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HEALTH LAW
FOULSTON SIEFKIN ISSUE ALERT

CMS Publishes 2009 IPPS Rule with Significant Stark Law Changes

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On August 19, 2008, the Centers for Medicare and Medicaid Services ("CMS") published in the Federal Register the Fiscal Year 2009 Inpatient Prospective Payment System Rule. The FY 2009 IPPS Rule included significant changes to the federal self-referral law, commonly known as the Stark Law. This Issue Alert describes these important changes.

- **The Stark Law Prohibition.** The Stark Law prohibits a physician from making referrals for "designated health services" ("DHS") payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (either through ownership or compensation) unless an exception applies. The Stark Law also prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those DHS rendered as a result of a prohibited referral.

- **The FY 2009 IPPS Rule.** Important changes to the Stark Law include (1) the prohibition of percentage-based payments and per-click arrangements for space and equipment leases; (2) clarification of the concept of when a physician is deemed to "stand in the shoes" of his or her physician organization; and (3) the prohibition of certain "under arrangements" transactions.

Many legitimate business arrangements between hospitals and physicians which were previously Stark Law compliant must now be restructured as a result of this new final rule. Although the rule is generally effective October 1, 2008, the effective date for many of the provisions which will require restructuring of current compliant arrangements (including the exceptions for space leases, equipment leases, fair market value compensation arrangements and indirect compensation arrangements) is October 1, 2009.

The changes to the Stark Law under the FY 2009 IPPS Rule have the following broad implications:

- **Space and Equipment Leases.** Probably the most significant changes in the 2009 IPPS Rule for Kansas hospitals and physicians relates to "per-click" rental charges in space and equipment leases. Many Kansas hospitals and physician groups are parties to space and equipment leases. The new regulations prohibit per-click (i.e., per-use or per unit-of-service) rental charges for space and equipment in leases between DHS entities and physicians to the extent such charges reflect services referred between the parties. This means that the prohibition applies when the physician is the lessor or when the physician is the lessee of space or equipment. CMS stated that it had concerns that such leases result in overutilization of services and

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create incentives for the lessee to refer patients to the leased space or equipment rather than to another more efficient provider. CMS is also concerned that these "per click" agreements may encourage anti-competitive behavior because some entities may enter into these arrangements out of fear of losing referrals. Hospitals should ensure that any new leases with physicians do not have per-click rental charges. Hospitals should also review all current leases that will not expire before October 1, 2009, and restructure any "per click" rental charges.

The 2009 IPPS Rule also prohibits the use of percentage-based compensation formulae in determining rental charges for the lease of office space and equipment, such as rental changes based on a percentage of the revenue generated by the lessee physician. CMS expressed a belief that such rental charge calculations impermissibly create an incentive for the lessor to increase referrals to the lessee. Percentage-based compensation arrangements are permitted in arrangements for a physician's personally performed services and for non-professional services (such as agreements for management or billing services).

There is no grandfathering of previous space and equipment leases. The prohibition on per-click and percentage-based rental charges for office space and equipment is effective October 1, 2009. All leases containing the above compensation arrangements as rent must comply with the above limitations on or before October 1, 2009.

- **Physician "Stand in the Shoes" Provisions.** CMS revised the final regulations from Phase III (issued in August 2007) to provide that a physician will "stand in the shoes" of his or her physician organization if the physician has an ownership or investment interest in the physician organization. This change is important for analyzing indirect compensation arrangements. This change becomes effective October 1, 2008.

- **Revision of Definition of DHS "Entity."** This definition was expanded to include the person or entity that has actually performed services that are billed as DHS, whether or not that person or entity presents a claim to Medicare for the DHS. Previously, the definition of "entity" only applied to entities that actually billed for the service. This is an important change. Contracts between hospitals located within non-rural areas and a group of physicians to provide emergency room services would no longer be permitted under these rules. The arrangement would need to be restructured on or before October 1, 2009.

- **Revision to Exception for Obstetrical Malpractice Insurance Subsidies.** This exception was expanded to include an alternative set of requirements under which hospitals, federally qualified health centers and rural health clinics (but not other entities) may provide obstetrical malpractice insurance subsidies to physicians in rural areas, HPSAs, and other areas with a demonstrated need, if certain requirements are met. CMS declined to expand the exception to other types of physician specialties.

- **Disclosure of Financial Relationships Report.** The 2009 IPPS Final Rule states that CMS will be proceeding with its proposal to send the Disclosure of Financial Relationships Report (the "DFFR") to hospitals (both general acute care and specialty hospitals). The DFFR is designed to collect information concerning the ownership and investment interests and compensation arrangements between hospitals and physicians. The DFFR was originally intended to be sent to 500 hospitals in September, 2007. However, in response to industry concern as to the time required to complete the report, CMS shortened the length of the report and the time anticipated to complete the same. In the final rule, CMS also indicated that it may decide to decrease (but not increase) the number of hospitals to which it will send the DFFR below the 500 hospitals originally planned. Hospitals will have 60 days to complete the DFFR. Failure to timely submit the requested information could result in civil monetary penalties of up to $10,000 per day.

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For a copy of the final IPPS rule, see: **http://edocket.access.gpo.gov/2008/pdf/E8-17914.pdf** or download it by **clicking here.** You can also download it by going to www.foulston.com under Related Links in the Health Care Practice Area.

For a detailed discussion of the new FY 2009 IPPS Rule with significant Stark Law changes, please join us for the Foulston Siefkin 2008 Kansas Health Law Institute in Wichita, Kansas, on September 10, 2008. For a program brochure or to register, go to www.foulston.com/healthlawinstitute.

For Further Information

Foulston Siefkin's health care lawyers maintain a high level of expertise regarding federal and state regulations affecting the health care industry. The firm devotes significant resources to ensure our attorneys remain up-to-date on daily developments. At the same time, the relationship of our health care law practice group with Foulston Siefkin's other practice groups, including the taxation, general business, labor and employment, and commercial litigation groups, enhances our ability to consider all of the legal ramifications of any situation or strategy. For additional information, contact **Scott Palecki** at (316) 291-9578, or spalecki@foulston.com. For more information on the firm, please visit our website at **www.foulston.com.**

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***NOTE**: <u>This document is for reference ONLY</u>. The official regulation text for §411.350 through §411.389 can be found in the August 18, 2008, Federal Register.*

§411.351 Definitions.

As used in this subpart, unless the context indicates otherwise:

Entity means—

(1) A physician's sole practice or a practice of multiple physicians or any other person, sole proprietorship, public or private agency or trust, corporation, partnership, limited liability company, foundation, nonprofit corporation, or unincorporated association that furnishes DHS. An entity does not include the referring physician himself or herself, but does include his or her medical practice. A person or entity is considered to be furnishing DHS if it—

(i) Is the person or entity that has performed services that are billed as DHS; or

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(ii) Is the person or entity that has presented a claim to Medicare for the DHS, including the person or entity to which the right to payment for the DHS has been reassigned in accordance with §424.80(b)(1) (employer) or (b)(2) (payment under a contractual arrangement) of this chapter (other than a health care delivery system that is a health plan (as defined at §1001.952(l) of this title), and other than any managed care organization (MCO), provider-sponsored organization (PSO), or independent practice association (IPA) with which a health plan contracts for services provided to plan enrollees).

(2) A health plan, MCO, PSO, or IPA that employs a supplier or operates a facility that could accept reassignment from a supplier under §424.80(b)(1) and (b)(2) of this chapter, with respect to any DHS provided by that supplier.

(3) For purposes of this subpart, “entity” does not include a physician's practice when it bills Medicare for the technical component or professional component of a diagnostic test for which the anti-markup provision is applicable in accordance with §414.50 of this chapter and section 30.2.9 of the CMS Internet-only Manual, publication 100–04, Claims Processing Manual, Chapter 1 (general billing requirements).

Physician means a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor, as defined in section 1861(r) of the Act. A physician and the professional corporation of which he or she is a sole owner are the same for purposes of this subpart.

Changes noted in this color are effective October 1, 2008.

Changes noted in this color are effective October 1, 2009.

Physician organization means a physician, a physician practice, or a group practice that complies with the requirements of §411.352.

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§411.353 Prohibition on certain referrals by physicians and limitations on billing.

(a) *Prohibition on referrals.* Except as provided in this subpart, a physician who has a direct or indirect financial relationship with an entity, or who has an immediate family member who has a direct or indirect financial relationship with the entity, may not make a referral to that entity for the furnishing of DHS for which payment otherwise may be made under Medicare. A physician's prohibited financial relationship with an entity that furnishes DHS is not imputed to his or her group practice or its members or its staff. However, a referral made by a physician's group practice, its members, or its staff may be imputed to the physician if the physician directs the group practice, its members, or its staff to make the referral or if the physician controls referrals made by his or her group practice, its members, or its staff.

(b) *Limitations on billing.* An entity that furnishes DHS pursuant to a referral that is prohibited by paragraph (a) of this section may not present or cause to be presented a claim or bill to the Medicare program or to any individual, third party payer, or other entity for the DHS performed pursuant to the prohibited referral.

(c) *Denial of payment for services furnished under a prohibited referral.* (1) Except as provided in paragraph (e) of this section, no Medicare payment may be made for a designated health service that is furnished pursuant to a prohibited referral. The period during which referrals are prohibited is the period of disallowance. For purposes of this section, with respect to the following types of noncompliance, the period of disallowance begins at the time the financial relationship fails to satisfy the requirements of an applicable exception and ends no later than—

(i) Where the noncompliance is unrelated to compensation, the date that the financial relationship satisfies all of the requirements of an applicable exception;

(ii) Where the noncompliance is due to the payment of excess compensation, the date on which all excess compensation is returned, by the party that received it, to the party that

paid it and the financial relationship satisfies all of the requirements of an applicable exception; or

(iii) Where the noncompliance is due to the payment of compensation that is of an amount insufficient to satisfy the requirements of an applicable exception, the date on which all additional required compensation is paid, by the party that owes it, to the party to which it is owed and the financial relationship satisfies all of the requirements of an applicable exception.

(2) When payment for a designated health service is denied on the basis that the service was furnished pursuant to a prohibited referral, and such payment denial is appealed—

(i) The ultimate burden of proof (burden of persuasion) at each level of appeal is on the entity submitting the claim for payment to establish that the service was not furnished pursuant to a prohibited referral (and not on CMS or its contractors to establish that the service was furnished pursuant to a prohibited referral); and

(ii) The burden of production on each issue at each level of appeal is initially on the claimant, but may shift to CMS or its contractors during the course of the appellate proceeding, depending on the evidence presented by the claimant.

(d) *Refunds.* An entity that collects payment for a designated health service that was performed pursuant to a prohibited referral must refund all collected amounts on a timely basis, as defined at §1003.101 of this title.

(e) *Exception for certain entities.* Payment may be made to an entity that submits a claim for a designated health service if—

(1) The entity did not have actual knowledge of, and did not act in reckless disregard or deliberate ignorance of, the identity of the physician who made the referral of the designated health service to the entity; and

(2) The claim otherwise complies with all applicable Federal and State laws, rules, and regulations.

(f) *Exception for certain arrangements involving temporary noncompliance.* (1) Except as provided in paragraphs (f)(2), (f)(3), and (f)(4) of this section, an entity may submit a claim or bill and payment may be made to an entity that submits a claim or bill for a designated health service if—

(i) The financial relationship between the entity and the referring physician fully complied with an applicable exception under §411.355, §411.356, or §411.357 for at least 180 consecutive calendar days immediately preceding the date on which the financial relationship became noncompliant with the exception;

(ii) The financial relationship has fallen out of compliance with the exception for reasons beyond the control of the entity, and the entity promptly takes steps to rectify the noncompliance; and

(iii) The financial relationship does not violate the anti-kickback statute (section 1128B(b) of the Act), and the claim or bill otherwise complies with all applicable Federal and State laws, rules, and regulations.

(2) Paragraph (f)(1) of this section applies only to DHS furnished during the period of time it takes the entity to rectify the noncompliance, which must not exceed 90 consecutive calendar days following the date on which the financial relationship became noncompliant with an exception.

(3) Paragraph (f)(1) may be used by an entity only once every 3 years with respect to the same referring physician.

(4) Paragraph (f)(1) does not apply if the exception with which the financial relationship previously complied was §411.357(k) or (m).

(g) <u>Special rule for certain arrangements involving temporary noncompliance with signature requirements</u>. (1) An entity may submit a claim or bill and payment may be made to an entity that submits a claim or bill for a designated health service if—

(i) The compensation arrangement between the entity and the referring physician fully complied with an applicable exception in §411.355, §411.356 or §411.357, except with respect to the signature requirement in §411.357(a)(1), §411.357(b)(1), §411.357(d)(1)(i), §411.357(e)(1)(i), §411.357(e)(4)(i), §411.357(l)(1), §411.357(p)(2), §411.357(q) (incorporating the requirement contained in §1001.952(f)(4)), §411.357(r)(2)(ii), §411.357(t)(1)(ii) or (t)(2)(iii) (both incorporating the requirement contained in §411.357(e)(1)(i)), §411.357(v)(7)(i), or §411.357(w)(7)(i); and

(ii) The failure to comply with the signature requirement was--

(A) Inadvertent, and the parties obtain the required signature(s) within 90 consecutive calendar days immediately following the date on which the compensation arrangement

becomes noncompliant (without regard to whether any referrals occur or compensation is paid during such 90-day period) and the compensation arrangement otherwise complies with all criteria of the applicable exception; or

(B) Not inadvertent, and the parties obtain the required signature(s) within 30 consecutive calendar days immediately following the date on which the compensation arrangement becomes noncompliant (without regard to whether any referrals occur or compensation is paid during such 30-day period) and the compensation arrangement otherwise complies with all criteria of the applicable exception.

(2) Paragraph (g)(1) of this section may be used by an entity only once every 3 years with respect to the same referring physician.

§411.354 Financial relationship, compensation, and ownership or investment interest.

(a) *Financial relationships.* (1) *Financial relationship* means—

(i) A direct or indirect ownership or investment interest (as defined in paragraph (b) of this section) in any entity that furnishes DHS; or

(ii) A direct or indirect compensation arrangement (as defined in paragraph (c) of this section) with an entity that furnishes DHS.

(2) *Types of financial relationships.* (i) A *direct* financial relationship exists if remuneration passes between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS without any intervening persons or entities between the entity furnishing DHS and the referring physician (or a member of his or her immediate family).

(ii) An *indirect* financial relationship exists under the conditions described in paragraphs (b)(5) and (c)(2) of this section.

(b) *Ownership or investment interest.* An ownership or investment interest in the entity may be through equity, debt, or other means, and includes an interest in an entity that holds an ownership or investment interest in any entity that furnishes DHS.

(1) An ownership or investment interest includes, but is not limited to, stock, stock options other than those described in §411.354(b)(3)(ii), partnership shares, limited

liability company memberships, as well as loans, bonds, or other financial instruments that are secured with an entity's property or revenue or a portion of that property or revenue.

(2) An ownership or investment interest in a subsidiary company is neither an ownership or investment interest in the parent company, nor in any other subsidiary of the parent, unless the subsidiary company itself has an ownership or investment interest in the parent or such other subsidiaries. It may, however, be part of an indirect financial relationship.

(3) Ownership and investment interests do not include, among other things—

(i) An interest in an entity that arises from a retirement plan offered by that entity to the physician (or a member of his or her immediate family) through the physician's (or immediate family member's) employment with that entity;

(ii) Stock options and convertible securities received as compensation until the stock options are exercised or the convertible securities are converted to equity (before this time the stock options or convertible securities are compensation arrangements as defined in paragraph (c) of this section);

(iii) An unsecured loan subordinated to a credit facility (which is a compensation arrangement as defined in paragraph (c) of this section);

(iv) An "under arrangements" contract between a hospital and an entity owned by one or more physicians (or a group of physicians) providing DHS "under arrangements" with the hospital (such a contract is a compensation arrangement as defined in paragraph (c) of this section); or

(v) A security interest held by a physician in equipment sold by the physician to a hospital and financed through a loan from the physician to the hospital (such an interest is a compensation arrangement as defined in paragraph (c) of this section).

(4) An ownership or investment interest that meets an exception set forth in §411.355 or §411.356 need not also meet an exception for compensation arrangements set forth in §411.357 with respect to profit distributions, dividends, or interest payments on secured obligations.

(5)(i) An *indirect ownership or investment interest* exists if—

(A) Between the referring physician (or immediate family member) and the entity furnishing DHS there exists an unbroken chain of any number (but no fewer than one) of persons or entities having ownership or investment interests; and

(B) The entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) has some ownership or investment interest (through any number of intermediary ownership or investment interests) in the entity furnishing the DHS.

(ii) An indirect ownership or investment interest exists even though the entity furnishing DHS does not know, or acts in reckless disregard or deliberate ignorance of, the precise composition of the unbroken chain or the specific terms of the ownership or investment interests that form the links in the chain.

(iii) Notwithstanding anything in this paragraph (b)(5), common ownership or investment in an entity does not, in and of itself, establish an indirect ownership or investment interest by one common owner or investor in another common owner or investor.

(iv) An indirect ownership or investment interest requires an unbroken chain of ownership interests between the referring physician and the entity furnishing DHS such that the referring physician has an indirect ownership or investment interest *in* the entity furnishing DHS.

(c) *Compensation arrangement.* A compensation arrangement is any arrangement involving remuneration, direct or indirect, between a physician (or a member of a physician's immediate family) and an entity. An “under arrangements” contract between a hospital and an entity providing DHS “under arrangements” to the hospital creates a compensation arrangement for purposes of these regulations. A compensation arrangement does not include the portion of any business arrangement that consists solely of the remuneration described in section 1877(h)(1)(C) of the Act and in paragraphs (1) through (3) of the definition of the term “remuneration” at §411.351. (However, any other portion of the arrangement may still constitute a compensation arrangement.)

(1)(i) A direct compensation arrangement exists if remuneration passes between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS without any intervening persons or entities.

(ii) Except as provided in paragraph (c)(3)(ii)(C) of this section, a physician is deemed to stand in the shoes of his or physician organization and have a direct compensation arrangement with an entity furnishing DHS if—

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(A) The only intervening entity between the physician and the entity furnishing DHS is his or her physician organization; and

(B) The physician has an ownership or investment interest in the physician organization.

(iii) A physician (other than a physician described in paragraph (c)(1)(ii)(B) of this section) is permitted to "stand in the shoes" of his or her physician organization and have a direct compensation arrangement with an entity furnishing DHS if the only intervening entity between the physician and the entity furnishing DHS is his or her physician organization.

(2) An *indirect compensation arrangement* exists if—

(i) Between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS there exists an unbroken chain of any number (but not fewer than one) of persons or entities that have financial relationships (as defined in paragraph (a) of this section) between them (that is, each link in the chain has either an ownership or investment interest or a compensation arrangement with the preceding link);

(ii) The referring physician (or immediate family member) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS, regardless of whether the individual unit of compensation satisfies the special rules on unit-based compensation under paragraphs (d)(2) or (d)(3) of this section. If the financial relationship between the physician (or immediate family member) and the person or entity in the chain with which the referring physician (or immediate family member) has a direct financial relationship is an ownership or investment interest, the determination whether the aggregate compensation varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS will be measured by the nonownership or noninvestment interest closest to the referring physician (or immediate family member). (For example, if a referring physician has an ownership interest in company A, which owns company B, which has a compensation arrangement with company C, which has a compensation arrangement with entity D that furnishes DHS, we would look to the aggregate compensation between company B and company C for purposes of this paragraph (c)(2)(ii)); and

(iii) The entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family

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member) receives aggregate compensation that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS.

(iv)(A) For purposes of paragraph (c)(2)(i) of this section, except as provided in paragraph (c)(3)(ii)(C) of this section, a physician is deemed to "stand in the shoes" of his or her physician organization if the physician has an ownership or investment interest in the physician organization.

(B) For purposes of paragraph (c)(2)(i) of this section, a physician (other than a physician described in paragraph (c)(2)(iv)(A) of this section) is permitted to "stand in the shoes" of his or her physician organization.

(3)(i) For purposes of paragraphs (c)(1)(ii) and (c)(2)(iv), a physician who "stands in the shoes" of his or her physician organization is deemed to have the same compensation arrangements (with the same parties and on the same terms) as the physician organization. For purposes of applying the exceptions in §411.355 and §411.357 to arrangements in which a physician stands in the shoes of his or her physician organization, the "parties" to the arrangements are considered to be the entity furnishing DHS and the physician organization (including all members, employees, or independent contractor physicians).

(ii) The provisions of paragraphs (c)(1)(ii) and (c)(2)(iv)(A) of this section—

(A) Need not apply during the original term or current renewal term of an arrangement that satisfied the requirements of §411.357(p) as of September 5, 2007 (see 42 CFR Parts 400-413, revised as of October 1, 2007);

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(B) Do not apply to an arrangement that satisfies the requirements of §411.355(e); and

(C) Do not apply to a physician whose ownership or investment interest is titular only. A titular ownership or investment interest is an ownership or investment interest 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.

(iii) An arrangement structured to comply with an exception in §411.357 (other than §411.357(p)), but which would otherwise qualify as an indirect compensation arrangement under this paragraph as of August 18, 2008, need not be restructured to

satisfy the requirements of §411.357(p) until the expiration of the original term or current renewal term of the arrangement.

(d) *Special rules on compensation.* The following special rules apply only to compensation under section 1877 of the Act and subpart J of this part:

(1) Compensation is considered "set in advance" if the aggregate compensation, a time-based or per-unit of service-based (whether per-use or per-service) amount, or a specific formula for calculating the compensation is set in an agreement between the parties before the furnishing of the items or services for which the compensation is to be paid. The formula for determining the compensation must be set forth in sufficient detail so that it can be objectively verified, and the formula may not be changed or modified during the course of the agreement in any manner that takes into account the volume or value of referrals or other business generated by the referring physician.

(2) Unit-based compensation (including time-based or per-unit of service-based compensation) is deemed not to take into account "the volume or value of referrals" if the compensation is fair market value for services or items actually provided and does not vary during the course of the compensation arrangement in any manner that takes into account referrals of DHS.

(3) Unit-based compensation (including time-based or per-unit of service-based compensation) is deemed not to take into account "other business generated between the parties," provided that the compensation is fair market value for items and services actually provided and does not vary during the course of the compensation arrangement in any manner that takes into account referrals or other business generated by the referring physician, including private pay health care business (except for services personally performed by the referring physician, which are not considered "other business generated" by the referring physician).

(4) A physician's compensation from a *bona fide* employer or under a managed care contract or other contract for personal services may be conditioned on the physician's referrals to a particular provider, practitioner, or supplier, provided that the compensation arrangement meets all of the following conditions. The compensation arrangement:

(i) Is set in advance for the term of the agreement.

(ii) Is consistent with fair market value for services performed (that is, the payment does not take into account the volume or value of anticipated or required referrals).

(iii) Otherwise complies with an applicable exception under §411.355 or §411.357.

(iv) Complies with both of the following conditions:

(A) The requirement to make referrals to a particular provider, practitioner, or supplier is set forth in a written agreement signed by the parties.

(B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.

(v) The required referrals relate solely to the physician's services covered by the scope of the employment or the contract, and the referral requirement is reasonably necessary to effectuate the legitimate business purposes of the compensation arrangement. In no event may the physician be required to make referrals that relate to services that are not provided by the physician under the scope of his or her employment or contract.

§411.357 Exceptions to the referral prohibition related to compensation arrangements.

For purposes of §411.353, the following compensation arrangements do not constitute a financial relationship:

(a) *Rental of office space.* Payments for the use of office space made by a lessee to a lessor if there is a rental or lease agreement that meets the following requirements:

(1) The agreement is set out in writing, is signed by the parties, and specifies the premises it covers.

(2) The term of the agreement is at least 1 year. To meet this requirement, if the agreement is terminated during the term with or without cause, the parties may not enter into a new agreement during the first year of the original term of the agreement.

(3) The space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any person or entity related to the lessor), except that the lessee may make payments for the

use of space consisting of common areas if the payments do not exceed the lessee's *pro rata* share of expenses for the space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using the common areas.

(4) The rental charges over the term of the agreement are set in advance and are consistent with fair market value.

(5) The rental charges over the term of the agreement are not determined—

(i) In a manner that takes into account the volume or value of any referrals or other business generated between the parties; or

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(ii) Using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space; or

(B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred between the parties.

(6) The agreement would be commercially reasonable even if no referrals were made between the lessee and the lessor.

(7) A holdover month-to-month rental for up to 6 months immediately following the expiration of an agreement of at least 1 year that met the conditions of paragraphs (a)(1) through (a)(6) of this section satisfies the requirements of paragraph (a) of this section, provided that the holdover rental is on the same terms and conditions as the immediately preceding agreement.

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(b) *Rental of equipment.* Payments made by a lessee to a lessor for the use of equipment under the following conditions:

(1) A rental or lease agreement is set out in writing, is signed by the parties, and specifies the equipment it covers.

(2) The equipment rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee and is not shared with or used by the lessor or any person or entity related to the lessor.

(3) The agreement provides for a term of rental or lease of at least 1 year. To meet this requirement, if the agreement is terminated during the term with or without cause, the parties may not enter into a new agreement during the first year of the original term of the agreement.

(4) The rental charges over the term of the agreement are set in advance, are consistent with fair market value, and are not determined—

(i) In a manner that takes into account the volume or value of any referrals or other business generated between the parties; or

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(ii) Using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed on or business generated through the use of the equipment; or

(B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred between the parties.

(5) The agreement would be commercially reasonable even if no referrals were made between the parties.

(6) A holdover month-to-month rental for up to 6 months immediately following the expiration of an agreement of at least 1 year that met the conditions of paragraph (b)(1) through (b)(5) of this section satisfies the requirements of paragraph (b) of this section, provided that the holdover rental is on the same terms and conditions as the immediately preceding agreement.

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(l) *Fair market value compensation.* Compensation resulting from an arrangement between an entity and a physician (or an immediate family member) or any group of physicians (regardless of whether the group meets the definition of a group practice set forth in §411.352) for the provision of items or services (other than the rental of office space) by the physician (or an immediate family member) or group of physicians to the entity, or by the entity to the physician (or an immediate family member) or a group of physicians, if the arrangement is set forth in an agreement that meets the following conditions:

(1) The arrangement is in writing, signed by the parties, and covers only identifiable items or services, all of which are specified in the agreement.

(2) The writing specifies the timeframe for the arrangement, which can be for any period of time and contain a termination clause, provided that the parties enter into only one arrangement for the same items or services during the course of a year. An arrangement made for less than 1 year may be renewed any number of times if the terms of the arrangement and the compensation for the same items or services do not change.

(3) The writing specifies the compensation that will be provided under the arrangement. The compensation must be set in advance, consistent with fair market value, and not determined in a manner that takes into account the volume or value of referrals or other business generated by the referring physician. Compensation for the rental of equipment may not be determined using a formula based on—

(i) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed on or business generated through the use of the equipment; or

(ii) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred between the parties.

(4) The arrangement is commercially reasonable (taking into account the nature and scope of the transaction) and furthers the legitimate business purposes of the parties.

(5) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(6) The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates a Federal or State law.

(p) *Indirect compensation arrangements.* Indirect compensation arrangements, as defined at §411.354(c)(2), if all of the following conditions are satisfied:

(1)(i) The compensation received by the referring physician (or immediate family member) described in §411.354(c)(2)(ii) is fair market value for services and items actually provided and not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician for the entity

furnishing DHS. Compensation for the rental of office space or equipment may not be determined using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space or to the services performed on or business generated through the use of the equipment; or

(B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred between the parties.

(ii) The compensation arrangement described in §411.354(c)(2)(ii) is set out in writing, signed by the parties, and specifies the services covered by the arrangement, except in the case of a *bona fide* employment relationship between an employer and an employee, in which case the arrangement need not be set out in a written contract, but must be for identifiable services and be commercially reasonable even if no referrals are made to the employer.

(iii) The compensation arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(r) *Obstetrical malpractice insurance subsidies.* Remuneration that meets all of the conditions or paragraph (1) or (2) of this section.

(1) Remuneration that meets all of the conditions set forth in §1001.952(o) of this title.

(2) A payment from a hospital, federally qualified health center, or rural health clinic that is used to pay for some or all of the costs of malpractice insurance premiums for a physician who engages in obstetrical practice as a routine part of his or her medical practice, if all of the following conditions are met:

(i)(A) The physician's medical practice is located in a rural area, a primary care HPSA, or an area with demonstrated need for the physician's obstetrical services as determined by the Secretary in an advisory opinion issued in accordance with section 1877(g)(6) of the Act; or

(B) At least 75 percent of the physician's obstetrical patients reside in a medically underserved area or are members of a medically underserved population.

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(ii) The arrangement is set out in writing, is signed by the physician and the hospital, federally qualified health center, or rural health clinic providing the payment, and specifies the payments to be made by the hospital, federally qualified health center, or rural health clinic and the terms under which the payments are to be provided.

(iii) The arrangement is not conditioned on the physician's referral of patients to the hospital, federally qualified health center, or rural health clinic providing the payment.

(iv) The hospital, federally qualified health center, or rural health clinic does not determine (directly or indirectly) the amount of the payment based on the volume or value of any actual or anticipated referrals by the physician or any other business generated between the parties.

(v) The physician is allowed to establish staff privileges at any hospital(s), federally qualified health center(s), or rural health clinic(s) and to refer business to any other entities (except as referrals may be restricted under an employment arrangement or services contract that complies with §411.354(d)(4)).

(vi) The payment is made to a person or organization (other than the physician) that is providing malpractice insurance (including a self-funded organization).

(vii) The physician treats obstetrical patients who receive medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

(viii) The insurance is a *bona fide* malpractice insurance policy or program, and the premium, if any, is calculated based on a *bona fide* assessment of the liability risk covered under the insurance.

(ix)(A) For each coverage period (not to exceed 1 year), at least 75 percent of the physician's obstetrical patients treated under the coverage of the obstetrical malpractice insurance during the prior period (not to exceed 1 year)—

(<u>1</u>) Resided in a rural area, HPSA, medically underserved area, or an area with a demonstrated need for the physician's obstetrical services as determined by the Secretary in an advisory opinion issued in accordance with section 1877(g)(6) of the Act; or

(<u>2</u>) Were part of a medically underserved population.

(B) For the initial coverage period (not to exceed 1 year), the requirements of paragraph (r)(2)(ix)(A) of this section will be satisfied if the physician certifies that he or she has a

reasonable expectation that at least 75 percent of the physician's obstetrical patients treated under the coverage of the malpractice insurance will—

(<u>1</u>) Reside in a rural area, HPSA, medically underserved area, or an area with a demonstrated need for the physician's obstetrical services as determined by the Secretary in an advisory opinion issued in accordance with section 1877(g)(6) of the Act; or

(<u>2</u>) Be part of a medically underserved population.

(x) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(3) For purposes of paragraph (r)(2) of this section, <u>costs of malpractice insurance premiums</u> means:

(i) For physicians who engage in obstetrical practice on a full-time basis, any costs attributable to malpractice insurance; or

(ii) For physicians who engage in obstetrical practice on a part-time or sporadic basis, the costs attributable exclusively to the obstetrical portion of the physician's malpractice insurance, and related exclusively to obstetrical services provided—

(A) In a rural area, primary care HPSA, or an area with demonstrated need for the physician's obstetrical services, as determined by the Secretary in an advisory opinion issued in accordance with section 1877(g)(6) of the Act; or

(B) In any area, provided that at least 75 percent of the physician's obstetrical patients treated in the coverage period (not to exceed 1 year) resided in a rural area or medically underserved area or were part of a medically underserved population.