available.

A high Medicaid facility is one that:

- is not the sole hospital in the county in which the hospital is located;
- for the three most recent fiscal years, has an annual percent of total Medicaid inpatient admissions equal to or greater than the average percent of such admissions for all hospitals in the same county during the most recent fiscal year for which data are available; and

¹⁶⁴ Social Security Act § 1877(d)(3) [42 U.S.C. § 1395nn(d)(3)] as amended by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, (March 23, 2010), as amended by the Health and Education Reconciliation Act of 2010, Pub. L. No. 111-152 §§ 6001 and 10602, § 1106 (March 30, 2010); 42 C.F.R. § 411.356(c)(3).

¹⁶⁵ Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships, 63 Fed. Reg. 1659, 1698 (pro-

posed Jan. 9, 1998) (Stark II proposed rule). While not having the force of law, agency interpretations in the proposed regulations may safely be relied upon absent contrary indications. (See Chapter 2205, Key Concepts and Terms, § 2205.10.30.10.)

¹⁶⁶ Stark II final rule, Phase III, 72 Fed. Reg. at 51043.

¹⁶⁷ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, §§ 6001 and 10602 (March 23, 2010), as amended by the Health and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 1106 (March 30, 2010).

- does not discriminate against beneficiaries of federal health care programs and does not permit physicians practicing at the hospital to do so.

Additional Requirements for Grandfathered Hospitals. Grandfathered hospitals must comply with certain disclosure, bona fide ownership and investment, and patient safety requirements.

Disclosure. Grandfathered hospitals are required to file annual reports with CMS identifying physician owners and to disclose to referred patients and on the hospital's website and in advertising materials that the hospital is physician-owned. These disclosure requirements also are incorporated in the Medicare conditions of participation for physician-owned hospitals.

Bona Fide Ownership and Investment. To ensure bona fide ownership and investment under the whole-hospital exception, the Stark regulations added by PPACA prohibit hospitals from:

- offering ownership or investment interests to a physician owner or investor on more favorable terms than the terms offered to others,¹⁶⁸ as the rule requires ownership and investment returns to be distributed to each owner or investor in the hospital in an amount that is directly proportional to his or her ownership or investment interest in the hospital;¹⁶⁹

- directly or indirectly providing loans or financing for any investment in the hospital by a physician owner or investor;

- directly or indirectly guaranteeing a loan, making a payment toward a loan, or otherwise subsidizing a loan, for any individual physician owner or investor or group of physician owners or investors that is related to acquiring any ownership or investment interest in the hospital; or

- offering a physician owner or investor the opportunity to purchase or lease any property under the control of the hospital or any other owner or investor in the hospital on more favorable terms than the terms offered to an individual who is not a physician owner or investor.

Furthermore, physician owners and investors are prohibited from receiving, directly or indirectly, any guaranteed receipt of or right to purchase other business interests related to the hospital, including the purchase or lease of any property under the control of other owners or investors in the hospital or located near the premises of the hospital. Finally, ownership and investment returns must be distributed to each owner or investor in the hospital in an amount that is directly proportional to his or her ownership or investment interest in the hospital.¹⁷⁰

Patient Safety. If the hospital does not have a physician available on the premises to provide services during all hours in which the hospital is providing services to the patient, the hospital must disclose this information to the patient and receive a signed acknowledgment from the patient. The hospital must have the capacity to provide assessment and initial treatment for all patients, and the ability to refer and transfer patients to hospitals with the capability to treat the needs of the patient that the hospital is unable to address.¹⁷¹

Hospitals should note that because states may enact greater restrictions than the federal Stark law by prohibiting all physician self-referrals to specialty hospitals, local law also must be considered. For situations in which a physician has a joint venture with a hospital, see *Chapter 1410, Joint Ventures and Acquisitions.*

2210.30 Compliance

2210.30.10

Overview

Medicare overpayments, including those resulting from Stark violations, not repaid within 60 days of being identified become an “obligation” under the False Claims Act.¹⁷² Consequently, there is now greater potential for Stark violations to present significant fraud and abuse exposure in the form of whistleblower suits.¹⁷³

Accordingly, hospitals and other health care providers should develop stringent audit and refund-processing policies and procedures to enable them to identify overpayments and/or potential Stark violations such that they can resolve, refund, and/or report in a timely manner.

If a question arises as to whether an arrangement technically complied with Stark, a hospital may consider whether one of the “temporary noncompliance” rules set forth below would be applicable.

If it appears that a violation may have occurred, then the hospital may want to consider utilizing the Self-Referral Disclosure Protocol (SRDP). The SRDP provides that the obligation to return overpayments under the FCA is tolled until a settlement agreement is entered into, CMS removes the disclosing entity from the SRDP, or the self-disclosing entity withdraws from the SRDP.

2210.30.20

Temporary Noncompliance Rules

Temporary Noncompliance. If an arrangement between an entity and a physician has fully complied with

¹⁶⁸ 42 U.S.C. § 1395nn(i)(1)(D)(ii).

¹⁶⁹ 42 U.S.C. § 1395nn(i)(1)(D)(v).

¹⁷⁰ 42 U.S.C. § 1395nn(i)(1)(D)(v).

¹⁷¹ 42 CFR § 411.362(b)(5).

¹⁷² 31 U.S.C. § 3729, *et. seq.*

¹⁷³ When overpayments are considered “identified” is not defined in PPACA. See Social Security Act § 1128J(d) [42 U.S.C. § 1320a-7b(a)(3)(d)].

an applicable Stark exception for at least 180 consecutive calendar days immediately preceding the date on which the arrangement became noncompliant, and the noncompliance is due to reasons beyond the control of the entity, then a Stark violation is not considered to have occurred if the parties rectify the noncompliance within 90 days.

CMS has stated that whether the noncompliance was beyond the entity's control is a case-by-case decision and has provided the example of noncompliance occurring due to loss of a HPSA designation for purposes of the physician retention payments exception or delays in obtaining fully signed copies of renewal agreements.¹⁷⁴

This dispensation is not afforded to arrangements falling within the nonmonetary compensation or incidental medical staff benefits exceptions. This special rule may only be used once every 3 years with respect to the same referring physician.¹⁷⁵

Temporary Noncompliance with Signature Requirements. Effective October 1, 2008, the Stark regulations include a special rule for compensation arrangements that fully comply with an applicable Stark exception, except with respect to the signature requirement.¹⁷⁶ Provided that the failure to obtain a signature was either (i) inadvertent and the parties obtain the signature within 90 consecutive calendar days of the arrangement becoming noncompliant or (ii) not inadvertent and the parties obtain the required signature within 30 consecutive calendar days, then Stark has not been violated. This special rule may, however, only be used once every 3 years with respect to the same referring physician.

In commentary, CMS has stated that a “not inadvertent” failure is a “knowing” failure to comply—for example, when a hospital needs to retain a physician's services on very short notice and faces either a Stark violation due to the lack of a signature or having to forgo the physician's services.¹⁷⁷

2210.30.30

Period of Disallowance

The period of disallowance is the timeframe during which a financial arrangement under the Stark law did not comply with a Stark exception. During this period of time, referrals are prohibited under the Stark law,¹⁷⁸ and no Medicare payments may be made for services associated with the prohibited referrals. Accordingly, any amounts actually paid as a result of those prohibited referrals must be refunded to the government.¹⁷⁹

The period of disallowance begins when the arrangement fails to meet the requirements of an applicable exception to Stark. As a consequence, the period of

disallowance is integrally related to the particular exception at issue.

Where the noncompliance is related to an issue other than the amount of compensation, the period of disallowance ends on the date when the financial relationship satisfies all the elements of the applicable exception.

Where the noncompliance is related to the payment of excess compensation, the period of disallowance ends when the recipient of the excess compensation returns it to the party that paid it and the arrangement otherwise satisfies a Stark exception. Similarly, if insufficient compensation has been paid, the period of disallowance ends when all amounts owed are paid and the arrangement otherwise satisfies a Stark exception.

In commentary, CMS gives the example of a contract between a physician and a hospital for personal services, where the physician is paid excess compensation for the period of January 1 through June 6. In this example, the parties ended the period of disallowance on June 6 when the physician paid back the excess compensation and the arrangement otherwise satisfied the personal services exception to Stark.¹⁸⁰

CMS has emphasized in commentary that while this rule sets the outside limit on the period of disallowance, the timeframe is ultimately determined on a case-by-case basis depending on the particular facts and circumstances of a given situation. Therefore, the parties to a prohibited arrangement remain free to argue, on a case-by-case basis, that the arrangement was out of compliance for a shorter period of time.¹⁸¹

2210.30.40

Self-Disclosure

To encourage health care providers to promptly self-disclose conduct that threatens federal health care programs with fraud or abuse, the HHS has developed provider self-disclosure protocols.

In a March 24, 2009, Open Letter to health care providers, HHS Inspector General Daniel R. Levinson announced that the OIG self-disclosure program, previously an avenue for resolving Stark and anti-kickback violations, no longer would accept disclosure of matters involving liability only under the physician self-referral law without a colorable anti-kickback statute violation for the same conduct.¹⁸²

Responding to this development and to longstanding industry complaints that the Stark law often imposes extraordinary liability for mere technical violations without regard to intent, Congress directed CMS to develop, in consultation with the OIG, a self-disclosure protocol under a disclosure provision set forth in

¹⁷⁴ 72 Fed. Reg. 51012, 51025-6 (Sept. 5, 2007); 69 Fed. Reg. 16053, 16057 (Mar. 26, 2004).

¹⁷⁵ 42 C.F.R. § 411.353(f).

¹⁷⁶ 42 C.F.R. § 411.353(g).

¹⁷⁷ 73 Fed. Reg. 48707.

¹⁷⁸ See 42 C.F.R. § 411.353(c).

¹⁷⁹ 42 C.F.R. § 411.353(b) and (d).

¹⁸⁰ See 73 Fed. Reg. 48434, 48702 (Aug. 19, 2008).

¹⁸¹ *Id.* at 48700.

¹⁸² OIG ‘Open Letter’ to Industry Cites Kickbacks in Self-Disclosure Protocol, 13 BNA's Health Care Fraud Report 258 (April 8, 2009).

PPACA for potential or actual Stark violations.¹⁸³ Accordingly, CMS released the self-referral disclosure protocol (SRDP) in September 2010.¹⁸⁴

Under the SRDP, all disclosures must be submitted to CMS electronically, with an original and one copy mailed to CMS's Technical Payment Policy Division. The disclosing party should receive an immediate electronic confirmation as well as a letter in which CMS either accepts or rejects the proposal.

Each submission must include:

- the name, address, national provider identification number, CMS certification number, and tax identification number of the disclosing party;
- a description of the potential self-referral violation being disclosed, including the financial relationships at issue, applicable dates, the period of noncompliance, and the names of entities and individuals believed to be implicated and an explanation of their roles in the matter;
- a statement from the disclosing party as to why it believes a violation has occurred, which should include a legal analysis and the elements of any Stark exceptions that were not met;
- a description of how the potential violation was discovered;
- a description of any compliance programs in place at the time of the potential violation;
- a description of any notices sent to other government agencies regarding the potential violation;

- a statement attesting whether the disclosing party has any past history of violations or criminal actions; and

- a statement as to whether the disclosing party is aware of the matter being under investigation by any other government agency.

The SRDP also calls for the disclosing party to submit a full financial analysis of any money that is potentially owed as a result of Stark law violations. Once CMS has received an SRDP submission, it may ask for additional documents to verify the disclosure and assist the inquiry. Disclosing parties will have at least 30 days to respond to any requests.

While CMS has expressly stated that it is not obligated to resolve a self-disclosed matter in any particular manner, CMS will consider reducing any monetary penalties or amounts owed by a provider based upon:

- the nature and extent of the improper or illegal practice;
- the timeliness of such self-disclosure;
- the provider's cooperation in providing additional information related to the disclosure;
- litigation risk associated with the matter disclosed; and
- the financial position of the disclosing party.¹⁸⁵

The SRDP also provides that CMS will work closely with a disclosing party that structures its disclosure in accordance with the SRDP to reach an effective and appropriate resolution.¹⁸⁶

2210.40 Gainsharing Arrangements

2210.40.10

Overview

“Gainsharing” generally refers to compensation structures that allow hospitals to share a portion of their cost savings with the physicians who help to generate those savings. Such arrangements implicate the federal Civil Monetary Penalties law (CMP Law), the federal anti-kickback statute (AKS), and the Stark law. The OIG has issued a special advisory bulletin and a number of advisory opinions discussing gainsharing arrangements in light of the CMP Law and the AKS.

The federal CMP Law generally prohibits hospital payments to physicians intended to induce the reduction or limitation of services to Medicare or Medicaid beneficiaries.¹⁸⁷ Likewise, the AKS prohibits the offer, payment, solicitation, or receipt of remuneration with the intent to induce or reward referrals.¹⁸⁸

Gainsharing arrangements are also “financial relationships” subject to the Stark law. Such arrangements

could feasibly be structured to comply with the Stark employment, personal services, or fair market value exceptions, provided that all of the requirements of each exception are met. In 2008, however, CMS proposed a new exception (42 C.F.R. § 411.357(x)) designed specifically for certain incentive payment and shared savings programs, including gainsharing arrangements.¹⁸⁹ In the regulatory commentary, CMS emphasized that transparency, quality controls and safeguards against payments for referrals would be essential to a compliant shared savings program. Later in 2008, CMS solicited additional comments on this proposed exception, but has not finalized it to date.¹⁹⁰

2210.40.20

Scope of the Prohibition

Fee-for-service or regular Medicare or Medicaid providers are subject to the gainsharing prohibition. The OIG has said that hospital-physician incentive plans

¹⁸³ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6409, the SRDP.

¹⁸⁴ *Id.*

¹⁸⁵ *Id.*

¹⁸⁶ *Id.*

¹⁸⁷ Social Security Act § 1128A(b)(1) [42 U.S.C. § 1320a-7a(b)(1)].

¹⁸⁸ *See* 42 U.S.C. § 1320a-7b(b).

¹⁸⁹ Medicare Physician Fee Schedule for CY 2009, 73 Fed. Reg. 38502, 38548 (July 7, 2008) (MPFS proposed rule CY 2009).

¹⁹⁰ 73 Fed. Reg. 69726 (Nov. 19, 2008).

that are limited to Medicare or Medicaid beneficiaries enrolled in risk-based managed care programs are regulated under the Social Security Act's physician incentive provisions¹⁹¹ and corresponding PIP regulations.¹⁹² Thus, hospital PIP plans limited to risk-based managed care programs are not subject to the gainsharing prohibition.

Hospital physician incentive plans that do not involve payments for direct patient care and so do not affect direct patient care responsibilities or referral patterns also are not covered by the gainsharing prohibition.¹⁹³ Examples of such plans are those designed to reward the timely review and completion of patient medical records.

The CMP prohibition speaks in terms of health care services. But the OIG has said that since health care items, such as hip joints, furnished to patients as part of inpatient hospital stays are integral to the medical care received, any payment to induce a reduction or limitation in the quality of items—such as a cheaper implant—also could implicate the law.¹⁹⁴

2210.40.30

Application to Particular Arrangements

OIG Special Advisory Bulletin. The OIG issued a special advisory bulletin in July 1999 indicating that those participating in gainsharing arrangements risked violation of the CMP Law and the federal anti-kickback statute.¹⁹⁵ The OIG stated that advisory opinions on individual gainsharing arrangements are inappropriate because such arrangements pose a “high risk of abuse” and require “ongoing oversight both as to quality of care and fraud that is not available through the advisory opinion process.”¹⁹⁶ The danger in gainsharing is that to retain or attract high-referring physicians, “hospitals will be under pressure from competitors and physicians to increase the percentage of savings shared with the physicians, manipulate the hospital accounts to generate phantom savings, or otherwise game the arrangement to generate income for referring physicians,” the OIG said.

Subsequently, the OIG has, however, issued a number of arrangement-specific advisory opinions approving certain gainsharing arrangements. In its advisory opinions, the OIG consistently identifies the following key concerns for shared saving arrangements: possible restrictions or limitations on patient care; physicians “cherry picking” healthier patients to refer to the hos-

pital offering the incentive; payments actually being made in exchange for referrals; and hospitals unfairly competing for physician loyalty and referrals.

Advisory Opinions. In approving arrangements, the OIG focuses on quality and the presence of certain key safeguards. As representative examples, the OIG issued two favorable advisory opinions in December 2007 and one in June 2009 that involved cardiac surgery at acute care hospitals. In the 2007 arrangements, the hospital agreed to share cost savings with a cardiac surgeon group and in the other, the hospital made a similar arrangement with an anesthesiologist group. In the most recent advisory opinion in 2009, the OIG analyzed a hospital's plan to share savings with physicians based on the physicians' use of selected medical devices and supplies for certain cardiac catheterization procedures.

In Advisory Opinion No. 07-21,¹⁹⁷ the requesting hospital said the program administrator for its gainsharing arrangement with a cardiac surgery group made 25 cost-saving recommendations that the surgeons could employ. Among these were not opening disposable components of cell-saver units until a patient experiences excessive bleeding, and replacing some items with less costly items. In connection with the first suggestion, the administrator recommended that the surgeons implement specific alternative clinical practices. In connection with the second, the administrator pointed out that in some cases the product substitutions would make no appreciable clinical difference, such as the switch to reusable blankets instead of disposable blankets.

In Advisory Opinion No. 07-22,¹⁹⁸ the administrator made five recommendations in three categories where anesthesiologists could reduce spending associated with the cardiac procedures. The administrator suggested, for example, limiting the use of a specific drug and a device used to monitor patients' brain function to cases where such items were clinically indicated; substituting less costly alternatives to certain products where clinically appropriate; and standardizing the use of certain fluid-warming hot lines where medically appropriate.

In its advisory opinions on these arrangements, the OIG identified specific safeguards it considered when deciding not to seek sanctions against the requestor under its CMP authority.¹⁹⁹

- transparency—the arrangements clearly identified cost-saving actions and resultant savings. The arrangements allowed for transparency and public scrutiny, as well as physician accountability “for any adverse

¹⁹¹ Social Security Act § 1876(i)(8) [42 U.S.C. § 1395mm(i)(8)], 1903(m)(2)(A)(x) [42 U.S.C. § 1396b(m)(2)(A)(x)].

¹⁹² Letter of Lewis Morris, Assistant Inspector General for Legal Affairs, U.S. Dep't of Health & Human Servs., Re: Social Security Act § 1128A(b)(1)-(2) and hospital-physician incentive plans for Medicare or Medicaid beneficiaries enrolled in managed care plans (Aug. 19, 1999).

¹⁹³ Civil Money Penalties for Hospital Physician Incentive Plans, 59 Fed. Reg. 61571 (proposed Dec. 1, 1994).

¹⁹⁴ HHS IG's McAnaney Answers Attorneys' Questions on Gainsharing, 3 BNA's Health Care Fraud Rep. 815 (Sept. 8, 1999).

¹⁹⁵ Special Advisory Bulletin on Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Service to Beneficiaries, 64 Fed. Reg. 37985, 37986 (July 14, 1999).

¹⁹⁶ *Id.*

¹⁹⁷ Office of Inspector Gen., U.S. Dep't of Health & Human Servs., Advisory Op. No. 07-21 (Jan. 14, 2008).

¹⁹⁸ Office of Inspector Gen., U.S. Dep't of Health & Human Servs., Advisory Op. No. 07-22 (Jan. 14, 2008).

¹⁹⁹ Office of Inspector Gen., U.S. Dep't of Health & Human Servs., Advisory Op. No. 07-21 (Jan. 14, 2008), 07-22 (Jan. 14, 2008), 09-06 (June 23, 2009), and 08-09 (Aug. 7, 2008).

effects of the arrangement, including any difference in treatment among patients based on non-clinical indicators.”

- no adverse effect on patient care—the requestors relied on credible medical evidence to determine that the implementation of the cost-saving measures would not adversely affect patient care, and the requestors said they periodically reviewed the arrangements for any adverse effects on clinical care;

- calculation of shared savings—savings would be calculated based on the hospital’s actual reduction in out-of-pocket acquisition costs for the applicable supplies. If a program lasts multiple years,²⁰⁰ the savings calculation is typically “rebased” annually to ensure that physicians are not compensated twice for the same cost reduction.

- no discrimination or disproportionate effect on federal program beneficiaries—the surgical procedures to which the arrangement applied were not disproportionately performed on federal health care program beneficiaries, and the amount of cost-savings to be paid to the physicians was calculated on the basis of all related services, regardless of patients’ insurance coverage.

- limits on shared savings—there were protections within the arrangements against inappropriate reductions in services to patients “by utilizing objective historical and clinical measures to establish baseline thresholds beyond which no savings accrued” to the physicians.

- disclosure and distribution to physicians—the physicians disclosed to patients their involvement in the arrangements, and profits from the arrangements would be distributed on a per capita basis to physicians by their respective group practices (this payment arrangement was regarded as mitigating any incentive individual physicians might have to generate disproportionate cost savings);

- product selection—when selecting “preferred products,” the hospital first considered whether the product was safe and effective, then whether it was clinically appropriate. Only then did the hospital consider cost in selecting products. The hospital’s internal report summarizing this analysis identified the vendors and products with specificity. In addition, the hospital retained credible medical documentation supporting a determination that patient care would not be adversely affected by limiting the choice of products. Other prod-

ucts would still be available if a physician felt it was clinically necessary to use a non-preferred product for a particular patient.²⁰¹

Carve-outs. If commercial-pay patients are segregated from Medicare/Medicaid patients, there is no Medicare/Medicaid link and the CMP law does not apply. However, the OIG has said the government will examine commercial pay carve-outs in the gainsharing context to make sure they are not camouflaging payments to physicians for reductions or limitations in services to Medicare or Medicaid patients.²⁰²

Medicare Secondary Payers. Where a gainsharing program intended for commercial-pay patients contains a small number of individuals in the risk pool who have primary coverage with an employer or commercial insurer and secondary coverage from Medicare, OIG spokespersons have said that the presence of the Medicare patients will not subject the program to enforcement action under the CMP law. The OIG’s stated policy is not to use the presence of beneficiaries with secondary coverage under Medicare to enforce Medicare and Medicaid anti-fraud and abuse statutes against commercial health care programs.²⁰³

2210.40.40

Congressional Initiatives

The Deficit Reduction Act of 2005 required CMS to establish a gainsharing demonstration project, which was designed to evaluate certain arrangements between hospitals and physicians that could potentially improve the quality and reduce the cost of patient care.²⁰⁴ PPACA extended this demonstration project until September 2011 and provided additional funds for it.²⁰⁵ It remains to be seen whether the results of this demonstration project could lead federal regulators to amend their guidance on gainsharing arrangements.²⁰⁶

PPACA also created a new care delivery model called the Accountable Care Organization (ACO), or the Medicare Shared Savings Program.²⁰⁷ In short, an ACO is an entity comprised of health care providers, including physicians and hospitals that agree to take on responsibility for caring for a group of at least five thousand assigned Medicare beneficiaries. ACO providers will be eligible to share in any cost savings achieved beyond a set minimum savings rate, as long as certain quality measures are also met. CMS has issued a Shared Savings Distribution Waiver, which waives the applicability of Stark, AKS, and the gainsharing prohibition for the purpose of distributing shared savings within an

²⁰⁰ See, e.g., Advisory Op. No. 08-21 (Nov. 25, 2008), No. 08-15 (Oct. 6, 2008).

²⁰¹ Although some of the arrangements described in other advisory opinions included not only product standardization, but also product substitutions and limitations on the use of certain supplies only on “as needed” basis, the regulatory analysis did not change. See, e.g., Advisory Op. No. 08-21 (Nov. 25, 2008) and No. 08-15 (Oct. 6, 2008).

²⁰² *Id.*

²⁰³ *Id.*

²⁰⁴ Pub. Law 109-171, § 5007 (Feb. 8, 2006).

²⁰⁵ Pub. Law 111-148, § 3027 (Mar. 23, 2010).

²⁰⁶ Special Advisory Bulletin on Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Service to Beneficiaries, 64 Fed. Reg. 37985, 37986 (July 14, 1999).

²⁰⁷ Pub. Law 111-148, § 3022 (Mar. 23, 2010). PPACA also provides for the creation of a pediatric ACO demonstration project. See *id.* at § 2706.

ACO.²⁰⁸ In order to qualify for this waiver, the following requirements must be met:

- the ACO must have entered into a participation agreement with CMS and remain in good standing under that agreement;
- the shared savings must have been earned by the ACO under the Medicare Shared Savings Program;
- the shared savings must have been earned by the ACO during the term of its participation agreement, even if the actual distribution of the shared savings occurs after the expiration of that agreement;
- the shared savings must be distributed to or among the ACO's participants, providers/suppliers, or

individuals or entities who were participants or providers/suppliers during the year in which the shared savings were earned;

- the shared savings must be used for activities that are reasonably related to the purposes of the Medicare Shared Savings Program; and
- with respect to the gainsharing prohibition, payments made directly or indirectly from a hospital to a physician must not be made knowingly to induce the physician to reduce or limit medically necessary items or services to patients under the direct care of that physician.

2210.50 Enforcement

2210.50.10

Overview

The most notable recent development in the resolution of Stark law cases is the release of the Self-Referral Disclosure Protocol (SRDP) on Sept. 23, 2010. (See § 2210.30.40, above.) The SRDP allows providers to self-disclose technical Stark violations and potentially resolve such cases at the lower end of the damages spectrum. CMS is not required, however, to reduce the amount of Stark liability, and providers are required to submit their legal analysis as to how a Stark violation occurred and their assessment of the total Stark liability. Given these elements, it remains to be seen how effective the SRDP will be viewed by providers.

Pleadings and decisions in recent whistleblower False Claims Act cases alleging Stark violations, such as *United States ex. rel. Singh v. Bradford Regional Medical Center*,²⁰⁹ *United States ex. rel. Drakeford v. Tuomey d/b/a Tuomey Healthcare System*²¹⁰, and *United States ex. rel. Kosenske v. Carlisle HMA, Inc.*,²¹¹ indicate that the government is closely scrutinizing the fair market value and commercial reasonableness of arrangements between hospitals and physicians. In *Tuomey*, the government alleged that a com-

pensation program designed to pay part-time employed physicians an amount equal to 131 percent of the physicians' net collections on procedures they performed was not fair market value or commercially reasonable.²¹² In *Bradford*, the government signaled that flat fees, with respect to leasing and noncompete payments, may take into account the volume or value of referrals, if the fee is set in a manner that takes into account referrals or if it includes some sort of payment above and beyond the market value of the physician's services or items provided. Finally, in *Kosenske*, the United States Court of Appeals for the Third Circuit held that an arrangement between a hospital and an anesthesiology group failed to satisfy the requirements of the personal services exception, and the Court explicitly rejected the notion that any arms' length negotiated agreement between unrelated parties in and of itself reflects fair market value.

Accordingly, government enforcement efforts related to the Stark law appear to continue to be driven mainly by private whistleblowers. Recent cases reveal a focus on whether arrangements between physicians and hospitals are commercially reasonable, reflect fair market value, and do not take into account referrals to the hospital.

²⁰⁸ CMS issued its final ACO rules in pre-publication form on October 20, 2011. The other waivers are the ACO Pre-Participation Waiver, the ACO Participation Waiver, the Compliance with the Physician Self-Referral Law Waiver, and the Waiver for Patient Incentives.

²⁰⁹ No. 1:04-cv-00186-MBC, 11/10/10 (W.D. Pa. 2010).

²¹⁰ No. 3:05-cv-02858-MJP (D.S.C. 2010).

²¹¹ 554 F.3d 88 (3rd Cir. 2009).

²¹² The U.S. Court of Appeals for the Fourth Circuit later overruled and remanded the lower court's ruling that required the hospital to repay the government \$44.9 million for Stark violations. *United States ex. rel. Drakeford v. Tuomey Healthcare System Inc.*, 4th Cir., No. 10-1819, March 30, 2012. Although most of the decision was based on procedural grounds, two judges on the three-judge panel went an extra step and laid out their views on what constituted violations of the Stark law.

2210.50.20

Settlements

Settlement	Alleged Misconduct	Resolution/Penalties
<i>United States v. Covenant Medical Center</i> (no complaint filed; settlement announced Aug. 25, 2009)	The government alleged that the hospital paid five employed physicians substantially in excess of fair market value.	The hospital agreed to pay the government \$4.5 million to settle alleged violations of Stark and the False Claims Act.
<i>United States ex rel. Boland v. Memorial Health Inc.</i> (S.D. Ga., No. CV406-157, settlement announced April 24, 2008)	Between January 2003 and December 2006, the hospital compensated employee ophthalmologists at levels that were not commercially reasonable and that exceeded the fair market value of the ophthalmologists' services.	The parent company agreed without admitting wrongdoing to pay \$5.08 million to resolve the allegations. In addition, Memorial entered into a corporate integrity agreement.
<i>United States ex rel. Burns v. Northside Hospital</i> (N.D. Ga., settlement 10/20/06)	The hospital provided employees free of charge to two physician-owned entities. The hospital also purchased platelet products from one of the entities at an inflated price and paid the physicians medical directorship fees in excess of fair market value.	The three defendants agreed to pay more than \$6.9 million to resolve the alleged False Claims Act and Stark law violations. They also entered into Certification of Compliance Agreements with the OIG.
<i>United States v. Beebe Medical Center</i> (D. Del. settlement announced March 20, 2006)	A financial arrangement between two gastroenterologists and the hospital allowed the physicians to receive 37 percent of the hospital's facility fee for medical procedures they performed at the hospital in 1997, in addition to their professional fees and other compensation that was greater than fair market value. The government alleged Stark and False Claims Act violations.	The medical center and two physicians agreed to pay the United States \$1 million to settle the allegations. The medical center also agreed to enter into a five-year corporate integrity agreement.
<i>United States v. Erlanger Medical Center</i> (E.D. Tenn., settlement 10/24/05)	The hospital entered into financial arrangements with physicians, allegedly intended to induce the physicians to refer their patients to hospital facilities. The government alleged violations of Stark, the anti-kickback law, and the False Claims Act from January 1995 through August 2003.	To settle the allegations, the hospital agreed to pay \$40 million—\$37 million to the federal government and \$3 million to Tennessee. In addition, the hospital entered into a comprehensive five-year corporate integrity agreement with the OIG.
<i>United States ex rel. Barbera v. AMISUB (North Ridge Hospital), Inc. and Tenet Healthcare Corp., Inc.</i> , No. 97-CV-6590 (S.D. Fla., settlement announced March 24, 2004)	The hospital and its parent companies entered into the prohibited financial relationships with employed physicians and a medical director in 1993 and 1994 and billed Medicare for referrals from these doctors through 2000. The alleged Stark violations gave rise to False Claims Act allegations.	The defendants agreed to pay \$22.5 million and enter into a five-year corporate integrity agreement with provisions regarding education, appointment of a compliance officer, and use of an Independent Review Organization.

Settlement	Alleged Misconduct	Resolution/Penalties
<p><i>United States ex rel. Scott v. Metropolitan Health Corp.</i>, No. 01-02CV485 (W.D. Mich. settlement announced Dec. 9, 2003)</p>	<p>A whistleblower alleged the hospital submitted claims to Medicare for services referred by a doctor whose practice the hospital had bought for a price above fair market value. The hospital's below-fair-market-value rental arrangement with two other physicians also allegedly violated the Stark law.</p>	<p>The hospital agreed to repay the Medicare program \$6.25 million to settle the False Claims Act suit. The agreement required the hospital to continue its existing corporate compliance program for three years and report to the OIG certain events applicable to federal health care programs.</p>
<p><i>United States ex rel. Johnson-Porchardt v. Rapid City Regional Hospital</i>, No. 5:01-CV-05019 (D.S.D., settlement announced Dec. 20, 2002)</p>	<p>The government alleged that the hospital improperly charged Medicare for referrals from oncology doctors with whom it had improper financial relationships, including a space lease with rent set below fair market value. The case arose from a qui tam case filed by an employee.</p>	<p>The hospital paid \$6 million to settle the claims. In addition, the physician practice agreed to pay \$525,000. The hospital and the group also entered into corporate integrity agreements with the OIG.</p>
<p><i>United States ex rel. Kenner v. St. Joseph's Hospital Corp.</i>, No. 95-641 (D. Colo. settled May 2, 2002)</p>	<p>The government alleged that the hospital and physician group had a prohibited financial relationship that resulted in the submission of false claims to Medicare and Medicaid.</p>	<p>The hospital paid \$3.75 million to settle the False Claims Act case and \$280,000 to settle state Medicaid billing allegations.</p>
<p><i>United States ex rel. Moradi v. Community Health Assn.</i>, No. 2:01-1282 (S.D.W.V., settlement announced April 14, 2002)</p>	<p>The hospital allegedly paid physicians in excess of Medicare and Medicaid reimbursement rates for referrals for diagnostic tests and supplies. The hospital also allegedly made payments that were disguised as salary guarantees and submitted claims for physician services provided by unauthorized practitioners.</p>	<p>The hospital agreed to pay \$750,000 and entered into a five-year corporate integrity agreement with the OIG.</p>

2210.50.30

Court Rulings

Case Citation	Facts	Outcome
<p><i>United States ex rel. Singh v. Bradford Regional Medical Center</i>, 752 F. Supp. 2d 602 (W.D. Pa. 2010)</p>	<p>The hospital subleased a nuclear camera from a physician practice and paid not only the pass-through cost of the lease, but also substantial additional compensation, including payment for a non-compete agreement and a guaranty of the practice's financial obligations under a second equipment lease. Whistleblower physicians brought this case against the hospital, the practice, and two physicians individually.</p>	<p>The court granted partial summary judgment, holding that the defendants violated Stark as a matter of law, but allowing the False Claims Act and anti-kickback claims to proceed. The court held that a flat fee could "take into account" referrals if the fee is determined in a manner that considers anticipated or actual referrals or if it exceeds fair market value.</p>

Case Citation	Facts	Outcome
<i>United States ex rel. Drakeford v. Tuomey d/b/a Tuomey Healthcare System, Inc.</i> , No. 3:05-CV-02858-MJP (D.S.C. 2010)	The hospital entered into part-time employment agreements with surgeons and paid compensation in excess of fair market value. The agreements included provisions preventing the surgeons from using a competing facility. The hospital allegedly ignored the warnings of counsel and prevented the whistleblower from raising his concerns to the hospital board.	A jury found the hospital had violated Stark but not the False Claims Act and awarded the government \$44.9 million. The government won a motion for a new trial on the False Claims Act finding. The appeals court later overruled and remanded the lower court’s ruling that required the hospital to repay the government \$44.9 million for Stark violations. <i>United States ex rel. Drakeford v. Tuomey Healthcare System Inc.</i> , 4th Cir., No. 10-1819, March 30, 2012.
<i>United States v. Sulzbach</i> , No. 07-61329-CIV (S.D. Fla. Apr. 16, 2010)	The government sued Tenet Healthcare Corporation’s general counsel individually under the False Claims Act for falsely certifying compliance with a corporate integrity agreement entered into by a predecessor entity. The attorney allegedly was aware that the hospital had entered into physician contracts where the compensation exceeded fair market value and resulted in financial losses for the hospital.	The defendant prevailed on a motion for summary judgment on the grounds that the statute of limitations had run before the government filed its complaint.
<i>United States ex rel. Villafane v. Solinger</i> , 543 F. Supp. 2d 678 (W.D.Ky. 2008)	The hospital made payments to referring pediatric cardiologists through their university employer, and the government alleged that the arrangement did not satisfy the AMC exception to Stark.	The court adopted a “goal and purpose-oriented perspective rather than a hyper-technical one” and found that the applicable party complied with the AMC exception. The court noted that it had found “arrangements which the AMC exception’s requirements are intended to weed out” and gave an example of a hospital that hired community cardiologists as part-time “clinical associate professors” at salaries close to those of its full-time cardiology faculty members, although the part-timers performed minimal or no services.
<i>United States ex rel. Kosenske v. Carlisle HMA, Inc.</i> , 554 F.3d 88 (3d Cir. 2009)	A whistleblower alleged that the hospital and its parent company submitted claims pursuant to a prohibited financial relationship with an anesthesiology group in violation of Stark and the False Claims Act. Specifically, the parties’ written agreement was out of date and did not describe the services actually being provided by the group.	The trial court granted summary judgment in favor of the hospital, but the circuit court reversed and remanded on the grounds that the hospital had failed to show that the arrangement represented a fair market value transaction.
<i>United States v. Rogan</i> , 517 F.3d 449 (7th Cir. 2008)	The government sued a hospital administrator under the civil False Claims Act for creating and concealing financial arrangements that allegedly violated Stark and the anti-kickback law.	The trial court ordered the defendant to pay more than \$64 million in treble damages and per-claim penalties. On appeal, the district court’s ruling was upheld.

Case Citation	Facts	Outcome
<p><i>Robert Wood Johnson University Hospital, Inc. v. Thompson</i>, No. Civ.A.04-142JWB (D.N.J. Apr. 15, 2004)</p>	<p>Several New Jersey hospitals challenged an HHS demonstration project that allowed the state hospital association to implement a gain-sharing project in which only a few hospitals would be allowed to participate. The plaintiffs alleged that the project violated Stark, the anti-kick-back statute and the Civil Monetary Penalties law.</p>	<p>The court held that the enabling statute for the demonstration project allowed a waiver of compliance with Stark. Although the court concluded that the defendants lacked the requisite intent to violate the anti-kick-back statute, it also held that the arrangement violated the prohibition on inducements to beneficiaries.</p>

2210.50.40

Stark Self-Disclosure Settlements

The Stark Self-Referral Disclosure Protocol was promulgated on May 6, 2011 pursuant to PPACA. CMS announces settlements under the Stark Self-Referral Disclosure Protocol on its website at www.cms.gov/PhysicianSelfReferral/. Prior to this, a number of potential

Stark law violations were resolved through the OIG Self Disclosure Protocol. Short summaries of these settlements are included at http://oig.hhs.gov/fraud/enforcement/cmp/self_disclosure.asp. In 2010, for example, there appear to have been at least 18 cases involving potential Stark violations resolved through self disclosure.

Chapter 2210—Exhibit 1

Relationships Between Physicians and Hospitals Checklist

The following list reflects key compliance requirements established by the Stark law, the civil monetary penalties provision, CMS regulations, and agency commentary.

General Checklist

- Basic Concepts and Rules.** Include in the provider’s written compliance materials for medical personnel a plain-English explanation why financial dealings between physicians and hospitals might implicate the Stark law and civil monetary penalties provision. Convey the basic rules that referrals of designated health services (DHS) cannot be made to entities with which a physician (or family member) has a financial relationship and that hospitals cannot pay physicians for reducing services to Medicare or Medicaid beneficiaries under the physician’s direct care.
- Exceptions to Self-Referral Prohibition.** Include in the compliance materials a plain-English explanation of the relevant Stark law exceptions (see *Stark Law Exceptions Applicable to Physician-Hospital Relationships*, § 2210.20.10).
- Training and Education.** Train relevant personnel to recognize financial relationships that would bar the referral of patients for DHS.
- Gainsharing Arrangements.** Train relevant personnel to recognize when arrangements exist that might reward a physician for reducing or limiting services to Medicare or Medicaid beneficiaries under his or her direct care. Require that all proposed cost reduction strategies that generate payments to physicians be reviewed by legal counsel in light of the 2010 amendment to the definition of “remuneration” in the civil monetary provisions of the anti-kickback statute.
- Fair Market Value Determinations.** Develop a process for making and reviewing determinations of fair market value. Depending on need, use an objective internal process and standardized data, an external consultant to survey national peer data, or both.
- Audits.** Referring to a detailed checklist of Stark law exceptions, examine financial relationships with DHS providers, including space and equipment rentals, as part of a regularly scheduled audit of operations.
- Written Agreements.** Require that all financial arrangements with physicians (and close family members) be in writing, signed by both parties, and reviewed by legal counsel. Indirect compensation arrangements need be signed only by those physicians who stand in the shoes of their physician organization and the entity furnishing DHS.

Problem Areas

The following questions, if answered no, might signal referrals prohibited under the Stark law or illegal gainsharing arrangements and should prompt immediate review by legal counsel.

- Is the remuneration a physician receives from a provider of DHS to which the physician refers patients consistent with fair market value? Except in the case of a physician incentive plan, is the compensation unrelated in any way to the volume or value of physician referrals for DHS?
- Are the physician’s property lease or equipment rentals, employment contracts, or other financial arrangements commercially reasonable, even if no referrals are made to the other party? Does each one further a legitimate business interest of the parties?
- Do agreements with physicians have automatic renewal provisions? Are services likely to end when the agreement expires?
- Are services performed under a personal services agreement consistent with all state and federal laws? Is the contract capable of being terminated prior to one year only for cause?
- Are all hospital payments to a physician (except fair market value payments received for designing cost saving protocols) unrelated to reducing or limiting services to beneficiaries under the physician’s direct care?

