

Chapter 2210

Relationships Between Physicians and Hospitals

Overview

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

This chapter discusses two major areas of concern related to financial relationships between hospitals and physicians—the Stark law regulating physician self-referrals and the prohibition on “gainsharing” under the Civil Monetary Penalties Law. 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 in a unified entity 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, commonly known as the “Stark law,”¹ seeks to remove incentives that could inappropriately tie a physician’s treatment decisions to his or her financial interest and result in inappropriate utilization of items or services covered by Medicare or Medicaid. 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 adopted and revised the regulations under the Stark law and issued associated commentary in three principal phases (in 2001, 2004, and 2007). However, new Stark rulemaking continues to appear as part of other regulations, particularly the annual Medicare physician fee schedule updates.²

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.³ Gainsharing is an issue only for Medicare and Medicaid fee-for-service systems; the prohibition⁴ 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

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General Prohibition and Key Terms

Overview. The Stark law prohibits a physician⁵ who has a “financial relationship” with an entity, such as a hospital, from making “referrals” to that entity for “designated health services” (DHS) covered by Medi-

care or Medicaid,⁶ unless the financial relationship fits within an enumerated exception in the Stark law.⁷ It also prohibits the submission of reimbursement claims resulting from such referrals. A “financial relationship” under Stark includes both ownership interests and compensation arrangements, and the relationship may be either direct or indirect.

¹ Social Security Act § 1877 [42 U.S.C. § 1395nn].

² See, e.g., Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Medicare Shared Savings Program Requirements, 81 Fed. Reg. 80,170, 80,524-34 (Nov. 15, 2016).

³ Social Security Act § 1128A(b) [42 U.S.C. § 1320a-7a(b)].

⁴ Office of Inspector Gen., U.S. Dep’t of Health & Human Servs., Advisory Op. No. 01-1 (Jan. 18, 2001).

⁵ Included in this prohibition is any entity that has a financial relationship with a member of the physician’s immediate family.

⁶ Technically, Medicaid referrals are included within the Stark law’s prohibitions. Social Security Act § 1903(s) [42 U.S.C. § 1396b(s)]. However, that provision does not provide for a direct penalty against the physician or DHS entity but instead effectively penalizes the relevant state Medicaid program by reducing federal Medicaid funding to that state by the amount of the “tainted” claim. For simplicity, the remainder of this chapter will refer to the application of the Stark law only to Medicare referrals, even though the same restrictions and exceptions apply with respect to Medicaid referrals as well.

⁷ Social Security Act § 1877 [42 U.S.C. § 1395nn].

The Scope of the Prohibition. Corresponding to the law's broad definition of "remuneration,"⁸ which is not limited to relationships involving Medicare patients or relationships that involve the provision of DHS, the Stark self-referral prohibition can reach a wide range of activities.

For example, assume a physician 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). Further increasing the complexity, because some of the links in the chain of relationships are ownership interests and some are compensation arrangements, the Stark 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 physician self-referral prohibition. If it is determined that the arrangement is not deemed to be a financial relationship under the Stark law, it is not necessary for the arrangement to comply with a Stark exception. On the other hand, if the arrangement is within the Stark law definition of financial relationship, then the law's prohibitions will apply unless the arrangement fits squarely within an exception.

Designated Health Services. The Stark law lists categories of designated health services (DHS) that Congress identified as being subject to overuse or inappropriate use if provided by an entity with which a physician has a financial relationship. 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.⁹

Definition of Entity. Prior to October 1, 2009, "entity" was defined in the Stark Law only as the person or entity that billed for DHS. Beginning on October 1, 2009, the definition of "entity" was expanded to include not only the billing person or entity, but also the person or entity who performed the services that are billed as DHS.¹⁰

As a result of the expanded definition of entity, a full-service, turnkey "under arrangements" service provider¹¹ may now be considered to be a DHS entity, even though the entity does not bill for the DHS. 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.

Exceptions. If a financial relationship exists between a physician and a DHS entity, any DHS referral by the physician to the entity violates the Stark law unless the relationship fits squarely within an exception to the law. There are a number of exceptions to the general Stark law prohibition on DHS referrals,¹² including those applicable:

- to both ownership interests and compensation arrangements;¹³
- only to ownership interests; and¹⁴

⁸ Social Security Act § 1877(h)(1)(B)-(C) [42 U.S.C. § 1395nn-(h)(1)(B)-(C)].

⁹ Notably, and despite earlier interpretations by CMS to the contrary, lithotripsy (shock wave treatment for the breakdown and removal of stones in the kidneys and ureter) is not considered DHS as a result of the decision in *American Lithotripsy Society v. Thompson*, 215 F. Supp. 2d 23 (D.D.C. 2002); see also Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Payments for Graduate Medical Education in Certain Emergency Situations; Changes to Disclosure of Physician Ownership in Hospitals and Physician Self-Referral Rules; Updates to the Long-Term Care Prospective Payment System; Updates to Certain IPPS-Excluded Hospitals; and Collection of Information Regarding Financial Relationships Between Hospitals, 73 Fed. Reg. 48,434, 48,719 (Aug. 19, 2008) (*hereinafter* FY 2009 IPPS final rule). CMS has noted, however, that regardless of whether lithotripsy is DHS,

contractual relationships between hospitals and physicians or physician practices regarding lithotripsy may 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. See Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships, 66 Fed. Reg. 856, 940 (Jan. 4, 2001) (*hereinafter* Stark II final rule, Phase I).

¹⁰ See FY 2009 IPPS final rule, 73 Fed. Reg. at 48,721-48,733; 42 C.F.R. § 411.351.

¹¹ An "under-arrangements" service provider is a provider that furnishes a service for which the hospital bills.

¹² Social Security Act § 1877(b)-(e) [-(e)].

¹³ 42 C.F.R. § 411.355.

¹⁴ 42 C.F.R. § 411.356.

- only to compensation arrangements¹⁵

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 a maximum 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 exceptions for physician services and in-office ancillary services.

Stark and Managed Care Plans. The Stark law does not directly apply to services furnished by certain prepaid plans,¹⁶ including services furnished by managed care plans, such as health maintenance organizations (HMOs), to their enrollees and services furnished to 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, healthcare 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.¹⁷

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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, the Stark law only applies where there is (i) a physician referral (ii) to a DHS entity (iii) with which the physician has a financial relationship (iv) for items or services to be provided to a Medicare or Medicaid beneficiary. The anti-kickback statute applies to a much broader range of transactions and relationships, as well as to all federal healthcare plans.

While many exceptions under the Stark law are similar to statutory exceptions or safe harbors under the anti-kickback statute, such as the exceptions for personal service arrangements and space and equipment rentals, the consequences of failing to satisfy a Stark exception can be quite different from the consequences of failing to fall within an anti-kickback statute safe harbor. The Stark law is a strict liability statute—a financial arrangement between a referring physician and a DHS entity means that the physician’s referral of Medicare or Medicaid patients to the entity for DHS violates the Stark law unless the arrangement fits precisely within an exception. However, a violation of 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 despite not meeting a safe harbor.

As part of the Patient Protection and Affordable Care Act of 2010 (ACA), Congress clarified that the element of “intent” under the anti-kickback statute does not require a showing of specific intent to violate the anti-kickback statute.¹⁸ The legislation also explicitly stated that a violation of the federal anti-kickback law is a false claim under the federal False Claims Act.¹⁹ However, despite the fact that federal prosecutors often argue that the submission of a claim arising out of a violation of the Stark law also renders that claim “false” within the meaning of the False Claims Act, that issue was not addressed in the ACA.

2210.20 Applicable Stark Exceptions

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Overview

In ensuring that physician/hospital relationships comply with the Stark law, compliance officers and counsel will find several statutory exceptions to be par-

ticularly pertinent including those for bona fide employment arrangements, personal services, remuneration unrelated to DHS, rental of space or equipment, physician recruitment, and isolated transactions.

The Stark regulations contain similar, typically more detailed exceptions corresponding to the statutory ex-

¹⁵ 42 C.F.R. § 411.357.

¹⁶ Excepted prepaid services are described in Social Security Act § 1877(b)(3) [42 U.S.C. § 1395nn(b)(3)].

¹⁷ 42 C.F.R. § 411.355(c).

¹⁸ 42 U.S.C. § 1320a-7b(b), as amended by the Patient Protection and Affordable Care Act (ACA), 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.

¹⁹ See also Tab 1400, Anti-Kickback—General Risk Areas.

ceptions. The regulations also contain a number of additional exceptions for hospital/physician relationships. Particularly relevant 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.

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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 standards²⁰ (see Chapter 1430, *Marketing Practices*, § 1430.10.20.40).

In order to satisfy the exception, remuneration under the compensation arrangement must be:

- for identifiable services,
- consistent with 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 may be paid a productivity bonus for personally performed services, including personally performed DHS.²¹ Also, unlike other Stark exceptions, a compensation arrangement with an employed physician does not have to be in writing, except in certain specific circumstances.²²

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Personal Services

The exception for personal services—including professional services but excluding the provision of items

or equipment of any kind—is one of the more useful exceptions for physician-hospital relations because it applies to such common situations as hospital-based physician contracts or medical director agreements for the provision of administrative services.

To meet the exception, the arrangement must:²³

- be in writing, be signed by the parties, and specify the services covered by the arrangement;²⁴
- 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);²⁵
- cover all services the physician or immediate family member will furnish to the hospital (this requirement is met if separate arrangements between the hospital 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);
- cover services that do not exceed, in the aggregate, those that are reasonable and necessary for the legitimate business purposes of the arrangement;
- not involve the counseling or promotion of a business arrangement or other activity that violates state or federal law; and
- provide for compensation that is set in advance, does not exceed fair market value (FMV), and, except in the case of a physician incentive plan meeting specific requirements, 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.²⁶ The agency has said that the compensation formula satisfies the set-in-advance requirement if it 1) is set forth in sufficient detail that it

²⁰ Social Security Act § 1877(e)(2) [42 U.S.C. § 1395nn(e)(2)]; 42 C.F.R. § 411.357(c).

²¹ 42 C.F.R. § 411.357(c)(4).

²² 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).

²³ Social Security Act § 1877(e)(3)(A) [42 U.S.C. § 1395nn(e)(3)(a)]; 42 C.F.R. § 411.357(d).

²⁴ CMS has clarified its position that an arrangement may satisfy the “in writing” requirement even if it is not reflected in a single document, but rather is reflected in a group of related writings. See Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016, 80 Fed. Reg. 70,885, 71,300-41 (Nov. 16, 2015). However, providers should be cautious when considering how far to take this interpretation. The U.S. District Court for the Western District of Pennsylvania ruled that several draft agreements and email chains outlining preliminary arrangements to establish

medical directorships with a hospital that were never actually executed by the physicians ran afoul of the Stark law requirement that these types of arrangements be memorialized in written agreements. The court said that the documents failed to outline an agreement on the essential terms of the medical directorships that would allow for the transparency and accountability that the Stark law requirement is designed to foster. *United States ex rel. Emanuele v. Medicor Assocs.*, 242 F. Supp. 3d 409, 421-24 (W.D. Pa. 2017).

²⁵ CMS has clarified its position that the arrangement may satisfy the requirement of a minimum one-year term even if there is not an express contractual provision specifying that term, as long as the arrangement has in fact been in effect for at least one year or, if terminated within the first year, the parties have not entered into an arrangement for substantially similar services until the expiration of one year from the commencement of the original term. See Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016, 80 Fed. Reg. 70,885, 71,300-41.

²⁶ 42 C.F.R. § 411.354(d)(1).

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.²⁷ Thus, for example, compensation that is based on a percentage of some objectively verifiable metric or on an hourly-rate basis will be deemed to be set in advance even though the aggregate dollar amount actually paid during a given contract period is not determined until the end of the period.

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 represents 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 the volume or value of DHS referrals.²⁸ 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 business.²⁹

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 (PIPs). 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.³⁰ The safe harbor set forth 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.³¹ 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 “[would] continue to scrutinize the fair market value of arrangements as fair market value is an essential element of many exceptions.”³²

Holdovers. In its CY 2016 Medicare Physician Fee Schedule final rule, CMS eliminated the time limits on holdovers (a personal service arrangement that contin-

ues in effect beyond its stated term), meaning that the holdover may be of any duration and not limited by the period of up to six months following the expiration of the agreement as the rule previously stated. The holdover provision applies so long as the terms and conditions remain the same as in the original contract, the compensation or rent remains at fair market value, and the parties can provide contemporaneous documentation showing their continued performance of the contract.³³

Personal services arrangements should not only be examined under the requirements of the Stark exception, but also must be considered with the anti-kickback law in mind (see *Chapter 1415, Personal Services and Management Agreements*).

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Remuneration Unrelated to DHS

The exception for remuneration that is not related to the provision of DHS³⁴ applies only to payments made (i) to a physician (ii) by a hospital,³⁵ it does not apply to remuneration from entities other than hospitals, nor to payments to a physician’s family members.

To fall within the exception, remuneration must be “wholly unrelated” to the provision of DHS.³⁶ This is not the case if the remuneration:

- is for 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.³⁷

A loan to a physician 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 members who are in a posi-

²⁷ *Id.*

²⁸ 42 C.F.R. § 411.354(d).

²⁹ *Id.*

³⁰ See Medicare Program; Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II) 69 Fed. Reg. 16,504, 16,123 (Mar. 26, 2004) (*hereinafter* Stark II interim final rule, Phase II).

³¹ Stark II final rule, Phase III, 72 Fed. Reg. at 51015; 42 C.F.R. § 411.354(d).

³² *Id.*

³³ 80 Fed. Reg. 70885, 71318-71319.

³⁴ Social Security Act § 1877(e)(4) [42 U.S.C. § 1395nn(e)(4)].

³⁵ 42 C.F.R. § 411.357(g).

³⁶ *Id.*

³⁷ Stark II final rule, Phase III, 72 Fed. Reg. at 51057.

tion 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.³⁸

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.³⁹

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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.⁴⁰ As with 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 even in the absence of referrals between the parties; and
- further the legitimate business purposes of the parties.

The exception also requires:

- 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 for the term of the lease.⁴¹

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 the lessee’s use. The lessee may, however, jointly use common areas if the lessee’s rental payments for common area space do not exceed its 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.

The lease may be terminated with or without cause during the first year of the term without causing the lease to fail the one-year term requirement, provided the parties do not enter into a new agreement during the original term.⁴² Where a lease agreement meets all of the exception’s requirements, holdovers are permitted for up to six months after the end of the lease term, provided the holdover rental is on the same terms and conditions as the immediately preceding lease.⁴³ Subleases also are permitted as long as the sublessor does not share the rented equipment or space with the sublessee (i.e., the sublessor and the sublessee may not use the rented space or equipment at the same time, nor may the sublessor use the rented space or equipment during a period when it is leased to the sublessee.⁴⁴

Sharing Arrangements. Office and equipment sharing arrangements do not typically meet the rental exception, due to 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”). In November 2015, CMS finalized a new Stark exception that protects certain “timeshare” arrangements for the use of office space, staff and equipment under a license arrangement (not a lease). The exception only applies to timeshare arrangements between a hospital or physician organization, as licensor; and a physician, as licensee, and the licensed space, personnel, equipment, supplies and services must be used predominantly to furnish evaluation and management services to patients of the licensee. The exception imposes several specific requirements, and cannot involve DHS, other than DHS incidental to the physician’s evaluation and management services.⁴⁵

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 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.⁴⁶ 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).⁴⁷ CMS does not interpret the revisions as prohibiting a lessor from charging

³⁸ Stark II interim final rule, Phase II, 69 Fed. Reg. at 16,094.

³⁹ W. Bradley Tully, Federal Self-Referral Law § 2400.06.G.2 (BNA’s Health Law & Bus. Series, No. 2400).

⁴⁰ Social Security Act § 1877(e)(1) [42 U.S.C. § 1395nn(e)(1)]; 42 C.F.R. §§ 411.357(a)-(b).

⁴¹ 42 C.F.R. §§ 411.357(a)-(b).

⁴² 42 C.F.R. § 411.357(a)(2).

⁴³ 42 C.F.R. § 411.357(a)(3).

⁴⁴ *Id.*

⁴⁵ 42 C.F.R. § 411.357(y); 80 Fed. Reg. at 71325-71333.

⁴⁶ FY 2009 IPPS final rule, 73 Fed. Reg. at 48710.

⁴⁷ FY 2009 IPPS final rule, 73 Fed. Reg. at 48710, 48713-13.

a lessee a pro rata share of expenses levied by a third party (e.g., property taxes or utilities).⁴⁸

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.⁴⁹

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 in addition to base rent) like the facility lease 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 not persuasive, 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.

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Physician Recruitment

The Stark law allows hospitals and certain other DHS entities to make payments in connection with physician recruitment to the entity's geographic service area provided that certain requirements are met.⁵⁰

The recruitment exception is intended to allow hospitals, federally qualified health centers (FQHCs), and rural health clinics (RHCs)⁵¹ to make payments in-

tended to induce a physician to relocate his or her practice to the geographic area served by the hospital—or other provider⁵²—and to become a member of the hospital's medical staff. The exception covers both recruitment-related payments made directly or indirectly to individual physicians and recruitment-related payments made to an existing medical practice that the physician is joining if the exception's stringent conditions are met.⁵³

Generally, where the hospital provides 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 that physician; *i.e.*, costs that the practice would not have incurred but for hiring the recruited physician, such as the costs associated with additional equipment, support staff or malpractice insurance premiums that are incurred solely because of the new physician. In general, the practice may not reallocate a portion of existing overhead costs (e.g., office rent) to the new physician. However, the Phase III Stark regulations permit a group practice located in a rural area or Health Professional Shortage Area 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 physician who retired, died, or relocated outside the hospital's geographic service area within the previous 12 months.⁵⁴

The exception further prohibits the physician practice that a recruited physician is joining from imposing practice restrictions that “unreasonably restrict” the recruited physician's ability to practice medicine in the geographic area served by the hospital.⁵⁵ 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,” according to CMS:⁵⁶

- 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;
- requiring the recruited physician to repay losses of his/her practice that are absorbed by the physician

⁴⁸ *Id.* at 48710-48711.

⁴⁹ *United States ex rel. Goodstein v. McLaren Regional Medical Center*, 202 F. Supp. 2d 671 (E.D. Mich.); see *Court Dismisses Facility Kickback Case, Finds Lease Not Above Fair Market Value*, 6 BNA's Health Care Fraud Rep. 189 (Mar. 6, 2002).

⁵⁰ Social Security Act § 1877(e)(5) [42 U.S.C. § 1395nn(e)(5)].

⁵¹ Stark II final rule, Phase III, 72 Fed. Reg. at 51048; 42 C.F.R. § 411.357(e)(6).

⁵² Although the statutory language speaks only of “hospitals”, CMS has expanded the exception by regulation to include FQHCs and RHCs. For convenience, the discussion below will refer only to hospitals, but it should also be understood to refer to these additional entities as well.

⁵³ 42 C.F.R. § 411.357(e)(4).

⁵⁴ 42 C.F.R. § 411.357(e)(4)(iii); Stark II final rule, Phase III, 72 Fed. Reg. at 51,052.

⁵⁵ 42 C.F.R. § 411.357(e)(4)(vi).

⁵⁶ Stark II final rule, Phase III, 72 Fed. Reg. at 51,053.

practice in excess of any hospital recruitment payments; and

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

Prior to Phase III, the recruitment exception provided that the practice could not impose “additional practice restrictions on the recruited physician other than conditions related to quality of care.”⁵⁷ CMS had indicated in the Phase II interim final rule that it believed that the imposition of a non-compete agreement on the recruited physician would violate this requirement.⁵⁸ This interpretation drew considerable criticism from those who pointed out that non-compete restrictions were fairly common features of physician practice employment agreements. As a result, in Phase III CMS revised the regulatory provision to add the “unreasonably restrict” concept noted above, and in its commentary implied (although it did not state directly) that a non-compete restriction that complied with state and local law would likely be permitted by the rule. However, CMS warned that any practice restrictions or conditions that do not comply with applicable state and local law “run a significant risk of being considered unreasonable.”⁵⁹

The written agreement between the hospital and the recruited physician must also be signed by the group practice if payments are being indirectly or directly made to a physician who joins an existing practice.⁶⁰ Counterpart signatures are permissible.⁶¹ In addition, the recruitment exception does not prohibit a hospital from requiring the practice to provide a guaranty of the recruited physician’s repayment obligation. However, CMS has warned against the practice of eliminating the physician’s obligation to reimburse the practice should the hospital draw upon the guaranty, which would potentially create a financial relationship between the practice and the physician that would not meet a Stark law exception.⁶²

CMS has also clarified what kinds of expenses qualify as recruitment expenses that 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.⁶³

The recruitment exception requires the physician to relocate his or her medical practice to the hospital’s geographic service area in order to become a member of the hospital’s medical staff. The exception apparently requires that the physician obtain active medical staff privileges at the hospital; CMS has stated in commentary that a hospital that has granted only courtesy privileges to a physician may not rely on the recruitment exception with respect to that physician.⁶⁴

“Relocation” has a defined meaning under the recruitment exception. The exception requires that the recruited physician relocate his or her medical practice from outside to inside the “geographic area served by the hospital.”⁶⁵ 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 to new patients (i.e., patients not seen at the physician’s former practice during the preceding three years).⁶⁶

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.⁶⁷

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 has 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.⁶⁸

⁵⁷ Stark II interim final rule, Phase II, 69 Fed. Reg. at 16,139

⁵⁸ 69 Fed. Reg. at 16,096-97

⁵⁹ Stark II final rule, Phase III, 72 Fed. Reg. at 51,054. Although CMS did not directly address this in its commentary, presumably the imposition on the recruited physician of a non-compete restriction more burdensome than that applicable to other physicians in the practice would also be considered unreasonable.

⁶⁰ 42 C.F.R. § 411.357(e)(4)(i).

⁶¹ 72 Fed. Reg. at 51051.

⁶² 72 Fed. Reg. at 51054 CMS has stated 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 such a provision cannot be amended to remove it, 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 (Sept. 2007).

⁶³ 72 Fed. Reg. at 51,052.

⁶⁴ 72 Fed. Reg. at 51,048.

⁶⁵ 42 C.F.R. § 411.357(e)(2).

⁶⁶ 42 C.F.R. § 411.357(e)(2)(iv).

⁶⁷ 42 C.F.R. § 411.357(e)(2)(iv).

⁶⁸ Centers for Medicare & Medicaid Servs., Advisory Op. No. CMS-AO-2006-01 (Nov. 6, 2006).

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 consists of the lowest number of contiguous ZIP codes from which the hospital draws 75 percent of its inpatients.⁶⁹

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.⁷⁰

In a few limited circumstances, physicians may take advantage of the recruitment exception without meeting the relocation requirement. 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 a similar entity operating correctional facilities) to serve 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.⁷¹

Such employment arrangements must be exclusive; i.e., the physician must have been employed by one of the above entities for at least two years immediately prior to the recruitment arrangement and may not have engaged in independent private practice during such two-year period. 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 before proposing to enter into a recruitment arrangement with that hospital.⁷² The rule also provides that the relocation requirement does not apply if the Secretary of Health and Human Services determines 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, a concession of very limited practical utility.⁷³

Where the recruited physician is a current medical resident or has been in medical practice for less than one year, the relocation requirement will not apply. Such a physician will not be considered to have an established practice. A residency includes all training, including post-residency fellowships.⁷⁴

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."⁷⁵ However, in November 2015, CMS finalized a Stark exception that protects remuneration from a hospital, FQHC or RHC to a physician to assist the physician in the recruitment of a non-physician practitioner to the hospital's service area, subject to a number of specific requirements.⁷⁶ For example, the remuneration from the hospital cannot exceed 50 percent of the actual compensation, signing bonus, and benefits paid by the physician to the non-physician practitioner during the first two years of the compensation arrangement, and the remuneration cannot take into account the volume or value of any referrals by the physician or the non-physician practitioner.⁷⁷

Physicians receiving recruitment assistance from a hospital 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.⁷⁸ 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.⁷⁹

Additionally, each arrangement must be set forth in writing and signed by the parties.⁸⁰ 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.⁸¹ 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. Thus, as a practical matter many hospitals, including investor-owned hospitals, will conduct and document a community need analysis before entering into a recruit-

⁶⁹ 42 C.F.R. § 411.357(e)(2)(i).

⁷⁰ Stark II final rule, Phase III, 72 Fed. Reg. at 51,050-51.

⁷¹ 42 C.F.R. § 411.357(e)(3).

⁷² 72 Fed. Reg. at 51,048.

⁷³ 42 C.F.R. § 411.357(e)(3)(iii).

⁷⁴ 42 C.F.R. § 411.357(e)(3); 72 Fed. Reg. at 51,051.

⁷⁵ 72 Fed. Reg. at 51,049.

⁷⁶ 42 C.F.R. § 411.357(x); 80 Fed. Reg. at 71,301-14.

⁷⁷ 42 C.F.R. § 411.357(x)(1)(iii).

⁷⁸ 42 C.F.R. § 411.357(e)(1)(iv).

⁷⁹ Stark II interim final rule, Phase II, 69 Fed. Reg. at 16,095; 72 Fed. Reg. at 51,049.

⁸⁰ 42 C.F.R. § 411.357(e)(1)(i).

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

ment arrangement even though the Stark exception does not require it.

2210.20.70

Isolated Transactions

The sale of a referring physician's practice to a hospital or other DHS entity, or the sale of other property between the parties, creates a compensation relationship that potentially violates Stark even if the subject matter of the transaction itself does not involve DHS. The isolated transaction exception covers such one-time business transactions, providing a means to effect such a transaction without a Stark violation.⁸² Such isolated transactions will not be considered compensation arrangements under Stark if certain conditions are met.⁸³

To qualify for the exception, the amount of remuneration under the transaction must:⁸⁴

- 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 covered by another exception) may occur between the DHS entity and physician for six months after an isolated transaction, except for commercially reasonable post-closing adjustments that do not take into account (directly or indirectly) the volume or value of referrals (*e.g.*, a post-closing working capital adjustment).

Despite industry criticism of the six-month limit on post-closing adjustments, CMS has stated that post-closing adjustments occurring more than six months after closing will be treated as new transactions that will then have to satisfy the requirements of an exception. However, CMS has stated that adjustments based on breaches of warranty are part of the original transaction and may occur at any time; they are not considered either post-closing adjustments or new transactions.⁸⁵

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 must independently meet the requirements of the isolated transactions exception.⁸⁶

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.⁸⁷

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.⁸⁸

2210.20.80

In-Office Ancillary Services

The Stark law allows physicians in group practices⁸⁹ to refer within their practice for certain types of DHS despite the fact that the referring physician has an ownership interest in or compensation relationship with the practice entity.⁹⁰ 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.⁹¹ Generally, the services must be performed or supervised by the referring physician or a "physician in the group practice," provided in the physician's or group's office, and billed by the physician or the group. It is possible for hospitals that employ physicians to organize those physicians into a group practice entity meeting the Stark definition, in which case the in-office ancillary services exception may be applicable to DHS referrals within

⁸² Social Security Act § 1877(e)(6) [42 U.S.C. § 1395nn(e)(6)]; 42 C.F.R. § 411.357(f).

⁸³ Stark II, Phase II, 69 Fed. Reg. at 16,098.

⁸⁴ Social Security Act § 1877(e)(6) [42 U.S.C. § 1395nn(e)(6)], *see also* 42 C.F.R. § 411.357(f).

⁸⁵ Stark II final rule, Phase III, 72 Fed. Reg. at 51,055.

⁸⁶ *Id.*

⁸⁷ 42 C.F.R. § 411.351.

⁸⁸ Stark II final rule, Phase III, 72 Fed. Reg. at 51,055. Note that the Phase III commentary unintentionally suggests that CMS is under the impression that negotiability of a promissory note provides the creditor with some form of security if the obligor defaults, presumably because a negotiable note may hypothetically be sold to a third party free and clear of any defenses

that might be asserted by the obligor. This theory ignores the fact that there is no established market for promissory notes between private parties, especially for notes where the obligor is in default. The result is that the parties may be able to rely on this exception to protect an installment sale even where the security for the installment payments is somewhat illusory.

⁸⁹ "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. Note that "group practice" is, under Stark, a precisely defined term, and many physician groups may not be organized in a way that meets the definition. *See Chapter 2215, Group Practices.*

⁹⁰ Social Security Act § 1877(b)(2) [42 U.S.C. § 1395nn(b)(2)].

⁹¹ 42 C.F.R. § 411.355(b).

the entity (i.e., where the group practice entity itself provides the DHS). However, if the hospital provides physician services through a hospital outpatient department rather than through a separate entity satisfying the group practice definition, the exception will not apply, and even if there is a separate group practice entity, the exception will not protect DHS referrals for items or services not provided by the group practice entity itself (e.g., it will not protect referrals from within the group for radiology services provided by the hospital's radiology department).

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. In order for the exception to protect referrals for the specified DME items, the arrangement under which the DME is provided must also not involve a violation of the anti-kick-back statute.

The Performance Requirement. Under the regulations, the services must be performed personally by:⁹²

- 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.

The Location Requirement. An item or service is “furnished” in the location where the service is actually performed or where an item is dispensed. The regulations also require 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;⁹³
- 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).

The Billing Requirement. The service must be billed by:⁹⁴

- 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 agent of the group practice, physician, or entity, provided that the arrangement meets certain requirements.

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.⁹⁵

Disclosure to Patients. Under provisions of the Patient Protection and Affordable Care Act of 2010, physicians relying on the in-office ancillary services exception to cover referrals for certain imaging services 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.⁹⁶ This disclosure requirement applies only to: MRI, CT, and PET imaging services. 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).⁹⁷ In commentary to the final rule, CMS clarified that: (i) the disclosure to the patient does not have to include the distance from the physician's office; (ii) the physician does not have to keep a signed patient acknowledgment on file (although CMS noted that, as a general compliance matter, some sort of documentation should probably be maintained); (iii) mailing or emailing the disclosure is acceptable, if verbal notification has occurred; and (iv) the physician is not prohibited from including language stating that its list of other suppliers is not an endorsement or recommendation of those suppliers.⁹⁸

The key guidelines for the disclosure are that it must be sufficient to 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.⁹⁹

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

⁹² 42 C.F.R. § 411.355(b)(1).

⁹³ 42 C.F.R. § 411.355(b)(2)(i).

⁹⁴ 42 C.F.R. § 411.355(b)(3).

⁹⁵ Stark II final rule, Phase III, 72 Fed. Reg. at 51,032-35.

⁹⁶ Social Security Act 1877(b)(2)[42 U.S.C. § 1395nn(b)(2)].

⁹⁷ 42 C.F.R. § 411.355(b)(7).

⁹⁸ 75 Fed. Reg. 73,169, 73,443-47 (Nov. 29, 2010).

⁹⁹ *Id.*

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.¹⁰⁰ 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 where he or she practices, and have a bona fide faculty appointment at the affiliated medical school or “accredited academic hospital;” and¹⁰¹
- provide either substantial academic or substantial clinical teaching services for which the physician is paid as part of the employment relationship.

A “component” of an academic medical center is 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 (either from the AMC or from each other).

Physician compensation must meet the following requirements:¹⁰²

- 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 must 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; instead, FMV is tested at the aggregate level, for compensation paid by all of the relevant AMC components. (For other regulatory purposes, each individual component may want to ensure that such compensation reflects fair market value.)¹⁰³

Finally, the academic medical center must meet the following conditions:¹⁰⁴

- 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 a single 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);

- 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.

An academic medical center, for purposes of the Stark exception, 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 (i) a majority of the medical staff consist of faculty physicians, and (ii) a majority of all hospital admissions are made by faculty physicians.¹⁰⁵

The regulation provides that any faculty member may be counted, including courtesy and volunteer faculty, in determining whether the majority tests are met.¹⁰⁶ 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 an AMC component. 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 for purposes of the calculation, then it must exclude all members of the courtesy staff.¹⁰⁷

An AMC need not have an accredited medical school as one of its components to qualify as an AMC. Rather, a teaching hospital may be the only component of the AMC to provide teaching and education if it meets the requirements for an “accredited academic hospital,” that is, a hospital or health system that sponsors four or more approved medical education programs.¹⁰⁸

¹⁰⁰ Stark II final rule, Phase I, 66 Fed. Reg. at 915; 42 C.F.R. § 411.355(e).

¹⁰¹ Defined at 42 C.F.R. § 411.355(e)(2).

¹⁰² 42 C.F.R. § 411.355(e)(1)(ii).

¹⁰³ Stark II final rule, Phase III, 72 Fed. Reg. at 51,037.

¹⁰⁴ 42 C.F.R. § 411.355(e)(1)(iii).

¹⁰⁵ 42 C.F.R. § 411.355(e)(2)(iii).

¹⁰⁶ *Id.*

¹⁰⁷ 42 C.F.R. § 411.355(e)(2)(iii). Stark II final rule, Phase III, 72 Fed. Reg. at 51,037.

¹⁰⁸ 42 C.F.R. § 411.357(e)(3).

Only one reported case to date has construed the Stark academic medical center exception.¹⁰⁹ 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

The exception for certain forms of non-monetary compensation might protect situations in which physicians or their immediate family members receive compensation from a hospital that is not covered in a formal, written agreement, as long as the compensation is not equivalent to a monetary payment.¹¹⁰ 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 for non-monetary compensation allows the physician to receive 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 compensation in each calendar year is valued in the aggregate at no more than the amount set annually by CMS;¹¹¹
- 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, the exception requires that the compensation must not violate the anti-kickback statute or any laws or regulations governing billing or claims submission.

The exception for non-monetary compensation allows hospitals to give small gifts and benefits, such as meals or gift baskets, to referring physicians. Hospitals should, however, track these free items and services to ensure that they do not, in the aggregate, exceed the allowable annual amount per physician. 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.¹¹²

When a hospital has inadvertently exceeded the non-monetary compensation limit by no more than 50 percent, physicians may repay certain excess non-monetary compensation within the same calendar year to preserve compliance with the Stark law. The physician who receives the compensation must return the excess 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 after receipt. This provision may only be used by a hospital once every three years with respect to the same referring physician.¹¹³ 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 non-monetary compensation limits.

2210.20.110

Fair Market Value Compensation

The Stark regulations provide an exception for fair market value (FMV) 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) if the arrangement is set forth in an agreement that meets the following conditions:¹¹⁴

- 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 (In November 2015, CMS finalized a rule permitting arrangements to be renewed any number of times so long as the terms of the arrangement and the compensation for the same items or services do not change.);¹¹⁵
- specifies the compensation under the arrangement (which must be set in advance; be consistent with fair market value; and 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;

¹⁰⁹ *United States ex rel. Villafane v. Solinger*, 543 F. Supp. 2d 678 (W.D. Ky. 2008).

¹¹⁰ 42 C.F.R. § 411.357(k).

¹¹¹ The regulations set the original threshold at \$300, indexed for inflation. For CY 2018, for example, this value is set at \$407.

See the Consumer Price Index-Urban All Item table promulgated by CMS.

¹¹² Stark II final rule, Phase I, 66 Fed. Reg. at 921.

¹¹³ Stark II final rule, Phase III, 72 Fed. Reg. at 51,058-59; 42 C.F.R. § 411.357(k)(3).

¹¹⁴ 42 C.F.R. § 411.357(l).

¹¹⁵ 80 Fed. Reg. at 71,314-21.

- 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 potentially applies, and in such circumstances the FMV exception may allow for greater flexibility in structuring arrangements.¹¹⁶ For example, the parties may choose to rely on the FMV exception for an arrangement that might otherwise meet the exception for personal services arrangements, because the FMV exception does not require the minimum one-year term required by the personal services arrangements exception. 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 to the rental of office space.¹¹⁷

Although this exception originally applied only to payments by an entity to a referring physician or a group of physicians for items and services, the Phase III final rule expanded it to cover payments by a physician or a group of physicians to an entity for items and services.¹¹⁸

This expansion has potential side effect of vastly narrowing a different Stark law exception—the “payments-by-a-physician” exception. That exception covers compensation paid by the physician (or his or her immediate family member) to a DHS entity if that compensation is 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.¹¹⁹ The “payments-by-a-physician” exception has always been of fairly limited utility, and the expansion of the FMV exception in Phase III may have made it almost completely irrelevant.

2210.20.120

Incidental Medical Staff Benefits

Stark contains an exception for the provision of certain incidental benefits of low value by hospitals to their medical staffs.¹²⁰ This 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)¹²¹ 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, is provided only during periods when the medical staff members are making rounds or performing other duties that benefit the hospital or its patients;
- is 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);
- is reasonably related to the provision of, or designed to facilitate directly or indirectly the delivery of, medical services at the hospital;
- is of low value¹²² (adjusted for inflation annually) with respect to each occurrence of the benefit; and
- is 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.¹²³

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.”¹²⁴

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.¹²⁵ “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

¹¹⁶ Stark II final rule, Phase I, 66 Fed. Reg. at 919.

¹¹⁷ Stark II final rule, Phase III, 72 Fed. Reg. at 51,059.

¹¹⁸ Stark II final rule, Phase III, 72 Fed. Reg. at 51,057.

¹¹⁹ 42 C.F.R. § 411.357(i)(2).

¹²⁰ 42 C.F.R. § 411.357(m).

¹²¹ 42 C.F.R. § 411.357(m)(8).

¹²² For CY 2018, for example, this value was set at \$34 per occurrence. See the Consumer Price Index-Urban All Item table promulgated by CMS.

¹²³ Stark II final rule, Phase I, 66 Fed. Reg. at 921.

¹²⁴ Stark II final rule, Phase III, 72 Fed. Reg. at 51,060.

¹²⁵ 42 C.F.R. § 411.357(o).

health care programs—billing, coding, documentation, etc. See *Chapter 207, Compliance Program Basics*. The exception does not limit training to hospital-related services, and could allow hospital-funded compliance training relating to private medical 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.¹²⁶

The exception 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.¹²⁷

2210.20.140

Indirect Compensation Arrangements

If there is an indirect compensation arrangement between a hospital and a physician (see *Chapter 2220, Direct and Indirect Relationships*), DHS referrals from the physician to the hospital are prohibited unless the arrangement fits within a compensation exception. The exception for indirect compensation arrangements will most frequently be applied for this purpose.¹²⁸ The exception has three elements:¹²⁹

- the compensation received by the physician or immediate family member must be 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, is signed by the parties,¹³⁰ 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; and

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

“*Stand in the Shoes*” Doctrine. Amendments to the definition of “compensation arrangement” in 2007 and 2008 substantially changed the analysis and determination as to whether a financial relationship between an entity and a referring physician is direct or indirect.¹³¹

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 a DHS entity, if (i) the only intervening entity between the physician and the DHS is his or her physician organization and (ii) he or she has an ownership interest in the physician organization (other than a merely titular interest).

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 meeting the Stark definition.¹³² 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 compensation exception; they are no longer analyzed as indirect compensation arrangements. The revised rule did provide, however, a limited grandfathering clause for the original term or current renewal term of any arrangement that

¹²⁶ *Id.*

¹²⁷ Stark II final rule, Phase III, 72 Fed. Reg. at 51,061.

¹²⁸ Note that not all arrangements in which a physician indirectly receives compensation from a hospital are “indirect compensation arrangements” within the meaning of that term under Stark. 42 C.F.R. § 411.354(c)(2) provides a fairly complex definition of “indirect compensation arrangement.” If the aggregate compensation received by the physician from the entity in the chain with which the physician has a direct compensation arrangement does not vary with or take into account the volume or value of DHS referrals, the arrangement is not an “indirect compensation arrangement” for purposes of Stark, even though it is an arrangement in which the physician indirectly receives compensation from a DHS entity; it is simply not an arrangement covered by Stark at all.

¹²⁹ 42 C.F.R. § 411.357(p).

¹³⁰ All physicians in a physician organization need not sign. 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., Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2010, 74 Fed. Reg. 61,738 (Nov. 25, 2009) (final rule with comment period).

¹³¹ Stark II final rule, Phase III, 72 Fed. Reg. at 51,027-28. Note that, as described in the following text, a physician stands in the shoes of his or her physician organization, but the reverse is not true; a direct compensation arrangement between a DHS entity and an individual physician is not attributed to other physicians in the same physician organization.

¹³² See 42 C.F.R. § 411.351.

met the requirements of the indirect compensation exception as of September 5, 2007.¹³³

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). As a result, 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 AMC, 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, 2008.¹³⁴

2210.20.150

Risk-Sharing Arrangements

CMS created an exception for compensation in connection with certain risk-sharing arrangements in 2004 to avoid having Stark disrupt various kinds of physician arrangements with managed care organizations that treat Medicare beneficiaries. The statutory prepaid plan exception was insufficiently broad to protect many of these financial arrangements.¹³⁵

The exception for compensation in connection with risk-sharing 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 provides 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 stat-

ute or any law or regulation governing billing or the submission of claims.¹³⁶

CMS defines “health plan” in the same manner as it is defined for purposes of the similar anti-kickback safe harbor.¹³⁷ The regulation does not define “risk-sharing.” However, CMS’s commentary¹³⁸ makes clear that, for Stark purposes, the term is interpreted more broadly than it is for purposes of the anti-kickback safe harbor.¹³⁹ 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.¹⁴⁰

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 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 DHS entity’s bona fide medical staff or in the entity’s local community or service area without regard to the volume or value of referrals or other business generated between the parties;
- the healthcare items and services provided are of a type routinely provided by the 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 healthcare 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.¹⁴¹

The exception does not protect professional courtesy provided by suppliers, such as laboratories or DME suppliers, but only that provided by hospitals and other providers with a formal medical staff. The entity is not required under Stark to notify an insurer when the professional courtesy involves a reduction of any coinsurance obligation (although insurers may independently require such notification).

Intra-Family Rural Referrals. Under the Stark regulations, a physician may refer patients living in a

¹³³ 42 C.F.R. § 411.354(c)(3)(ii).

¹³⁴ 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. 64,161 (Nov. 15, 2007).

¹³⁵ 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 16,056.

¹³⁶ 42 C.F.R. § 411.357(n).

¹³⁷ 42 C.F.R. § 1001.952(l)(2).

¹³⁸ Stark II final rule, Phase I, 66 Fed. Reg. at 912.

¹³⁹ *Id.*

¹⁴⁰ Stark II interim final rule, Phase II, 69 Fed. Reg. at 16,114.

¹⁴¹ 42 C.F.R. § 411.357(s).

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 under 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.¹⁴²

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.¹⁴³ 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.¹⁴⁴

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.¹⁴⁵

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 has said.¹⁴⁶

2210.20.170

Physician Services

The statutory exception for physician services 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.¹⁴⁷ The exception applies only to

physician services and to "incident to" services that qualify as physician services under the Stark rule.¹⁴⁸

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,¹⁴⁹ or the safe harbor for obstetrical malpractice insurance subsidies,¹⁵⁰ is excepted from Stark.¹⁵¹

On October 1, 2008, CMS provided an alternative set of requirements for the obstetrical malpractice insurance subsidy exception. The requirements were set forth in response to criticisms that, under the prior rule, even an arrangement that received a favorable advisory opinion under the anti-kickback statute from the OIG would fail to satisfy the Stark exception if the arrangement did not meet all the conditions set forth in the safe harbor. The alternative 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 (i) is 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) serves patients at least 75 percent of whom reside in a medically underserved area or are part of a medically underserved population.¹⁵²

The arrangement must be set out in writing and signed, and must 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.¹⁵³

¹⁴² 42 C.F.R. § 411.353(j).

¹⁴³ 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 (Apr. 14, 2004).

¹⁴⁴ Stark II interim final rule, Phase II, 69 Fed. Reg. at 16,084.

¹⁴⁵ Stark II final rule, Phase III, 72 Fed. Reg. at 51,040, citing 65 Fed. Reg. 82,228-33 (Dec. 27, 2000).

¹⁴⁶ Stark II final rule, Phase III, 72 Fed. Reg. at 51,040.

¹⁴⁷ 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).

¹⁴⁸ 42 C.F.R. § 410.20.

¹⁴⁹ 42 C.F.R. § 1001.952(f).

¹⁵⁰ 42 C.F.R. § 1001.952(o).

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

¹⁵² 42 C.F.R. § 411.357(r)(2).

¹⁵³ 42 C.F.R. § 411.357(r)(2)(ix).

2210.20.190**Retention Payments in Underserved Areas**

Payments to a physician in order to retain the physician in the service area of a hospital, FQHC, or RHC are excepted from the self-referral prohibition if several conditions are met.¹⁵⁴ Unlike the recruitment exception, the retention exception does not permit payments to be made to a physician indirectly through a medical group practice; the payments must be made to the physician individually.

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 or a health professional shortage area (HPSA), regardless of the physician's specialty, or an area with a demonstrated need for the physician (as determined in a CMS advisory opinion). Furthermore, the hospital can only enter into one retention arrangement with a particular referring physician every five years. The amount and terms of the payment may not be altered during the term of the arrangement in any manner that takes into account the volume or value of referrals or other business generated by the physician.¹⁵⁵

The arrangement must also satisfy the following conditions:

- the physician must have a firm written recruitment or employment offer¹⁵⁶ from another hospital, academic medical center, physician organization, FQHC, or RHC that is not related to the entity making the retention payment, and such offer would require the physician to move his or her practice both (i) at least 25 miles and (ii) 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 comparable physician services 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, FQHC, or RHC would otherwise have to expend to recruit a replacement physician.

In addition, in certain circumstances, retention payments may 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, FQHC, or RHC (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, FQHC, or RHC 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).¹⁵⁷

2210.20.200**Community-Wide Health Information Systems**

A hospital or other DHS entity may furnish a physician with information technology as part of a community-wide health information system without creating a financial relationship under the Stark law.¹⁵⁸ The arrangement must meet the following requirements:

- 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 by the physician 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 drug benefit in the Medicare program.¹⁵⁹ As part of the 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 implementing this exception.¹⁶⁰ 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 were effective as of October 10, 2006. A similar exception covering elec-

¹⁵⁴ 42 C.F.R. § 411.357(t).

¹⁵⁵ 42 C.F.R. § 411.357(t)(3).

¹⁵⁶ Such offers must specify the remuneration being offered. See 42 C.F.R. § 411.357(t).

¹⁵⁷ 42 C.F.R. § 411.357(t)(2).

¹⁵⁸ 42 C.F.R. § 411.357(u).

¹⁵⁹ Pub. L. No. 108-173, § 101, establishing Social Security Act § 1860D-2.

¹⁶⁰ 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. 45,140 (Aug. 8, 2006) (final rule).

tronic health records, which may have more utility, was promulgated at the same time (see § 2210.20.220).

The regulations provide that the provision of electronic prescribing technology is excepted from the self-referral prohibition if several conditions are met:¹⁶¹

- 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 practice¹⁶² to a prescribing healthcare professional who is a member¹⁶³ of the group practice; or (3) by a prescription drug plan sponsor or Medicare Advantage organization to pharmacists and pharmacies that participate in the network of such sponsor or organization and to prescribing healthcare 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 (including any person acting 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);¹⁶⁴ 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),¹⁶⁵ excepting from the self-referral prohibition certain arrangements involving the provision of interoperable¹⁶⁶ 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 a DHS entity (other than a lab company) to a physician.¹⁶⁷ 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.¹⁶⁸

The EHR exception also prohibits donor-imposed limitations on a physician's right to use the items for any patient¹⁶⁹ as well as any actions to disable or limit the interoperability of any software component or impose any other barriers to compatibility.¹⁷⁰ 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 or services, a condition of doing business with the donor.¹⁷¹

In selecting software recipients and determining the amount or nature of the items and services they are to receive, the donor may not directly take into account the volume or value of the recipient's referrals to the donor or other business generated between the parties.¹⁷² 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;

¹⁶¹ 42 C.F.R. § 411.357(v).

¹⁶² "Group practice" is defined at 42 C.F.R. § 411.352.

¹⁶³ "Member" is defined at 42 C.F.R. § 411.351.

¹⁶⁴ 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 available 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).

¹⁶⁵ Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements, 71 Fed. Reg. 45,140.

¹⁶⁶ 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.

¹⁶⁷ 42 C.F.R. § 411.357(w)(1).

¹⁶⁸ 42 C.F.R. § 411.357(w)(8).

¹⁶⁹ 42 C.F.R. § 411.357(w)(9).

¹⁷⁰ 42 C.F.R. § 411.357(w)(3).

¹⁷¹ 42 C.F.R. § 411.357(w)(5).

¹⁷² 42 C.F.R. § 411.357(w)(6).

- 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; or

- the level of uncompensated care provided by the physician;

- or if it is made in 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;¹⁷³

- 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 services¹⁷⁴ —(neither the donor nor any party related to the donor may 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;¹⁷⁵

- 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;¹⁷⁶ and

- the arrangement may not violate the anti-kickback law or regulations governing billing or claims submissions.¹⁷⁷

Finally, the transfer of the items or services must have occurred and all requirements of the exception must have been satisfied on or before the sunset date for the regulation, which is currently December 31, 2021.¹⁷⁸

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.¹⁷⁹ 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 the proposed arrangement was not a Stark compensation arrangement in need of an exception.¹⁸⁰

According to CMS, the hospital already had developed a proprietary healthcare software information system that allowed staff physicians to view patient data, order tests, and communicate lab test results. Furthermore, the physicians could already 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.

2210.20.230

Assistance in Compensating Nonphysician Practitioners

Effective January 1, 2016, CMS adopted a Stark exception covering remuneration provided by a hospital, FQHC, or RHC to a physician to compensate a nonphysician practitioner (NPP —defined as a physician assistant, nurse practitioner, clinical nurse specialist, certified nurse midwife, clinical social worker, or clinical psychologist) for the provision of patient care services,¹⁸¹ provided that the following conditions are met:

- the arrangement must be in writing and signed by the hospital (or FQHC or RHC), the physician, and the NPP;

- the arrangement is not conditioned on the physician's or the NPP's referrals to the DHS entity;

- the remuneration from the DHS entity does not exceed 50 percent of the NPP's actual compensation, signing bonus and benefits paid by the physician (or the physician organization in the shoes of which the physician stands) during a period not to exceed the first two consecutive years of the compensation arrangement between the physician (or physician organization) and the NPP, and is not determined in a manner that takes into account, directly or indirectly, the volume or value of actual or anticipated referrals by the physician, any physician in the physician's practice, the recruited NPP, or any other NPP in the physician's practice, or any other business generated between the parties;

¹⁷³ 42 C.F.R. § 411.357(w)(7).

¹⁷⁴ 42 C.F.R. § 411.357(w)(4).

¹⁷⁵ 42 C.F.R. § 411.357(w)(10).

¹⁷⁶ 42 C.F.R. § 411.357(w)(11).

¹⁷⁷ 42 C.F.R. § 411.357(w)(12).

¹⁷⁸ 78 Fed. Reg. 78,751, 78,755-57.

¹⁷⁹ 42 C.F.R. § 411.351.

¹⁸⁰ CMS Advisory Op. No. AO-2008-01 (May 20, 2008).

¹⁸¹ 42 C.F.R. § 411.357(x).

- the compensation (including signing bonus and benefits) paid to the NPP by the physician does not exceed fair market value for the patient care services furnished by the NPP to patients of the physician's practice;

- the NPP has not, within one year prior to the commencement of his or her compensation arrangement with the physician or physician organization, either practiced in the geographic area served by the DHS entity or been employed or engaged to provide patient care services by a physician or physician organization that has a medical practice site located in the geographic area serviced by the DHS entity, even if the NPP did not furnish services at the practice site;

- the NPP's compensation arrangement is directly with the physician or the physician organization, and substantially all the services the NPP furnishes to patients of the physician's practice are primary care services or mental health care services;

- the physician does not impose practice restrictions on the NPP that unreasonably restrict the NPP's ability to provide patient care services in the geographic area served by the DHS entity; and

- the arrangement does not violate the anti-kick-back statute or any federal or state law or regulation governing billing or claims submission.¹⁸²

Records of the actual amount of remuneration provided by the DHS entity to the physician and by the physician to the NPP must be maintained for at least six years and made available to HHS upon request.¹⁸³

A particular hospital, FQHC, or RHC may rely on this exception only once every three years with respect to the same referring physician. However, this limitation does not apply if

- the NPP is replacing another NPP who terminated his or her employment or contractual arrangement with the physician or physician organization within one year after the arrangement commenced and

- the remuneration provided to the physician is provided during a period that does not exceed two consecutive years measured from the commencement date of the arrangement between the physician the NPP who is being replaced.¹⁸⁴

2210.20.240

Timeshare Arrangements

Also effective January 1, 2016, CMS adopted an exception for remuneration provided under "timeshare" arrangements for the use of premises, equipment, personnel, supplies, or services on a limited or as-needed basis, provided the following conditions were met:

- the arrangement is set out in writing, be signed by the parties, and specify the premises, equipment, personnel, items, supplies, and services covered by the arrangement;

- the arrangement is between a physician (or physician organization as to which the physician stands in the shoes) and either a hospital or a physician organization of which the physician is not an owner, employee or contractor (unrelated physician organization);

- the premises, items and services covered by the arrangement are used predominantly for the provision of evaluation and management (E/M) services to patients and must be used on the same schedule (i.e., all premises, items and services covered by the arrangement must be used during the same interval, so that, for example, the arrangement cannot cover premises and equipment at one time and supplies and personnel at another time);

- the equipment covered by the arrangement is located in the same building where the E/M services are provided, must not be used to furnish DHS, other than DHS incidental to the E/M services and furnished at the time of the patients E/M visit, and must not be advanced imaging equipment, radiation therapy equipment, or clinical or pathology laboratory equipment (other than equipment used to perform CLIA-waived laboratory tests);

- the arrangement is not conditioned on the referral of patients by the physician to the hospital or unrelated physician organization;

- the compensation over the term of the arrangement is set in advance, consistent with fair market value, and not determined either 1) in a manner that takes into account, directly or indirectly, the volume or value of referrals or other business generated between the parties or 2) using a formula based either on a percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services provided while using the premises, items or services covered by the arrangement or on per-unit fees that are not time-based, to the extent that such fees reflect services provided to patients of the party providing the premises, items or services by the physician who uses such premises, items or services under the arrangement;

- the arrangement would be commercially reasonable even if no referrals were made between the parties;

- the arrangement does not violate the anti-kick-back statute or any federal or state law or regulation governing billing or claims submission; and

- the arrangement does not convey a "possessory leasehold interest" in the office space that is the subject of the arrangement.¹⁸⁵

2210.20.250

Ownership Interests in "Whole 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) may be excepted

¹⁸² 42 C.F.R. § 411.357(x)(1).

¹⁸³ 42 C.F.R. § 411.357(x)(2).

¹⁸⁴ 42 C.F.R. § 411.357(x)(7).

¹⁸⁵ 42 C.F.R. § 411.357(y).

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, such as a particular department or service.¹⁸⁶

CMS also takes the position that a physician may 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.¹⁸⁷

Scope of Excepted Referrals. The exception covers any DHS the hospital provides. Referrals by the referring physician to the hospital itself 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.¹⁸⁸ Therefore, a physician may 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 with 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. The ACA banned the creation of new physician-owned hospitals after December 31, 2010. Physician-owned hospitals with a Medicare provider agreement in effect at that time were grandfathered, although the ACA froze aggregate physician ownership in such existing physician-owned hospitals at its level as of March 23, 2010.¹⁸⁹

Physician-owned hospitals are also banned from expanding their facility capacity, except in very limited circumstances as prescribed by regulations adopted in 2012 and 2015. 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, on that later date), unless the Secretary grants an exception.

An "applicable hospital" or high Medicaid facility may request an exception to the expansion limitation once every two 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 five-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 healthcare programs and does not permit physicians practicing at the 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 percentage of total Medicaid inpatient admissions equal to or greater than the average percentage of such admissions for all hospitals in the same county during the most recent fiscal year for which data are available; and
- does not discriminate against beneficiaries of federal healthcare programs and does not permit physicians practicing at the hospital to do so.

Additional Requirements for Grandfathered Hospitals. Grandfathered hospitals must comply with certain

¹⁸⁶ 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, (Mar. 23, 2010), as amended by the Health and Education Reconciliation Act of 2010, Pub. L. No. 111-152 §§ 6001 and 10602, § 1106 (Mar. 30, 2010); 42 C.F.R. § 411.356(c)(3).

¹⁸⁷ 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.)

¹⁸⁸ Stark II final rule, Phase III, 72 Fed. Reg. at 51,043.

¹⁸⁹ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, §§ 6001 and 10602 (Mar. 23, 2010), as amended by the Health and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 1106 (Mar. 30, 2010).

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, amendments to the Stark law added by ACA prohibit hospitals from:

- offering ownership or investment interests to a physician owner or investor on more favorable terms than the terms offered to others;
- 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.¹⁹⁰

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.¹⁹¹

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.¹⁹²

Some states place greater restrictions on physician ownership in hospitals or may prohibit it altogether; so state law should be carefully reviewed and considered as well. For considerations relating to joint ventures between physicians and a hospital, see *Chapter 1410, Joint Ventures and Acquisitions*.

2210.30 Compliance

2210.30.10

Overview

Under the Affordable Care Act (ACA), where a provider has received Medicare overpayments, including those resulting from Stark violations, and has not repaid such overpayments within 60 days of identifying them, they become an “obligation” under the False Claims Act.¹⁹³ Consequently, there is now greater potential for Stark violations to present significant fraud and abuse exposure in the form of whistleblower suits, because the retention of a payment received with respect to a claim that was prohibited under Stark is now not simply retention of an overpayment that must be refunded, but can constitute a violation of the False Claims Act.¹⁹⁴

Accordingly, hospitals and other healthcare providers should develop stringent audit and refund-processing

policies and procedures to enable them to promptly identify overpayments and/or potential Stark violations so 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.¹⁹⁵

person has identified an overpayment when that person “has or should have, through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment.” Medicare Program; Reporting and Returning of Overpayments, 81 Fed. Reg. 7653 (Feb. 12, 2016); 42 CFR § 401.305.

¹⁹⁵ See CMS Voluntary Self-Referral Disclosure Protocol, and discussed below.

¹⁹⁰ 42 U.S.C. § 1395nn(i)(1)(D)(i)-(iv), (iv).

¹⁹¹ 42 U.S.C. § 1395nn(i)(1)(D)(v), (vi).

¹⁹² 42 CFR § 411.362(b)(5).

¹⁹³ See Social Security Act § 1128J(d) [42 U.S.C. § 1320a-7k]; 31 U.S.C. § 3729, *et. seq.*

¹⁹⁴ When overpayments are considered “identified” is not defined in the ACA. See Social Security Act § 1128J(d) [42 U.S.C. § 1320a-7k]. However, the implementing regulations state that a

2210.30.20**Temporary Noncompliance Rules**

Temporary Noncompliance. If an arrangement between an entity and a physician has fully complied with 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 so long as 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. For example, CMS has indicated that noncompliance occurring due to loss of a HPSA designation for purposes of the physician retention payments exception or due to delays in obtaining fully signed copies of renewal agreements are examples of noncompliance resulting from circumstances beyond the entity's control.¹⁹⁶

The exception for temporary noncompliance does not apply to arrangements that had previously complied with the exceptions for non-monetary compensation or incidental medical staff benefits. In addition, a DHS entity may rely on the temporary noncompliance rule only once every three years with respect to the same referring physician.¹⁹⁷

Temporary Noncompliance with Signature Requirements. Effective since 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.¹⁹⁸ If the parties obtain the required signature(s) within 90 calendar days after the financial relationship began (without regard to whether any referrals occurred or compensation was paid during the 90-day period), Stark has not been violated. This special rule may likewise be relied upon by an entity only once every three years with respect to the same referring physician.

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,¹⁹⁹ 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 (and, if retained for more than 60 days after they have been identified, could constitute FCA violations).²⁰⁰

The period of disallowance begins at the point 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.²⁰¹

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.²⁰²

2210.30.40**Self-Disclosure**

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

In a March 2009 Open Letter to healthcare 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 Stark law unless the self-disclosure included a colorable anti-kickback statute violation for the same conduct.²⁰³

Responding to this development and to long-standing industry complaints that the Stark law often imposes extraordinary liability for mere technical violations without regard to intent, Congress, as part of the ACA, directed CMS to develop, in consultation with the OIG,

¹⁹⁶ 72 Fed. Reg. 51,012, 51,025-6 (Sept. 5, 2007); 69 Fed. Reg. 16,053, 16,057 (Mar. 26, 2004).

¹⁹⁷ 42 C.F.R. § 411.353(f).

¹⁹⁸ 42 C.F.R. § 411.353(g).

¹⁹⁹ See 42 C.F.R. § 411.353(c).

²⁰⁰ 42 C.F.R. § 411.353(b) and (d).

²⁰¹ See FY 2009 IPPS final rule, 73 Fed. Reg. at 48,702.

²⁰² *Id.* at 48,700.

²⁰³ OIG 'Open Letter' to Industry Cites Kickbacks in Self-Disclosure Protocol, 13 BNA's Health Care Fraud Report 258 (Apr. 8, 2009).

a self-disclosure protocol for potential or actual Stark violations.²⁰⁴ Accordingly, CMS released the Stark self-referral disclosure protocol (SRDP) in September 2010 and subsequently revised it in 2014 and again in 2017.²⁰⁵

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:

- an SRDP Disclosure Form;
- a Physician Information Form;
- a Financial Analysis Worksheet; and
- a certification page provided by the self-disclosing party.

The SRDP form allows the disclosing party to provide information about the party, the history of abuse, the pervasiveness of noncompliance and steps taken to prevent future noncompliance. The required information includes:

- the disclosing party's name, address, national provider identification number, CMS certification number(s) and tax identification number(s);
- the name and address of the disclosing party's designated representative for purposes of the disclosure;
- a determination and statement of the type(s) of noncompliance being disclosed relative to the disclosing party's similar financial relationships or similar services furnished;
- an indication of whether the disclosing party has knowledge that the matter is under current inquiry by a government agency or contractor, and if it does have knowledge of a pending inquiry, the identity of the government entity or individual representatives involved;

● if the disclosing party is under investigation or other inquiry for any other matters relating to a federal healthcare program (including matters it disclosed to other government entities), similar information relating to those other matters;

● a statement indicating whether the disclosing party has a history of "similar conduct" or was the subject of any prior criminal, civil and regulatory enforcement actions (including payment suspensions); and

● a statement indicating whether the disclosing party has taken steps to prevent future noncompliance, and, if so, a brief summary of the steps, or, if not, a brief explanation of why the steps are unnecessary.

The SRDP also calls for the disclosing party to submit a full financial analysis of any amounts that are 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.²⁰⁶

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.²⁰⁷

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 from adopting particular measures, such as treatment protocols or product standardization, 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 CMP Law generally prohibits hospital payments to physicians intended to induce the reduction or limitation of services to Medicare or Medicaid beneficiaries.²⁰⁸ Likewise, the AKS prohibits the offer, payment, solicitation, or receipt of remuneration with the intent to induce or reward referrals.²⁰⁹

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 (to be designated as 42 C.F.R.

²⁰⁴ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6409.

²⁰⁵ See CMS, Voluntary Self-Referral Disclosure Protocol.

²⁰⁶ *Id.*

²⁰⁷ *Id.*

²⁰⁸ Social Security Act § 1128A(b)(1) [42 U.S.C. § 1320a-7a(b)(1)].

²⁰⁹ See 42 U.S.C. § 1320a-7b(b).

§ 411.357(x)) designed specifically for certain incentive payment and shared savings programs, including gainsharing arrangements.²¹⁰ 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, as of September 2018, has taken no further action to finalize the exception.²¹¹

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 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 program (PIP) provisions²¹² and corresponding PIP regulations.²¹³ Thus, hospital PIP plans limited to risk-based managed care programs are not subject to the gainsharing prohibition.

The CMP prohibition speaks in terms of healthcare services. But the OIG has said that since healthcare 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.²¹⁴

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.²¹⁵ 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.”²¹⁶ 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, however, the OIG has 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 hospital offering the incentive; payments actually being made in exchange for referrals; and hospitals unfairly competing for physician loyalty and referrals.

Advisory Opinions. In approving gainsharing 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. 07-21,²¹⁷ 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 experienced 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.

²¹⁰ Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; and Revisions to the Amendment of the E-Prescribing Exemption for Computer Generated Facsimile Transmissions; Proposed Rule, 73 Fed. Reg. 38,502, 38,548 (July 7, 2008) (*hereinafter* CY 2009 MPFS Proposed Rule).

²¹¹ Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; E-Prescribing Exemption for Computer-Generated Facsimile Transmissions; and Payment for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), 73 Fed. Reg. 69,726 (Nov. 19, 2008).

²¹² 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)].

²¹³ 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).

²¹⁴ HHS IG's McAnaney Answers Attorneys' Questions on Gainsharing, 3 BNA's Health Care Fraud Rep. 815 (Sept. 8, 1999).

²¹⁵ Special Advisory Bulletin on Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Service to Beneficiaries, 64 Fed. Reg. 37,985, 37,986 (July 14, 1999).

²¹⁶ *Id.*

²¹⁷ Office of Inspector Gen., U.S. Dep't of Health & Human Servs., Advisory Op. No. 07-21 (Jan. 14, 2008).

In Advisory Opinion No. 07-22,²¹⁸ 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.²¹⁹

- 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 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 affects 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,²²⁰ 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—the arrangements contained protections 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, and 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 products would still be available if a physician felt it was clinically necessary to use a non-preferred product for a particular patient.²²¹

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.²²²

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 healthcare programs.²²³

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.²²⁴ The ACA extended this demonstration project until September 2011 and provided additional funds for it.²²⁵ CMS's final report concluded that the demonstration project showed some cost savings without an ad-

²¹⁸ Office of Inspector Gen., U.S. Dep't of Health & Human Servs., Advisory Op. No. 07-22 (Jan. 14, 2008).

²¹⁹ 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).

²²⁰ See, e.g., Advisory Op. No. 08-21 (Nov. 25, 2008), No. 08-15 (Oct. 6, 2008).

²²¹ 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).

²²² *Id.*

²²³ *Id.*

²²⁴ Pub. Law 109-171, § 5007 (Feb. 8, 2006).

²²⁵ Pub. Law 111-148, § 3027 (Mar. 23, 2010).

verse impact on quality of care.²²⁶ It remains to be seen whether the results of this demonstration project could lead federal regulators to amend their guidance on gain-sharing arrangements.²²⁷

The ACA also created the Accountable Care Organization (ACO) as the centerpiece of gainsharing-like initiative, the Medicare Shared Savings Program.²²⁸ In short, an ACO is an entity comprising different types of healthcare providers (and potentially payors as well), including physicians and hospitals that agree to take on responsibility for caring for a group of at least 5,000 assigned Medicare beneficiaries. ACO providers are 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 ACO.²²⁹ 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 regulatory development in the resolution of Stark law cases is the release of the Self-Referral Disclosure Protocol (SRDP). (See § 2210.30.40, above.) As described 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. Through 2017, CMS has reported 280 settlements under the SRDP, with individual settlements ranging from \$60 to nearly \$1.2 million and total settlements of over \$27 million. An additional 119 SRDP disclosures were withdrawn, closed without settlement or settled by law enforcement agencies.²³⁰

2210.50.20

Selected Stark Law Settlements

Settlement	Alleged Misconduct	Resolution/Penalties
<i>United States ex rel. Mohatt v. Healthcenter Northwest, LLC</i> , No. 9:18-cv-00080 (D. Mont. settlement effective date Sept. 27, 2018).	A group of 63 physicians allegedly received compensation from a hospital network in Montana through either direct or indirect financial relationships with the network in return for referrals. The compensation agreements with physicians allegedly took into account the volume of referrals and exceeded the fair market for the services that the physicians provided to the hospitals.	The hospital owner agreed to pay \$24 million to settle the allegations. See <i>Doctors' Overpayment Drives \$24M Settlement by Hospital System</i> , Bloomberg Law News (Oct. 1, 2018).

²²⁶ CMS, Medicare Gainsharing Demonstration: Final Report to Congress (June 3, 2014).

²²⁷ Special Advisory Bulletin on Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Service to Beneficiaries, 64 Fed. Reg. 37,985, 37,986 (July 14, 1999).

²²⁸ Pub. Law 111-148, § 3022 (Mar. 23, 2010). The ACA also provides for the creation of a pediatric ACO demonstration project. See *id.* at § 2706.

²²⁹ 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.

²³⁰ See CMS, Self-Referral Disclosure Protocol Settlements.

Settlement	Alleged Misconduct	Resolution/Penalties
<i>In Re: Health Management Associates, Inc. Qui Tam Litigation (No. II)</i> (Second Settlement here), No. 1:14-mc-00339 (D.D.C. settlements effective date Sept. 24, 2018).	A group of hospitals formerly operating under the corporate umbrella of Health Management Associates, LLC allegedly paid physicians for patient referrals and submitted inflated claims for emergency department facility fees as part of a scheme to increase inpatient emergency department admissions and provided another physician group and physician free office space and space as well as direct payments that exceeded overhead and administrative costs in return for patient referrals.	The hospitals agreed to pay \$260 million to settle the allegations. See <i>Hospital Chain HMA Pays \$260M to Resolve Fraud Cases</i> , Bloomberg Law News (Sept. 25, 2018).
<i>United States ex rel. Johnson v. Post Acute Medical, LLC</i> , No. 1:17-cv-01269 (M.D. Pa. settlement effective date Aug. 13, 2018).	A company that operates or manages twenty-five long term care and rehabilitation hospitals in many states allegedly paid physicians to refer Medicare and Medicaid patients to its hospitals and allegedly traded patient referrals with other healthcare providers in violation of the anti-kickback statute and the Stark Law.	The company agreed to pay \$13.1 million to resolve the allegations. See <i>Hospital Company Will Pay \$13M to Resolve Kickback Claims</i> , Bloomberg Law News (August 16, 2018).
<i>United States ex rel. Carbone v. William Beaumont Hospital</i> , No. 2:11-cv-12117 (E.D. Mich. settlement effective date July 31, 2018).	A hospital allegedly provided physicians with compensation substantially in excess of fair market value and free or below-fair market value office space and employees in return for referrals.	The hospital agreed to pay \$84.5 million to settle the allegations. See <i>Detroit Health System Forks Over \$84.5M to Settle Fraud Claims</i> , Bloomberg BNA's Health Care Daily Report (August 6, 2018).
<i>United States ex rel. Folta v. Health Quest Systems, Inc.</i> , No. 1:15-cv-00396 (N.D.N.Y. settlement effective date June 29, 2018).	A New York hospital allegedly provided compensation to two referring physicians that exceeded the fair market value for the administrative services they provided at the hospital in an effort to induce them to refer patients to the hospital.	The hospital agreed to pay \$15.6 million to settle those and other associated allegations. See <i>Upstate N.Y. Hospital Agrees to \$15.6M Fraud Settlements</i> , Bloomberg BNA's Health Care Daily Report (July 11, 2018).
<i>United States ex rel. Allison v. Southwest Orthopaedic Specialists PLLC</i> , No. 5:16-cv-00569 (W.D. Okla. settlement effective date May 31, 2018).	An orthopaedic practice in Oklahoma allegedly billed federal and state health care programs for medically unnecessary ultrasound needle placement guidance procedures, billed for surgical assistant services that were not provided, and violated the Stark and Anti-Kickback Laws	The practice agreed to pay \$670,000 to settle the allegations. See <i>Okla. Doctors Pay \$670,000 to End Some Fraud Charges</i> , Bloomberg BNA's Health Care Daily Report (July 17, 2018).
<i>Mercy Health</i> , (N.D. Ohio self-disclosure settlement effective date May 10, 2018).	A hospital group in Ohio and Kentucky self-disclosed that it may have directly or indirectly provided excessive compensation to six physicians over the course of three years in violation of the Stark Law and the Anti-Kickback Statute.	The group agreed to pay \$14.25 million to resolve the allegations. See <i>DOJ, Ohio Hospital Settle False Claims Act Allegations</i> , Bloomberg BNA's Health Law Reporter (May 17, 2018)

Settlement	Alleged Misconduct	Resolution/Penalties
<i>United States ex rel. Kopko v. Georgia Bone & Joint, LLC</i> , No.3:13-cv-00067 (N.D. Ga. settlement effective date Mar. 29, 2018).	Orthopaedic and anesthesia providers provided a free medical director to a surgery center to induce the center to choose to perform more procedures at the surgery center rather than at one of the orthopaedic clinics.	The providers agreed to pay \$3.2 million to resolve the allegations.
<i>United States ex rel. IIRT LLC v. Sightline Health LLC</i> , No. 3:16-cv-03203 (N.D. Tex. settlement effective date Mar. 29, 2018).	A radiation therapy company targeted physicians and paid kickbacks to physicians in exchange for patient referrals to the company's cancer treatment centers. The company paid referring physicians a share of its profits in investment arrangements that were set up to allow physicians to profit from the referrals. The company also set up a series of leasing companies in which physicians could invest and through which the company distributed profits generated through treating those referred patients.	The company agreed to pay \$11.5 million to resolve the allegations. See <i>Radiation Therapy Company to Pay \$11.5M Fraud Settlement</i> , Bloomberg BNA's Health Law Reporter (Apr. 5, 2018)
<i>United States ex rel. Emanuele v. Medicor Associates, Inc.</i> , No. 1:10-cv-00245 (W.D. Pa. settlement effective date Mar. 5, 2018).	A hospital paid a cardiology group up to \$2 million per year under twelve physician and administrative services arrangements that were created to secure Medicare patient referrals. The hospital allegedly had no legitimate need for the services contracted for, and in some instances the services either were duplicative or were not performed.	The hospital and physician group agreed to pay \$20.8 million to resolve the allegations. See <i>Hospital, Physician Group Settle Fraud Charges for \$20.8M</i> , Bloomberg BNA's Health Care Fraud Report (Nov. 22, 2017)
<i>Dr. Aytac Apaydin and Dr. Stephen Worsham</i> (N.D. Cal. self-disclosure settlements effective date Jan. 24, 2018).	Two urologists who own and operate a practice submitted false claims in violation of the Stark law and anti-kickback statute. The physicians solicited other urologists to enter into lease agreements with a company that they owned. Under those lease agreements, the lessee urologist could bill for and profit from the referrals of certain services performed there, in violation of the law.	The urologists agreed to pay a combined \$1 million to resolve the allegations. See <i>Two Calif. Urologists to Pay \$1M to Settle False Claims Case</i> , Bloomberg BNA's Health Law Reporter (Feb. 1, 2018)
<i>United States ex rel. Deshpande v. Jamaica Hospital Medical Center</i> , No. 1:13-cv-04030 (E.D.N.Y. settlement effective date Sept. 13, 2017).	A group of Queens, N.Y. hospitals allegedly provided compensation to physicians in the absence of written documentation signed by the parties and allowed physicians to use hospital space for their private medical practices without complying with the requirements of the Stark Law.	The hospitals agreed to pay \$4 million to resolve the allegations. See <i>New York Hospital Owner Settles Medicare Kickback Case for \$4M</i> , Bloomberg BNA's Health Care Fraud Report (Sept. 27, 2017)

Settlement	Alleged Misconduct	Resolution/Penalties
<i>Family Medicine Centers of South Carolina LLC</i> (D.S.C. self-disclosure settlement effective date Sept. 11, 2017).	A physician practice allegedly improperly paid its physicians to refer laboratory and diagnostic tests to the practice itself and then paid them a percentage of the reimbursement received for the tests.	The practice and its owners agreed to pay \$1.6 million to resolve the allegations. The owners were also prevented from retaining management roles at the practice for 5 years. See <i>Physician Practice, Owners Pay \$2M to Settle Lab Fraud Charges</i> , Bloomberg BNA's Health Care Fraud Report (Sept. 13, 2017)
<i>Home Health Care of East Tennessee, Inc.</i> (E.D. Tenn. self-disclosure settlement effective date Sept. 5, 2017).	Several affiliated home health providers in eastern Tennessee allegedly billed Medicare for home health services that, in some cases, they couldn't be reimbursed for because of compensation agreements or other financial relationships with referring physicians	The companies agreed to pay \$1.8 million to resolve the allegations. See <i>Medicare Referrals to Cost Tennessee Home Health Providers \$1.8M</i> , Bloomberg BNA's Health Care Fraud Report (Sept. 13, 2017)
<i>United States ex rel. Holden v. Mercy Hospital Springfield</i> , No. 6:15-cv-03283 (W.D. Mo. settlement effective date May 18, 2017).	A Missouri hospital and its affiliated clinic allegedly paid employed physicians in part based on the volume and value of their referrals to the hospital's oncology infusion center	The hospital and clinic agreed to pay \$34 million to resolve the allegations. See <i>Missouri Hospital to Pay \$34M to Settle Questionable Payments to Cancer Docs</i> , Bloomberg BNA's Health Care Fraud Report (May 24, 2017)
<i>United States ex rel. Drakeford v. Tuomey Healthcare Sys. Inc.</i> , No.3:05-cv-2858 (D.S.C. settlement announced Sept. 27, 2016).	The former chief executive officer of a hospital was involved in its scheme to defraud Medicare and Medicaid where it entered into contracts with physicians that required them to refer outpatient procedures to the hospital in exchange for compensation that far exceeded fair market value and included money that the hospital received from Medicare for the referred procedures.	The CEO agreed to pay \$1 million and be excluded for four years from participating in federal healthcare programs to resolve the allegations. See 190 <i>BNA's Health Care Daily Report</i> (Sept. 30, 2016).
<i>United States ex rel. Schaengold v. Mem'l Health, Inc.</i> , No. 4:11-cv-00058-JRH-BKE (S.D. Ga. settlement announced Feb. 8, 2016).	A hospital hired three primary care physicians specifically to boost referrals within its healthcare system in order to compete with another hospital. The hospital paid the physicians above-market rates in exchange for referrals.	The hospital agreed to pay \$9.9 million to resolve the claims. See 27 <i>BNA's Health Care Daily Report</i> (Feb. 2, 2016).
<i>United States ex rel. Drakeford v. Tuomey Healthcare Sys. Inc.</i> , No. 3:05-cv-02858 (MBS) (D.S.C. settlement announced Oct. 16, 2015).	A hospital entered into contracts with physicians that required them to refer outpatient procedures to the hospital in exchange for compensation that far exceeded fair market value and included money that the hospital received from Medicare for the referred procedures.	The hospital agreed to pay \$72.4 million to resolve the claims. See 201 <i>BNA's Health Care Daily Report</i> (Oct. 19, 2015).

Settlement	Alleged Misconduct	Resolution/Penalties
<i>United States ex rel. Reilly v. N. Broward Hosp. Dist.</i> , No. 0:10-cv-60590 (S.D. Fla. settlement announced Sept. 15, 2015).	A hospital district that operates hospitals and other healthcare facilities entered into compensation agreements with nine physicians from 2000 to 2014 in which the hospital district provided compensation that exceeded the fair market value of physician services and took into account the value of the physicians' referrals to the healthcare facilities within the district.	The hospital district agreed to pay \$69.5 million to resolve the claims. See 179 <i>BNA's Health Care Daily Report</i> (Sept. 16, 2015).
<i>United States ex rel. Jones, Hollingsworth, and Rukavina v. St. Joseph Health System et. al.</i> , No. 11-cv-00081-GFVT (E.D. Ky. settlement announced Oct. 21, 2014).	Two cardiologists entered into sham management agreements with a hospital where the physicians were paid to provide management services that they did not provide. The physicians also entered into an exclusive agreement with the hospital to refer patients to the hospital for services.	The physicians agreed to pay \$380,000 to resolve the claims. See 18 <i>BNA's Health Care Fraud Rep.</i> 924 (Oct. 29, 2014).
<i>United States ex rel. Williams v. Banks-Jackson-Commerce Hosp. and Nursing Home Auth.</i> , No. 1:08-cv-3235 (N.D. Ga. settlement announced Sept. 22, 2014).	A hospital compensated a cardiologist for professional services and medical director services in excess of fair market value for referring patients to the hospital, which in turn billed Medicare for the referred services rendered.	The cardiologist agreed to pay \$200,000 and the hospital agreed to pay \$329,000 and entered into a corporate integrity agreement that included independent review of the hospital's payments to doctors who made referrals. See 185 <i>BNA's Health Care Daily Report</i> (Sept. 24, 2014).
Ashland Hospital Corporation d/b/a King's Daughters Medical Center (E.D. Ky. settlement announced May 28, 2014).	A hospital paid unreasonably high salaries that were in excess of fair market value to several cardiologists who referred cardiovascular services to the hospital, which billed Medicare and Medicaid for the referred services.	To settle the allegations, the hospital agreed to pay \$40.9 million and entered into a five-year corporate integrity agreement. See 103 <i>BNA's Health Care Daily Report</i> (May 29, 2014).
Devender Batra and Belmont Cardiology Inc., (N.D. W.Va., Apr. 17, 2014).	A cardiologist and his medical corporation caused two hospitals to submit fraudulent claims to Medicare from Jan. 2009 to Aug. of 2010. The cardiologist had improper compensation arrangements with the hospitals that led to false claims for prohibited referrals for various health services.	The cardiologist agreed to pay \$1 million to resolve the allegations. See 18 <i>BNA's Health Care Fraud Rep.</i> 362 (Apr. 30, 2014).
<i>United States ex rel. Schubert v. All Children's Health Sys., Inc.</i> , No. 8:11-cv-1687 (M.D. Fla. settled Apr. 2, 2014).	Hospital executives ignored a whistleblower's proposed market-rate compensation plan and instead pursued pediatricians with pay packages that resulted in operating losses for the group but generous referrals for the hospital. The hospital also operated a physician bonus scheme intended to increase referrals.	The hospital agreed to pay \$7 million to settle the allegations. See 18 <i>BNA's Health Care Fraud Rep.</i> 374 (Apr. 30, 2014).

Settlement	Alleged Misconduct	Resolution/Penalties
<i>United States ex rel. Baklid-Kunz v. Halifax Hosp. Med. Ctr.</i> , No. 6:09-cv-01002-GAP-TBS (M.D. Fla. settlement Mar. 10, 2014).	A hospital incorporated referrals into the bonuses of oncologists and neurologists, and admitted patients when not medically necessary to increase Medicare billing rates.	The hospital agreed to pay \$85 million to resolve the allegations, and entered into a corporate integrity agreement with the OIG. See 18 <i>BNA's Health Care Fraud Rep.</i> 233 (Mar. 19, 2014).
<i>United States ex rel. Luque v. Adventist Health</i> , No. 2:08-CV-1272 (E.D. Cal. settlement announced May 13, 2013).	A hospital system improperly compensated physicians who referred patients to a hospital by transferring assets, including medical and non-medical supplies and inventory, in a transaction that appeared to be below fair market value. The hospital also paid referring physicians compensation that was above fair market value to provide teaching services at its family practice residency program.	The hospital system agreed to pay \$11.5 million to the federal government and \$2.6 million to the California Department of Health Care Services to resolve the allegations.
Sisters of Charity of Leavenworth Health System (D. Mont. settlement announced May 1, 2013)	Two hospitals self-reported possible Stark self-referral law and False Claims Act violations to the U.S. Attorney's Office, including instances of physician compensation arrangements that took referral volumes or values into account. As many as 86 employed physicians had improper compensation contracts from 2003 through 2010, and as many as 53 additional independent physicians and physician groups with improper compensation arrangements for referrals.	The hospitals agreed to a \$3.95 million settlement with the Department of Justice.
Intermountain Health Care Inc. (D. Utah settlement Apr. 3, 2013).	A health system disclosed to the DOJ that between 2000 and 2009, it had employed a physician bonus formula based on the value of a patient referral that might have run afoul of Stark and FCA statutes. The health system also disclosed that it may have entered into below-market office leases with physicians during the same time period, and entered into compensation arrangements that were not fully memorialized in a written agreement.	The health system agreed to pay \$25.5 million to resolve the Stark law and FCA allegations.
<i>United States ex rel. DePace v. Cooper Health System</i> , No. 08-cv-5626-JEI (D. N.J. settlement Jan. 24, 2013).	A cardiologist whistleblower was among the physicians recruited by the health system to serve on its advisory board. An investigation revealed that the health system's payments of \$18,000 a year to the physicians were at least partly intended to induce them to refer patients to the health system.	The health system agreed to pay the United States and the state of New Jersey \$12.6 million to resolve allegations that its payments to certain physicians violated state and federal laws prohibiting kickbacks and physician self-referrals. (22 <i>BNA's Health Law Rep.</i> 167, Jan. 31, 2013.)

Settlement	Alleged Misconduct	Resolution/Penalties
<i>Freeman Health System</i> (Joplin, Mo., settlement announced Nov. 5, 2012).	A hospital system disclosed to the U.S. Attorney's Office that some of its physicians were eligible for incentive compensation that may have taken into account the value and volume of their referrals. Prosecutors alleged that the hospitals created an incentive system for about 70 physicians at clinics run by the health system, in which the physicians received incentive payments based on the revenue generated from referrals for diagnostic tests and other services.	The hospital system agreed to pay \$9.3 million to resolve the allegations. (16 <i>BNA's Health Care Fraud Rep.</i> 897, Nov. 14, 2012.)
<i>United States ex rel. Bingham v. HCA</i> , No. 1:08-cv-7 (E.D. Tenn. settlement announced Sept. 19, 2012).	A hospital corporation, through two subsidiaries, allegedly entered into a number of financial transactions with a physicians' group, to induce the physicians to refer patients to the company's facilities. The deals, which were made in 2007, included leasing office space from the physicians' group at a "commercially unreasonable and excessive rental rate," prosecutors claimed. The hospital was charged with violating the Ethics in Patient Referral Act and the Anti-Kickback Statute, in addition to the False Claims Act and the Tennessee Medicaid False Claims Act by submitting claims to government health care programs for services that were ordered or arranged for by providers that benefited from the illegal financial arrangements.	The company agreed to pay \$16.5 million to resolve the allegations.
<i>United States ex rel. Curry v. Harmon County Healthcare Authority</i> , No. CIV-09-01321 (W.D. Okla. settlement announced June 18, 2012).	The government alleged that the health care authority entered into a generous physician recruitment agreement with a physician to persuade him to establish a medical practice in Harmon County. The original agreement guaranteed the physician an income of \$180,000 per year and also provided office space, clinical furnishings, staff, and billing and collecting for a portion of that term. It also compensated the physician for covering the emergency room and for certain patient referrals. The hospital renewed the three-year agreement twice. The hospital authority paid the physician \$418,750 to terminate the agreement despite the relator's representation that the agreement was illegal and no payment was required to terminate it.	Under the settlement, the physician agreed to pay \$1 million, and the hospital agreed to pay \$550,000 to settle alleged violations of the Stark law and the False Claims Act. The doctor and hospital have also agreed to five-year corporate integrity agreements that include additional regulatory compliance and monitoring.
<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.

Settlement	Alleged Misconduct	Resolution/Penalties
<i>United States ex rel. Boland v. Memorial Health Inc.</i> No. CV406-157 (S.D. Ga. settlement announced Apr. 24, 2008).	From 2003 through 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 Oct. 20, 2006).	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 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 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 Mar. 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.
<i>United States ex rel. Scott v. Metropolitan Health Corp.</i> , No. 01-02CV485 (W.D. Mich. settlement announced Dec. 9, 2003)	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.	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.

Settlement	Alleged Misconduct	Resolution/Penalties
<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)	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.	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.
<i>United States ex rel. Kenner v. St. Joseph's Hospital Corp.</i> , No. 95-641 (D. Colo. settled May 2, 2002)	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.	The hospital paid \$3.75 million to settle the False Claims Act case and \$280,000 to settle state Medicaid billing allegations.
<i>United States ex rel. Moradi v. Community Health Assn.</i> , No. 2:01-1282 (S.D.W.V., settlement announced Apr. 14, 2002)	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.	The hospital agreed to pay \$750,000 and entered into a five-year corporate integrity agreement with the OIG.

2210.50.30

Court Rulings

Case Citation	Facts	Outcome
<i>United States ex rel. Drakeford v. Tuomey d/b/a Tuomey Healthcare System, Inc.</i> , 792 F.3d 364 (4th Cir. 2015), affirming 976 F. Supp. 2d 776 (D.S.C. 2013).	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 district court jury found that the hospital had violated the Stark law and FCA by submitting about \$39 million in improper claims. That verdict came in a retrial ordered by the U.S. Court of Appeals for the Fourth Circuit after the appellate court vacated a previous verdict and damage award of \$44.9 million. The court ordered the hospital to pay nearly \$237.5 million for submitting the false claims, and the Fourth Circuit affirmed that decision.
<i>United States ex rel. Robinson-Hill v. Nurses' Registry & Home Health Corp.</i> , No. 2:08-cv-00145, 2015 BL 226555 (E.D. Ky. July 15, 2015).	A home health care agency allegedly sent gift baskets and tickets to sporting events and private parties to physicians who referred patients to the agency. The government claimed these gifts constituted a financial relationship that violated the Stark law. The defendants claimed that the gifts fit within the non-monetary compensation exception to the Stark law.	The court denied summary judgment to the defendants, finding that the gifts may have violated the anti-kickback statute and thus didn't qualify for the non-monetary compensation exception to the Stark law.

Case Citation	Facts	Outcome
<i>United States ex rel. Baklid-Kunz v. Halifax Hospital Medical Center</i> , No. 6:09-cv-01002, 2014 BL 4820 (M.D. Fla. Jan. 8, 2014).	Two hospital-employed psychiatrists received incentive payments on top of their base salary that reflected the hospital's collections minus their base salaries. A relator alleged that this arrangement, couple with referrals from the psychiatrists for designated health services constituted a Stark law violation. The hospital claimed that the referrals fell within the bona fide employment exception to the Stark law.	The court denied summary judgment to the hospital, finding that the incentive payment structure meant the physician's remuneration would increase if the volume of their referrals to the hospital for DHS increased. As a result, the payments didn't qualify for the Stark law exception.
<i>United States ex rel. Singh v. Bradford Regional Medical Center</i> , 752 F. Supp. 2d 602 (W.D. Pa. 2010)	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. Whistle-blower physicians brought this case against the hospital, the practice, and two physicians individually.	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.
<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.

Case Citation	Facts	Outcome
<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.
<i>Robert Wood Johnson University Hospital, Inc. v. Thompson</i> , No. Civ.A.04-142JWB (D.N.J. Apr. 15, 2004)	Several New Jersey hospitals challenged an HHS demonstration project that allowed the state hospital association to implement a gainsharing project in which only a few hospitals would be allowed to participate. The plaintiffs alleged that the project violated Stark, the anti-kickback statute and the Civil Monetary Penalties law.	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-kickback statute, it also held that the arrangement violated the prohibition on inducements to beneficiaries.

2210.50.40**Stark Self-Disclosure Settlement Information**

The Stark Self-Referral Disclosure Protocol was promulgated on May 6, 2011 pursuant to the ACA. CMS

provides aggregate data on settlements (but not information on specific settlements) under the Stark Self-Referral Disclosure Protocol on its website.