The Stark Law Rules of the Road

An overview of the Stark Law to help interested physicians acquire an introductory knowledge of this intricate law

AMA
AMERICAN MEDICAL ASSOCIATION

Rules of the Road—how physicians can navigate the Stark Law

I. Purpose of this document

1.1 What is the purpose of this "Rules of the Road" document? The Stark statute and regulations (collectively referred to as the "Stark Law") significantly restricts physician referral patterns and limits many but not all types of business relationships into which physicians may enter. This "Rules of the Road" document discusses many of the key requirements of and exceptions to the Stark Law, as the AMA understands them to currently exist, and highlights areas where physicians retain flexibility.

1.2 This document is intended only to be an introduction to certain aspects of the Stark Law. This document is intended to help interested physicians acquire an introductory knowledge of the Stark Law. This document does not describe all of the Stark Law's aspects—even in an introductory manner. The Stark Law is complicated, and its application in any specific situation is heavily dependent on the facts of that unique situation. Instead, this document discusses, through examples where appropriate, some of the aspects of the Stark Law that may be most germane to the types of transactions and business relationships in which physicians most frequently find themselves involved.

1.3 Legal disclaimer. This document is intended to provide only general information about the Stark Law based on the AMA's current understanding. The examples discussed are illustrative only and should not be used as a basis for determining compliance with the Stark Law. The AMA provides this document with the express understanding that this document does not create an attorney-client relationship between the AMA and the reader, and the AMA is not providing legal advice. The reader should seek legal advice from retained legal counsel when assessing compliance with the Stark Law (including assessing changes in the Stark Law or other developments since the preparation of this document.)

II. What is the Stark Law and what does it prohibit?

2.1 The Stark Law's initial prohibition applied only to clinical lab services. The Stark Law, also known as the Ethics in Patient Referrals Act of 1989 (the Act), became effective on January 1, 1992.[1] The Act, as amended over time along with its associated regulations, is frequently referred to as the "Stark Law" because Congressman Pete Stark sponsored the bill that ultimately became the Act. On its effective date, the Stark Law (Stark I) prohibited physicians from ordering clinical laboratory services for Medicare patients from an entity with whom the physician (or an immediate family member of that physician) had a "financial relationship."

2.2 The Stark Law prohibition today applies to a broader range of "designated health services." Effective January 1, 1995, the Stark Law's prohibition was

[1] The Stark statute is located at 42 USC § 1395nn and the regulations at 42 CFR § 411.350 et seq.

expanded to include other services in addition to clinical laboratory services (Stark II). Currently, the Stark Law prohibits:

(1) a physician from referring Medicare patients to entities for the provision of designated health services (DHS) if the physician (or an immediate family member) has a direct or indirect financial relationship with that entity; [2] and

(2) an entity that furnishes DHS pursuant to a prohibited referral from billing the Medicare program or any individual, third party payer, or other entity for the DHS.[3]

This document discusses DHS in detail in VII.

III. What happens if the Stark Law is violated?

3.1 Denial of payment. The Medicare program is prohibited from paying for DHS furnished pursuant to a prohibited referral.[4]

3.2 Refund of payments. Any entity that that collects a payment for DHS that was performed pursuant to a prohibited referral must timely refund such payment.[5]

3.3 Imposition of civil monetary penalties by the Centers for Medicare and Medicaid Services (CMS). Any person or entity who bills Medicare for a DHS that the person or entity knew, or should have known, resulted from a prohibited referral is subject to a civil money penalty of not more than $15,000 for each such service.[6]

3.4 Assessment of a penalty by the Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services (DHHS). Any person or entity who bills Medicare for DHS that the person or entity knew, or should have known, resulted from a prohibited referral is also subject to an assessment by the OIG of three times the amount claimed for the DHS.[7]

3.5 Civil monetary penalty for involvement in a circumvention scheme. Any physician or other entity that enters into an arrangement or scheme (such as a cross-referral arrangement) that the physician or entity knows or should know has a

[2] 42 USC § 1395nn(a)(1)(A); 42 CFR § 411.350(a), 42 CFR § 411.353(a)

[3] 42 USC § 1395nn(a)(1)(B); 42 CFR § 411.353(b)

[4] 42 USC § 1395nn(g)(1); 42 CFR § 411.353(c)(1)

[5] 42 USC § 1395nn(g)(2)

[6] 42 USC § 1395nn(g)(3)

[7] See 42 CFR § 1003.100(b)(viii)

principal purpose of assuring referrals by the physician to a particular entity which, if the physician directly made referrals to such entity, would violate the Stark Law, is subject to a civil money penalty of not more than $100,000 for each such arrangement or scheme.[8]

3.5.1 Example of a possible circumvention scheme. Suppose Physician A has an ownership interest in an independent diagnostic treatment facility (IDTF 1). Suppose also that Physician A is not permitted under the Stark Law to refer Medicare patients to the IDTF 1 for the provision of DHS. Suppose that Physician B practices in the same town as Physician A and also has an ownership interest in another IDTF (IDTF 2) to which she is not permitted to refer Medicare patients for the provision of DHS. Finally, suppose that the Stark Law does not prohibit Physician A from referring to IDTF 2 and Physician B is not prohibited from referring to IDTF 1. Physicians A and B would enter into a prohibited circumvention scheme if Physician A agreed to refer all of his/her Medicare patients to IDTF 2 in exchange for Physician B agreeing to refer all of his/her Medicare patients to IDTF 1.

3.6 Exclusion from Federal health care programs. A violation of the Stark Law can result in exclusion from federal health care programs.[9]

IV. When does a "referral" occur?

4.1 The Stark Law only applies to a physician when he or she makes a "referral." The Stark Law does not apply to all physician activities. Instead, the Stark Law only applies when a physician has made a "referral," as defined by the Stark Law. Accordingly, in terms of deciding whether or not the Stark Law applies, the physician must ask whether or not he or she is making Stark Law referrals.

4.2 What is a referral? The following describe the different types of conduct that constitute, and do not constitute "referrals" under the Stark Law.

4.2.1 A referral is a request, order, or certification. A "referral" is the request by a physician for, the ordering of, or the certifying or recertifying of the need for, any DHS, including the request for a consultation with another physician and any test or procedure ordered by or to be performed by (or under the supervision of) that other physician. A "referral" does not include DHS *personally performed or provided by* the referring physician.[10]

[8] 42 USC § 1395nn(g)(4)

[9] 42 USC § 1395nn(g)(3) and (4)

[10] 42 USC § 1395nn(h)(5)(A); 42 CFR § 411.351

4.2.2 A referral is also the establishment of a plan of care. A referral is also the establishment of a plan of care by a physician that includes the provision of DHS, but again, does not include any DHS *personally performed or provided by* the referring physician.[11]

4.2.3 Conduct that does not constitute a "referral." The Stark Law excepts specific types of conduct from the definition of "referral." If a physician's conduct falls within the categories described in the following subsections, the physician has not made a referral and the Stark Law does not apply.

4.2.3.1 A physician personally performing a DHS does not constitute a "referral." A referral does not occur when a referring physician personally performs the DHS.[12]

(1) Example of a DHS that is personally performed by a physician. Suppose a physician examines a patient and determines that the patient requires an antigen to treat an allergic reaction. The physician would not make a referral for the provision of that antigen if the physician personally administered the antigen to the patient.[13] *However,* if the antigen were administered by another physician in the referring physician's group practice, the provision of the antigen would occur pursuant to a referral (although the referral could potentially fit into the Stark Law physician services or in-office ancillary services exceptions.)[14]

4.2.3.2 Certain requests by pathologists, radiologists, or radiation oncologists are not "referrals." A request by a pathologist for clinical diagnostic laboratory tests and pathological examination services, a request by a radiologist for diagnostic radiology services, and a request by a radiation oncologist for radiation therapy or ancillary services necessary for, and integral to, the provision of radiation therapy, are not referrals if:

(1) the request results from a consultation initiated by another physician; and

(2) the tests or services are furnished by or under the supervision of the pathologist, radiologist, or radiation oncologist, or under the supervision of a pathologist, radiologist, or radiation oncologist, respectively, in the

[11] 42 USC § 1395nn(h)(5)(B); 42 CFR § 411.351

[12] 42 CFR § 411.351.

[13] 69 FR 16054, 16063; See 69 FR 16070

[14] See 69 FR 16070

same group practice as the pathologist, radiologist, or radiation oncologist.[15]

4.2.3.3 What if a physician writes an order for DHS but does not direct where the Medicare beneficiary should receive those DHS? It appears that in certain circumstances, a physician's ordering a DHS may not constitute a "referral" even if the Medicare beneficiary receives those DHS from an entity with which the physician has a financial relationship. Commentary from CMS seems to suggest that the ordering physician does not suggest or otherwise influence where the patient receives the ordered DHS, and the Medicare beneficiary obtains the DHS from an entity with whom the physicians has a compensation arrangement, the physician will not have made a "referral" to that entity.[16]

V. If a referral occurred, did the physician make the referral?

5.1 A physician can make a referral even if he or she is not the one who orders or requests the DHS. A physician can make a Stark Law referral even if he or she does not actually order or request the DHS, depending on the extent to which the physician controls those who are performing the ordering or requesting.

5.1.1 Example illustrating how a referral may be attributed to a physician even if the physician did not actually make the referral. Suppose a physician assistant who works in a physician's practice refers a patient to a particular imaging facility because the physician has instructed her clinical staff to refer certain diagnostic procedures to that facility. Because the referral would be made pursuant to the physician's instructions, i.e., pursuant to the physician's control, CMS would treat the physician assistant's referral as if the physician herself made the referral.[17]

VI. Are the referred items or services for a *Medicare* beneficiary?

6.1 The Stark Law only applies when the referral concerns a Medicare beneficiary. If the patient involved is not a Medicare beneficiary, then the Stark Law does not apply.

[15] 42 USC § 1395nn(h)(5)(C); 42 CFR § 411.351

[16] 66 FR 856, 873

[17] See e.g., the discussion at 66 FR 900

VII. Is the referral for DHS?

7.1 The Stark Law only applies to referrals for DHS. The Stark Law does not apply to all health care services. The Stark Law only applies to referrals for DHS.

7.1.1 Example of a referral not involving a DHS. Suppose a physician refers a Medicare patient to a hospital in order to receive lithotripsy services. The physician would not have made a *referral for DHS*, because lithotripsy is not DHS.[18]

7.2 What is a "designated health service?" DHS includes any of the following services:

(1) clinical laboratory services;

(2) physical therapy, occupational therapy, and outpatient speech-language pathology services;

(3) radiology and certain other imaging services, except for the following, which are not considered to be DHS

(a) X-ray, fluoroscopy, or ultrasound procedures that require the insertion of a needle, catheter, tube, or probe through the skin or into a body orifice;

(b) radiology or certain other imaging services that are integral to the performance of a medical procedure that is not identified on the list of CPT/HCPCS codes as a radiology or certain other imaging service and is performed:

(i) immediately prior to or during the medical procedure; or

(ii) immediately following the medical procedure when necessary to confirm placement of an item placed during the medical procedure.

radiology and certain other imaging services that are "covered ancillary services," as defined at 42 CFR § 416.164(b), for which separate payment is made to an ambulatory surgery center;

(4) radiation therapy services and supplies;

(5) durable medical equipment and supplies;

(6) parenteral and enteral nutrients, equipment, and supplies;

(7) prosthetics, orthotics, and prosthetic devices and supplies;

[18] 73 FR 48719. *See also American Lithotripsy Society v. Thompson*, 215 F. Supp. 2d 23 (D.D.C. 2002).

(8) home health services;

(9) outpatient prescription drugs; and

(10) inpatient and outpatient hospital services.[19]

7.3 "Designated Health Services" does not include services that are reimbursed as part of a composite rate. Generally, "DHS" does not include services that are reimbursed by Medicare as part of a composite rate (for example, ASC services, except to the extent that services listed section 7.2(1) – (10) above are themselves payable through a composite rate (for example, all services provided as home health services or inpatient and outpatient hospital services are DHS).[20]
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7.4 DHS includes professional and technical components. Some DHS, such as diagnostic imaging tests, have both a technical component (the performance of the test itself) and a professional component (the interpretation of the test). Both the technical and professional components of a DHS are themselves DHS.[21]

7.5 Health care services that are not DHS when furnished outside of inpatient and outpatient settings may be transformed into DHS when furnished in those settings. One potential trap concerning DHS and the Stark Law can occur when a health care service that is not a DHS outside of the hospital setting becomes a DHS when provided in the hospital setting.

7.5.1 Example illustrating how a non-DHS can be transformed into a DHS in the hospital setting. Diagnostic cardiac catheterization services are not DHS when provided outside of the hospital outpatient or inpatient context. Such services do become DHS when they are furnished in a hospital inpatient or outpatient setting because inpatient and outpatient hospital services are DHS.[22]

7.6 How can a physician know if a particular service is a DHS? *CMS defines some DHS through specific CPT and HCPCS codes on its Website.* CMS publishes a list that defines all DHS under the following categories in terms of specific CPT/HCPCS codes: (1) clinical laboratory services; (2) physical therapy services, occupational therapy services, outpatient speech-language pathology services; (3) radiology and certain other imaging services; and (4) radiation therapy services and supplies. These CPT/HCPCS codes can be accessed at

[19] 42 USC § 1395nn(h)(6); 42 CFR § 411.351

[20] 42 CFR § 411.351; see e.g., the discussion starting at 69 FR 16111

[21] For example, see the discussion at 66 FR 924

[22] See e.g., 66 FR 929

http://www.cms.gov/PhysicianSelfReferral/40_List_of_Codes.asp. The remaining categories of DHS are not defined through specific CPT or HCPCS codes.

VIII. Is the referral to an "entity that furnishes DHS"? Even if a (1) physician (2) makes a referral (3) for DHS (4) for a Medicare beneficiary, the Stark Law does not apply unless the DHS are furnished by an "entity" that furnishes DHS.

8.1 What is an "entity?" The term "entity" itself is defined broadly. It can, for example, be a solo or group practice medical practice. But "entity" can also be a corporation, partnership, limited liability company, foundation, nonprofit corporation, or unincorporated association that furnishes DHS. So an "entity" could include a physician professional association, a hospital, a nursing facility, an independent diagnostic treatment facility.[23]

8.2 What is an "entity that furnishes DHS?" There are two types of entities that "furnish DHS."

8.2.1 An "entity that furnishes DHS" can be an entity or person that bills the Medicare program for DHS services. An entity that furnishes DHS is an entity or person that bills the Medicare program for DHS.[24]

8.2.1.1 Examples of entities that bill Medicare for the provision of DHS. All of the following would constitute "entities furnishing DHS": a hospital billing the Medicare program for the provision of a CT scan; a solo physician practitioner billing the Medicare program for administering drugs in her or her office; a medical practice billing Medicare for an interpretation of an MRI scan performed by one of the group's physician members.

8.2.2 An "entity that furnishes DHS" can be an entity or person that *performs* DHS services that are billed to the Medicare program. Effective October 1, 2009, CMS expanded the definition of "entity that furnishes DHS" to include those persons or entities that perform DHS, even if another person or entity bills the Medicare program for those DHS.[25]

8.2.2.1 Example of an entity that performs, but does not bill, the Medicare program. Suppose a hospital wishes to provide cardiac catheterization (CC) services to its patients, but does not own the equipment. A physician group practice in town does, however, own CC equipment. Rather than purchasing the CC equipment and providing those services itself, the hospital and the group practice enter into an "under arrangements"

[23] 42 CFR § 411.351

[24] 42 CFR § 411.351

[25] 42 CFR § 411.351; See also the discussion beginning at 73 FR 48721

transaction by, for example, creating a joint venture which would own the CC equipment. The hospital would purchase the cardiac catheterization services for its patients from the joint venture and bill the Medicare program for those services. The group practice would furnish all of the equipment, personnel, and supplies necessary to provide those services through the joint venture, and would refer Medicare patients to the joint venture. Because of the expansion of the definition of "entity that furnishes DHS" to include an entity or person that *performs* DHS, the joint venture would be considered a DHS entity, in addition to the hospital.[26]

8.2.2.2 So what does it mean to "perform" a DHS? CMS has not defined the word "performs." CMS has stated, however, that:

> "We do not consider an entity that leases or sells space or equipment used for the performance of the service, or furnishes supplies that are not separately billable but used in the performance of the medical service, or that provides management, billing services, or personnel to the entity performing the service, to perform DHS."[27]

(1) Example of an arrangement involving physicians that would not appear to cross the "performs" threshold. Suppose a physician group practice owns a mobile CT scanner. The practice leases the use of the scanner to a local hospital one day a week, and hospital staff performs the tests using the scanner while it is at the hospital. In such a case, the practice would not become a DHS entity by leasing the scanner to the hospital because leasing in and of itself does not constitute the performance of DHS. In the final Medicare Physician Fee Schedule for 2010, CMS acknowledged that it had received numerous questions concerning the meaning of "performs" and solicited comments concerning whether or not it should define or clarify this phrase, and if so, how. CMS has yet to provide further clarification.[28]

IX. Does the physician or the physician's "immediate family member" have a "financial relationship" with the entity furnishing DHS services? Even if a physician (1) makes a referral of (2) a Medicare beneficiary for (3) DHS to (4) an entity that furnishes DHS, the Stark Law may not apply. In order for the Stark Law to be applicable, a "financial relationship" must exist between the physician or the physician's immediate family member and the entity that furnishes DHS (subsequently for convenience referred to as "entity"). And, even if a financial relationship exists between

[26] See the discussion starting at 73 FR 48721

[27] 73 FR 48726

[28] 74 FR 61933-61934

the physician or the physician's family member and the entity, the Stark Law will not apply if a Stark Law exception applies.

9.1 There are four kinds of "financial relationships." There are four types of financial relationships: (1) direct ownership/investment interests; (2) indirect ownership/investment interests; (3) direct compensation arrangements; and (4) indirect compensation arrangements. Understanding the nature of the financial relationship involved is vital because the nature of the financial relationship determines what, if any, Stark Law exceptions may apply.[29]

9.2 Stark Law financial relationships may exist not only between physicians and entities but also between a member of the physician's immediate family and the entity. The Stark Law defines an "immediate family member" to include a physician's: husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.[30] A financial relationship involving any person falling under one of the aforementioned categories will trigger the Stark Law prohibition.

9.2.1 Example illustrating a financial relationship between a physician and an entity created via a family member. Suppose a physician in solo practice has her office in a building owned by her and six other physicians, one of whom is her step brother. The building contains a laboratory that is owned by a group practice in which the step brother is a shareholder. The Stark Law would prohibit her from referring Medicare beneficiaries to the lab for the provision of DHS unless the financial relationship between the lab and the physician's step brother met the requirements of a Stark Law exception.[31]

9.3 What is an ownership or investment interest? An ownership or investment interest in an entity furnishing DHS can be through equity, debt, stock, 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.[32]

9.3.1 What is a direct ownership/investment interest? A direct ownership/investment interest exists when there is no intervening

[29] 42 USC § 1395nn(a)(2); 42 CFR § 411.354(a)(1)

[30] 42 CFR § 411.351

[31] See 60 FR 41938-41939

[32] 42 USC § 1395nn(a)(2); 42 CFR § 411.354(b)(1)

ownership/investment interest between the physician (or immediate family member) and the entity.[33]

9.3.1.1 Examples illustrating direct ownership/investment interests. A physician shareholder in a physician group would have a direct ownership/investment interest in an entity if the group practice billed the Medicare program for providing DHS services, e.g., physical therapy services. A physician would also have a direct ownership/investment interest in an entity if the physician owned stock in a for-profit general acute care hospital or in an IDTF that served Medicare beneficiaries.

9.3.2 What is an indirect ownership or investment interest? An indirect ownership or investment interest exists if the following two requirements are satisfied.

9.3.2.1 Does an unbroken chain of ownership/investment interests exist between the physician and the entity? There must exist between the physician (or family member) and the entity an unbroken chain of any number (but no less than one) of persons or entities having ownership or investment interests.[34]

(a) Example of an unbroken chain of ownership/investment interests. Suppose a physician's step-daughter has an ownership interest in a local nursing home. The nursing home in turn owns a portion of a corporation that provides durable medical equipment (DME). An unbroken chain of ownership/investment interests exists between the step-daughter and the DME corporation, because the stepdaughter has a direct ownership/investment interest in the nursing home, and the nursing home has an ownership/investment interest in the DME corporation.[35]

9.3.2.2 The DHS provider must "know" that the referring physician or the physician's family member has an ownership or investment interest in the entity. The entity must have actual knowledge of, or act in reckless disregard or deliberate ignorance of, the fact that the referring physician (or family member) has some ownership/ investment interest (through any number of intermediary ownership or investment interests) in the entity.[36]

(1) To what extent is an entity responsible for investigating whether a referring physician (or family member of that physician) has an

[33] 42 CFR § 411.354(a)(2)(i)

[34] 42 CFR § 411.354(a)(5)(i)(A); 42 CFR § 411.354(a)(5)(iv)

[35] Other examples and further discussion can be found starting at 69 FR 16057

[36] 42 CFR § 411.354(a)(5)(i)(B)

indirect ownership or investment interest in the entity? The "knowledge" requirement of section 9.3.2.2 does not require an entity to affirmatively investigate every possible indirect ownership or investment interest that a referring physician may have with the entity. Instead, an entity has a duty to make a reasonable inquiry concerning a possible indirect ownership or investment interest if the entity learns of facts that would make a reasonable person suspect that such an indirect ownership/investment exists.[37]

9.3.3 Ownership in a subsidiary company does not create an ownership interest in the parent company. If a physician has an ownership or investment interest in a subsidiary company, that ownership or investment interest does not create an ownership or investment interest in the parent company, or 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. The ownership of investment interest in the subsidiary may, however, be a part of an indirect financial relationship.[38]

9.3.4 Common ownership in an entity by itself does not create an ownership or investment interest in another common owner. If a physician has a common ownership or investment interest in an entity, that interest does not, in and of itself, establish an indirect ownership or investment interest by the physician in another common owner, or investor.[39]

9.4 What is a compensation arrangement? A "compensation arrangement" is any arrangement involving *remuneration*, direct or indirect, between a physician (or family member) and an entity.[40] The term "remuneration" includes any remuneration, directly or indirectly, overtly or covertly, in cash or in kind.[41] The Stark statute and regulations list a few limited circumstances that do not constitute "remuneration" for purposes of the Stark Law.[42]

9.4.1 What is a direct compensation arrangement? A direct compensation arrangement exists if remuneration passes between the referring physician (or

[37] 66 FR 856, 865

[38] 42 CFR § 411.354(b)(2)

[39] 42 CFR § 411.354(b)(5)(iii)

[40] 42 USC § 1395nn(h)(1)(A)

[41] 42 USC § 1395nn(h)(1)(B).

[42] 42 USC § 1395nn(h)(1)(c); 42 CFR § 411.351

family member) and the entity furnishing DHS without any intervening persons or entities.[43]

9.4.1.1 Examples of direct compensation arrangements. The following would all constitute direct compensation arrangements between a physician and an entity:

(1) a nursing home paying a physician via an independent contractor relationship to serve as the nursing home's medical director;

(2) a physician renting office space from a hospital;

(3) a hospital renting equipment from a physician;

(4) a hospital directly employing a physician.

9.4.2 What is an indirect compensation arrangement? An indirect compensation arrangement exists between a referring physician (or family member) and an entity if the following apply.[44]

9.4.2.1 Does an unbroken chain of any number (but not less than one) of financial relationships exist between the physician and the entity? An unbroken chain of financial relationships must exist between the physician (or family member) and the DHS entity. At least one of these financial relationships must be a compensation arrangement. However, so long as one of the financial relationships in the unbroken chain is a compensation arrangement, it does not matter if the other financial relationships are direct or indirect ownership interests.[45]

(1) Example of an unbroken chain of at least two financial relationships. Suppose a physician owns stock in a for-profit hospital. The hospital contracts with a clinical laboratory to provide specific laboratory services to the hospital's patients, and that the physician orders tests for Medicare beneficiaries from that laboratory. An unbroken chain of financial relationships—one being a compensation arrangement—exists between the physician and the laboratory, i.e., (1) the physician has a direct ownership/investment interest in the hospital, and (2) the hospital has a compensation arrangement with the laboratory.[46]

[43] 42 CFR § 411.354(c)(1)(i); see also the general discussion starting at 66 FR 865

[44] See the general discussion starting at 66 FR 865

[45] 42 CFR § 411.354(c)(2)

[46] 66 FR 866

9.4.2.2 Does the physician (or family member) receive 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?[47] To determine whether or not this factor applies, an initial question must be answered, namely, which compensation arrangement must be analyzed.

(1) What compensation arrangement needs to be examined if the physician's direct financial relationship in the unbroken chain of financial relationships is an ownership/investment interest? If the physician's direct financial relationship is an ownership/investment interest, the determination of 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 is determined by examining the compensation arrangement closest to the referring physician.[48]

(a) Example illustrating how to identify the compensation arrangement that must be examined. Suppose Physician A holds a one percent ownership interest in a management services organization (MSO). The MSO provides physician practice management services to Group Practice P. Group Practice P owns and operates an MRI on its premises, and Physician P frequently refers Medicare patients to the group practice for MRI tests. In this example, Physician A's direct financial relationship is her one percent ownership interest in the MSO. The compensation arrangement closest to Physician A is the compensation arrangement under the management contract between the MSO and Group Practice P. Accordingly, it is that compensation arrangement that must be analyzed to determine whether the aggregate compensation varies with or takes into account, the volume or value of referrals or other business generated by Physician A for Group Practice P.[49]

(b) Second example illustrating how to identify the compensation arrangement that must be examined. Suppose Physician P has an ownership interest in Company A. Company A, in turns, owns Company B. Company B has a compensation arrangement with Company C. Finally, Company C has a compensation arrangement with a DHS entity to which Physician P refers Medicare patients for the provision of DHS. In this example, the compensation arrangement

[47] 42 CFR § 411.354(c)(2)(ii)

[48] 42 CFR § 411.354(c)(2)(ii)

[49] 66 FR 869-870

between Company B and Company C would be analyzed to determine whether the aggregate compensation varies with or takes into account, the volume or value of referrals or other business generated by Physician P for DHS entity.[50]

(2) What compensation arrangement needs to be examined if the physician's direct financial relationship in the unbroken chain of financial relationships is a compensation arrangement? If the physician's direct financial relationship is a compensation arrangement, then the focus is on that compensation arrangement.

(a) Example illustrating how to identify the compensation arrangement that must be examined. Suppose a management company has contracted with a hospital to provide management services. The management company in turn hires a physician group to provide some of the services that the management company is obligated to provide to the hospital under the management contract. Physician A is an employee of the physician group, and refers Medicare patients to the hospital for DHS. Three compensation arrangements exist in this example: (1) compensation from the hospital to the management company; (2) compensation from the management company to the physician group; and (3) the compensation paid by the physician group to Physician A. To determine if an indirect compensation arrangement exists between the hospital and Physician A, the direct compensation arrangement between Physician A and the physician group must be analyzed to determine whether the aggregate compensation varies with or takes into account, the volume or value of referrals or other business generated by Physician A for the hospital.[51]

(3) Example illustrating aggregate compensation that varies with or takes into account, volume or value of referrals or other business generated—no direct ownership/investment interest involved. Suppose a physician has invented a surgical implant. A hospital in which the physician performs surgeries purchases the implants, which the physician inserts into Medicare patients during certain surgical procedures. In this case, the hospital is the DHS entity because it bills the Medicare program for the provision of the implant, which is a DHS. The medical device company that manufactures the implant makes a royalty payment to the physician every time the implant is used. To determine if an indirect compensation arrangement exists, the compensation arrangement closest to the physician, i.e., the royalty payments, must be

[50] 42 CFR § 411.354(c)(2)(ii)

[51] 72 FR 51028-51029

analyzed to determine whether the aggregate compensation varies with or takes into account, the volume or value of referrals or other business generated by the physician for the hospital. In this case, the aggregate compensation does take into account the volume or value of referrals or other business generated because the physician receives a royalty payment every time he uses the implant in surgical procedures he performs at the hospital.[52] Referrals to the hospital will not be permitted under the Stark Law unless that compensation arrangement satisfies the requirements of the indirect compensation arrangement exception more fully described at XVI.

(4) Example illustrating aggregate compensation that varies with or takes into account, volume or value of referrals or other business generated—direct ownership/investment interest involved. Suppose physician A has an ownership interest in a physical therapy company B. The physical therapy company has a contract with a skilled nursing facility (SNF) whereby the SNF purchases physical therapy services from company B when such services are needed by the patient. The SNF then bills the Medicare program for those physical therapy services. Physician A refers patients to the SNF, and develops each such residents' plans of care, which sometime include the provision of physical therapy services When such services are required, physician A has instructed SNF staff to utilize the services of physical therapy company B. In this case, the SNF is a DHS entity because it is billing the Medicare program for the provision of DHS, i.e., the physical therapy services. Since company B is compensated on a per service basis that reflects referrals by physician A, the aggregate compensation between company B and the SNF varies with or takes into account, the volume or value of referrals or other business generated by the physician for the hospital.[53] The referrals and the hospital's billing will not be permitted under the Stark Law unless that compensation arrangement satisfies the requirements of the indirect compensation arrangement exception at XVI.

(4) Example illustrating how a aggregate compensation involving a *fixed* monthly payment can nevertheless vary or take into account, volume or value of referrals or other business generated. *U.S. ex rel. Singh v. Bradford Regional Medical Center*, 752 F.Supp.2d 602 (W.D.Pa. 2010) involved litigation focusing on the fair market value of payments

[52] 69 FR 16060

[53] 66 FR 868

made by a hospital to sublease a nuclear camera from a physician group. The hospital's accountant determined that the hospitals lease payments reflected fair market value. The accountant reached this conclusion by comparing the revenues the hospital expected to secure with the sublease with the revenues the hospital expected to receive without the sublease. The court concluded that the fair market value appraisal took factored in the value of expected referrals. Thus, although the monthly sublease payments were the same each month, those payments still took into account the volume or value of referrals because they were based on the fair market value appraisal.[54] For further information, see the discussion of *Bradford* at 16.2.1.3.

9.4.2.3. The entity must "know" that the referring physician receives aggregate compensation that varies with referrals or business generated. An indirect compensation arrangement will exist between the referring physician and the entity if the entity has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or 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.[55]

X. What is the "Stand in the Shoes" requirement and what is its effect on Stark Law financial relationships?

10.1 What is the "stand in the shoes" (SITS) requirement? More specifically, a physician is deemed to "stand in the shoes" of his or her physician organization if:

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

(2) the physician has an ownership or investment interest in the physician organization.[56]

10.1.1 Example illustrating the application of the SITS requirement. Suppose Physician A is an employee and shareholder in a group practice. The group practice leases medical office space from Hospital B, to which physician A refers Medicare patients for the provision of DHS. Prior to the application of the SITS requirement, Physician A might have had an indirect compensation arrangement with the hospital (depending on the satisfaction of other criteria) because the

[54] Id. at 623

[55] 42 CFR § 411.354(c)(2)(iii)

[56] 42 CFR § 411.354(c)(1)(ii); 42 CFR § 411.354(c)(2)(iv)(A)

group practice (the “physician organization” in this case) was an intervening organization between Physician A and the DHS entity, i.e., Hospital B. Because, under the SITS requirement, Physician A has the same financial relationship that his or her physician organization has with Hospital B, the Physician A now has a direct compensation arrangement with the hospital because the group practice has a direct compensation arrangement with the Hospital B, namely, the office lease.[57]

10.2 What is a “physician organization?” The SITS requirement applies to "physician organizations." The Stark Law defines "physician organization" as a physician, a physician practice, or a group practice that complies with the requirements of the Stark definition of "group practice."[58] A “physician practice” is a "medical practice comprised of two or more physicians organized to provide patient care services (regardless of its legal form or ownership)."[59] A “physician practice” may also include a group of physicians who practice together but who do not qualify as a Stark "group practice."[60] Just because an entity provides patient care services through employed or contracted physicians, that fact alone does not make that entity a “physician practice.” For example, even though a hospital provides medical, surgical, or psychiatric care and treatment through employed or contracted physicians, a hospital is not a “physician practice” or a “physician organization.”[61]

10.3 Physicians who are permitted, but not required, to stand in the shoes of their physician organizations. The following types of physicians are permitted, but not required, to stand in the shoes of their physician organizations.[62]

10.3.1 “Titular” owners Titular owners in a physician organization are permitted to stand in the shoes of that organization. A “titular” owner is a physician who has an ownership interest in the physician organization but who cannot receive the benefits of ownership, e.g., the right to receive profit distributions, dividends, or other types of returns on investment.[63]

[57] 72 FR 51028. See also 72 FR 51047.

[58] 42 CFR § 411.351. The definition of “group practice” for Stark Law purposes is located at 42 USC § 1395nn(h)(4) and 42 CFR § 411.352.

[59] CMS Frequently Asked Question Answer #8879, accessible at http://questions.cms.hhs.gov/app/answers/detail/a_id/8879/kw/physician%20organization

[60] CMS Frequently Asked Question Answer #8879, accessible at http://questions.cms.hhs.gov/app/answers/detail/a_id/8879/kw/physician%20organization

[61] CMS Frequently Asked Question Answer #8879, accessible at http://questions.cms.hhs.gov/app/answers/detail/a_id/8879/kw/physician%20organization

[62] 42 CFR § 411.354(c)(1)(iii); 42 CFR § 411.354(c)(2)(iv)(B). See also the discussion starting at 73 FR 48693.

[63] 42 CFR § 411.354(c)(3)(ii)(C)

10.3.2 Employees and independent contractors. Physicians who are only employees of, or independent contractors to, a physician organization are permitted to stand in the shoes of that physician organization.[64]

10.5 Why is it important to know whether a physician is required to stand in the shoes of his or her physician organization? In some cases the SITS requirement will result in the creation of a direct compensation arrangement between a referring physician and an entity where previously only an indirect compensation arrangement may have existed. When such a direct compensation arrangement is created, the physician will not be able to refer to the entity unless a Stark Law exception for direct compensation arrangements applies. If the application of the SITS requirement does not create a direct compensation arrangement, an indirect compensation arrangement may still apply. If an indirect compensation arrangement exists, the affected physician(s) will be prohibited from referring to the entity unless the requirements of the exception for indirect compensation arrangements are satisfied.[65]

10.6 Although some physicians may not be required to stand in the shoes of their physician organization, those physicians may nevertheless elect, or be required, to do so. As the example in section 10.4 illustrates, the SITS requirement may dictate that some physician referral relationships involving a physician organization may need to satisfy a direct compensation arrangement exception, while other relationships may need to satisfy the requirements of the exception for indirect compensation arrangements. In order to simplify compliance, non-titular physicians may elect, or be required by their physician organizations, to stand in the shoes of their physician organization so that the physician organization need only ensure satisfaction of direct compensation arrangement exceptions rather than having to monitor continually which physicians have direct compensation arrangements and those that have indirect compensation arrangements, and whether those arrangements satisfy applicable exceptions.[66]

XI. Exceptions to the Stark Law's general self-referral prohibition.

11.1. The Stark Law contains numerous exceptions. Even if a physician refers a Medicare beneficiary for DHS to an entity with whom the physician (or the physician's family member) has a financial relationship, the Stark Law may not ultimately prohibit that referral. This is because the Stark Law has over thirty exceptions that may permit an otherwise prohibited referral.

[64] See e.g., the discussion at 73 FR 48693 et seq.

[65] See e.g., the discussion beginning at 72 FR 51027

[66] 42 CFR § 411.354(c)(1)(iii)

11.2 A financial relationship need satisfy only one exception. A financial relationship need only satisfy one exception in order the permit an otherwise prohibited referral. For example, if a compensation arrangement satisfies the in-office ancillary services exception, that arrangement need not satisfy any other Stark Law exception.

11.3 In many cases, there may be a choice of exceptions that may apply to a financial relationship. In many cases, a number of exceptions may be available to exempt a financial relationship. For example, a compensation arrangement between a hospital and a physician relating to on-call services might be excepted under the exception for personal services arrangements or the exception for fair market value payments.

11.4 Types of Stark Law Exceptions. There are three broad types of Stark Law exceptions. Those exceptions can be organized in the following manner:

(1) exceptions applicable to ***both*** ownership/investment interests ***and*** compensation arrangements;

(2) exceptions applicable only to ownership/investment interests;

(3) exceptions applicable only to compensation arrangements;

(a) the exception that is applicable to indirect compensation arrangements.

XII. Exceptions applicable to both ownership/investment interests and compensation arrangements—the physician services and in-office ancillary services exceptions.

12.1 There are nine exceptions that apply to both ownership investment interests and compensation arrangements. These are the exceptions for:

(1) physician services[67];

(2) in-office ancillary services[68];

(3) services furnished by an organization (or its contractors or subcontractors) to enrollees[69];

(4) services provided by academic medical centers[70];

[67] 42 USC § 1395nn(b)(1); 42 CFR § 411.355(a)

[68] 42 USC § 1395nn(b)(2); 42 CFR § 411.355(b)

[69] 42 USC § 1395nn(b)(3); 42 CFR § 411.355(c)

(5) implants furnished by an ASC[71];

(6) EPO and other dialysis-related drugs[72];

(7) preventive screening tests, immunizations, and vaccines;[73]

(8) eyeglasses and contact lenses following cataract surgery;[74] and

(9) intra-family members in rural areas.[75]

This document will focus on the physician services and in-office ancillary services exception.

12.3 Why is the notion of a "group practice" important for the physician services and in-office ancillary services exceptions? The physician services exception allows a physician to refer a DHS that is a physician service to another physician who is either: (1) ***a member*** of the same group practice as the referring physician; or (2) a physician ***in the same group practice*** as the referring physician.[76] The in-office ancillary services exception permits a group practice to provide and bill for DHS that are ancillary to professional services provided by (1) a member of the same group practice as the referring physician; or (2) a physician in the same group practice as the referring physician.[77] (The in-office ancillary service also permits a solo practitioner to provide and bill for DHS that are ancillary to the physician's professional services.)

12.4 Group practices have a special status under the Stark Law in terms of providing compensation to their physicians. For example, under the Stark Law exception for bona fide employment arrangements, an employed physician may receive a productivity bonus based directly on the DHS that the physician personally performs.[78] However, the physician may not receive a productivity bonus for any DHS that the physician does not personally perform, e.g., DHS that are ancillary to

[70] 42 CFR § 411.355(e)

[71] 42 CFR § 411.355(f)

[72] 42 CFR § 411.355(g)

[73] 42 CFR § 411.355(h)

[74] 42 CFR § 411.355(i)

[75] 42 CFR § 411.355(j)

[76] 42 CFR § 411.355(a)(1)

[77] 42 CFR § 411.355(b)(1)

[78] 42 USC § 1395nn(e)(2); 42 CFR § 411.357(c)(4)

the physicians personally performed services. A group practice can also pay a physician: (1) a productivity bonus based directly on DHS that are incident to services that the physician personally performs; and (2) a productivity bonus for DHS that the physician does not personally perform or that are not provided "incident to" the personally performed services, so long as the productivity bonus is ***not directly related*** to the volume or value of the physician's DHS referrals.[79] A group practice may also compensate a physician under a profit sharing program, so long as the profit shares are not determined in any manner that is ***directly*** related to the volume or value of referrals of DHS by the physician.[80]

12.5 So what does it mean for a physician to be a "member of the group practice," or a "physician in the group practice?"

12.5.1 When is a physician a "member of a group practice?" "Member of a group practice" means:

(1) a physician owner of a group practice;

(2) a physician employee of the group practice;

(3) a locum tenens physician, or

(4) an on-call physician while the physician is providing on-call services for members of the group practice.[81]

A physician is a member of the group during the time he or she furnishes "patient care services" to the group.[82] An independent contractor or a leased employee is not a member of the group, unless the leased employee meets the definition of an "employee" under the Stark Law. An "employee" under the Stark Law means any individual who, under the common law rules that apply in determining the employer-employee relationship (as applied for purposes of section 3121(d)(2) of the Internal Revenue Code of 1986), is considered to be employed by, or an employee of, an entity. (Application of these common law rules is discussed in 20 CFR 404.1007 and 26 CFR 31.3121(d)-1(c).)[83]

12.5.2 When is a physician "in the group practice?" "Physician in the group practice" means:

[79] 42 USC § 1395nn(h)(4)(B)(i); 42 CFR § 411.352(i)

[80] 42 USC § 1395nn(h)(4)(B)(i); 42 CFR § 411.352(i)

[81] 42 CFR § 411.351

[82] 42 CFR § 411.351

[83] 42 CFR § 411.351

(1) a member of the group practice; or

(2) an independent contractor physician during the time the independent contractor is furnishing patient care services for the group practice under a contractual arrangement directly with the group practice to provide services to the group practice's patients *in* the group practice's facilities.[84]

12.6 So when is a physician practice a "group practice" that can be eligible to utilize the physician services or in-office ancillary services exception? In order to qualify as a Stark Law group practice, the physician practice must satisfy the following requirements.

12.6.1 Single legal entity. The physician practice must be a "single legal entity." That legal entity may assume any legal form permitted by the applicable state, e.g., a partnership, professional corporation, professional association, limited liability company, nonprofit corporation, or faculty practice plan.[85]

12.6.2 At least two members. The physician practice must have at least two physicians who are "members" of the practice.[86]

12.6.3 Full range of service. Each physician who is a member of the practice must furnish substantially the full range of patient care services that the physician routinely furnishes, including medical care, consultation, diagnosis, and treatment, through the joint use of shared office space, facilities, equipment, and personnel.[87]

12.6.3.1 What are "patient care services?" "Patient care services" means any task(s) performed by a physician in the group practice that addresses the medical needs of specific patients or patients in general, regardless of whether they involve direct patient encounters or generally benefit a particular practice. Patient care services can include, for example, the services of physicians who do not directly treat patients, such as time spent by a physician consulting with other physicians or reviewing laboratory tests, or time spent training staff members, arranging for equipment, or performing administrative or management tasks.[88]

12.6.4 "Substantially all" of the patient care services of all the physician

[84] 42 CFR § 411.351

[85] 42 USC § 1395nn(h)(4)(A); 42 CFR § 411.352(a)

[86] 42 USC § 1395nn(h)(4)(A); 42 CFR § 411.352(b)

[87] 42 USC § 1395nn(h)(4)(i); 42 CFR § 411.352(c)

[88] 42 CFR § 411.351

members of the group must be furnished through the group. To qualify as a Stark Law group practice, "substantially all," i.e., at least 75 percent, of the total patient care services provided by members of the group must be furnished through the group, billed under a billing number assigned to the group, and the amounts received must be treated as receipts of the group.[89]

12.6.4.1 How can a group practice determine if the total patient care provided by its members satisfies the "substantially all" test? A group practice can determine whether or not its physician members in the aggregate satisfy the "substantially all" requirement by measuring the total time each member spends on patient care services. The time spent may be documented by any reasonable means (including, but not limited to, time cards, appointment schedules, or personal diaries).[90] But CMS permits any other measure to determine whether or not the "substantially all" requirement is satisfied, so long as the measure is reasonable, fixed in advance of the performance of the services being measured, uniformly applied over time, verifiable, and documented.[91]

12.6.4.2 Example illustrating how one can determine what percent of a physician's patient care services is provided through the group. Suppose that a physician practices 40 hours a week and spends 30 hours a week on patient care services for a group practice. The physician therefore spends 75 percent of his or her time providing patient care services for the group, i.e., 40 divided by 30 = 75%.[92]

12.6.4.3 Another example illustrating circumstances in which group members satisfy the "substantially all" requirement. Suppose ten physicians provider patient care services through a group practice. Eight of these physicians give 100% of their patient care time to the group practice. A ninth physician devotes 80% of her time to the group practice, and the tenth physician gives 10% of his time to the practice. To determine compliance with the "substantially all" requirement, the total percent of all the group's physicians are added and then divided by the number of physicians. The eight physicians that devote 100% of their time to the group result in a figure of 800%, while the ninth physician's time amounts to 80% and the tenth physician's time is 10%. Thus, the total time in terms of a percentage is 890% (800% + 80% + 10%). Dividing 890% by the number of physicians (10) results in 89%. The group satisfies the "substantially all" requirement because

[89] 42 USC § 1395nn(h)(4)(ii); 42 CFR § 411.352(d)(1)

[90] 42 CFR § 411.352(d)(1)(i)

[91] 42 CFR § 411.352(d)(1)(ii)

[92] 42 CFR § 411.352(d)(1)(i)

89% of the total time spent by the group's physicians is devoted to the group.[93]

12.6.4.4 Example illustrating circumstances in which group members do not satisfy the "substantially all" requirement. Suppose in another group practice, two physician partners spend 100 percent of their patient care hours through the group. Five part-time physician employees spend 70 percent each, and two other part-time physician employees spend 25 percent of their time at the group practice. A contractor physician devotes 10 percent. In aggregate, these percentages results in 610 percent, i.e., 200% + 350% + 50% + 10% = 610%. The percentage allotted to each physician is 61%, 610%, divided by 10 = 61%. Because 61 percent is assigned to each physician, which includes members of the group, the group fails to satisfy the "substantially all" test.[94]

12.6.4.5 Delay of the application of the "substantially all" requirement when a group practice is in its "start up" period. During a group practice's start up period (not to exceed 12 months) that begins on the date of the initial formation of a new group practice, a group practice must make a reasonable, good faith effort to ensure that the group practice complies with the "substantially all" requirement. The group must comply with the requirement as soon as practicable, but no later than 12 months from the date on which the group practice was initially formed.[95]

12.6.4.6 What if a group practice recruits a physician, and the addition of the new physician results in noncompliance with the "substantially all" test? If a group practice adds a new member who has relocated his or her practice to join the group and if adding that new member would result in the existing group practice not meeting the "substantially all" requirement, the group practice has 12 months following the addition of the new member to comply with the "substantially all" requirement if the following conditions are satisfied:

(1) during this 12-month period the group practice must comply with the "substantially all" requirement if the new member is not counted as a member of the group; and

(2) The new member's employment with, or ownership interest in, the group practice is documented in writing no later than the beginning of his

[93] 60 FR 41932-41933

[94] 60 FR 41934

[95] 42 CFR § 411.352(d)(5)

or her new employment, ownership, or investment.[96]

12.6.4.7 Exception to the "substantially all" test with respect to Health Professional Shortage Areas. The "substantially all" test does not apply to any group practice that is located solely in a Health Professional Shortage Area ("HPSA"). If a group practice is located outside of a HPSA, any time spent by a group practice member providing services in a HPSA should not be used to calculate whether the group practice has met the substantially all test, regardless of whether the member's time in the HPSA is spent in a group practice, clinic, or office setting.[97]

(1) How can the physician find out if he or she is located in a HPSA? A physician interested in determining the location of HPSAs in the U.S. can do so by accessing the HHS Health Services and Services Administration at http://bhpr.hrsa.gov/shortage/index.htm.

12.6.5 Physician-patient encounters. Members of the practice must personally conduct no less than 75 percent of the physician-patient encounters of the practice.[98]

12.6.6 Unified business. The physician practice must be a unified business having at least the following features:

12.5.6.1 Centralized decision-making. The physician practice must have decision-making by a body representative of the physician practice that maintains effective control over the practice's assets and liabilities; and

12.5.6.2 Consolidated operations. The physician practice must have consolidated billing, accounting, and financial reporting operations.[99]

12.6.7 Distribution of expenses and income. The overhead expenses of, and income from, the practice must be distributed according to methods that are determined before the receipt of payment for the services giving rise to the overhead expense or producing the income. Nothing in this section prevents a group practice from adjusting its compensation methodology prospectively, subject to restrictions on the distribution of revenue from DHS required by the Stark Law.[100]

[96] 42 CFR § 411.352(d)(6)(i)

[97] 42 CFR § 411.352(D)(3)

[98] 42 USC § 1395nn(h)(4)(A)(v); 42 CFR § 411.352(h)

[99] 42 CFR § 411.352(f)(1)

[100] 42 USC § 1395nn(h)(4)(A)(iii); 42 CFR § 411.352(e)

12.6.8 Volume or value of referrals. A group generally may not compensate physicians based directly or indirectly on the volume or value of their referrals. However, as further described in section 12.6.8.1 a group practice may in some circumstances compensate physicians using a productivity bonus or via a profit sharing methodology.[101]

12.6.8.1 How can a group practice compensate a physician in the group practice using a productivity bonus? A group practice may compensate a physician in the group practice if the bonus satisfies the following requirements.

(1) The productivity bonus may be based *directly* on DHS personally performed by the referring physician. A physician can receive a bonus directly related to ordered DHS when the DHS are personally performed by the physician.[102]

(a) Example illustrating a productivity bonus based directly on personally performed DHS. Suppose a physician frequently orders ultrasounds for Medicare patients. The physician personally interprets the ultrasounds. The group practice that employs the physician can pay the physician a productivity bonus for providing that the interpretations, e.g., the group practice could at the end of the practice's fiscal year pay the physician a productivity bonus based on the number of ultrasound reads the physician performed over the course of that year.[103]

(2) The productivity bonus may be based *directly* on DHS that are "incident to" services that the referring physician personally performs. A group practice may pay a physician a productivity bonus based directly on DHS that are performed "incident to" services personally performed by the physician.[104] Further information concerning "incident to" requirements can be found in section 60.1 et seq of Medicare Benefit Policy Manual Chapter 15 – Covered Medical and Other Health Services, which can be accessed at http://www.cms.gov/manuals/Downloads/bp102c15.pdf. See also https://www.cms.gov/MLNMattersArticles/downloads/SE0441.pdf from the Medicare Learning Network.

[101] 42 USC § 1395nn(h)(4)(A)(iv); 42 CFR § 411.352(g)

[102] 42 USC § 1395nn(h)(4)(B)(i); 42 CFR § 411.352(i)(1)

[103] See e.g., 66 FR 876

[104] 42 CFR § 411.352(i)(1); see e.g., the discussion at 72 FR 51023-51024

(a) Example illustrative a productivity bonus based directly on DHS performed "incident to" services personally performed by the referring physician. Suppose that, after performing a physical examination of a Medicare patient, a physician member of Group Practice A determines that the patient requires physical therapy services. These physical therapy services are performed according to all of the "incident to" coverage requirements of the Medicare program. Because the physical therapy services are performed "incident to" a service "personally performed" by the physician, Group Practice A may pay the physician a productivity bonus based directly on the provision of those physician therapy services.[105]

(b) However, a physician may not be paid a productivity bonus based directly on DHS referrals on an "incident to" bases when those referrals are for DHS that have their "own separate and independently listed benefit category." CMS has stated that only those services that do not have their own separate and independently listed benefit category may be billed as ''incident to'' a physician service. Based on this rationale, CMS takes the position that diagnostic X-ray tests, diagnostic laboratory tests, and other diagnostic tests, may not be billed as ''incident to." Consequently, a group practice may not pay a physician a productivity bonus that is based directly on such tests, unless the physician personally performed the tests.[106]

(3) A group practice can pay a physician a productivity bonus for DHS that the physician does not personally perform or that are not provided "incident to" the physician's services. A group practice can pay a physician a productivity bonus for DHS that the physician does not personally perform or that are not provided "incident to" the physicians personally performed services, so long as the productivity bonus is ***not directly related*** to the volume or value of the physician's DHS referrals.[107] A productivity bonus must be calculated in a reasonable and verifiable manner that is not directly related to the volume or value of the physician's referrals of DHS.[108] A productivity bonus will be deemed not to relate directly to the volume or value of referrals of DHS if one of the following conditions is met:

[105] See 72 FR 51024

[106] See e.g., the discussion at 72 FR 51061.

[107] 42 CFR § 411.352(i)(1)

[108] 42 CRF § 411.352(i)(3)

(a) the bonus is based on the physician's total patient encounters or relative value units (RVUs);[109]

(b) the bonus is based on the allocation of the physician's compensation attributable to services that are not DHS payable by any Federal health care program or private payer;[110] or

(c) revenues derived from DHS are less than 5 percent of the group practice's total revenues, and the allocated portion of those revenues to each physician in the group practice constitutes 5 percent or less of his or her total compensation from the group practice.[111]

The three methods described above in 12.6.8.1(3) are not exclusive. A group practice can utilize other methodologies to calculate productivity bonuses. However, those methodologies must ensure that bonuses are distributed in a reasonable and verifiable manner that is not directly related to the volume or value of the physician's DHS referrals when those referrals are not "incident to" the referring physician's personally performed services.[112]

12.6.8.2 How can a group practice compensate a physician in the group practice based on a profit-sharing program?

(1) Profit sharing cannot be based on any methodology that is directly related to the volume or value of the physician's referrals. A physician in the group practice may be paid a share of overall profits of the group, provided that the share is not determined in any manner that is *directly* related to the volume or value of referrals of DHS by the physician.[113]

(2) What does it mean to share in "overall profits?" "Overall profits" means the group's entire profits derived from DHS payable by Medicare or Medicaid or the profits derived from DHS payable by Medicare or Medicaid of any component of the group practice that consists of at least five physicians.[114]

[109] 42 CRF § 411.352(i)(3)(i)

[110] 42 CRF § 411.352(i)(3)(ii)

[111] 42 CRF § 411.352(i)(3)(iii)

[112] 42 CRF § 411.352(i)(3)

[113] 42 USC § 1395nn(h)(4)(B)(i)

[114] 42 CRF § 411.352(i)(2)

(3) How overall profits can be divided. Overall profits can be divided in any a reasonable and verifiable manner that is not directly related to the volume or value of a physician's referrals of DHS.[115] The share of overall profits will be deemed not to relate directly to the volume or value of referrals if one of the following conditions is met:

(a) the group's profits are divided per capita (for example, per member of the group or per physician in the group);[116]

(b) revenues derived from DHS are distributed based on the distribution of the group practice's revenues attributed to services that are not DHS payable by any Federal health care program or private payer;[117] or

(c) revenues derived from DHS constitute less than 5 percent of the group practice's total revenues, and the allocated portion of those revenues to each physician in the group practice constitutes 5 percent or less of his or her total compensation from the group.[118]

The distribution methodologies described in 12.6.8.2(3) are not exclusive. A group practice can utilize other profit distribution methodologies, but those methodologies must ensure that profits are divided in a reasonable and verifiable manner that is not directly related to the volume or value of the physician's DHS referrals.[119]

(4) A group practice can implement a profit-sharing methodology with regard to a subgroup of its physicians, so long as the subgroup or "pool" is made up of at least five physicians. A group practice does not have to use the same profit sharing methodology for all of the physicians in the group practice. Instead, the group practice may use different methodologies for practice subgroups that are comprised of at least five (5) physicians. For example, a group practice could organize a pool based on the specialty or location of the physicians involved.[120]

[115] 42 CRF § 411.352(i)(2)

[116] 42 CRF § 411.352(i)(2)(i)

[117] 42 CRF § 411.352(i)(2)(ii)

[118] 42 CRF § 411.352(i)(2)(iii)

[119] 42 CFR § 411.352(i)(2)

[120] 42 CFR § 411.352(i)(2)

12.7 How can physicians in a group practice utilize the physician services exception? The physician services exception protects referrals for DHS physician services within a group practice in the following circumstances.

12.7.1 Referral within the group is permitted when the referred physician service is personally performed by a member of, or a physician in, the same group practice as the referring physician. Suppose Physicians A and B is both members of the same group practice. Suppose also that Physician A refers Medicare inpatients for ultrasound services. Under the physician services exception, Physician B could interpret the result of the ultrasound test and the group practice could bill the Medicare program for the provision of that DHS professional component.[121]

12.7.2 Referral within the group is permitted when the referred physician service is supervised by a member of, or a physician in, the same group practice as the referring physician. Under the physician services exception, the same result would occur as described in 12.7.1 above if Physician B supervised the interpretation of the ultrasound.[122]

12.8 How can a physician in a solo practice or physicians in a group practice utilize the in-office ancillary services exception? The in-office ancillary services exception allows a physician to refer DHS ancillary services (other than durable medical equipment (excluding infusion pumps) and parenteral and enteral nutrients, equipment, and supplies) within his or her practice, i.e., services that are ancillary to the physician's professional services. Physicians in solo as well as Stark Law group practice settings can avail themselves of the in-office ancillary services exception. The in-office ancillary services exception has three general requirements concerning: (1) who can provide the ancillary DHS; (2) where the ancillary DHS must be furnished; and (3) who can bill for the provision of the DHS.

12.8.1 Who can provide the ancillary DHS? The ancillary services that are DHS must be personally performed by either:

(1) the referring physician himself or herself;[123]

(2) a physician who is a member of the same group practice as the referring physician;[124] or

[121] 69 FR 16100.

[122] 69 FR 16100

[123] 42 CFR § 411.355(b)(1)(i)

[124] 42 CFR § 411.355(b)(1)(ii)

(3) an individual who is supervised by the referring physician or, if the referring physician is in a group practice, by another physician in the group practice, provided that the supervision complies with all other applicable Medicare payment and coverage rules for the services.[125]

12.8.1.1 Example 1 illustrating who can provide the ancillary DHS. Suppose that, in the course of examining a patient, a primary care physician takes a tissue sample for later examination. The physician is a member of a group practice which has its own laboratory equipment that is located on the group's premises. The physician sends the tissue sample to the lab, which is supervised by a pathologist pursuant to an independent contractor relationship with the group practice. Under appropriate supervision of the pathologist, a lab technician prepares the tissue for the pathologist's examination. The pathologist then performs the exam, and communicates her findings to the primary care physician. In this example, both the provision of both the technical and professional components of the DHS (the lab test) would be provided in a manner satisfying requirements specified in section 12.8.1.

12.8.2 Where must the DHS be furnished? The DHS must be provided in (1) the same building where the referring physician or member of the group practice provides services that are not related to the furnishing of DHS or (2) in a "centralized building."[126]

12.8.2.1 When are DHS furnished in the "same building" as the referring physician?

(1) What is a "building." In order for a structure to qualify as a building that may be the "same building" in which the referring physician provides services not related to the provision of DHS, the building must be a structure with, or combination of structures that share, a single street address as assigned by the U.S. Postal Service. The Stark Law definition of "building" excludes all exterior spaces (for example, lawns, courtyards, driveways, parking lots) and interior loading docks or parking garages. "Building" does not include a mobile vehicle, van, or trailer.[127]

12.8.2.2 If the structural test is satisfied, there are three separate tests to determine if the DHS are actually furnished in the same building in which the physician provides services unrelated to the provision of DHS.

[125] 42 USC § 1395nn(b)(2)(A)(i); 42 CFR § 411.355(b)(1)(iii)

[126] See 42 USC § 1395nn(b)(2)(A)(ii)

[127] 42 CFR § 411.351

(1) The 35/30-hour per week test. Under this test, referred DHS are performed in the same building as the referring physician if

(a) the building is a building in which the referring physician, or his or her group practice, has an office that is normally open to their patients at least 35 hours per week;[128] and

(b) the referring physician, or one or more members of his or her group, regularly practices medicine and furnishes physician services to patients in that office at least 30 hours per week. [129]

(2) The 8/6 hour per week test. Under this test, DHS is furnished in the same building as the referring physician if:

(a) the patient receiving the DHS usually receives physician services from the referring physician, or members of the referring physician's group practice (if any), in the building;[130]

(b) the referring physician, or the referring physician's group practice, owns or rents an office in the building that is normally open to the physician's or group's patients for medical services at least 8 hours per week;[131] and

(c) the referring physician regularly practices medicine and furnishes physician services to patients at least 6 hours per week.[132]

(3) The 8/6 hour-physician presence test. Under this test, DHS is furnished in the same building as the referring physician if:

(a) the referring physician, or the referring physician's group practice, owns or rents an office in the building that is normally open to the physician's or group's patients for medical services at least 8 hours per week;[133]

[128] 42 CFR § 411.355(b)(2)(i)(A)(1)

[129] 42 CFR § 411.355(b)(2)(i)(A)(2)

[130] 42 CFR § 411.355(b)(2)(i)(B)(1)

[131] 42 CFR § 411.355(b)(2)(i)(B)(2)

[132] 42 CFR § 411.355(b)(2)(i)(B)(3)

[133] 42 CFR § 411.355(b)(2)(i)(C)(2)

(b) the referring physician, or one or more members of the referring physician's group practice, regularly practices medicine and furnishes physician services to patients at least 6 hours per week;[134]

(c) the referring physician (1) is present in the office and orders the DHS during a patient visit; or (2) the referring physician, or a member of the referring physician's group practice (if any), is present in the office while the DHS is furnished.[135]

12.8.2.3 When are DHS furnished in a "centralized building?" A centralized building may be all or part of a building, a mobile vehicle, van, or trailer that is owned or leased by the group practice. In order to qualify as a centralized building, the building (or part of the building), mobile vehicle, van, or trailer must: (1) be owned or leased by the group practice on a full-time basis (that is, 24 hours per day, 7 days per week, for a term of not less than 6 months); and (2) be used exclusively by the group practice. A group practice may provide services to other providers or suppliers (for example, purchased diagnostic tests) in the group practice's centralized building. A group practice may have more than one centralized building.[136]

12.8.3 Who must bill for the DHS? In order to satisfy the in-office ancillary services exception, only the following may bill for the DHS[137]:

(1) the physician performing or supervising the service;[138]

(2) the group practice of which the performing or supervising physician is a member under a billing number assigned to the group practice;[139]

(3) the group practice if the supervising physician is a "physician in the group practice" under a billing number assigned to the group practice;[140]

[134] 42 CFR § 411.355(b)(2)(i)(C)(3)

[135] 42 CFR § 411.355(b)(2)(i)(C)(1)

[136] 42 CFR § 411.351; 42 CFR § 411.355(b)(2)(ii) and (iii)

[137] See 42 USC § 1395nn(b)(2)(B)

[138] 42 CFR § 411.355(b)(3)(i)

[139] 42 CFR § 411.355(b)(3)(ii)

[140] 42 CFR § 411.355(b)(3)(iii)

(4) an entity that is wholly owned by the performing or supervising physician or by that physician's group practice under the entity's own billing number or under a billing number assigned to the physician or group practice;[141] or

(5) an independent third party billing company acting as an agent of the physician, group practice, or entity.[142]

12.8.4 Disclosure requirements applicable to the in-office ancillary services exception created by the Patient Protection and Affordable Care Act.

12.8.4.1. General requirement under the Patient Protection and Affordable Care Act. Section 6003 of the Patient Protection and Affordable Care Act (ACA) added a new patient disclosure to the in-office ancillary services exception.[143] Under the ACA, at the time a physician makes a referral for magnetic resonance imaging (MRI), computed tomography (CT), positron emission tomography (PET), or any other designated health services specifies that the Secretary of the U.S. Department of Health and Human Services determines appropriate, the physician must inform the patient in writing at the time of the referral that the patient may obtain the referred DHS from an entity other than the one in which the physician has a financial relationship. When making this written notification, the physician must provide the patient with a written list of certain other persons who furnish the DHS in the area in which the patient resides.

12.8.4.2 Final regulatory requirements. CMS published final regulations implementing section 6003 in the final 2011 Medicare Physician Fee Schedule.[144] Under the final regulations application to section 6003, physicians referring a Medicare patient for MRI, CT, and PET services under the in-office ancillary exception must provide written notice to the patient at the time of the referral that the patient may receive the MRI, CT, or PET services from a Medicare *supplier* other than the referring physician or the referring physician's group practice. The notice must satisfy the following requirements. disclosure obligations became effective January 1, 2011.

(a) The notice must list alternative suppliers, if possible. The written notice must include a list of at least 5 other Medicare suppliers that are located within a 25-mile radius of the referring physician's office that provide the MRI, CT, or PET services for which the patient is being

[141] 42 CFR § 411.355(b)(3)(iv)

[142] 42 CFR § 411.355(b)(3)(v)

[143] Section 6003 is codified at 42 USC § 1395nn(b)(2)(B

[144] 42 CFR § 411.355(b)(7)

referred.[145] "Suppliers" includes physicians but not hospitals, which are Medicare "providers." If there are fewer than 5 other suppliers located within a 25-mile radius of the physician's office location at the time of the referral, the physician must list all of the other suppliers of the imaging service that are present within a 25-mile radius of the referring physician's office location. However, no written list of alternate suppliers is required if no other suppliers provide the services for which the patient is being referred within the 25-mile radius. [146]

(b) The notice should be reasonably understandable. The notice should be written in a manner sufficient to be reasonably understood by all patients and should include for each supplier on the list, at a minimum, the supplier's name, address, and telephone number.[147]

(c) No signature requirement, but the physician must be able to demonstrate compliance. The referring physician is not required to have the patient sign the disclosure. Nor is the physician required to place the specific disclosure in the patient's medical record. However, the physician must be able to demonstrate that he or she has complied with the disclosure requirement. One way to demonstrate this compliance would be to indicate in the patient's medical record that such disclosure was made.[148]

XIII. Exceptions applicable only to ownership/investment interests. A number of Stark Law exceptions apply to ownership/investment interests but not to compensation arrangements. These exclude from the Stark Law ownership/investment interests in an entity that a physician or the family member has: (1) though publicly-traded securities; (2) though mutual funds; (3) in a rural area; (4) in a "whole" hospital; and (5) in a hospital located in Puerto Rico. This document will briefly discuss (1) through (4).

13.1 Exception when ownership/investments interest in an entity is held though publicly-traded securities. A physician can refer a Medicare patient to an entity in which the physician has an ownership/investment interest for DHS when that ownership/investment interest is through publicly-traded securities. This exception applies when the securities are:

(1) listed for trading on the New York Stock Exchange, the American Stock Exchange, or any regional exchange in which quotations are published on a daily

[145] 42 CFR § 411.355(b)(7)(i)

[146] 42 CFR § 411.355(b)(7)(ii)

[147] 42 CFR § 411.355(b)(7)(i)

[148] 75 FR 73604-73605

basis, or foreign securities listed on a recognized foreign, national, or regional exchange in which quotations are published on a daily basis;[149] *or*

(2) traded under an automated interdealer quotation system operated by the National Association of Securities Dealers;[150] *and*

(3) in a corporation that had stockholder equity exceeding $75 million at the end of the corporation's most recent fiscal year or on average during the previous 3 fiscal years.[151]

13.1.1 Example illustrating the application of the exception for ownership via publicly-traded securities. A physician inherits stock in a publicly traded clinical lab corporation whose shares are traded on the New York Stock Exchange and whose shareholder equity satisfies the $75 million test under (3) above. The corporation owns and operates a lab close to where the physician practices. The exception permits the physician to refer Medicare beneficiaries to the local lab for the provision of DHS.

13.2 Exception when the physician's ownership interest is though a mutual fund. A physician can refer a Medicare patient to an entity in which the physician has an ownership/investment interest when that interest is through a mutual fund. The exception applies if the mutual fund had, at the end of its most recent fiscal year, or on average during the previous 3 fiscal years, total assets exceeding $75 million.[152]

13.2.1 Example illustrating the application of the exception for ownership via a mutual fund. Suppose a physician has $20,000 invested in a mutual fund. The mutual fund, in turn, holds stock in a publicly traded clinical lab corporation that operates locally. The mutual fund satisfies the conditions specified in section 13.2. The exception permits the physician to refer Medicare patients to the lab for the provision of DHS.

13.3 Exception when the physician's ownership/investment interest is in a "rural provider." A physician may refer Medicare beneficiaries to an entity for the provision of DHS if the entity qualifies as a "rural provider." To qualify as a "rural provider," substantially all, (i.e., not less than 75%) of the DHS that are furnished by the entity must be furnished to individuals who reside in a rural area.[153] "Rural area" is any area outside of a Metropolitan Statistical Area. [154]

[149] 42 USC § 1395nn(c)(1)(A)(i); 42 CFR § 411.356(a)(1)(i)

[150] 42 USC § 1395nn(c)(1)(B); 42 CFR § 411.356(a)(1)(ii)

[151] 42 USC § 1395nn(c)(2); 42 CFR § 411.356(a)(2)

[152] 42 CFR § 411.356(b)

[153] 42 CFR § 411.356(c)(1)

[154] 42 CFR § 411.351

13.3.1 What does "substantially all" mean? An entity provides "substantially all" of its DHS to persons living in a rural area when at least 75 percent of the DHS that the entity provides are furnished to persons who live in a rural area.[155]

13.3.2 What is a "rural area?" A "rural area" means any area that has not been designated as Metropolitan Statistical Area ("MSA") by the U.S. Office of Management and Budget. Individuals residing in a Micropolitan Statistical Area live in a "rural area" for Stark Law purposes because Micropolitan Statistical Areas do not fall within the definition of an MSA.[156]

13.3.3. How can a physician find out if patients live in a rural area? The list of current MSAs can be accessed at http://www.census.gov/population/www/metroareas/metrodef.html.

13.3.5. The rural provider exception cannot be used in lieu of the whole hospital exception. Physicians with ownership or investment interests in entire hospitals cannot except DHS referrals to that hospital using the rural provider exception. Instead, such physicians must use the exception described in section 13.4 below.[157]

13.4 Exception when the ownership/investment interest is in a hospital (the "whole hospital" exception). A physician (or family member) with a direct or an indirect ownership or investment interest in an entire hospital may make a DHS referral to a hospital. Prior to the enactment of the ACA, a physician could refer a Medicare beneficiary for DHS to a hospital in which the physician had an ownership/investment interest so long as requirements 13.4.1 and 13.4.2 were satisfied. Section 6001 of the ACA added a number of additional requirements to the "whole hospital" exception, which are described below from section 13.4.3 to 13.4.8.[158] In order to qualify for this exception, however, the following requirements must be satisfied.

13.4.1 Authorized to provide services. The referring physician must be authorized to perform services at the hospital, e.g., be a member of the hospital's

[155] 42 CFR § 411.356(c)(1)

[156] 42 CFR 412.62(f)(iii)

[157] 42 USC § 1395nn(i)

[158] Section 6001 is codified at 42 U.S.C. §§ 1395nn(d)(2) and 1395nn(i). Relevant regulations are located at 42 CFR § 411.356(c) and 42 C.F.R. § 411.362.

medical staff.[159]

13.4.2 Ownership in the hospital itself. The referring physician's ownership or investment interest must be in the hospital itself, i.e., the entire hospital, and not merely in a subdivision of the hospital.[160]

13.4.3. Provider agreement by December 31, 2010. The hospital must have a provider agreement with the Medicare program in effect by December 31, 2010.[161]

13.4.4 Ownership or investment on December 31, 2011. The hospital had physician ownership or investment on December 31, 2011.[162]

13.4.5 Limitation on the hospital's expansion. The hospital cannot expand the number of licensed operating rooms, procedure rooms, and beds beyond the number of operating rooms, procedure rooms, and beds for which the hospital was licensed on March 23, 2010.[163]

13.4.5.1 Exception to prohibition on expansion of facility capacity. The ACA requires the Secretary of DHHS to develop a process under which an "applicable hospital" or a "high Medicaid facility" may apply for an exception to the limitation on hospital expansion.

(1) What is an "applicable hospital?" An "applicable hospital" is a hospital:

(a) that is located in a county in which the percentage increase in the population during the most recent 5-year period (as of the date on which the hospital makes an application for an expansion) is at least 150 percent of the percentage increase in the population growth of the State in which the hospital is located during that period, as estimated by Bureau of the Census;[164]

(b) whose annual percent of total inpatient admissions that represent

[159] 42 USC § 1395nn(d)(3)(A); 42 CFR § 411.356(c)(3)(i)

[160] 42 USC § 1395nn(d)(3)(C); 42 CFR § 411.356(c)(3)(iii)

[161] 42 USC § 1395nn(i)(1)(A)(ii)

[162] 42 USC § 1395nn(i)(1)(B)

[163] 42 USC § 1395nn(i)(A)(ii)

[164] 42 USC § 1395nn(i)(3)(E)(i)

inpatient admissions under the Medicaid program is equal to or greater than the average percent with respect to such admissions for all hospitals located in the county in which the hospital is located;[165]

(c) that does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries;[166]

(d) that is located in a State in which the average bed capacity in the State is less than the national average bed capacity;[167] and

(e) that has an average bed occupancy rate that is greater than the average bed occupancy rate in the State in which the hospital is located.[168]

(2) What is a "high Medicaid facility?" A "high Medicaid facility" is a hospital that:

(a) is not the sole hospital in a county;[169]

(b) with respect to each of the 3 most recent years for which data are available, has an annual percent of total inpatient admissions that represent inpatient admissions under the Medicaid program that is estimated to be greater than such percent with respect to such admissions for any other hospital located in the county in which the hospital is located;[170] and

(c) does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries.[171]

(3) What is the definition of the term "procedure rooms?" "Procedure

[165] 42 USC § 1395nn(i)(3)(E)(ii)

[166] 42 USC § 1395nn(i)(3)(E)(iii)

[167] 42 USC § 1395nn(i)(3)(E)(iv)

[168] 42 USC § 1395nn(i)(3)(E)(v)

[169] 42 USC § 1395nn(i)(3)(F)(i)

[170] 42 USC § 1395nn(i)(3)(F)(ii)

[171] 42 USC § 1395nn(i)(3)(F)(iii)

rooms" includes rooms in which catheterizations, angiographies, angiograms, and endoscopies are performed, except such term shall not include emergency rooms or departments (exclusive of rooms in which catheterizations, angiographies, angiograms, and endoscopies are performed).[172]

(4) If a hospital is granted an exception from the prohibition on expansion, just how much can the hospital expand? If the Secretary of DHHS grants an applicable hospital an exception to the limitation on expansion, an applicable hospital will be permitted to increase the number of operating rooms, procedure rooms, and beds beyond what the number of operating rooms, procedure rooms, and beds for which the hospital was licensed as of March 23, 2010. If the hospital did not have a Medicare provider agreement in effect on March 23, 2010, but did have such a Medicare agreement on December 31, 2010, the hospital may increase the number of operating rooms, procedure rooms, and beds beyond what the hospital was licensed to have on the effective date of the agreement. However, no increase can exceed the number of operating rooms, procedure rooms, and beds for which the hospital is licensed to the extent such increase would exceed 200 percent of the number of operating rooms, procedure rooms, and beds for which the hospital was licensed as of March 23, 2010, or on the effective date of the Medicare agreement.[173]

(5) Expansion is limited to facilities on the main campus of the hospital. If the Secretary of DHHS grants an applicable hospital an exception to the limitation on expansion, any increase in the number of operating rooms, procedure rooms, and beds for which the hospital is licensed may only occur in facilities on the main campus of the hospital.[174]

(6) An applicable hospital may apply for an exception once every two years. An applicable hospital may apply for an exception up to once every 2 years.[175]

13.4.6 Conflict of interest.

13.4.6.1 Disclosures to the Secretary of DHHS. The hospital must annually submit to the Secretary of DHHS a report containing a detailed description of:

[172] 42 USC § 1395nn(i)(3)(G)

[173] 42 USC § 1395nn(i)(3)(C)(i)-(iii)

[174] 42 USC § 1395nn(i)(3)(D)

[175] 42 USC § 1395nn(i)(3)(B)

(1) the identity of each physician owner or investor and any other owners or investors of the hospital;[176] and

(2) the nature and extent of all ownership and investment interests in the hospital.[177]

13.4.6.2 Disclosure to the patient. The hospital must require any referring physician owner or investor in the hospitals to disclose the following to a patient being referred to the hospital, within a time period that permits the patient to make a meaningful decision regarding the receipt of care:

(1) the physician's ownership or investment interest in the hospital;[178] and

(2) if applicable, any such ownership or investment interest of the treating physician.[179]

The disclosure must be made within a time period that permits the patient to make a meaningful decision regarding how and where the patient will seek treatment.

13.4.6.3 No conditioning of referrals. The hospital cannot condition any physician ownership or investment interests either directly or indirectly on a physician owner or investor making or influencing referrals to the hospital or otherwise generating business for the hospital.[180]

13.4.6.4 Disclosure to the public. The hospital must disclose the fact physicians own or invest in the hospital:

(1) on any public website for the hospital;[181] and

(2) in any public advertising for the hospital.[182]

[176] 42 USC § 1395nn(i)(1)(C)(i)(I)

[177] 42 USC § 1395nn(i)(1)(C)(i)(II)

[178] 42 USC § 1395nn(i)(1)(C)(ii)(I)

[179] 42 USC § 1395nn(i)(1)(C)(ii)(II)

[180] 42 USC § 1395nn(i)(1)(C)(iii)

[181] 42 USC § 1395nn(i)(1)(C)(iii)(I)

[182] 42 USC § 1395nn(i)(1)(C)(iv)(II)

13.4.6.5 Financial relationship between the physician and hospital. The financial relationship between the investing or owning physician must satisfy the following requirements:

(1) the percentage of the total value of the ownership or investment interests held by physician investors in the aggregate in the hospital, or in an entity whose assets include the hospital, cannot be greater than the percentage that existed as of March 23, 2010;[183]

(2) any ownership or investment interests that the hospital offers to a physician owner or investor cannot be offered on more favorable terms than the terms offered to a person who is not a physician owner or investor;[184]

(3) the hospital (or any owner or investor in the hospital) cannot directly or indirectly provide loans or financing for any investment in the hospital by a physician owner or investor;[185]

(4) the hospital (or any owner or investor in the hospital) cannot directly or indirectly guarantee a loan, make a payment toward a loan, or otherwise subsidize 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;[186]

(5) ownership or investment returns must be distributed to each owner or investor in the hospital in an amount that is directly proportional to the ownership or investment interest of such owner or investor in the hospital;[187]

(6) physician owners and investors cannot receive, 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;[188] and

[183] 42 USC § 1395nn(i)(1)(D)(i)

[184] 42 USC § 1395nn(i)(1)(D)(ii)

[185] 42 USC § 1395nn(i)(1)(D)(iii)

[186] 42 USC § 1395nn(i)(1)(D)(iv)

[187] 42 USC § 1395nn(i)(1)(D)(v)

[188] 42 USC § 1395nn(i)(1)(D)(vi)

(7) the hospital cannot offer 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.[189]

13.4.7 Notifying patients that a physician will not be on hospital premises continually. If the hospital admits a patient, but does not have a physician available on the hospital premises during all of the hours in which the hospital is providing services to the patient, the hospital must, prior to admitting the patient:

(1) disclose to the patient the fact that a physician will not be available on the hospital's premises during all of the hours in which the hospital is providing services to the patient;[190] and

(2) obtain from the patient a signed acknowledgment that the patient understands that a physician will not be continually present.[191]

13.4.8 Hospital capacity. The hospital must have the capacity to:

(1) provide assessment and initial treatment for patients;[192] and

(2) refer and transfer patients to hospitals with the capability to treat the needs of the patient involved.[193]

13.4.9 Limitation on the conversion of ambulatory surgery centers. The hospital cannot have been converted from an ambulatory surgical center to a hospital on or after March 23, 2010.[194]

XIV. Three key concepts associated with a number of exceptions applicable to compensation arrangements. The fair market value, "volume or value," and "set in advance" are key concepts which often play a central role in whether or not a compensation arrangement satisfies a Stark Law exception.

[189] 42 USC § 1395nn(i)(1)(D)(vii)

[190] 42 USC § 1395nn(i)(1)(E)(i)(I)

[191] 42 USC § 1395nn(i)(1)(E)(i)(II)

[192] 42 USC § 1395nn(i)(1)(E)(ii)(I)

[193] 42 USC § 1395nn(i)(1)(E)(ii)(II)

[194] 42 USC § 1395nn(i)(1)(F)

14.1. The "fair market value" requirement. The concept of "fair market value" is a core component of many of the Stark Law exceptions for compensation arrangements. The following compensation arrangement exceptions have a fair market value requirement: academic medical centers (this exception also applies to ownership/investment interests); rental of office space; rental of equipment; bona fide employment relationships; personal service arrangements; isolated transactions; group practice arrangements with a hospital; payments by a physician; fair market value compensation; indirect compensation arrangements.

14.1.1 The Stark Law's definition of "fair market value." Under the Stark Law, "fair market value" means the value in arm's-length transactions, consistent with the general market value. "General market value" means the price that an asset would bring as the result of bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement. Usually, the fair market price is the price at which bona fide sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in bona fide service agreements with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals.[195]

14.1.1.1 Additional specifications with respect to certain leases. With respect to the exceptions for office space leases, equipment leases, and equipment leases falling under the exception for fair market value compensation, "fair market value" means the value of rental property for general commercial purposes (not taking into account its intended use). In the case of a lease of space, this value may not be adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor when the lessor is a potential source of patient referrals to the lessee. For purposes of this definition, a rental payment does not take into account intended use if it takes into account costs incurred by the lessor in developing or upgrading the property or maintaining the property or its improvements.[196]

14.1.2 The Stark Law's definition of "fair market value." The Stark Law has a specific definition of "fair market value" that can differ significantly from how fair market value is determined in other commercial contexts. Failure to apply the

[195] 42 USC § 1395nn(h)(3); 42 CFR § 411.351

[196] 42 CFR § 411.351

specific Stark definition can result in a failure to satisfy a Stark Law exception. In the Stark Law, "fair market value" means more than just the arms-length negotiations that might suffice in other commercial contexts. A case illustrating this point is *U.S. ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88, 94 (3d Cir.2009), which is discussed more fully at 14.7.4 below. In *Kosenske*, the lower court had concluded that a compensation arrangement between a hospital that operated a pain clinic and physicians who performed pain management services at the clinic satisfied the fair market value requirement of the personal service arrangement exception because the consideration involved in the arrangement was the result of negotiations between unrelated parties that, by definition, reflected fair market value.[197] The appeals court disagreed, noting that the Stark Law's definition of "fair market value" means "the price that an asset would bring as the result of bona fide bargaining between well-informed buyers and sellers *who are not otherwise in a position to generate business for the other party"*, and the hospital and the anesthesia group were in a position to generate business for one another.[198] The court in *U.S. ex rel. Singh v. Bradford Regional Medical Center*, 752 F.Supp.2d 602 (W.D.Pa. 2010), reached a similar conclusion by rejecting the notion that a practice arrived as a result of a back and forth negotiation between a physician group and a hospital was sufficient by itself to satisfy the Stark Law's fair market value requirements.[199]

14.2 The "volume or value" or "other business generated" requirement. Several Stark Law exceptions applicable to compensation arrangements contain a requirement that the compensation arrangement cannot take into account the volume or value of any referrals or other business generated between the parties. The following compensation arrangement exceptions contain this "volume or value requirement: rental of office space; rental of equipment; bona fide employment relationships; personal service arrangements; physician recruitment; isolated transactions; certain arrangements with hospitals; group practice arrangements with a hospital; charitable donations by a physician; nonmonetary compensation; fair market value compensation; medical staff incidental benefits; indirect compensation arrangements; retention payments in underserved areas; community-wide health information systems; electronic prescribing items and services; electronic health records items and services.

14.3 The "set in advance" requirement. A number of exceptions for direct compensation arrangement exceptions require that the compensation involved must be "set in advance." Under the Stark Law, compensation is "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

[197] Id. at 96

[198] Id. at 97

[199] Id. at 623-624

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.[200] The following compensation arrangements contain a "set in advance" requirement: academic medical centers (this exception also applies to ownership/investment interests); rental of office space; rental of equipment; personal service arrangements; fair market value compensation.

14.3.1. Unit-based compensation can be deemed to not take into account the volume or value of referrals. 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.[201] However, as is more fully discussed below, unit-based compensation methodologies are no longer permitted for leases of office space or equipment under the exceptions for: rental of office space; rental of equipment; fair market value compensation; and indirect compensation arrangements.

14.3.2 Unit-based compensation can be deemed to not take into account "other business generated between the parties. Unit-based (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).[202] However, as is more fully discussed below, unit-based compensation methodologies are no longer permitted for leases of office space or equipment under the exceptions for: rental of office space; rental of equipment; fair market value compensation; and indirect compensation arrangements.

XV. Exceptions that apply when the referring physician has a *direct* compensation

[200] 42 CFR § 411.354(d)(1)

[201] 42 CFR § 411.354(d)(2)

[202] 42 CFR § 411.354(d)(3)

arrangement with the DHS entity.

15.1 List of exceptions applicable to direct compensation arrangements. A number of Stark Law exceptions permit a physician to refer a Medicare beneficiary to an entity for the provision of DHS notwithstanding the existence of a direct compensation arrangement between the physician and the entity These exceptions do not apply to physician ownership/investment interests in the entity. The following are all of the Stark Law exceptions that apply to direct compensation arrangements:

(1) rental of office space;[203]

(2) rental of equipment;[204]

(3) bona fide employment relationships;[205]

(4) personal service arrangements;[206]

(5) remuneration provided by a hospital to a physician if such remuneration does not relate to the provision of designated health services;[207]

(6) physician recruitment;[208]

(7) isolated transactions;[209]

(8) group practice arrangements with a hospital;[210]

(9) payments by a physician for items and services;[211]

(10) charitable donations by a physician;[212]

[203] 42 USC § 1395nn(e)(1)(A); 42 CFR § 411.357(a)

[204] 42 USC § 1395nn(e)(1)(B); 42 CFR § 411.357(b)

[205] 42 USC § 1395nn(e)(2); 42 CFR § 411.357(c)

[206] 42 USC § 1395nn(e)(3); 42 CFR § 411.357(d)

[207] 42 USC § 1395nn(e)(4); 42 CFR § 411.357(g)

[208] 42 USC § 1395nn(e)(5); 42 CFR § 411.357(e)

[209] 42 USC § 1395nn(e)(6); 42 CFR § 411.357(f)

[210] 42 USC § 1395nn(e)(7); 42 CFR § 411.357(h)

[211] 42 USC § 1395nn(e)(8); 42 CFR § 411.357(i)

(11) nonmonetary compensation;[213]

(l2) fair market value compensation;[214]

(13) medical staff incidental benefits;[215]

(14) risk-sharing arrangements;[216]

(15) compliance training;[217]

(16) referral services;[218]

(17) obstetrical malpractice insurance subsidies;[219]

(18) professional courtesy;[220]

(19) retention payments in underserved areas;[221]

(20) community-wide health information systems;[222]

(21) electronic prescribing items and services;[223] and

[212] 42 CFR § 411.357(j)

[213] 42 CFR § 411.357(k)

[214] 42 CFR § 411.357(l)

[215] 42 CFR § 411.357(m)

[216] 42 CFR § 411.357(n)

[217] 42 CFR § 411.357(o)

[218] 42 CFR § 411.357(q)

[219] 42 CFR § 411.357(r)

[220] 42 CFR § 411.357(s)

[221] 42 CFR § 411.357(t)

[222] 42 CFR § 411.357(u)

[223] 42 CFR § 411.357(v)

(22) electronic health records items and services.[224]

This document will discuss some of the more commonly used exceptions listed above.

15.3.1 Some direct compensation arrangements prohibit the use of "per-unit," per-click, or percentage-based formulas. Notwithstanding the Stark Law's description of "set in advance" in section 14.3, four exceptions for compensation arrangements do not permit the use of "per-unit," "per click," or percentage-based compensation formulas. These exceptions are the exceptions for: (1) the rental of office space; (2) the rental of equipment; (3) fair market value compensation; and (4) indirect compensation arrangements. These four exceptions do, however, permit the use of time-based formulae, so long as the time periods involved cover a sufficient length of time, i.e., to constitute a legitimate block lease. This issue is discussed in further detail below.

15.4 Exception when the direct compensation arrangement is in the form of payments for the rental of office space. A physician may refer a Medicare beneficiary to an entity for the provision of DHS in cases where the compensation arrangement between the physician and entity takes the form of payments to rent office space.

15.4.1 Requirements of the rental of office space exception. To satisfy the rental of office space exception, the rental arrangement must satisfy the following requirements.

15.4.1.1 Written agreement specifying rented premises. The rental agreement must be set out in writing, signed by the parties, and specify the premises covered by the agreement.[225]

15.4.1.2 The term of the lease must be for at least one year. The term of the agreement must be for at least 1 year. 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.[226]

15.4.1.3 The leased space must be reasonable and necessary. The space rented or leased cannot exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental**.**[227]

[224] 42 CFR § 411.357(w)

[225] 42 USC § 1395nn(e)(1)(A)(i); 42 CFR § 411.357(a)(1)

[226] 42 USC § 1395nn(e)(1)(A)(iii); 42 CFR § 411.357(a)(2)

[227] 42 USC § 1395nn(e)(1)(A)(ii); 42 CFR § 411.357(a)((3)

15.4.1.4 The lease must be commercially reasonable. The agreement must commercially reasonable even if no referrals were made between the lessee and the lessor.[228]

15.4.1.5 The leased space must be exclusively used by the lessee. The space rented or leased must be used exclusively by the lessee when being used by the lessee, 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.[229]

15.4.1.6 "Set in advance." The rental charges over the term of the lease or rental agreement must set in advance.[230]

15.4.1.7 Fair market value. The rental charges over the term of the lease or rental agreement must be consistent with fair market value.[231]

15.4.2 Example of an application of the rental of office space exception. Suppose that a medical group rents office space in a medical building that is owned by a hospital to which physician in the group refer Medicare patients for the provision of DHS. The office lease payments create a compensation arrangement between the group's physicians and the hospital. However, if the lease satisfies the exception's requirements, the group's physicians may refer Medicare patients to the hospital for DHS notwithstanding that compensation arrangement.

15.4.3 Prohibited methods of determining rental or lease charges. The rental charges over the term of the agreement cannot be determined:

(1) in a manner that takes into account the volume or value of any referrals or other business generated between the parties; [232] or

(2) 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;[233] or

[228] 42 USC § 1395nn(e)(1)(A)(v)

[229] 42 USC § 1395nn(e)(1)(A)(ii); 42 CFR § 411.357(a)(3)

[230] 42 USC § 1395nn(e)(1)(A)(iv); 42 CFR § 411.357(a)(4)

[231] 42 USC § 1395nn(e)(1)(A)(iv); 42 CFR § 411.357(a)(4)

[232] 42 USC § 1395nn(e)(1)(A)(iv); 42 CFR § 411.357(a)(5)(i)

[233] 42 CFR § 411.357(a)(5)(ii)(A)

(b) per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.[234]

15.4.3.1 What is a "per unit of service rental charge?" In a "per unit" rental payment arrangement for office space, lease payments are made only when the leased office space is used. "Per unit" rental payments may sometimes be referred to as "per click" or "on demand" rental payments.

(1) Example of an arrangement not satisfying the exception for the rental of office space because of the prohibition on so-called "per-unit" based lease payments. Suppose a hospital owns MRI equipment that is located in a suite in a medical office building. Suppose a physician group in the community pays the hospital a fixed amount of money for use of the suite every time an MRI is performed on a patient that the group refers to the MRI. The fixed payment here would be an example of a "per unit" charge for use of the office space in which the MRI is located. Accordingly, this type of rental arrangement for the lease of office space would not satisfy the requirements of the rental of office space exception.[235]

15.4.3.4 What is the difference between a "per-unit" or "per-click" lease payment and a "block lease" and why is the difference important? Although the Stark Law prohibits the use of "per-unit" or "per click" payments with respect to the exceptions for office space rentals, equipment rentals, fair market value compensation, and indirect compensation arrangements, CMS has indicated that some "block time" leasing arrangements may be of sufficient duration to not raise concerns associated with "per unit" or "per click" leases.[236] Rather than the lessee paying the lessor only when office space or equipment is actually used, which is the case under a "per- unit" or "per-click" lease arrangement, in a block lease the lessee pays the lessor for a period of time for the use of the office space or equipment, regardless of whether or not the lessee actually uses the equipment.

15.4.3.5 What period of time must a lease cover in order to quality as a block lease rather than a "per-unit" or "per-click" lease arrangement? CMS appears to suggest that a "block time" lease of a duration greater than

[234] 42 CFR § 411.357(a)(5)(ii)(B)

[235] See the discussion starting at 73 FR 48713

[236] See 73 FR 48719-48720

four hours once a week may be of a sufficient length to not fall under the "per-unit" or "per-click" prohibition.[237]

15.4.4 Protection for certain holdover leases. A holdover month-to-month lease can satisfy the exception so long as:

(1) no more than 6 months have passed since the expiration of the immediately preceding lease:

(2) the holdover lease satisfies the other requirements of the exception; and

(3) the holdover lease is on the same terms and conditions as the immediately preceding agreement.[238]

15.5 Exception when the compensation arrangement is in the form of a payment for the rental of equipment. A physician may refer a Medicare beneficiary to an entity for the provision of DHS in cases where compensation arrangement between the physician and entity takes the form of payments to rent equipment.

15.5.1 Requirements of the rental of equipment exception. To satisfy the equipment rental exception, the rental arrangement must satisfy the following requirements.

15.5.1.1 Written agreement specifying leased equipment. The rental or lease agreement must be set out in writing, signed by the parties, and specify the equipment covered by the lease agreement.[239]

15.5.1.2 The term of the lease must be for at least one year. The agreement must be for a term of at least 1 year. 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.[240]

15.5.1.3 The leased equipment must be reasonable and necessary. The equipment rented or leased cannot exceed what is reasonable and necessary for the legitimate business purposes of the lease or rental.[241]

15.5.1.4 The lease must be commercially reasonable. The lease must be commercially reasonable even if no referrals were made between the lessee and lessor.[242]

[237] 73 FR 48720

[238] 42 CFR § 411.357(a)(7)

[239] 42 USC § 1395nn(e)(1)(B)(i); 42 CFR § 411.357(b)(1)

[240] 42 USC § 1395nn(e)(1)(B)(iii); 42 CFR § 411.357(b)(3)

[241] 42 USC § 1395nn(e)(1)(B)(ii); 42 CFR § 411.357(b)(2)

[242] 42 USC § 1395nn(e)(1)(B)(v); 42 CFR § 411.357(b)(5)

15.5.1.5 The leased equipment must be exclusively used by the lessee. The equipment must be used exclusively by the lessee when being used by the lessee and cannot be shared with or used by the lessor or any person or entity related to the lessor.[243]

15.5.1.6 "Set in advance." The rental charges over the term of the agreement must be set in advance.[244]

15.5.1.7 Fair market value. The rental charges over the term of the lease or rental agreement must be consistent with fair market value.[245]

15.5.2 Example of an arrangement satisfying the exception for rental of equipment. Suppose a group practice operates an office on the third floor of a medical office building owned by a hospital. Suppose that the first floor of the building contains high-end clinical laboratory equipment that the hospital owns. The hospital uses the equipment for its own patients but also leases its use to physicians in the community. If all of the requirements of the exception for rental of equipment are satisfied, group practice physicians could refer Medicare patients for the provision of DHS to the hospital even though a compensation arrangement, i.e., the group practice's lease payments to the hospital, exists between the hospital and the practice.

15.5.3 Prohibited methods of determining rental or lease charges. The rental charges over the term of the agreement cannot be determined:

(1) In a manner that takes into account the volume or value of any referrals or other business generated between the parties;[246] or

(2) 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;[247] or

(b) per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.[248]

15.5.4 Protection for certain holdover leases. A holdover month-to-month lease for the equipment can satisfy the exception so long as:

[243] 42 USC § 1395nn(e)(1)(B)(ii); 42 CFR § 411.357(b)(2)

[244] 42 USC § 1395nn(e)(1)(B)(iv); 42 CFR § 411.357(b)(4)

[245] 42 USC § 1395nn(e)(1)(B)(iv); 42 CFR § 411.357(b)(4)

[246] 42 USC § 1395nn(e)(1)(B)(iv); 42 CFR § 411.357(b)(4)(i)

[247] 42 CFR § 411.357(b)(4)(ii)(A)

[248] 42 CFR § 411.357(b)(4)(ii)(B)

(1) no more than 6 months have passed since the expiration of the immediately preceding lease:

(2) the holdover lease satisfies the other requirements of the exception for lease of rental charges; and

(3) the holdover lease is on the same terms and conditions as the immediately preceding agreement.[249]

15.6 The exception for bona fide employment relationships. Notwithstanding the Stark Law's prohibition against DHS referrals in the presence of compensation arrangements, a physician may refer a Medicare beneficiary to an entity for the provision of DHS in cases where compensation arrangement between the physician and entity is part of a bona fide employment relationship.

15.6.1 Requirements of the bona fide employment relationship exception. To satisfy the bona fide employment relationship exception, the employment relationship must satisfy the following requirements. Note that, unlike the exceptions for the rental of office space and equipment, as well as the exception for personal services arrangements, the bona fide employment relationship exception need not be in writing.

15.6.1.1 Identifiable services. The physician's employment must be for identifiable services.[250]

15.6.1.2 Commercial reasonableness. The remuneration provided to the physician must be commercially reasonable even if no referrals were made to the employer.[251]

15.6.1.3 Fair market value. The amount of the remuneration that the physician receives must be consistent with the fair market value of the services provided by the physician.[252]

15.6.1.4 General rule—remuneration cannot reflect volume or value of referrals. Except as described in section 15.6.1.4(1) below, the amount of the remuneration that the physician employee receives cannot be determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the physician.[253]

(1) Remuneration can include productivity bonuses for DHS that are personally performed by the physician. Although remuneration paid to

[249] 42 CFR § 411.357(b)(6)

[250] 42 USC § 1395nn(e)(2)(A); 42 CFR § 411.357(c)(1)

[251] 42 USC § 1395nn(e)(2)(C); 42 CFR § 411.357(c)(3)

[252] 42 USC § 1395nn(e)(2)(B)(i); 42 CFR § 411.357(c)(2)(i)

[253] 42 USC § 1395nn(e)(2)(B)(ii); 42 CFR § 411.357(c)(2)(ii)

the physician cannot take generally take into account the volume or value of the physician's DHS referrals, remuneration under the bona fide employment relationship exception may take the form of a productivity bonus that based on DHS that are performed personally by the physician or an immediate family member of the physician.[254]

(a) Example of productivity bonus permitted by the exception for bona fide employee relationships. Suppose a physician's spouse furnishes occupational therapy services as an employee of an occupation therapy facility. Although (1) the spouse is an immediate family member of the physician, and (2) a compensation arrangement in the form of a salary exists between the spouse and a DHS entity (the occupational therapy facility), the physician could nevertheless refer Medicare patients to the facility for the provision of DHS (the occupational therapy services) if that compensation arrangement satisfies the requirements available for bona fide employee relationships.[255]

15.6.2 Recent litigation concerning the bona fide employment exception. In *U.S. Campbell, et al.*, 2011 WL 43013 (D.N.J.).In *Campbell*, the University of Medicine and Dentistry of New Jersey (UMDNJ) entered into a written part-time employment agreement with a cardiologist who had a private cardiology practice in the community. Under the arrangement, the cardiologist would serve as a clinical assistant professor performing services such as teaching, lecturing, research, and patient care activities in exchange for an annual salary.[256] During the arrangement, the cardiologist referred Medicare patients to UMDNJ.[257] The court found that the cardiologist failed to perform services specified in the agreement, and that the agreement did not require him to perform those services.[258] Accordingly, the court held that the compensation arrangement did not satisfy the requirements of the Stark Law's bona fide employee arrangements exception because the agreement did not meet the exception's fair market value and commercially reasonableness requirements.[259] Rather than securing the physician's bona fide services, the agreement served other purposes, "such as compensation for patient referrals.[260] See also United States *ex rel. Drakeford v. Tuomey, d/b/a Tuomey Healthcare System*, 2010 WL 4000188 (D.S.C. 2010),

[254] 42 USC § 1395nn(e)(2)(D); 42 CFR § 411.357(c)(4)

[255] 63 FR 1708

[256] Id. at 1, 7

[257] Id. at 6

[258] Id. at 7-8

[259] Id. at 8

[260] Id. at 8

where a judge entered a jury verdict of over $44 million against a defendant hospital for violating the Stark Law by entering into part-time arrangements with referring physicians that failed to satisfy the requirements of the bona fide employee relationship exception because the compensation did not meet the exception's fair market value and commercial reasonableness requirements and took into account the volume or value of referrals or other business generated between the parties.[261]

15.7. Exception for personal service arrangements. A physician may make a DHS referral to an entity even if a compensation arrangement exists between the entity and the physician, when that arrangement can be structured to satisfy the requirements of the personal service arrangements exception.

15.7.1. Requirements of the personal services arrangements exception. A compensation arrangement must meet the following requirements to fall under the personal services arrangements exception.

15.7.1.1 Written agreement. The arrangement between the physician and the entity must be set out in writing, signed by the parties, and specify the services covered by the arrangement.[262]

15.7.1.2 Comprehensive coverage of services. The arrangement must cover all of the services that the physician (or an immediate family member of the physician) will provide to the entity.[263]

15.7.1.3 Services must be reasonable and necessary. The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement.[264]

15.7.1.4 The term of the agreement must be for at least one year. The term of the arrangement must be for at least one year. If the arrangement is terminated during the term with or without cause, the parties may not enter into the same or substantially the same arrangement during the first year of the original term of the arrangement.[265]

15.7.1.5 "Set in advance." The compensation to be paid over the term of the arrangement must be set in advance.[266]

[261] S. Scheutzow and S. Eisenberg, "The Employee Exceptions To The Anti-Kickback And Stark Laws After Tuomey: What's A Physician's Employer To Do?," 4 J. Health & Life Sci. L. 146, 164 (2011)

[262] 42 USC § 1395nn(e)(3)(A)(i); 42 CFR § 411.357(d)(1)(i)

[263] 42 USC § 1395nn(e)(3)(A)(ii); 42 CFR § 411.357(d)(1)(ii)

[264] 42 USC § 1395nn(e)(3)(A)(iii); 42 CFR § 411.357(d)(1)(iii)

[265] 42 USC § 1395nn(e)(3)(A)(iv); 42 CFR § 411.357(d)(1)(iv)

[266] 42 USC § 1395nn(e)(3)(A)(v); 42 CFR § 411.357(d)(1)(v)

15.7.1.6 Fair market value. The compensation to be paid cannot exceed fair market value.[267]

15.7.1.7 The compensation cannot reflect the volume or value of referrals. The compensation under the arrangement cannot be determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.[268]

15.7.1.8 Other state or federal law. The services to be performed under the arrangement do not involve the counseling or promotion or a business arrangement or other activity that violates and state or federal law.[269]

15.7.2 Example of an arrangement satisfying the exception for personal services arrangements. Suppose a laboratory contracts with a physician to provide consultation services, e.g., reviewing anatomic pathology specimens, interpreting holter monitors and electrocardiograms, and analyzing Pap tests. In this case, the lab's payments under the contract create a compensation arrangement between the physician and lab, and the exception for bona fide employment relationships is not available because the lab is not employing the physician. If however, the compensation arrangement satisfies the requirements of the exception for personal services arrangements, the physician will be permitted to order DHS for Medicare patients from the lab notwithstanding that compensation arrangement.[270]

15.7.3 Protection for holdover personal services arrangements. A holdover month-to-month personal services arrangements contract can satisfy the exception so long as:

(1) no more than 6 months have passed since the expiration of the immediately preceding contract:

(2) the holdover period satisfies the other requirements of the exception for personal services arrangements; and

(3) the holdover arrangement is on the same terms and conditions as the immediately preceding personal services contract.[271]

15.7.4. Recent litigation illustrating a failure to satisfy the personal service arrangement exception . *U.S. ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88, 94 (3d Cir.2009) involved an arrangement that failed to satisfy the requirements of the personal service arrangement exception. In 1992, an

[267] 42 USC § 1395nn(e)(3)(A)(v); 42 CFR § 411.357(d)(1)(v)

[268] 42 USC § 1395nn(e)(3)(A)(v); 42 CFR § 411.357(d)(1)(v)

[269] 42 USC § 1395nn(e)(3)(A)(vi); 42 CFR § 411.357(d)(1)(vi)

[270] 60 FR 41928

[271] 42 CFR § 411.357(d)(1)(vii)

anesthesia group entered into a contract with a hospital, under which the group would be the exclusive provider of anesthesia services at the hospital.[272] The hospital would provide at no charge the space, equipment, and supplies that the group needed to provide the anesthesia services.[273] In 1998, the hospital constructed a new, stand-alone pain clinic three miles from the hospital, where the anesthesia group provided pain management services that the hospital did not charge the anesthesia group for the use of space, equipment, of personnel.[274] A lower court found that the hospital's provision of fee space, equipment, and personnel at the pain clinic created a compensation arrangement between the hospital and the anesthesia group.[275]The lower court held, however, that the compensation arrangement and associated referrals and Medicare billings did not violate the Stark Law because the compensation arrangement was covered by the 1992 agreement and that agreement satisfied the requirements of the personal service arrangements exception.[276] The appeals court reversed the lower court, holding that the pain clinic arrangement did not satisfy the requirements of the personal services arrangement exception on the grounds that the arrangement represented a "very substantial change from the 1992 agreement."[277] The court also concluded that even if a written agreement covered the pain clinic arrangement, the agreement specified nothing concerning the consideration that the anesthesia group was receiving for its services.[278]

15.8 Fair market value compensation exception. A physician may make a DHS referral to an entity even if a compensation arrangement exists between the entity and the physician, when that arrangement can be structured to satisfy the requirements of the fair market value compensation exception.

15.8.1. Requirements of the fair market value compensation exception. A compensation arrangement must meet the following requirements to fall under the fair market value compensation exception.

15.8.1.1 Written agreement. The arrangement must be in writing, and signed by the parties, and must cover only identifiable items or services, all of which are specified in the agreement.[279]

[272] Id. at 91

[273] Id

[274] Id. at 93

[275] Id. at 95

[276] Id. at 95-96

[277] Id. at 97.

[278] Id. Further discussion of the *Kosenske* case and concerns implicated by that decision can be found at P. Sutton, "The Stark Law in Retrospect," 20 Annals of Health Law 15 (2011).

[279] 42 CFR § 411.357(l)(1)

15.8.1.2 Specified time period, which can be for a term of less than one year. The written agreement must specify the time period of the arrangement. There is no restriction concerning the period of time covered by the agreement, and the agreement may contain a termination clause. Accordingly, unlike the exceptions for personal services arrangements, and the rental of office space and equipment, the written agreement may cover a period of time that is less than one year.[280]

(1) Only one arrangement for the same items or services can be made over the course of a year. Although parties may enter into an agreement covering a period of time that is less than one year and include a termination clause in that agreement, the parties may enter into only one arrangement for the same items or services during the course of a year.[281]

(2) Renewal of arrangements for a period of less than one year is permitted. An arrangement made for less than one (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.[282]

15.8.1.3 Compensation must be specified. The arrangement must specify the compensation that will be provided under the arrangement.

15.8.1.4 "Set in advance." The compensation to be paid over the term of the arrangement must be set in advance.[283]

15.8.1.5 Fair market value. The compensation to be paid must be consistent with fair market value.[284]

15.8.1.6 The compensation cannot reflect the volume or value of referrals. The compensation under the arrangement cannot be determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.[285]

15.8.1.7 The arrangement must be commercially reasonable. The arrangement must be commercially reasonable (taking into account the nature and scope of the transaction) and must further the legitimate business purposes of the parties.[286]

[280] 42 CFR § 411.357(l)(2)

[281] 42 CFR § 411.357(l)(2)

[282] 42 CFR § 411.357(l)(2)

[283] 42 CFR § 411.357(l)(3)

[284] 42 CFR § 411.357(l)(3)

[285] 42 CFR § 411.357(l)(3)

[286] 42 CFR § 411.357(l)(4)

15.8.1.8 No violation of the other federal or state laws. The arrangement cannot violate the federal anti-kickback statute or any Federal or State law or regulation governing billing or claims submission.[287] The services to be performed under the arrangement cannot involve the counseling or promotion of a business arrangement or other activity that violates a Federal or State law.[288]

15.8.2 Payments for the rental of equipment will not satisfy the exception for fair market value compensation if those payments are based on a percentage of revenue or per-unit methodology. In some cases the exception for fair market value compensation may be used to except a compensation arrangement involving the rental of equipment. But such payments cannot satisfy the requirements of the fair market value compensation exception if those payments are 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 through the use of the equipment;[289] 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.[290]

15.8.3 Example regarding use of the fair market value compensation exception.

15.8.3.1 Example illustrating an arrangement that could satisfy the requirements of the fair market value compensation exception. Suppose a physician group has MRI equipment through which it provides MRI tests to its patients and patients in the community. Suppose also that the equipment experiences technical issues that require considerable maintenance. Consequently, the practice is unable to utilize the MRI equipment with sufficient frequency to meet the demands of the practice for a few months. During the few months that the MRI equipment is not fully operational, the physician group leases the use of a local hospital's mobile MRI equipment on a part-time basis, which provides MRI tests on the physician group's premises. Because the term of the equipment lease is less than one year, the compensation arrangement between the group and the hospital, i.e., the groups lease payments, cannot satisfy the requirements of the exception for equipment leases. However, if the compensation arrangement satisfies the requirements of the fair market value compensation exception, the physician

[287] 42 CFR § 411.357(l)(5)

[288] 42 CFR § 411.357(l)(6)

[289] 42 CFR § 411.357(l)(3)(i)

[290] 42 CFR § 411.357(l)(3)(ii)

group's physicians would be able to refer Medicare patients to the hospital for the provision of DHS notwithstanding that arrangement.[291]

15.8.4 The exception for fair market value compensation may only be used for *items and services*. The text of the exception for fair market value compensation states that the exception applies to *items and services.* Because of its limitation to items and services, the fair market value compensation exception cannot be used in all contexts. For example, the fair market value compensation exception cannot protect office space lease arrangements because such arrangements involve office space, not items of services.[292] Physician recruitment arrangements also cannot quality for the fair market value compensation exception.[293]

15.9 The exception for nonmonetary compensation. A physician can make DHS referrals to an entity if the compensation arrangement between the entity and the referring physician can be structured to fit the exception for nonmonetary compensation.

15.9.1 Requirements and considerations applicable to the exception for nonmonetary compensation. The compensation arrangement must satisfy the following requirements.

15.9.1.1 Limit on aggregate compensation. For the calendar year 2011, the compensation cannot exceed an aggregate of $359.00. The limit is adjusted every year for inflation. CMS displays after September 30 each year both the increase in the CPI-U for the 12-month period and the new nonmonetary compensation limit on the physician self-referral Web site: http://www.cms.gov/PhysicianSelfReferral/50_CPI-U_Updates.asp.[294]

15.9.1.2 Volume or value of referrals. The compensation cannot be determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician.[295]

15.9.1.3 No physician solicitation. The compensation may not be solicited by the physician or the physician's practice (including employees and staff members of the practice).[296]

[291] 72 FR 51057

[292] 72 FR 51059

[293] 72 FR 51094

[294] 42 CFR § 411.357(k)(2)

[295] 42 CFR § 411.357(k)(1)(i)

[296] 42 CFR § 411.357(k)(1)(ii)

15.9.1.4 No violation of other state or federal law. The compensation arrangement cannot violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submission.[297]

15.9.1.5 One local medical staff appreciation event permitted. In addition to nonmonetary compensation up to the limit specified in section 15.9.1.1, an entity that has a formal medical staff may provide one local medical staff appreciation event per year for the entire medical staff. Any gifts or gratuities provided in connection with the medical staff appreciation event are subject to the 15.9.1.1 limit.[298]

15.9.2 Circumstances where payment in excess of the limit specified in 15.9.1.1 can still fit within the exception for nonmonetary compensation. If an entity has inadvertently provided nonmonetary compensation to a physician in excess of the limit specified in 15.9.1.1, such compensation is nevertheless deemed to be within the limit if:

(1) the value of the excess nonmonetary compensation is no more than 50 percent of the limit;[299] and

(2) the physician returns to the entity the excess nonmonetary compensation:

(a) by the end of the calendar year in which the excess nonmonetary compensation was received; or

(b) within 180 consecutive calendar days following the date the excess nonmonetary compensation was received by the physician, whichever is earlier.[300]

The ability to repay of excess amounts described in 15.9.1.1 can be utilized only once every 3 years with respect to the same referring physician.[301]

15.9.3 Example illustrating the application of the nonmonetary compensation exception. For example, suppose a hospital gives nonmonetary compensation with a value of $250 to a physician on April 15, and then on August 15 inadvertently makes another gift to the same physician valued at $200. The total nonmonetary compensation to the physician is $450, which is less than 150 percent of the amount allowed ($359 × 150 percent = $538.50). If the physician repays the excess of $91 ($450 - $359 = $91) by December 31, the entity can

[297] 42 CFR § 411.357(k)(1)(iii)

[298] 42 CFR § 411.357(4)

[299] 42 CFR § 411.357(k)(3)(i)

[300] 42 CFR § 411.357(k)(3)(ii)

[301] 42 CFR § 411.357(k)(3)(iii)

continue to maintain compliance under the nonmonetary compensation exception.[302]

15.10 Exception for medical staff incidental benefits. A physician can make DHS referrals to a hospital if the compensation arrangement between the hospital and the referring physician can be structured to fit the exception applicable to the provision of medical staff benefits.

15.10.1 Requirements applicable to the exception for medical staff incidental benefits. In order to satisfy the requirements of this exception, the compensation arrangement must satisfy the following requirements.

15.10.1.1 The benefits must be offered to all members of the medical staff. The benefits must be offered to all members of the medical staff practicing in the same specialty (but not necessarily accepted by every member to whom it is offered).[303]

15.10.1.2 Campus requirement. The benefits must be provided by the hospital and used by the medical staff members only on the hospital's campus.[304]

(1) Examples of medical staff incidental benefits satisfying the "on campus" requirement. Compensation that includes internet access, pagers, or two-way radios that are used away from the campus but are used only to access hospital medical records or information or to access patients or personnel who are on the hospital campus, as well as the identification of the medical staff on a hospital web site or in hospital advertising, all satisfy the "on campus" requirement.[305]

15.10.1.3 Value of volume of referrals. The benefits must be offered without regard to the volume or value of referrals or other business generated between the parties.[306]

15.10.1.4 The benefits must be provided when medical staff members are engaged in services or activities that benefit the hospital. Except with respect to identification of medical staff on a hospital web site or in hospital advertising, the benefits must be provided only during periods when the medical staff members are making rounds or are engaged in other services or activities that benefit the hospital or its patients.[307]

[302] 72 FR 51058-51059

[303] 42 CFR § 411.357(m)(1)

[304] 42 CFR § 411.357(m)(3)

[305] 42 CFR § 411.357(m)(3)

[306] 42 CFR § 411.357(m)(6)

[307] 42 CFR § 411.357(m)(2)

15.10.1.5 Reasonable relation to services at the hospital. The benefits must be reasonably related to the provision of, or designed to facilitate directly or indirectly the delivery of, medical services at the hospital.[308]

15.10.1.6 The value of the benefits for 2011 must be less than $30. For the calendar year 2010, the value of the benefits must be less than $30 with respect to each occurrence of the benefit. The value of the compensation is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index -- Urban All Items (CPI-I) for the 12 month period ending the preceding September 30. CMS displays after September 30 each year both the increase in the CPI-I for the 12 month period and the new limits on the physician self-referral web site: https://www.cms.gov/PhysicianSelfReferral/50_CPI-U_Updates.asp.[309]

15.10.1.7 No violation of other federal or state law. The compensation arrangement does not violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submission.[310]

15.10.2 Example illustrating application of the exception for medical staff incidental benefits. A hospital offers all physicians on its medical staff free parking in the hospital parking garage. The value of the parking is $18 per day. Provision of the free parking would fall under the exception for medical staff incidental benefits because value of each occurrence of the free parking is less than $30.

15.10.3 Aside from the limit that applies to the value of each occurrence of the incidental benefit ($30 for 2011), there is no upward limit to the total value of the incidental benefits that may be provided to the medical staff. As 15.9.2 illustrates, so long as each occurrence of the incidental benefit falls under the monetary limit ($30 for 2011), there is no limit in the aggregate to the value of the incidental benefits.

15.11 The exception for compliance training. A physician can make a DHS referral to an entity if the compensation arrangement between the entity and the physician takes the form of compliance training.

15.11.1 Requirements applicable to the exception for compliance training.

15.11.1.1 What is the definition of "compliance training" for the purposes of the compliance training exception. "Compliance training" includes:

(1) training regarding the basic elements of a compliance program (for example, establishing policies and procedures, training of staff, internal monitoring, or reporting);

[308] 42 CFR § 411.357(m)(4)

[309] 42 CFR § 411.357(m)(5)

[310] 42 CFR § 411.357(m)(7)

(2) specific training regarding the requirements of Federal and State health care programs (for example, billing, coding, reasonable and necessary services, documentation, or unlawful referral arrangements); or

(3) training regarding other Federal, State, or local laws, regulations, or rules governing the conduct of the party for whom the training is provided.[311]

15.11.1.2 The physicians must be from the entity's local community or service area. The compliance training must be provided to physicians (or to the physician's immediate family member or office staff) who practice in the entity's local community or service area.[312]

15.11.1.3 Location of training. The location of the training must be held in the entity's local community or service area.[313]

15.11.2 Compliance training may contain continuing medical education credit. "Compliance training" includes programs that offer continuing medical education credit, provided that compliance training is the *primary* purpose of the program.[314]

XVI. The exception for indirect compensation arrangements. A physician may make a DHS referral to an entity if the compensation arrangement satisfies the requirements of the exception for indirect compensation arrangements.

16.1 Requirements of the exception for indirect compensation arrangements.

16.1.1 Fair market value. The compensation received by the referring physician (or immediate family member) represents the fair market value for services and items actually provided.[315]

16.1.2 Volume of value of referrals. The compensation cannot be 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.[316]

16.1.3 Written specification of services. The compensation arrangement must be set out in writing, signed by the parties, and must specify the services covered by the indirect compensation arrangement.[317]

[311] 42 CFR § 411.357(o).

[312] 42 CFR § 411.357(o)

[313] 42 CFR § 411.357(o)

[314] 42 CFR § 411.357(o) (italics added)

[315] 42 CFR § 411.357(p)(1)(i)

[316] 42 CFR § 411.357(p)(1)(i)

16.1.3.1 Exception to the writing requirement for bona fide employment relationships. If the indirect compensation arrangement takes the form of a bona fide employment relationship between an employer and an employee, the arrangement need not be set out in a written contract, but the arrangement must be for identifiable services and be commercially reasonable even if no referrals are made to the employer.[318]

16.1.4 No violation of state or federal law. The indirect compensation arrangement in its entirety cannot violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submission.[319]

16.2 The requirements of the exception for indirect compensation arrangements are applied to the compensation arrangement nearest to the referring physician. In determining whether a compensation arrangement satisfies the requirements of the exception for indirect compensation arrangements, the focus is on the compensation arrangement "nearest" the referring physician

16.2.1 Examples illustrating the compensation arrangement to which the requirements of the exception for indirect compensation arrangements are applied.

16.2.1.1 Example where the financial relationship is not a direct ownership/investment interest. In the royalty payment example provided at 9.4.2.2(3), the surgeon's referrals and the hospital's ability to bill Medicare for the implants would comply with the Stark Law if the royalty payments were structured to satisfy the requirements of the exception for indirect compensation arrangements, e.g., the royalty payments would have to reflect fair market value.[320]

16.2.1.2 Example where the financial relationship nearest the physician is an ownership or investment interest. In the example involving physical therapy services and SNF patients at 9.4.2.2(4), the physician's physical therapy referrals and the SNF's billing Medicare for those services would be permitted under the Stark Law if the compensation arrangement between the SNF and the physical therapy services company satisfied the requirements of the indirect compensation arrangement exception.

16.2.1.3 Recent litigation illustrating a failure to comply with the indirect compensation arrangements exception: *U.S. ex rel. Singh v. Bradford Regional Medical Center,* 752 F.Supp.2d 602 (W.D.Pa. 2010).

[317] 42 CFR § 411.357(p)(2)

[318] 42 CFR § 411.357(p)(2)

[319] 42 CFR § 411.357(p)(3)

[320] 69 FR 16060

(a) The transaction. *Bradford* concerned an equipment sublease between a two-physician a medical practice and Bradford Regional Medical Center (the hospital). Prior to 2001, the practice was a significant source of referrals to the hospital for diagnostic tests performed by a nuclear camera located at the hospital.[321] In 2001, the group acquired its own nuclear camera.[322] In an effort to secure future referrals from the group, the hospital entered into a five-year equipment sublease agreement, under which the hospital would sublease the use of a nuclear camera located in the group's practice.[323] The sublease contained a restrictive covenant, which prohibited the group's two physicians from owning or operating competing nuclear cardiology imaging equipment, or providing other outpatient diagnostic imaging services, within thirty miles of the hospital.[324]

(b) Creation of an independent compensation arrangement. The court found that the transaction created an independent compensation arrangement between the group's two individual physicians and the hospital. First, an unbroken chain of more than one financial relationship existed between the group's referring physicians and the hospital, i.e., the two individual group physicians had an ownership interest in the group, and the group in turn had a compensation relationship with the hospital via the sublease.[325] (*Note that the two physicians were not required to stand-in-the-shoes of their physician organization (the group) because CMS had not yet adopted the SITS requirement).* Second, before entering into the sublease, hospital retained an accountant to perform a fair market value appraisal of the sublease's restrictive covenants.[326] In concluding that the hospital's payments for the restrictive covenants reflected fair market value, the accountant based his appraisal on a comparison between the revenues the hospital expected to generate with the sublease in place to the revenues the hospital expected to receive without the sublease. The accountant also factored in the expectation that the group would be referring business to the hospital if the hospital board adopted the sublease.[327] Based in part on this appraisal, the court concluded that the aggregate compensation between the group and the hospital under the

[321] Id. at 606

[322] Id. at 607

[323] Id. at 609-611

[324] Id. at 611

[325] Id. at 620

[326] Id. at 622

[327] Id. at 610, 622

sublease took into account the volume or value of referrals generated by the two physicians for the hospital.[328]

(c) Failure to satisfy the indirect compensation arrangement exception. The court held that the sublease independent compensation arrangement did not satisfy the fair market value requirement of the independent compensation arrangement exception. The court noted that while the negotiated lease payments might have represented fair market value *as between the hospital and the group*, the payments did not reflect the Stark Law's definition of "fair market value," because those payments were greater than what the hospital would have paid in the absence of the group's two physicians' ability to provider referrals to the hospital's nuclear camera business.[329]

16.3 Payments for the rental of equipment or office space will not satisfy the exception for indirect compensation arrangements if those payments are based on a percentage of revenue or per-unit methodology. In some cases the exception for indirect compensation arrangements may be used to except a compensation arrangement involving the rental of equipment or office space. But such payments cannot satisfy the requirements of the exception for indirect compensation arrangements if those payments are 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 to the services performed on or business generated through the use of the equipment;[330] 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.[331]

XVI. Exception when a financial relationship temporarily fails to comply with a Stark Law exception.

17.1 The exception for temporary noncompliance takes two forms: noncompliance beyond the entity's control and signature-related noncompliance. The Stark Law contains an exception applicable when a financial relationship temporarily fails to comply with a Stark Law exception. This exception for temporary noncompliance takes two forms: (1) when the noncompliance is due to circumstances beyond the entity's control; and (2) the noncompliance is due solely because the parties failed to obtain a signature that was required by a Stark Law exception.

[328] Id. at 623

[329] Id. at 633

[330] 42 CFR § 411.357(p)(1)(ii)(A)

[331] 42 CFR § 411.357(p)(1)(ii)(B)

17.1.1 Exception when noncompliance is beyond an entity's control.[332]

17.1.1.1 Exception for temporary noncompliance due to circumstances beyond the control of the entity. If a financial relationship becomes noncompliant with a Stark Law exception due to circumstances beyond the entity's control, an entity may submit claims for DHS services to the Medicare Program pursuant to otherwise prohibited referrals if the following requirements are satisfied.

(1) The financial relationship fully complied with a Stark Law exception for 180 consecutive days prior to the noncompliance. The financial relationship must have fully complied with a Stark Law exception for at least 180 consecutive calendar days immediately preceding the date on which the financial relationship became noncompliant with the exception.[333]

(2) The noncompliance must have been beyond the entity's control. The financial relationship must have become noncompliant with the exception for reasons beyond the control of the entity, and the entity promptly takes steps to rectify the noncompliance.[334]

(3) The financial relationship does not violate other federal or state legal requirements. The financial relationship does not violate the anti-kickback statute, and the DHS claims submitted by the entity otherwise comply with all applicable Federal and State laws, rules, and regulations.[335]

(4) The entity must rectify the noncompliance within 90 days. The entity must rectify the noncompliance within a period of time that cannot exceed 90 consecutive calendar days following the date on which the financial relationship became noncompliant with the exception.[336]

17.1.1.2 Example of temporary noncompliance due to circumstances beyond the entity's control. Suppose that, for several years, physicians have been lawfully referring to a laboratory in which they have ownership interests because those ownership interests satisfied the rural provider exception. Suppose though that on January 1, 2010, the geographic area in which the lab is located is changed from a rural area to an MSA, and this change results in physicians' ownership/investment interests in the entity no longer complying

[332] 42 C.F.R. § 411.353(f)

[333] 42 C.F.R. § 411.353(f)(1)(i)

[334] 42 C.F.R. § 411.353(f)(1)(ii)

[335] 42 C.F.R. § 411.353(f)(1)(iii)

[336] 42 C.F.R. § 411.353(f)(2)

with the requirements of the rural provider exception. At the expiration of 90 days from January 1, the laboratory and physician owners must comply with another exception or find some other way of not violating the Stark Law.[337]

17.1.1.3 The exception cannot be used when the noncompliance involves the exceptions for nonmonetary compensation or medical staff incidental benefits. An entity cannot take advantage of the exception for temporary noncompliance beyond its control if the noncompliance at issue is noncompliance with either the exception for nonmonetary compensation or the exception for medical staff incidental benefits.[338]

17.2.1 Exception for temporary noncompliance with signature requirements of Stark Law exceptions. Many Stark Law exceptions applicable to compensation arrangements contain a signature requirement. An entity may submit claims for DHS services to the Medicare Program even if a compensation arrangement exists that does not comply with a signature requirement of an applicable Stark Law exception, provided the following requirements apply.

17.2.1.1 The compensation arrangement fully complies with a specific Stark Law exception (except for the signature requirement). The compensation arrangement between the entity and the referring physician must, except for the signature requirement, otherwise fully comply with a Stark Law exception.[339]

(1) If the failure to obtain the signature was *inadvertent*, then the signature must be obtained within 90 days of the date upon which the compensation arrangement became noncompliant. If the failure to obtain the signature was inadvertent, the parties can bring the arrangement within the applicable exception if the parties obtain the required signature(s) within 90 consecutive calendar days immediately following the date on which the compensation arrangement became 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.[340]

(2) If the failure to obtain the signature was *not inadvertent*, then the signature must be obtained within 30 days of the date upon which the compensation arrangement became noncompliance. If the failure to obtain the signature was not inadvertent, the parties can bring the arrangement within the applicable exception if the parties obtain the required signature(s) within 30 consecutive calendar days immediately

[337] 69 FR 16057

[338] 42 C.F.R. § 411.353(f)(4)

[339] 42 CFR § 411.353(g)(1)(i)

[340] 42 CFR § 411.353(g)(1)(ii)(A)

following the date on which the compensation arrangement became 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.[341]

(a) Example illustrating a not inadvertent failure to obtain a signature. Suppose that a hospital unexpectedly loses the services of a specialist who was providing on-call services to the hospital's emergency department. The hospital approaches Physician A, and asks her to begin immediately providing the needed specialty services to the hospital in exchange for a stipend. On January 1, 2010, the hospital forwards a draft an on-call agreement to the physician and her lawyer for legal review, although the lawyer is on vacation at the time. On January 5, Physician A begins providing on-call services and receives her first stipend payment. Both the hospital and physician are completely aware that the agreement has not been signed, and are waiting for the lawyer to return to review the document for Physician A. The lawyer returns on January 15, and Physician A signs the Agreement on January 20th. Assuming that the agreement otherwise complied with the requirements of the exception for personal services arrangements, the hospital may submit claims to the Medicare program for DHS referrals from Physician A that were made to the hospital during the period between January 5 and January 20 because the signature requirement was satisfied within the 30-day window.[342]

17.2 The exception for noncompliance can only be used once every three years by an entity for the same referring physician.[343]

XVIII. The new CMS Voluntary Self-Referral Disclosure Protocol (SRDP)

Section 6409 of the ACA, requires the Secretary of HHS to develop a protocol under which physicians and health care providers may disclosure actual or potential violations of the Stark Law. One of the reasons underlying the need for a specific Stark Law self-disclosure protocol was the OIG's March 2009 clarification that the OIG Self-Disclosure Protocol could no longer be used for potential or actual Stark Law violations if those violations did not also involve a "colorable" violation of the antikickback statute. After this clarification, there was no official HHS protocol through which physicians and health care providers could self-disclose potential or actual violations of the Stark Law that did not implicate the antikickback statute. In September 2010, CMS announced the new

[341] 42 CFR § 411.353(g)(1)(ii)(B)

[342] 73 FR 48707

[343] 42 CFR § 411.353(g)(2)

CMS Voluntary Self-Referral Disclosure Protocol (SRDP).

One positive aspect of section 6409 is that, under the SRDP, HHS is allowed to reduce the amounts to which a physician or health care provider has been overpaid due to a Stark Law violation. The possibility of negotiated payments is a positive development because, prior to section 6409, the CMS appeared to take the position that it was statutorily prohibited from reducing overpayment amounts.

18.1 How does a physician initiate a disclosure under the SRDP?

The disclosure must be submitted electronically to 1877SRDP@cms.hhs.gov. In addition, the disclosing party must submit an original and 1 copy by mail to the Division of Technical Payment Policy, ATTN: Provider and Supplier Self-Disclosure, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Mailstop C4-25-02, Baltimore, MD 21224-1850. Submissions by facsimile will not be accepted. When the disclosing party submits a disclosure electronically, CMS will immediately send a response email acknowledging receipt of the submission. After reviewing the submission, CMS will send a letter to the disclosing party or its representative either accepting or rejecting the disclosure.

18.2 What general information must be disclosed?

18.2.1. Information about the disclosing party. The disclosure must contain a description of the name, address, national provider identification numbers (NPIs), CMS Certification Number(s) (CCN), and tax identification number(s) of the disclosing party. If the disclosing party is an entity that is owned, controlled or is otherwise part of a system or network, the disclosure must include a description or diagram that explains the pertinent relationships and the names and addresses of any related entities, as well as any affected corporate divisions, departments or branches.

18.2.2 Description of the matter that is being disclosed. The disclosure must include a description of the nature of the matter being disclosed. This aspect of the disclosure must include the specific time periods the disclosing party believes it may have been out of compliance with the Stark Law (and, if applicable, the dates or a range of dates whereby the conduct was cured), and the type of DHS claims at issue.

18.2.3. Reasons why a violation may have occurred. The disclosure must contain a statement from the disclosing party regarding why it believes a Stark Law violation law may have occurred, including a complete legal analysis of how the Stark Law applies to the conduct at issue and any physician self-referral exception that applies to the conduct and/or that the disclosing party attempted to use. This legal analysis must identify and explain which element(s) of the applicable exception(s) were met and which element(s) were not met. In addition, the disclosure should include a description of the potential causes of the incident

or practice (e.g., intentional conduct, lack of internal controls, circumvention of corporate procedures or Government regulations).

18.2.4. Basis of discovery. The disclosure must describe the circumstances under which the disclosed matter was discovered and what measures were taken to address the issue and prevent future Stark Law violations.

18.2.5. Compliance history. The disclosure must contain a statement identifying whether the disclosing party has a history of conduct similar to the actual or potential violation that is the subject of the disclosure, or has any prior criminal, civil, and regulatory enforcement actions (including payment suspensions) against it.

18.2.6. Compliance efforts. The disclosure must contain a description of the adequacy of any pre-existing compliance program that the disclosing party had prior to disclosing the potential or actual Stark Law violation, and all efforts by the disclosing party to prevent a recurrence of the potential or actual violation, e.g., new accounting or internal control procedures, increased internal audit efforts, increased supervision by higher management or through training.

18.2.7. Identification of other notifications. The disclosure must describe notices, if applicable, that the disclosing party has provided to other government agencies, e.g., the Securities and Exchange Commission or the Internal Revenue Service, in connection with the disclosed matter.

18.2.8. Knowledge of current investigations. The disclosure must indicate whether the disclosing party has knowledge that the matter being disclosed is under current inquiry by a Government agency or contractor. If the disclosing party has knowledge of a pending inquiry, the disclosure must identify any such Government entity or individual representatives involved. The disclosing party must also disclose whether it is under investigation or other inquiry for any other matters relating to a Federal health care program, including any matters it has disclosed to other Government entities, and provide similar information relating to those other matters.

18.3 What specific financial information must be disclosed?

18.3.1. Financial analysis. The disclosing party must be expected to conduct a financial analysis, and then report its findings to CMS. The financial analysis should:

(a) set forth the total amount, itemized by year, that is actually or potentially due and owing based upon the applicable “look back” period (the “look back” period is the time during which the disclosing party may not have been in compliance with the Stark Law);

(b) describe the methodology used to determine the amount that is actually or potentially due and owing; and

(c) provide a summary of auditing activity undertaken and a summary of the documents relied upon.

18.3.2. Certification requirements. The disclosing party, or in the case of an entity its Chief Executive Office, Chief Financial Officer, or other authorized representative of the disclosing party, must certify that all of its submissions are, to the best of the party's or individual's knowledge, truthful and based on a good faith effort to bring the matter to CMS' attention for the purpose of resolving any potential liabilities relating to the Stark Law.

18.3.3. Verification by CMS. Once it has received a disclosing party's disclosure submission, CMS will begin its verification of the disclosure information. The extent of CMS' verification effort will depend, in large part, upon the quality and thoroughness of the submissions received. Matters uncovered during the verification process, which are outside of the scope of the matter disclosed to CMS, may be treated as new matters outside the SRDP. To facilitate CMS' verification and validation processes, CMS must have access to all financial statements, notes, disclosures, and other supporting documents without the assertion of privileges or limitations on the information produced. In the normal course of verification, CMS will not request production of written communications subject to the attorney-client privilege. There may be documents or other materials, however, that may be covered by the work product doctrine, but which CMS believes are critical to resolving the disclosure. CMS is prepared to discuss with a disclosing party's counsel ways to gain access to the underlying information without the need to waive the protections provided by an appropriately asserted claim of privilege. CMS may request additional information, such as financial statements, income tax returns, and other documents, if needed. If additional information is requested, a disclosing party will be given at least 30 days to furnish the information.

18.3.4. Receipt of Payments. Because of the need to verify the information provided by a disclosing party, CMS will not accept payments of presumed overpayments determined by the disclosing party prior to the completion of CMS' inquiry. CMS encourages the disclosing party to place the funds in an interest-bearing escrow account to ensure adequate resources have been set aside to repay amounts owed. While the matter is under CMS inquiry, the disclosing party may not make payment relating to the disclosed matter to Federal health care programs or their contractors without CMS' prior consent. If CMS consents, the disclosing party will be required to acknowledge in writing that the acceptance of any such payment by the government does not constitute the government's agreement as to the amount of losses suffered by government programs as a result of the disclosed matter, and does not relieve the disclosing party of any criminal, civil, or civil monetary penalty liability, nor does it offer a defense to any further

administrative, civil, or criminal actions against the disclosing party.

18.3.5. Cooperation and Removal from the SRDP and Timeliness of Disclosure. CMS expects that the disclosing party will cooperate in good faith throughout the entire SRDP. CMS expects to receive documents and information from the disclosing party that relate to the disclosed matter without the need to resort to compulsory methods. If a disclosing party fails to work in good faith with CMS to resolve the disclosed matter, CMS will take into account this lack of good faith when CMS determines how to resolve appropriately the disclosed matter. Intentionally submitting of false or otherwise untruthful information, or intentionally omitting relevant information as part of the SRDP, will be referred by CMS to DOJ or other Federal agencies and could, in itself, result in criminal and/or civil sanctions, as well as exclusion from participation in the Federal health care programs. Furthermore, it is imperative for disclosing parties to disclose matters in a timely fashion once identified. For example, section 6402 of the ACA establishes a deadline for reporting and returning overpayments by the later of: (1) the date which is 60 days after the date on which the overpayment was identified; or (2) the date any corresponding cost report is due, if applicable.[344]

However, while the ACA established the previously-mentioned 60-day deadline for reporting and returning overpayments, at the time the physician or health care provider submits a disclosure under the SRDP (and receives email confirmation from CMS that the disclosure has been received), the obligation under Section 6402 of the ACA to return any potential overpayment within 60 days will be suspended until a settlement agreement is entered, the provider of services or supplier withdraws from the SRDP, or CMS removes the provider of services or supplier from the SRDP.

18.3.6. Factors that CMS Considered in Reducing the Amounts Owed. Section 6409 of the ACA permits CMS to negotiate overpayment amounts for potential or actual Stark Law. The factors CMS may consider in reducing the amounts otherwise owed include: (1) the nature and extent of the improper or illegal practice; (2) the timeliness of the self-disclosure; (3) the cooperation in providing additional information related to the disclosure; (4) the litigation risk associated with the matter disclosed; and (5) the financial position of the disclosing party. While CMS may consider these factors in determining whether reduction in any amounts owed is appropriate, under the SRDP CMS is not legally obligated to reduce any such amounts. CMS will make an individual determination as to whether a reduction is appropriate based on the facts and circumstances of each disclosed actual or potential violation.

18.3.7. Relation to the CMS Stark Advisory Process. The SRDP is separate from the Stark Law advisory process. Consequently, a physician or health care

[344] See 42 U.S.C. § 1320a-7k(d)(2).

provider may not disclose an actual or potential violation(s) through the SRDP and request an advisory opinion for conduct underlying the same arrangement(s) concurrently. The SRDP can be accessed at the following Web site: https://www.cms.gov/PhysicianSelfReferral/Downloads/6409_SRDP_Protocol.pdf.

18.4 Recent activity. At the time of writing, one settlement, involving Saints Medical Center in Massachusetts, had been completed under the SRDP. Under the settlement, Saints Medical Center agreed to pay $579,000, which, according to the Center's press release, was "less than the reserve Saints set aside in fiscal year 2009 to address this issue, which was based on management's estimate of the low end of the range of the potential obligation."[345]

XIX. Stark Advisory Opinion Process. CMS is required to issue written advisory opinions concerning whether a physician referral relating to designated health services (other than a clinical laboratory service) is prohibited under the Stark Law.[346] The regulations implementing CMS advisory opinions are detailed and set forth a number of limitations on the kinds of questions that can be asked.[347] For example, CMS will not address the fair market value of something or whether an individual is a *bona fide* employee. In addition, CMS will not accept an advisory opinion if a matter is under investigation or it believes it cannot make an informed opinion. CMS has issued nine advisory opinions, which can be accessed at http://www.cms.gov/PhysicianSelfReferral/95_advisory_opinions.asp#TopOfPage.

XX. Conclusion

Although the Stark Law does restrict circumstances in which a physician may refer a Medicare beneficiary for the provision to DHS to an entity with which the physician has a financial relationship, that referral arrangement must satisfy a number of specific requirements before actually implicating the Stark Law. And, even if the referral arrangement falls within Stark Law's general prohibitions, many exceptions exist which may protect the arrangement from the Stark Law's application.

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[345] See the related Saints Medical Center's press release, which may be accessed at http://www.saintsmedicalcenter.com/news/CMS/.

[346] 42 USC § 1395nn(g)(6)

[347] The advisory opinion regulations can be accessed on the CMS web site at http://www.cms.gov/PhysicianSelfReferral/95_advisory_opinions.asp#TopOfPage.

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