

TITLE 42 -- PUBLIC HEALTH  
CHAPTER IV -- CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH AND  
HUMAN SERVICES  
SUBCHAPTER B -- MEDICARE PROGRAM  
PART 411 -- EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT  
SUBPART J -- FINANCIAL RELATIONSHIPS BETWEEN PHYSICIANS AND ENTITIES FURNISHING DES-  
IGNATED HEALTH SERVICES

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*42 CFR 411.354*

§ 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 her physician organization and have a direct compensation arrangement with an entity furnishing DHS if--

(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 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) of this section, 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. When applying the exceptions in § 411.355 and § 411.357 of this part to arrangements in which a physician stands in the shoes of his or her physician organization, the relevant referrals and other business generated "between the parties" are referrals and other business generated between the entity furnishing DHS and the physician organization (including all members, employees, and 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);

(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 19, 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 actu-

ally 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.

**HISTORY:** [66 *FR* 856, 958, Jan. 4, 2001; 66 *FR* 60154, 60155, Dec. 3, 2001; 67 *FR* 70322, Nov. 22, 2002; 68 *FR* 20347, Apr. 25, 2003; 68 *FR* 74491, Dec. 24, 2003; 69 *FR* 16054, 16133, Mar. 26, 2004; 69 *FR* 35529, June 25, 2004; 72 *FR* 51012, 51086, Sept. 5, 2007, as corrected at 72 *FR* 68075, 68076, Dec. 4, 2007; 72 *FR* 64161, Nov. 15, 2007; 73 *FR* 48434, 48751, Aug. 19, 2008, as corrected at 73 *FR* 57541, 57543, Oct. 3, 2008; 74 *FR* 61738, 62006, Nov. 25, 2009]

**AUTHORITY:** AUTHORITY NOTE APPLICABLE TO ENTIRE PART:

Secs. 1102, 1860D-1 through 1860D-42, 1871, and 1877 of the Social Security Act (42 *U.S.C.* 1302, 1395w-101 through 1395w-152, 1395hh, and 1395nn).

**NOTES:** [EFFECTIVE DATE NOTE: 72 *FR* 64161, Nov. 15, 2007, provides: "The provisions of this final rule are effective December 4, 2007 as specified in the September 5, 2007 final rule (72 *FR* 51012). However, the date of applicability of the provisions of § 411.354(c)(1)(ii), § 411.354(c)(2)(iv), and § 411.354(c)(3) with respect to certain compensation arrangements involving physician organizations and academic medical centers or integrated section 501(c)(3) health care systems, as described herein, are delayed until December 4, 2008."; 73 *FR* 48434, 48751, Aug. 19, 2008, amended this section, effective Oct. 1, 2008; 74 *FR* 61738, 62006, Nov. 25, 2009, revised paragraph (c)(3)(i), effective Jan. 1, 2010.]

**NOTES APPLICABLE TO ENTIRE CHAPTER:**

[PUBLISHER'S NOTE: Nomenclature changes affecting Chapter IV appear at 45 *FR* 53806, Aug. 13, 1980; 50 *FR* 12741, Mar. 29, 1985; 50 *FR* 33034, Aug. 16, 1985; 51 *FR* 41338, Nov. 14, 1986; 53 *FR* 6634, Mar. 2, 1988; 53 *FR* 47201, Nov. 22, 1988; 56 *FR* 8852, Mar. 1, 1991; 66 *FR* 39450, 39452, July 31, 2001; 67 *FR* 36539, 36540, May 24, 2002; 77 *FR* 29002, 29028, May 16, 2012.]

NOTES APPLICABLE TO ENTIRE PART:

[PUBLISHER'S NOTE: For Federal Register citations concerning Part 411 Interpretations, see: 70 FR 13397, Mar. 21, 2005.]

[PUBLISHER'S NOTE: Nomenclature changes affecting part 411 appear at 71 FR 9466, 9471, Feb. 24, 2006, as confirmed at 73 FR 9679, 9684, Feb. 22, 2008.]

[PUBLISHER'S NOTE: 72 FR 13710, Mar. 23, 2007, provides "This notice extends the timeline for publication of the Phase III final rule through March 26, 2008. In accordance with section 1871(a)(3)(C) of the Act, the March 26, 2004 interim final rule [69 FR 16054] shall remain in effect through March 26, 2008 (unless Phase III is published and becomes effective before March 26, 2008)."]

**LexisNexis (R) Notes:**

CASE NOTES

CASE NOTES Applicable to entire Part:Part Note

*United States Ex Rel. Villafane v. Solinger*, 543 F. Supp. 2d 678, 2008 U.S. Dist. LEXIS 28766 (WD Ky Apr. 8, 2008).

**Overview:** Defendants' motion for summary judgment was granted because defendants met the legal requirements of the academic medical center (AMC) exception with regard to Medicaid reimbursement claims, as such, there remained no underlying Stark law, 42 U.S.C.S. § 1395nn violation upon which plaintiffs' FCA claim could proceed.

- With regard to reimbursement under Medicaid, 42 C.F.R. § 411.354(d)(2) states that 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 designated health services. Go To Headnote

*United States v. Solinger*, 457 F. Supp. 2d 743, 2006 U.S. Dist. LEXIS 75063 (WD Ky Oct. 12, 2006).

**Overview:** Hospital and various medical personnel were allowed to show they satisfied Academic Medical Center exception to the Stark law, 42 C.F.R. § 411.355(e), by showing that referring physicians were bona fide employees of medical school, faculty practice plan, or hospital, on full-time basis, and that they were licensed to practice medicine in Kentucky.

- Under the Stark statute, prohibited financial relationships include indirect compensation arrangements when the referring physician receives aggregate compensation that varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing designated health services. 42 C.F.R. § 411.354(c)(2) (2006). Go To Headnote

*United States Ex Rel. Singh v. Bradford Reg'l Med. Ctr.*, 752 F. Supp. 2d 602, 2010 U.S. Dist. LEXIS 119355 (WD Pa Nov. 10, 2010).

**Overview:** Where a compensation arrangement between a medical center and doctors was arrived at by taking into account anticipated referrals from the doctors, the arrangement was not for "fair market value" under the Stark Act. However, whether the violations were done knowingly for purposes of the False Claims Act would have to be decided by a factfinder.

- Under the Stark Act, 42 U.S.C.S. § 1395nn, a physician has a financial relationship with an entity if the physician has an ownership or investment interest in the entity, or a compensation arrangement with it.

42 U.S.C.S. § 1395nn(a)(2). A "compensation arrangement" is defined as any arrangement involving any remuneration between a physician and an entity. 42 U.S.C.S. § 1395nn(h)(1)(A). Similarly, the Stark regulations define "compensation arrangement" as any arrangement involving remuneration, direct or indirect, between a physician and an entity. 42 C.F.R. § 411.354(c). "Remuneration," in turn, is defined under the Stark Act as any remuneration, directly or indirectly, overtly or covertly, in cash or in kind. 42 U.S.C.S. § 1395nn(h)(1)(B). Go To Headnote

- With respect to the Stark Act regulations, under the definition of "direct compensation arrangement" in 42 C.F.R. § 411.354(c)(1), some arrangements that may not have qualified as an "indirect compensation arrangement" under the prior definition that existed before September 5, 2007 requiring that the remuneration vary with or otherwise reflect (or take into account) the volume or value of referrals, are now considered "direct compensation arrangements" without any need for an examination of whether the remuneration varies with or otherwise reflects referrals. Go To Headnote
- The Stark Act regulations set forth a grandfather clause providing that a "stands in the shoes" provision 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. 42 C.F.R. § 411.354(c)(3)(ii)(A). Go To Headnote
- Under the Stark Act regulations, the definition of an "indirect compensation arrangement" requires (i) that there exists an unbroken chain of persons or entities that have financial relationships between them; (ii) that the aggregate compensation received by the physician varies with, or otherwise reflects or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the Designated Health Services; and (iii) the entity furnishing Designated Health Services has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the physicians aggregate compensation varies with, or otherwise reflects or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity. 42 C.F.R. § 411.354(c)(2)(i)-(iii) Go To Headnote
- Under the Stark Act regulations, the determination of whether compensation varies with or takes into account referrals for an entity providing Designated Health Services is measured by the nonownership or noninvestment interest closest to the referring physician. 42 C.F.R. § 411.354(c)(2)(ii). Go To Headnote
- The Stark Act regulation that addresses the physician's compensation exception states that the compensation may be conditioned on the physician's referrals so long as it meets all of the enumerated conditions, including that the compensation arrangement 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). 42 C.F.R. § 411.354(d)(4)(ii). Thus anticipated referrals are a proper consideration under the Stark Act, 42 U.S.C.S. § 1395nn. Go To Headnote
- Under the Stark Act, 42 U.S.C.S. § 1395nn, the court examines whether there is a prohibited financial relationship involving a compensation arrangement involving indirect remuneration, and such remuneration can be, as broadly described in the Act, overt or covert, in cash or in kind. 42 U.S.C.S. § 1395nn(a)(2), (h)(1)(A), and (h)(1)(B). To find an "indirect compensation arrangement," the regulations require, as one element, that the aggregate compensation received by the physician varies with, or otherwise reflects or takes into account referrals. 42 C.F.R. § 411.354(c)(2)(ii). The logical structure of the Stark Act and applicable regulations therefore suggest that the proper order is to first determine whether an indirect compensation arrangement exists, meaning whether it satisfies the definition, before turning to the question of whether an exception applies. This straightforward interpretation means there is no fair market value analysis at the first stage of determining whether an indirect compensation arrangement exists. Go To Headnote
- Under the regulations for the Stark Act, 42 U.S.C.S. § 1395nn, payment based on a percentage of collections, is not covered by the provisions of 42 C.F.R. § 411.354(d)(2). Go To Headnote

*United States Ex Rel. Villafane v. Solinger*, 543 F. Supp. 2d 678, 2008 U.S. Dist. LEXIS 28766 (WD Ky Apr. 8, 2008).

**Overview:** *Defendants' motion for summary judgment was granted because defendants met the legal requirements of the academic medical center (AMC) exception with regard to Medicaid reimbursement claims, as such, there remained no underlying Stark law, 42 U.S.C.S. § 1395nn violation upon which plaintiffs' FCA claim could proceed.*

- With regard to reimbursement under Medicaid, the Stark law states that if a physician or a member of his immediate family has a "financial relationship" with an entity providing healthcare services: (A) the physician may not make a referral to the entity for the furnishing of designated health services; and (B) the

entity may not present or cause to be presented a claim under this subchapter or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A). 42 U.S.C.S. § 1395nn(a)(1). The regulations implementing the Stark law define a "financial relationship," which may include a direct or indirect compensation arrangement with an entity that furnishes designated health services. 42 C.F.R. § 411.354(a)(1)(ii). A "compensation arrangement," in turn, can be any arrangement involving remuneration, direct or indirect, between a physician and an entity. 42 C.F.R. § 411.354(c). Go To Headnote

- With regard to reimbursement under Medicare, an indirect compensation arrangement, which is present where: (i) between the referring physician and the entity furnishing designated health services there exists an unbroken chain of any number (but not fewer than one) of persons or entities that have financial relationships between them; (ii) the referring physician receives aggregate compensation from the person or entity in the chain with which the physician has a direct financial relationship that varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the designated health services; and (iii) the entity furnishing designated health services has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician receives aggregate compensation that varies with, or otherwise reflects, the value or volume of referrals or other business generated by the referring physician for the entity furnishing the designated health services. 42 C.F.R. § 411.354(c)(2). Go To Headnote
- With regard to reimbursement under Medicaid and the Stark law, an indirect compensation arrangement exists: (i) between the referring physician and the entity furnishing designated health services there exists an unbroken chain of any number (but not fewer than one) of persons or entities that have financial relationships between them; (ii) the referring physician receives aggregate compensation from the person or entity in the chain with which the physician has a direct financial relationship that varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the designated health services; and (iii) the entity furnishing the designated health services has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician receives aggregate compensation that varies with, or otherwise reflects, the value or volume of referrals or other business generated by the referring physician for the entity furnishing the designated health services. 42 C.F.R. § 411.354(c)(2). Go To Headnote

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- With regard to reimbursement under Medicaid, the Stark law states that if a physician or a member of his immediate family has a "financial relationship" with an entity providing healthcare services: (A) the physician may not make a referral to the entity for the furnishing of designated health services; and (B) the entity may not present or cause to be presented a claim under this subchapter or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A). 42 U.S.C.S. § 1395nn(a)(1). The regulations implementing the Stark law define a "financial relationship," which may include a direct or indirect compensation arrangement with an entity that furnishes designated health services. 42 C.F.R. § 411.354(a)(1)(ii). A "compensation arrangement," in turn, can be any arrangement involving remuneration, direct or indirect, between a physician and an entity. 42 C.F.R. § 411.354(c). Go To Headnote
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ferring physician receives aggregate compensation that varies with, or otherwise reflects, the value or volume of referrals or other business generated by the referring physician for the entity furnishing the designated health services. *42 C.F.R. § 411.354(c)(2)*. Go To Headnote

With regard to reimbursement under Medicaid and the Stark law, an indirect compensation arrangement exists: (i) between the referring physician and the entity furnishing designated health services there exists an unbroken chain of any number (but not fewer than one) of persons or entities that have financial relationships between them; (ii) the referring physician receives aggregate compensation from the person or entity in the chain with which the physician has a direct financial relationship that varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the designated health services; and (iii) the entity furnishing the designated health services has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician receives aggregate compensation that varies with, or otherwise reflects, the value or volume of referrals or other business generated by the referring physician for the entity furnishing the designated health services. *42 C.F.R. § 411.354(c)(2)*. Go To Headnote