Stark Physician Self-referral Prohibition

Review of Statute and Regulations

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I. Statutory Self-Referral Prohibition (42 U.S.C. § 1395nn)

A. A physician may not make a referral to an entity in which he or she (or an immediate family member) has a financial relationship for a designated health service unless the arrangement is covered by a statutory or regulatory exception.

B. Designated health services include: clinical laboratory services; physical and occupational therapy services; radiology services, including MRI, CT and ultrasound; radiology and other imaging services, radiation therapy services and supplies, durable medical equipment and supplies; parenteral and enteral nutrients, equipment and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; inpatient and outpatient hospital services.

II. Penalties

A. Any person who submits or causes to be submitted a claim for a service that the person knows or should know is for a service that results from a prohibited self-referral, or does not make for each such service a required refund, can be assessed a civil monetary penalty of up to $15,000 for each such service plus two times the reimbursement claimed, and can be excluded from Medicare and Medicaid participation.

B. Circumvention Schemes - A civil monetary penalty of up to $100,000 and exclusion can be imposed on persons who enter into circumvention schemes (such as a cross-referral arrangement).

C. Qui Tam Actions Alleging Violation of Anti-kickback Statute and Stark Law.

1. See United States ex rel. Thompson v. Columbia Healthcare Corp., 125 F.3d 899 (5th Cir. 1997).
III. Final Regulations

A. Phase I


B. Phase II


2. The effective date of the regulation is July 26, 2004.

C. Phase III


2. The effective date of these regulations is December 4, 2007.

3. Phase III notice of delay, published November 15, 2007, effective immediately upon publication, delayed, until December 4, 2008, the “stand in the shoes” provisions made final in the Phase III final rule for academic medical centers and integrated 501(c)(3) health care systems.

4. The “stand in the shoes” rules were finalized in the FY 2009 Inpatient Prospective Payment System (IPPS) final rule, published August 18, 2008, but applied only to physician owners of physician-owned organizations.

IV. Key Definitions

A. Designated Health Services (DHS)

1. A list published on an annual basis in the Federal Register and on CMS's website identifies specific CPT and HCPCS codes for certain categories of DHS and for certain excepted services.

   a. The list applies to PT; OT; SLP; clinical lab services; radiology; radiation therapy services and supplies; preventive screening tests; immunizations and vaccines; and drugs for patients undergoing dialysis.

      (1) Specific carve outs:

      i. Implants in ASC
ii. Preventive screening/ immunizations  
iii. Eyeglasses and contact lenses  
iv. EPO in ESRD facilities  
v. DHS paid as part of a composite payment under another Medicare benefit not subject to Stark B Referral.

2. Request/ordering or certifying medical necessity (including tests ordered pursuant to consult).
   a. Does not include services personally performed by the referring physician.  
   b. Does include “incident to” services performed by employees or other group practice physicians.

3. Referral imputed to physician if he/she "directs" or "controls" person making it.  
   a. Includes NP and PA referrals.

4. Special rules for pathologists, radiologists and radiation oncologists provide that additional services ordered by them are not referrals if:
   a. Pursuant to a request for a consultation  
      (1) Physician's opinion sought  
      (2) Request documented on chart  
      (3) Written report  
   b. Under supervision of consulting physician. “Supervision" need only be at a level that meets Medicare coverage rules.

B. Entity

1. A medical practice that furnishes DHS.

2. A person or entity is furnishing DHS if it is the entity to which CMS makes payment for DHS directly or upon reassignment or, effective October 1, 2009, the entity that performs the service, regardless of whether it bills for the service.
a. CMS expanded the definition of “entity” in the FY 2009 IPPS Final Rule to include entities that “perform” DHS services, notwithstanding that another entity bills Medicare for the service. The purpose of this expansion was to prohibit physician-owned entities from providing services “under arrangements” to hospitals.

b. CMS has not defined the word “perform” under the expanded definition and rather defaults to the “common” meaning of “perform” to determine whether an entity has performed a service. As a result of numerous inquiries to CMS regarding when an entity is considered to be “performing” DHS, CMS recently requested public comments regarding whether the agency needs to further clarify when an entity is considered to be performing DHS in the FY 2010 Final Physician Fee Schedule Rule. 74 Fed. Reg. 61,738, 61,933 (Nov. 25, 2009)

3. An entity may be solo practice, group practice, nonprofit foundation, IPA, a health plan (or MCO, PSO, etc.) that employs a DHS supplier or operates a facility accepting reassignment under § 424.80(b)(1) and (b)(2).

4. Entity does not include a physician's medical practice billing for purchased diagnostic tests in accordance with 42 C.F.R. § 424.50.

5. Lithotripsy is not a DHS. Under certain circumstances, a hospital may use a per-use or percentage-based compensation formula to compensate a physician-owned entity that provides a lithotripter and skilled technician to the hospital on an “under arrangements” basis without violating the physician self-referral law. If the entity merely leases equipment, the entity is not “performing” the service and therefore not a DHS entity. CMS Frequently Asked Question #9556 (January 22, 2009).

C. Radiology and Other Imaging Services

1. Identified exclusively by CPT/HCPCS list.

2. Includes: x-rays, ultrasound or other imaging services, computerized axial tomography, or magnetic resonance imaging.

3. Does not include:

   a. x-ray, fluoroscopy, or ultrasound procedures that require the insertion of a needle, catheter, tube, or probe through the skin or into the body

   b. radiology procedures that are integral to the performance of a nonradiological medical procedure and performed
(1) during the nonradiological procedure or
(2) immediately following such procedure when necessary to confirm the placement of an item during such procedure

D. Radiation Therapy Services and Supplies

1. Identified exclusively by CPT/HCPCS list

E. EKGs, ECGs, and Pulmonary Function Tests

1. Pulmonary function testing and EKGs and ECGs are not DHS, unless furnished in a hospital setting.

F. Remuneration

1. Any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind.

2. The following are not considered remuneration:
   a. Forgiveness of amounts owed for inaccurate tests or procedures, mistakenly performed tests or procedures, or the correction of minor billing errors.
   b. Furnishing of items, devices, or supplies (not including surgical items, devices, or supplies) that are used solely to collect, transport, process, or store specimens for the entity furnishing the items, devices, or supplies.
   c. Payment made by an insurer or a self-insured plan (or a subcontractor of the insurer or plan) to a physician to satisfy a claim, submitted on a fee-for-service basis, for the furnishing of health services by that physician.

G. Employee

1. The statute defines employee as an individual who would be considered an employee under the usual common law rules applicable in determining the employer-employee relationship (as applied for purposes of section 3121(d)(2) of the Internal Revenue Code); however, there is no presumption of an employer-employee relationship.

H. Immediate Family Member
1. Husband/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 grandparent or grandchild.

I. Clinical Laboratory Services

1. Specifically identified by CPT/HCPCS list.
   a. Any service not specifically identified as a clinical laboratory service on the CPT/HCPCS list is not a clinical laboratory service.

2. Although some items appear on the CPT/HCPCS list as DHS, they may otherwise qualify for an exception.

J. Physical Therapy Services

1. Specifically identified by CPT/HCPCS list
   a. Any service not specifically identified as a physical therapy service on the CPT/HCPCS list is not a physical therapy service.

2. Outpatient physical therapy services (including speech-language pathology services) defined in the Medicare statute, regardless of who provides them, if the services include the following:

   a. Assessments, function test and measurements of strength, balance, endurance, range of motion, and activities of daily living.

   b. Therapeutic exercises, massage, and use of physical medicine modalities, assistive devices, and adaptive equipment.

   c. Establishment of a maintenance therapy program for an individual whose restoration potential has been reached.

      ▪ Maintenance therapy itself is not covered as part of these services.

   d. Speech-language pathology services for the diagnosis and treatment of speech, language, and cognitive disorders that include swallowing and other oral-motor dysfunctions.

K. Occupational Therapy Services

1. Specifically identified by CPT/HCPCS list
a. Any service not specifically identified as an occupational therapy service on the CPT/HCPCS list is not an occupational therapy service.

2. Outpatient occupational therapy services defined in the Medicare statute, regardless of who provides them, if the services include the following:
   
a. Teaching of compensatory techniques to permit an individual with a physical or cognitive impairment or limitation to engage in daily activities.

b. Evaluation of an individual's level of independent functioning.

c. Selection and teaching of task-oriented therapeutic activities to restore sensory-integrative function.

d. Assessment of an individual's vocational potential, except when the assessment is related solely to vocational rehabilitation.

L. Durable Medical Equipment (DME) and Supplies

1. Equipment that: can withstand repeated use; is primarily and customarily used for a medical purpose; is not generally useful in the absence of illness or injury; and, can be used in the home.

M. Parenteral and Enteral Nutrients, Equipment, and Supplies

1. Parenteral nutrients, equipment, and supplies: those items and supplies needed to provide nutriment to a patient with permanent, severe pathology of the alimentary tract that does not allow absorption of sufficient nutrients to maintain strength commensurate with the patient's general condition.

2. Enteral nutrients, equipment, and supplies: those items and supplies needed to provide enteral nutrition to a patient with a functioning gastrointestinal tract who, due to pathology to or nonfunction of the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with his or her general condition.

N. Prosthetics, Orthotics, and Prosthetic Devices and Supplies

1. Orthotics: leg, arm, back and neck braces

2. Prosthetics: artificial legs, arms, and eyes
3. Prosthetic devices: devices that replace all or part of an internal body organ, including colostomy bags, and one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens.

4. Prosthetic supplies: supplies that are necessary for the effective use of a prosthetic device (including supplies directly related to colostomy care).

O. Home Health Services

1. Same definition given in Medicare statute and regulation at section 409, subpart E.

P. Outpatient Prescription Drugs

1. All prescription drugs covered under Medicare Parts B and D.

2. Provision of antigens is protected under the physician services or in-office ancillary services exceptions.
   a. No referral if antigens are personally furnished by the referring physician.

3. Drugs administered in the physician office setting are outpatient prescription drugs; however, drugs administered in a physician's office will probably fit in the in-office ancillary services exception.

Q. Inpatient and Outpatient Hospital Services

1. Inpatient Hospital Services
   a. Those services defined in the Medicare statute and include inpatient psychiatric hospital services and inpatient critical access hospital services.
   b. Includes:
      (1) Services furnished either by the hospital directly or under arrangements made by the hospital with others.
   c. Does not include:
      (1) Emergency inpatient services provided by a hospital located outside of the U.S.
(2) Emergency inpatient services provided by a non-participating hospital within the U.S.

(3) Dialysis furnished by a hospital that is not certified to provide ESRD services.

(4) Professional services performed by physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, certified registered nurse anesthetists, and qualified psychologists if Medicare reimburses the services independently and not as part of the inpatient hospital service (even if billed under assignment or reassignment).

2. Outpatient Hospital Services

a. Includes:
   (1) Therapeutic, diagnostic, and partial hospitalization services listed in Medicare statute.
   (2) Outpatient services furnished by a psychiatric hospital.
   (3) Outpatient critical access hospital services.
   (4) Services furnished either by the hospital directly or under arrangements made by the hospital with others.

b. Does not include:
   (1) Emergency services furnished by a non-participating hospital.
   (2) Professional services performed by physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, certified registered nurse anesthetists, and qualified psychologists if Medicare reimburses the services independently and not as part of the outpatient hospital service (even if billed under assignment or reassignment).

c. Lithotripsy is not considered an "inpatient or outpatient service"; however, contractual arrangements between hospitals and physicians or physician practices regarding lithotripsy constitute financial relationships and must qualify for an exception if the physician refers patients to the hospital for services that otherwise constitute an inpatient or outpatient service or another DSH.
R. Professional Services as Designated Health Services

1. DHS definitions encompass both the professional and technical components of a service.

2. Physician services that are DHS, however, may fall into one of the exceptions.
   a. For example, the physician services exception would apply if a physician refers a hospital inpatient for ultrasound services furnished in the hospital, and the professional services are provided by another physician in the same group practice.

S. DHS Components of Physician Services Implicate Statute

1. DHS that include a physician component are within scope of statute.

T. Physician Organization

1. Includes a physician (including a professional corporation of which the physician is the sole owner), a physician practice, or a group practice that complies with the requirements of § 411.352.

2. Excludes organizations, providers or other entities that are not “physician organizations,” e.g.,
   a. A hospital (or other Part A provider) is not considered to be a “physician organization” merely because it has employment or contractual arrangements with physicians for the provision of patient care services. [Q & A #8881].
   b. Federally qualified health centers (FQHCS) [Q & A #8883].
   c. A single legal entity (that does not satisfy the requirements of a group practice for purposes of (§ 411.352) that encompasses (that is, operates) a faculty practice plan and either a medical school or hospital, or both.
      (1) A medical school that does not operate a faculty practice plan but employs physicians to provide clinical and academic services.
      (2) A staffing company that does not directly provide and bill for patient care services, but merely facilitates the provision of physicians to hospitals and other health care providers, is not a “physician organization.”
3. The term “physician practice” as used in the definition of “physician organization” was clarified by CMS in Q & A 8879 as a medical practice comprised of two or more physicians organized to provide patient care services (regardless of its legal form or ownership). For example, a “physician practice” may be a group of physicians that practice together but do not meet all of the requirements of § 411.352 for “group practices” for purposes of satisfying the requirement of the physician services and in–office ancillary services exceptions. CMS notes that the provisions of patient care services by employed or contracted physicians does not automatically cause an entity to be considered a “physician practice” (and, thus, a “physician organization”). For example, a hospital, which, in general term is an institution that provides medical, surgical, or psychiatric care and treatment for the sick or the injured, is not considered a “physician practice” or “physician organization” even though it employs or contracts with two or more physicians to provide patient care services to its inpatients and outpatients.

4. Physician ownership is not a prerequisite for meeting the definition of “physician organization” or “physician practice.” With respect to a group practice (which is a “physician organization”), the single legal entity that is the group practice may be organized by any party or parties, including, but not limited to, physicians, health care facilities, or other persons or entities. Likewise, physician ownership is not determinative as to whether an entity (regardless of its legal form) is a “physician practice.” [Q & A #8887]

5. For purposes of satisfying the requirements of an exception to the physician self-referral prohibition, CMS considers a physician owner, whether or not he or she “stands in the shoes” of his or her physician organization, to have signed a written agreement when the authorized signatory of the physician organization has signed the agreement. [Q&A #8885, CY 2010 Final Physician Fee Schedule, 74 Fed. Reg. 61,738, 61,932-33 (Nov. 25, 2009)]

V. Regulatory Gloss on Compensation

A. Physician Compensation

1. Different exceptions based on whether physicians are in a group practice, independent contractors, or employees.

2. Group practices receive favored treatment in statute and can provide compensation to physicians in group regardless of status as owners, employees, or independent contractors for incident-to services.
3. Under employment, personal services, fair market value and academic medical center exceptions, rules are mostly consistent.

   a. Physicians can be paid based on the following:

      (1) Percentage of revenues or collections for personally performed services (but not incident to services).

         (a) Established with specificity prospectively

         (b) Objectively verifiable

         (c) Not changed over course of agreement based on volume or value of referrals or other business generated.

      (2) Productivity bonus on personally performed services.

      (3) Participation in physician incentive plan related to health plan enrollees.

4. Other business generated does not include personally performed services; but does include technical component of personally performed services.

5. While a physician’s investment or ownership interest in a retirement plan is considered a compensation arrangement between the physician and the plan, effective October 1, 2009, if the retirement plan invests in a DHS entity, the physician will be considered as having an ownership interest in that DHS entity.

B. Volume or Value

1. Compensation generally may not take into account the volume or value of referrals or business otherwise generated between the parties.

2. Some exceptions may not take into account other business generated.

   a. Does not include personally performed services.

3. Permits time-based, unit-based, or percentage based payments (per click).

   a. Deemed not to take into account volume or value.

   b. Set at fair market value at inception of arrangement.
c. Does not change during term of arrangement in manner that accounts for DHS referrals.

   (1) Payments may decrease as volume increases to accurately reflect fair market value (i.e., costs decrease as volume increases).

d. Not permitted for office space and equipment leases as of October 1, 2009.

4. Allows compensation arrangements that require physicians to refer to particular DHS entity where:

   a. Compensation is set in advance.

   b. Consistent with fair market value.

   c. Ensures patient choice.

   d. Ensures insurers choice.

   e. Ensures physician's independent medical judgment.

   f. The required referral relates solely to physician's services covered under the arrangement and the referral requirement is reasonably necessary to effectuate the legitimate purpose of the compensation relationship.

VI. Knowledge Exception

A. Payment will be made to entity for a prohibited referral if:

1. Entity did not have actual knowledge or act in reckless disregard or deliberate ignorance of identity of referring physician.

2. Claim otherwise complies with Medicare rules.

B. No affirmative duty to inquire absent "reason to suspect".

VII. Direct and Indirect Financial Arrangements

A. Direct financial relationship: An arrangement between the entity furnishing DHS and a referring physician or an immediate family member with no person or entity (other than agents) interposed between them (i.e., between a physician and a hospital).
1. Stock options received as compensation do not constitute ownership until actually exercised.

2. A physician and his or her solely owned professional corporation are the same entity for purposes of the statute.

3. Common ownership in an entity does not create an indirect ownership interest by one common owner in another common owner.
   - Such common ownership can, however, be a "link" in a chain of financial relationships constituting an indirect compensation arrangement.

B. Indirect ownership exists when:

1. There is an unbroken chain of any number (more than one) of persons or entities between the referring physician (or immediate family member) and the entity furnishing DHS and;

2. The entity providing DHS has actual knowledge or acts in deliberate ignorance that the referring physician (or family member) has such an interest:
   - The entity need not know the precise composition of the chain or the specific terms of the investments in the chain, for an indirect ownership interest to exist

C. Definition of indirect compensation arrangement has three elements:

1. There must exist between the referring physician and the entity providing DHS an unbroken chain of persons or entities that have financial relationships between them (that is, each link in the chain has either an ownership or investment interest or compensation arrangement with the preceding link).

2. The aggregate compensation received by the referring physician from the person or entity in the chain with which the physician has a direct financial relationship varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS.
   a. If the financial arrangement between the physician and the person or entity in the chain with which the physician has the direct financial relationship is an ownership or investment interest, the government will look to the relationship between the owned entity and the next person or entity in the chain with which the owned
entity has a direct financial relationship until it reaches a compensation arrangement with an "unowned" entity (i.e., the government looks for the first compensation relationship in the unbroken chain of financial relationships).

b. Any "per-service" or "per-use" payment arrangement between the owned entity and the entity furnishing the DHS that is based, in whole or in part, on the referrals or other business generated by the referring physician for the entity furnishing DHS would be considered to be based on the volume or value.

(1) Stark exceptions containing a requirement that compensation not take into account "the volume or value of referrals" permit time-based or unit-of-service payments (i.e., per-use payments) so long as the payment per unit is at fair market value and does not vary over the term of the agreement.

- For purposes of determining whether a compensation arrangement is indirect, if the total compensation varies or reflects the number or value of referrals or other business generated by the physician, the second element of the definition of the indirect compensation arrangement would be met.

3. The entity furnishing DHS must have actual knowledge that the aggregate compensation received by the referring physician from the entity with which the physician has a financial relationship varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS, or has acted in reckless disregard or deliberate ignorance of the existence of such relationship.

D. Indirect Compensation Exception

1. The indirect compensation arrangement exception has three requirements:

a. Compensation received by the referring physician from the person or entity in the chain with which the referring physician has the direct financial relationship is fair market value for the items or services provided under the arrangement and does not take into account the value or volume of referrals or other business generated by the referring physician for the entity furnishing DHS.

b. The compensation arrangement between the referring physician and the person or entity in the chain with which the physician has
the direct financial relationship is set out in writing, signed by the parties, and specifies the services covered by the arrangement.

c. The compensation arrangement does not violate the antikickback statute or any laws or regulations governing billing or claims submission.

2. When the financial relationship between a physician and a person or entity with whom the physician has a direct financial relationship is an ownership or investment interest, the requirements of the exception are applied to the first compensation arrangement in the chain of relationships between the physician and entity furnishing DHS.

E. “Stand-In-The-Shoes”

1. Physician owners “stand in the shoes,” or stated another way, stand in place of his or her group practice (or other “physician organization” such as a solo practitioner physician, including a professional corporation of which the physician is the sole owner or other physician practice) when determining existence and nature of compensation arrangements. Thus, if a physician owner of a group contracts with a hospital, the individual physician will “stand in the shoes” of the group practice, and therefore have a direct compensation arrangement with the hospital.

The “stand-in-the-shoes” rule only applies to physician owners of physician-owned organizations. However, titular owners, such as physicians in a captive PC, would not stand in the shoes of a physician-owned organization. In addition, physicians who are non-owners of a physician organization, such as employees, may choose to stand in the shoes of their physician organization

2. A “physician organization” includes a physician practice, a physician group practice, or a professional corporation of which the referring physician is the sole owner.

3. Grandfather provision applies to arrangements in existence prior to the publication date of Phase III (September 5, 2007) that comply with the Phase II indirect compensation arrangement exception. These “grandfathered” arrangements need not be amended during the original term of the arrangement or the current renewal term to comply with Stark in light of the stand-in-the-shoes rule.

4. [Q & A # 8886] CMS subsequently clarified that the Phase III “stand in the shoes” grandfathered provision does not apply to an arrangement that, as of September 5 2007, did not meet the definition of an “indirect compensation arrangement” (and was not directly between a physician and
a DHS entity) but which would have satisfied the requirements of the exception for indirect compensation arrangements in 42 C.F.R. § 411.357 (p) if it had been applicable. To qualify for the “grandfathering provision,” the arrangement, as of September 5, 2007, must have (i) met the definition of an “indirect compensation arrangement” and (ii) satisfied the requirements of the exception for indirect compensation arrangements in § 411.357(p). If an arrangement satisfied both of the criteria, it need not be amended during its original term or the current renewal term (that is, the renewal term the arrangement is in as of September 5, 2007) to comply with the requirements of another exception.

5. CMS has also clarified that when analyzing whether a compensation arrangement takes into account the referrals between a DHS entity and the physician who “stands in the shoes” of the physician organization, the relevant referrals are not just the referrals made by the physicians who “stand in the shoes,” and, rather, encompass all referrals and other business generated by all physicians in the physician organization, including all members, employees and independent contractor physicians. CY 2010 Final Physician Fee Schedule, 74 Fed. Reg. at 61,932-33.

VIII. Physician Services Exception

A. According to the Secretary, the physician services exception is of "limited application" except for the protection of the narrow class of physician services that are in the definition of DHS (specifically, radiology).

B. Enables physicians in a group practice to refer DHS services to one another.

C. Requirements for Exception

1. Services must be personally performed.

a. By a physician who is a member of the same group practice or who is a physician in the same group practice as the referring physician or

b. Under the supervision of another physician who is a member of the referring physician's group practice or is a physician in the same group practice as the referring physician:

   (1) The supervision must meet the requirements of all of the applicable Medicare payment and coverage rules.

   (2) Supervision requirement duplicates that of the in-office ancillary services requirement.
D. The rule does not extend to independently billed nonphysician practitioners.

1. Professional services billed independently by nonphysician practitioners are not defined as physician services.
   a. These services might qualify for the in-office ancillary services exception.

2. Referrals by nonphysician practitioners generally do not implicate the Stark statute, as it only applies to physician financial arrangements.
   a. The statute can be implicated if the referrals by nonphysician practitioners are directed by a physician.

3. Services for nonphysician practitioners' professional services provided incident to a physician's service are protected.
   a. Physician services include only those incident-to services that are physician services under § 410.20(a):
      (1) Includes the provision of antigens by an allergist; does not include services such as diagnostic tests or physical therapy.

IX. In-office Ancillary Exception

A. Applies to services that are truly ancillary to the medical services being provided by the physician's practice.

B. Requirements for Exception

1. Certain DHS which are ancillary to referring physician professional services.

2. Personally furnished by the referring physician, a physician who is a member of the referring physician's group practice, or individuals directly supervised by the referring physician or by a physician in the referring physician’s group practice.

3. Provided in a centralized building or in the same building in which the referring physician furnishes some physician services unrelated to the furnishing of DHS. Such unrelated services need not represent the full range of physician services unrelated to furnishing DHS that the referring physician routinely provides. In addition, the receipt of DHS may be the primary purpose for the patient’s contact with the referring physician.
4. Billed by the physician performing or supervising the performance of the service (or by the physician's group practice) by an entity wholly owned by the group practice, or by a third-party billing agent.

C. Disclosure Requirement:

1. With respect to MRI, CT, and PET services identified as “radiology and certain other imaging services” on the List of CPT/HCPCS Codes provided on or after January 1, 2011, the referring physician must:
   a. Disclose in writing to the patient that he or she may obtain such services from a person other than the referring physician, a physician who is a member of the same group practice, or an individual directly supervised by the referring physician or by another physician in the group practice; and
   b. Provide the patient with a list of at least other 5 suppliers who furnish such services within a 25-mile radius of the referring physician’s office location at the time of the referral, except:
      1. 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.
      2. If no other suppliers provide the services for which the individual is being referred within the 25-mile radius, provision of the written list of alternate suppliers is not be required.
   c. 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.

D. Furnished

1. Services are "furnished" for purposes of the exception:
   a. In a location where the service is actually performed or
   b. When an item is dispensed to a patient in a manner sufficient to satisfy Medicare payment and coverage rules.
2. Outpatient prescription drugs (including chemotherapy drugs) are protected under the in-office ancillary exception.

3. DME, including crutches, canes, walkers, and folding manual wheelchairs, as well as blood glucose monitors, are protected as long as:
   
   a. The patient needs the items in order to ambulate and leave the physician's office.
   
   b. The items are furnished to the patient as part of the condition for which the physician-patient encounter occurred.
   
   c. The "same building" requirements of the in-office ancillary services requirement are met.
   
   d. The items are furnished personally by the referring physician, a physician who is a member or an independent contractor of the group.
   
   e. The physician or group practice which furnishes the item satisfies the Medicare supplier standards.
   
   f. The arrangement does not violate the federal anti-kickback statute.
   
   g. All other requirements of the in-office ancillary services exception are met.

4. The furnishing of external ambulatory infusion pumps can be protected also, if the requirements of the exception are met, the additional DME requirements listed above need not be met.

5. Hospital services do not qualify as in-office ancillary services.

6. Physicians who provide DME must obtain a DMEPOS supplier number.
   
   a. CMS takes the position that it is practically impossible for a physician to personally furnish DME. According to CMS, a physician would have to be enrolled as Medicare DME supplier and personally perform all of the duties of a DME supplier to personally furnish DME.
   
   b. Continuous positive airway pressure equipment ("CPAP") is DME that does not qualify for the in-office ancillary services exception.

E. Direct Supervision
1. No longer need to meet strict requirement of "direct supervision" (in the office suite).
   a. Supervision requirements for applicable Medicare coverage and payment rules apply for the specific service at issue.

2. Independent contractors, although not members of the group, are permitted to supervise the provision of ancillary services if considered a physician in the group practice.

3. Solo practitioners can furnish DHS through a shared facility in the same building as long as all of the other requirements of the in-office ancillary services exception are met.

4. A group practice may provide and bill for ancillary services provided in shared office space using shared equipment if the service is furnished personally by the referring physician, furnished by a member of the referring physician’s group practice or supervised by the referring physician or a physician in the group and the arrangement otherwise complies with Medicare coverage and reimbursement regulations [Q & A #8890].

F. Same Building

1. Ancillary services must be furnished in same building as non-DHS physician services or, if a group practice, in a centralized building.

2. Definition of Building
   a. Defined as structure with a single street address designated by the post office.
   b. Space need not be adjacent to where the physician or group provides DHS services.
   c. Excludes exterior spaces, internal loading docks, parking garages, mobile vehicles, vans and trailers.
   d. Physicians can purchase diagnostic tests-physician groups that bill for purchased diagnostic tests not considered "entity" even though group is billing.
   e. Can include a SNF, other facility, or a patient's home.
   f. Physicians may share DHS facilities in the same building, as long as the supervision, location, and billing requirements are met.
3. Same Building Requirements

a. Same building must be one in which referring physician or member of group practice furnishes physician services unrelated to DHS.

b. Three alternative tests apply to solo and group practices to determine whether a DHS is furnished in the same building.

If the building is one in which the referring physician or group practice has an office that is normally open to patients at least 35 hours per week, and the referring physician or group members regularly practices medicine and furnishes physician services to patients in that office at least 30 hours per week.

(1) "Some" of the services must be physician services that are unrelated to DHS (federal or private pay).

(2) If the building is one in which the referring physician or group practice has an office that is normally open to patients at least eight hours per week and the referring physician regularly practices medicine and furnishes physician services to patients in that office at least six hours per week (including "some" that are unrelated to DHS).

   (a) Other members in group do not count.

   (b) Patient must come to that building to also receive non-DHS services from referring physician or group practice members.

(3) If the building is one in which the referring physician or group has an office that is normally open eight hours per week, and the referring physician or group member regularly practices medicine and furnishes physician services to patients at least six hours per week in that office (including "some" services that are unrelated to DHS).

   (a) Referring physician must be present and order the DHS in connection with a patient visit during the time the office is open or the referring physician or a group practice member is present while the DHS is furnished during the time the office is open.

   (b) Requires presence in the building, not necessarily the same space.
10. Centralized Building Requirements

a. Group practices can provide ancillary DHS services in a centralized building.

b. Can include a mobile vehicle, van or trailer if it is owned or leased on an exclusive basis by the group.

c. Centralized buildings cannot be shared.

11. Billing Requirement

a. DHS can be billed by:

(1) The physician performing or supervising the performance of the service.

(2) The physician's group practice.

(3) The group practice if the supervising physician is a physician in the group practice.

(4) An entity wholly owned by the performing or supervising physician or that physician's group practice (joint ventures between group practices and individual group practice physicians or that include other providers or investors do not qualify as wholly owned entities).

(5) A third-party billing agent.

G. Referral to a Spouse

1. Referrals to spouses are permissible if the referral is for a physician service unrelated to the furnishing of DHS.

2. Any subsequent DHS referrals by the spouse may fit within the in-office ancillary services exception.

X. Group Practice Definition
A. Not an exception in and of itself

B. Definition

1. A group of two or more physicians legally organized as a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association.

   a. In which each physician who is a member of the group furnishes/provides substantially the full range of services which the physician routinely furnishes, including medical care, consultation, diagnosis, or treatment, through the joint use of shared office space, facilities, equipment and personnel (full range of service test).

   b. For which substantially all of the services of the physicians who are members of the group are furnished through the group and are billed under a billing number assigned to the group and amounts so received are treated as receipts of the group (substantially all test).

   c. In which the overhead expenses of and the income from the practice are distributed in accordance with methods previously determined (distribution of expenses and income).

   d. In which there is a unified business having centralized decision making and consolidated billing, accounting and financial reporting (unified business test).

   e. In which no physician who is a member of the group directly or indirectly receives compensation based on the volume or value of referrals by the physician (except, as noted below, for permitted profit distributions and personal productivity bonuses).

   f. In which members of the group personally conduct at least 75% of the physician-patient encounters of the group practice (physician-patient encounters test).

2. In addition, the statute provides a physician in a group practice may be paid a share of overall profits of the group, or a productivity bonus. With regard to profit sharing, profits must be allocated in a manner that does not directly relate to DHS referrals, including any DHS billed as “incident to” services. For productivity bonuses, CMS permits such payments to be based directly on services that the physician personally performed and services “incident to” such personally performed services (even if “incident to” services are otherwise DHS).
C. Single Legal Entity

1. Two or more physicians who are legally organized as a partnership, professional corporation (PC), foundation, not-for-profit corporation, faculty practice plan, or similar association.

2. Can be any form recognized by the state in which the entity achieves its legal status.

   a. For groups that operate in more than one contiguous state, as long as both entities have identical ownership, governance and operation they will be considered a single legal entity if state law requires separate legal entities.

3. Hospital-employed physicians are not a group practice, unless a separate legal entity.

D. Examples of Group Practices

1. A partnership between two or more physicians.

2. A partnership between one physician and another party, provided that the partnership employs at least one other physician.

3. A partnership between two nonphysician parties if it employs at least two physicians.

4. A corporation or limited liability company with one or more physician shareholders or members, provided that if there is only one physician shareholder or member, it must employ at least one other physician.

5. A corporation or limited liability company owned by nonphysicians, provided that it employs at least two physicians.

6. A single legal entity owned by two or more physicians through their individual professional corporations.

7. A solo practitioner who is organized as a legal entity and who employs at least one other full-time physician (this is the first time that the Secretary has acknowledged that a solo practitioner who employs a full-time physician can qualify as a group practice).

8. A single legal entity that involves two or more physicians through employment or indirect ownership, provided that the "investing" or "owner" entities are not themselves group practices.
E. Members of the Group

1. Group practices must have at least two physicians who are "members of the group."

2. Leased employees are members of the group to the extent a leased employee is a bona fide employee under the IRS rules.

3. Independent contractors are not members of the group, but they may be "physicians in the group" if they have a direct contractual relationship with the group as opposed to the independent contractor having a contract with a staffing company and only when performing services in group practice’s facilities.
   
   a. May take part in profit-sharing and productivity bonuses.
   
   b. May meet the supervision requirements for purposes of the in-office ancillary services exception.

   (i) In Q & A #8888, CMS clarifies that to be considered a “physician in the group practice,” an independent contractor physician must furnish 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. If a physician group practice (Group 1) has a written contractual agreement with another physician group practice (Group 2) for the services of a physician in Group 2, [Physician A], Physician A may either sign an agreement directly with Group 1, or sign the agreement between Group 1 and Group 2 in order to be considered a "physician in the group practice". If the latter option is selected, the written agreement between Group 1 and Group 2 must identify Physician A by name, and also identify the services he is to perform for Group 1. If this is satisfied, Group 1 may bill for the services provided to its patients by Physician A.

   Though CMS has stated that, unlike independent contractors, leased employees cannot be considered physicians in the group, if a leased employee arrangement is structured in compliance with the above FAQ, it seems as if such “leased employee” would constitute a physician in the group.

4. Membership in the group of nonphysician practitioners is irrelevant for the group practice definition.

5. Locum tenens and on-call physicians will be considered members of the group.
6. Physicians who opt-out of Medicare may be members of the group.

7. A physician's financial relationship with an entity that provides DHS will not necessarily be imputed to the group.

F. Range of Care

1. Patient care services are any physician's tasks that address the medical needs of specific patients or patients in general or that benefit the practice.

2. If a physician furnishes patient care services exclusively within the group, then whatever services he or she furnishes will constitute the full range of that physician's routine patient care services.

   a. If a physician provides services both inside and outside of the group, then the services for the group's patients must be comparable in scope to those provided outside of the group setting.

   b. Services that do not involve caring for patients will not be considered.

G. "Substantially All" Test

1. Requires that at least 75% of the total patient care services of the group practice's members be furnished through the group and billed under a billing number assigned to the group.

   a. The payments received for those services must be treated as receipts of the group.

2. Although "actual time spent" performing patient care services remains the available default standard, group practices may adopt alternative measures provided they are:

   a. Reasonable

   b. Fixed in advance of the performance of the services being measured.

   c. Uniformly applied over time

   d. Verifiable

   e. Documented
3. Group practice must aggregate all of the patient care services that each of its members provides both inside and outside of the practice to determine whether 75% of the services are furnished through the group.

4. The professional component of services provided by a member physician under a global payment mechanism may be included in calculating the 75% of patient care services requirement for purposes of the substantially all test, even though a hospital or another group may actually bill Medicare directly for the physician services.

5. A group practice may have more than one billing number, as long as the billing number belongs to the group and the receipts are treated as receipts of the group.

6. A start-up group need not meet the test initially, but it must make a "reasonable, good faith effort to ensure that the group practice complies with [this requirement] as soon as practicable, but no later than 12 months from the date of the initial formation of the group practice."

7. A group that adds a new physician member who has relocated (as defined in the physician recruitment exception) will have a 12-month grace period to comply as long as the group is compliant with the substantially all test if the new physician is not counted and the new physician's employment or ownership interest is documented in writing before the arrangement begins.

8. The substantially all test will not apply to group practices located solely in a HPSA.

9. For group practices located outside of a HPSA, any time spent providing services to patients in a HPSA should not be counted to determine if the group met the substantially all test.

10. Physician services donated to free clinics and services to academic medical centers are not counted to determine if the group meets the substantially all test, if the arrangements are structured so that such services are provided through the group, though no actual bill is sent.

H. Distribution of Expenses and Income

1. Overhead expenses of, and income from, the group 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.

2. A compensation method that directly relates to the volume or value of Medicare referrals or is retroactively adjusted would not meet definition.
3. Groups are not prevented from adjusting their compensation methodologies prospectively, as often as they like, as long as the other elements of the definition and an exception are met.

I. "Unified Business" Test

1. Group practice must be a "unified business"

2. Requirements
   a. Centralized decision-making by a body representative of the group practice that maintains effective control over the group's assets and liabilities.
   b. Consolidated billing, accounting, and financial reporting.

3. A group may utilize cost center and location-based accounting, provided that the group meets the other requirements of the regulation.

4. A group with more than one payment methodology may still qualify as a unified business.

J. Volume or Value of Referrals

1. A member of the group practice may not directly or indirectly receive compensation based on the volume or value of referrals by that physician, except as provided for productivity bonuses and profit sharing.

K. Physician-patient Encounters

1. Members of the group must personally conduct no less than 75% of the physician-patient encounters of the group practice.

2. Patient encounters should be measured "per capita, not by time."

3. Independent contractors or leased employees are not considered in determining whether this test has been met.

L. Productivity Bonuses and Profit Shares

1. Physicians may be paid a share of overall profits of the group or a productivity bonus based on services personally performed or services incident to such personally performed services.
3. The share or bonus may not be determined "in any manner which is directly related to the volume or value of referrals by such physician" (emphasis added).

4. Group practice compensation formulae that are only indirectly related to the volume or value of referrals of DHS are permissible.

5. A group practice may segregate its DHS revenues from its other revenues for purposes of compensating physicians.

6. Overall profits
   a. Defined as "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."
   b. Any grouping of five physicians is permissible.

7. Distribution of Overall Profits
   a. Certain methodologies for distribution of overall profits are deemed not to relate to the volume or value of referrals:
      (1) A per capita division of the overall profits.
      (2) A distribution of DHS revenues based on the distribution of the group practice's revenues attributable to services that are not DHS.
      (3) Any distribution of DHS revenues, if the DHS revenues of the group are less than 5% of the group's total revenues and if no physician's allocated portion of these revenues is more than 5% of the physician's total compensation from the group practice.
      (4) Distribution may not directly relate to “incident to services.”
   b. A group practice may utilize any other distribution method as long as the methodology is reasonable and verifiable and not directly related to the volume or value of the physician's referrals of DHS.

8. Distribution of Productivity Bonuses
a. Certain methodologies for distribution of productivity bonuses are deemed not to relate to the volume or value of referrals:

(1) A productivity bonus based on the physician's total patient encounters or relative value units.

(2) A productivity bonus based on the allocation of the physician's compensation that is attributable to non-DHS.

(3) Any productivity bonus that includes DHS revenues if the group practice's DHS revenues are less than 5% of the group practice's total revenues and if no physician receives an allocated portion of those revenues that is more than 5% of his or her total compensation from the group.

b. Any allocation of a productivity bonus which is determined to be "reasonable and verifiable [and not directly related to the volume or value of the physician's referrals of DHS" is also permitted.

a. Productivity bonuses may be based directly on a physician's personal productivity.

b. Physicians may not be paid any bonus based directly on their referrals of DHS performed by someone else within the group, unless those services are provided incident to the physician's personally performed services.

- “Incident to services” has the same definition as under the Medicare billing rules and applies to both services and supplies.

- The incident-to services must be directly supervised by the physician, i.e., the physician must be present in the office suite and immediately available to provide assistance and direction and the person performing the incident to services must be an employee (or leased employee) of the physician.

XI. Prepaid Plan and Risk Sharing Exceptions

A. Managed care organizations are deemed to be entities furnishing DHS if the managed care organizations bill Medicare, but the statute protects referrals for services furnished by managed care organizations to their enrollees, as well as any entity, provider, or supplier furnishing the services under a contract or subcontract with the managed care organization
B. Protection extends to prepaid plans under Medicaid to address referrals of items or services provided to Medicaid managed care patients

1. Creates exceptions for the following Medicaid programs:
   a. Managed care organization contracting with a state.
   b. Prepaid inpatient health plan or prepaid ambulance health plan.
   c. Health insuring organization.
   d. Entity operating under a demonstration project.

2. Final regulations for § 1903(s) of the Act have been deferred.
   a. CMS determined such referrals would not result in denial of payment under § 1877 of the Act and would therefore not result in denial of federal financial participation under § 1903(s) of the Act.

C. New compensation exception for bona fide risk-sharing arrangements.

1. Between physicians and a health plan for the provision of items and services to enrollees of health plans.

2. Statutory exception need not apply.

3. Differs from the risk-sharing exception under the antikickback statute.

D. The definition of entity permits physician ownership of network-type HMOs, MCOs, provider-sponsored organizations, and independent practice associations by clarifying that the definition of entity furnishing DHS is the person or entity to which Medicare makes payment for the DHS directly or on assignment.

1. Does not apply where the person or entity has reassigned right to payment to an employer, a facility, or a health care delivery system.
   a. Then the person or entity furnishing DHS is the person or entity to which payment has been reassigned.

2. For managed care-type organizations, the person or entity that could accept reassignment from a supplier is the entity furnishing DHS.

E. The exception applies only to the financial arrangements for the services to enrollees of the plans identified in the regulations - not to other lines of business that the managed care organization may have.
F. Participation by two physicians in the same managed care organization does not create a financial relationship between the two physicians.

G. The exception covers all risk-sharing compensation paid to physicians by an entity downstream of any type of health plan, insurance company, HMO, or IPA.

XII. Exception for Services Furnished Under Certain Payment Rates

A. Former exception deemed unnecessary because the definition of designated health services excludes services reimbursed by Medicare as part of a composite rate (such as an ASC, SNF, ESRD facility, etc.).

B. Services separately listed in section 1877(h) of the Act (home health and hospital services) are DHS notwithstanding that they are paid on composite basis.

XIII. Academic Medical Center Exception

A. Exception takes into account the unique relationship among faculty, medical centers, and teaching institutions and the educational and research roles of faculty in those settings.

B. Requirements for exception.

1. Referring physician requirements

   a. Must be bona fide employee of component of academic medical center.

      (1) Must be full time or substantial part time.

      (2) Component

         i. Affiliated medical school, faculty practice plan, hospital, teaching facility, institution of higher education, departmental professional corporation, or nonprofit support organization whose primary purpose is supporting the teaching mission of the academic medical center.

         ii. Components may or may not be separate legal entities.

   b. License to practice medicine in state in which physician practices.
c. Bona fide faculty appointment at affiliated medical school or at one or more of the educational programs at the accredited academic hospital.

d. Provides substantial academic or substantial clinical teaching services (or a combination of academic and clinical teaching services) for compensation.

(1) Parties are to use a reasonable and consistent method for calculating a physician's academic and clinical teaching services.

(2) Regulation contains a safe harbor if physician spends at least 20% of professional time or eight hours per week providing academic and/or clinical teaching services.

(3) Physicians who fail to meet the safe harbor still may qualify.

e. Referring physician's compensation arrangement cannot violate the antikickback statute.

f. Referring physician's compensation arrangement cannot violate any federal or state law or regulation governing billing or claims submission.

g. Total compensation from all components of academic medical center to the referring physician must be set in advance, in the aggregate not to exceed fair market value, and not take into account volume or value of referrals.

2. Academic medical center requirements

a. Transfers of money between components must directly or indirectly support missions of teaching, indigent care, research, or community service.

b. Relationships must be set forth in written agreement or other written documents adopted by each component.

- If the academic medical center is one legal entity, this requirement may be satisfied if transfers are reflected in routine financial reports covering the components.
c. Money for research must be to support bona fide research or teaching and must be consistent with the terms and conditions of the grant.

3. Academic medical center definition

a. Accredited medical school or accredited academic hospital.
   - Accredited academic hospital means a hospital or health system that sponsors four or more approved medical education programs.

b. One or more faculty practice plan affiliated with the medical school, the affiliated hospital(s), or the accredited academic hospital.

c. One or more affiliated hospitals where the majority of the medical staff consists of physicians who are faculty members and the majority of hospital admissions are made by physician faculty members.
   (1) Individual physicians with the same class of privileges must either be included or excluded for purposes of determining whether a majority of physicians on an affiliated hospital’s medical staff are faculty members of the affiliated medical school
   (2) The same hospital may be both the affiliated hospital and the accredited academic hospital.
   (3) Faculty member may be a physician on the faculty of either the affiliated medical school or one or more of the educational programs at the accredited academic hospital.
   (4) Faculty from affiliated medical school and educational programs at accredited academic hospital may be aggregated in satisfying the majority standards members.
   (5) Residents and nonphysician professionals need not be counted.
   (6) Courtesy and volunteer faculty may be counted.

4. Written documentation of relationship among components need not be a single agreement and instead may be a series of agreements.
Documentation may be financial reports if components are part of a single legal entity.

XIV. Specific Exception for Implants in ASC

A. Requirements for Exception

1. Implants used are furnished by the referring physician or a member of his or her group practice with which the referring physician has a financial relationship.

2. Implant is implanted in the patient during a surgical procedure performed in the same ASC where the implant is furnished.

3. Arrangement does not violate the anti-kickback statute.

4. Billing and claims submission for implants complies with all federal and state laws.

5. Billing for implant is done by ASC, not physician.

6. Exception applies only to implanted prosthetics, prosthetic devices, and DME.

B. The exception does not apply to any financial relationships between the referring physician and any entity other than the ASC where it is C. In Q & A # 8007, CMS interpreted this exception to include implanted brachytherapy services.

XV. Exception for EPO and Other Dialysis Related Drugs Furnished in or by ESRD Facility

A. Requirements for Exception

1. The EPO or drugs must be identified on CMS's CPT/HCPCS list.

   a. List has been expanded.

   b. Term EPO includes both epoetin alfa and darbepoetin alfa (Aranesp).

2. The EPO or drugs must be administered or dispensed to a patient in or by the ESRD facility.

   a. Drugs dispensed by an ESRD facility for use in patient's home qualify for the exception.
3. Arrangement must not violate the anti-kickback statute.

4. Billing and claims submission for EPO and other drugs must comply with all federal and state laws.

B. The exception does not apply to any financial relationships between the referring physician and any entity other than the ESRD facility that furnishes the EPO or other drugs.

XVI. Exception for Preventive Screening Tests, Immunizations, and Vaccinations

A. Requirements for Exception
   1. Services must be identified on CMS's CPT/HCPCS List.
   2. Tests must be subject to CMS-mandated frequency limits.
   3. Arrangement does not violate the anti-kickback statute.
   4. Billing and claims submission for tests complies with all federal and state laws.

XVII. Exception for Eyeglasses and Contact Lenses Following Cataract Surgery

A. Requirements for Exception
   1. Eyeglasses or contact lenses must be provided in accordance with Medicare coverage and payment policies.
   2. Arrangement does not violate the anti-kickback statute.
   3. Billing and claims submission for eyeglasses or contact lenses must comply with all federal and state laws.

XVIII. Exception for Intra-family Rural Referrals

A. Requirements for Exception
   1. The patient resides in a rural area.
   2. No other person is available to furnish the services.
      a. In a timely manner in light of the patient's condition.
      b. Within 25 miles of the patient's residence.
3. For patients who receive services where they reside (e.g., home health or in-home DME), there is no other person available to furnish the services in a timely manner in light of the patient's condition.

4. The financial relationship must not otherwise violate the anti-kickback statute or any other federal or state law or regulation governing billing or claims submission.

B. Reasonable Inquiries

1. The referring physician or immediate family member must make reasonable inquiries as to the availability of other persons or entities, but they are not required to make inquiries for persons or entities farther than 25 miles or 45 minutes from the patient's residence.

2. Reasonable inquiry may include consulting.

   a. Telephone directories

   b. Professional associations

   c. Other providers

   d. Internet resources

3. Does not permit a referring physician to take into account the quality of other available DHS entities.

XIX. Exceptions for Publicly Traded Securities and Mutual Funds

A. Publicly Traded Securities

1. Ownership of investment securities that at the time the DHS referral was made could be purchased on the open market does not constitute a financial relationship.

2. Securities must be in a corporation that has stockholder equity exceeding $75 million Stock options received as compensation will not be considered ownership or investment interest until exercised.

B. Mutual Funds

1. Ownership of shares in a regulated investment company as defined in section 851(a) of the Internal Revenue Code of 1986, if company has total assets exceeding $75 million, does not constitute a financial relationship.
C. There are no reporting requirements for shareholder information regarding financial relationships that satisfy exceptions for publicly traded securities or mutual funds.

XX. Exception for Ownership/Investment in Specific Providers

A. Puerto Rico

1. Ownership or investment interest in a hospital located in Puerto Rico does not constitute a financial relationship in the case of DHS furnished by such a hospital.

B. Rural Provider

1. Ownership or investment interest in a rural provider for a DHS furnished in a rural area by the rural provider does not constitute a financial relationship

2. Rural provider means an entity that furnishes at least 75% of its total DHS to residents of a rural area.

3. Rural area means an area that is not an urban area.

4. To the extent that the entity is a hospital, it must meet all of the requirements set forth in Section C. below.

C. Physician-Owned Hospitals

1. Sections 6001 and 10601 of the Patient Protection and Affordable Health Care Act, Pub. L. No. 111-148 (Mar. 23, 2010) and Section 1106 of the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152 (Mar. 30, 2010) amended the rural provider and “whole hospital” ownership exceptions to effectively bar future physician investment in hospitals, while providing a grandfathering provision for existing hospitals that have physician investment and a provider agreement by December 31, 2010. As discussed in below, the grandfathered hospitals are subject to a number of limitations, including a prohibition on increasing the aggregate percentage of physician investment in the hospital, or an entity with ownership in the hospital, as of March 23, 2010, and restrictions regarding the expansion of hospital. CMS’ final regulations relating to these provisions appear at 75 Fed. Reg. 72260 (Nov. 24, 2010) (to be codified at 42 C.F.R. § 411.362).

2. To qualify for the rural provider exception or “whole hospital” ownership exception, a physician-owned hospital must meet each of the following requirements within 18 months of March 23, 2010:
a. The hospital must have: (1) physician ownership and investment; and (2) a Medicare provider agreement in effect as of December 31, 2010.

b. Unless an exception is granted (discussed below), a hospital cannot expand the number of operating rooms, procedure rooms or licensed beds that were in place as of the March 23, 2010 (or in the case of a hospital that did not have a provider agreement in effect as of that date, the effective date of such provider agreement, which must be in place by December 31, 2010).

c. Conflicts of Interest Requirements:

   1. Pursuant to the ACA provisions, a hospital must submit an annual report to the Secretary disclosing the identity of all owners and investors in the hospital, along with the nature and extent of their ownership and/or investment. The Secretary must publish this information on the CMS website and update such information annually. CMS has yet to issue regulations to specify the procedures for such disclosures.

   2. Hospital must require that each referring physician agree, as a condition of medical staff membership or admitting privileges to provide each patient a written disclosure of his or her ownership or investment interest in the hospital (and, if applicable, the ownership or investment interest of any treating physician) to all patients whom the physician refers to the hospital. The disclosure must be sufficient to allow the patient to “make a meaningful decision regarding the receipt of care.”

   3. Hospital cannot condition any ownership or investment interests on the physician owner or investor influencing referrals or otherwise generating business for the hospital.

   4. Hospital must disclose the fact that it is physician-owned on any public website or advertising for the hospital.

d. Ensuring Bona Fide Investment Interests:

   1. The percentage of the total value of ownership or investment interests held in the hospital, or any entity whose assets including the hospital, by physician owners and investors in the aggregate must not exceed such percentage in effect on March 23, 2010.
2. The hospital must not offer physician owners or investors more favorable terms for ownership or investment.

3. The hospital and its owners must not: (1) directly or indirectly provide loans or financing for any investment in the hospital by a physician owner or investor; (2) directly or indirectly, guarantee a loan, make a payment toward a loan, or otherwise subsidize a loan for any physician owner or investor related to acquiring an interest in the hospital; (3) offer a physician owner/investor, directly or indirectly, any guaranteed right to purchase other business interests related to the hospital, including the purchase or lease of any property under control of other owners or investors; or (4) offer any physician owner or investor the opportunity to purchase or lease any property under the control of the hospital or any other owner/investor on terms more favorable than individuals who are not physician owners/investors.

4. Distributed returns must be directly proportional to amount of ownership or investment interest in the hospital.

e. Patient Safety Requirements:

1. If a hospital does not have a physician on the premises during all hours that a patient is admitted, the hospital must disclose that fact upon admission and obtain a written acknowledgement from the patient.

2. Hospital must have capacity to: (1) provide assessment and initial treatment for patients; and (2) refer and transfer patients to a hospital capable of treating a patient, where the hospital lacks such capability.

3. Existing hospitals must implement these patient safety requirements by September 23, 2011.

f. The hospital must not have been converted from an ASC on or after March 23, 2010.

3. Criteria for Hospital Seeking Exception to Prohibition on Facility Expansion:

a. Must be either:
1. **Applicable Hospital** – hospital must meet the following criteria: (1) located in county that has percentage increase in population that is 150% greater than the percentage increase in population of the state in most recent 5-year period; (2) has annual percent of Medicaid inpatient admissions that is equal to or greater than average percent of such admissions for all hospitals in county in most recent fiscal year; (3) does not discriminate federal health care program beneficiaries; (4) located in state which average bed capacity is less than national average in most recent fiscal year; and (5) has average bed occupancy rate that is greater than the average in the state during the most recent year.

2. **High Medicaid Facility** – meeting the following criteria (1) not the sole hospital in its county; (2) annual percent of total Medicaid inpatient admissions is estimated to be greater than percent with respect to such admissions at any other hospital located in the same county; and (3) does not discriminate federal health care program beneficiaries.

b. Hospital must submit written or electronic request to CMS setting forth specified information, including documentation to support its qualification as an Applicable Hospital or High Medicaid Facility, and calculations regarding its baseline operating rooms, procedure rooms and beds, and proposed expansion.

c. Hospital must disclose that it is requesting an expansion on its website. Hospital’s community has opportunity to provide CMS with input regarding the expansion within 30 days after CMS publishes notice of hospital’s request in Federal Register.

d. CMS must publish final determination in Federal Register no later than 60 days after receiving completed request.

e. If granted, the permitted increase:

1. may not result in the hospital’s number of operating rooms, procedures rooms and beds exceeding 200% of baseline number

2. must occur in facilities on hospital’s main campus

f. Determinations made under exception process are not subject to administrative or judicial review
XXI. Exceptions for Rental of Office Space and Equipment

A. Requirements for Exception

1. Lease agreement is in writing.

2. Space/equipment leased does not exceed what is reasonable and necessary for legitimate business purposes, even if no referrals were generated between the parties.

3. Space or equipment is used exclusively by lessee. With respect to office-sharing arrangements,
   a. A lessee must have exclusive use of the leased space or equipment, with the exception of common areas.
   b. Exam rooms are not common areas.
   c. No distinction is made between block leases, which are typically exclusive use arrangements, versus cost sharing arrangements where physicians typically share space, equipment and costs on a non-exclusive basis.

4. Term is at least one year.
   a. Parties may amend lease agreements during the first year provided no change is made to the rental charge.
   b. Such amendments do not require the agreement to be extended for an additional year.
   c. If the parties wish to change any material lease term, including the amount paid, the amount of space leased, or type of equipment rented, the existing agreement should be terminated and a new agreement entered into.
   d. The new agreement may not begin until the first year of the original lease is complete.

5. Month-to-month holdover leases are allowed for up to six months if they continue on the same terms and conditions as the original lease.
   a. Lessors may charge a premium for holdover terms provided such premiums are set in advance and do not take into account the
volume or value of referrals or other business generated by the parties.

b. CMS declined to extend the holdover period beyond six months in cases where a landlord is trying to evict a tenant.

6. Rental charges over term are set in advance and do not take into account the volume or value of referrals or other business generated between the parties.

   a. Effective as of October 1, 2009 percentage and per click payments are prohibited for rental of office space or equipment.

7. The lease would be commercially reasonable even if there were no referrals between the parties.

8. The fair market value exception is not applicable to office space or equipment leases.

XXII. Employment Exception

A. Requirements for Exception

1. The employer and physician (or immediate family member) have a bona fide employment relationship.

2. Employment is for identifiable services.

3. Remuneration for the employment is consistent with fair market value and, except for certain permitted productivity bonuses, does not take into account the volume or value of referrals.

4. Agreement would be commercially reasonable even if no referrals were made to the employer.

B. Because personally performed DHS are not referrals under the statute, employed physicians can be paid in a manner directly correlating to their own personal labor but are not permitted to receive payment for generating referrals of DHS performed by others.

XXIII. Exception for Personal Services Arrangements

A. Requirements for Exception

1. The arrangement is in writing, signed by the parties, and specifies the services covered by the agreement.
2. The arrangement covers all services to be provided by physician to entity.

3. The aggregate services contracted for do not exceed those reasonable and necessary for the legitimate business purposes of the arrangement.

4. The term is at least one year
   a. If parties terminate during the term they may not enter into the same or substantially the same arrangement during the first year of the original term.
   b. There is a six month holdover provision similar to the office space and equipment rental exception.
   c. Amendments to the compensation paid under a personal services agreement should be accomplished by terminating the existing agreement and entering into a new agreement.
   d. Provisions regarding termination/amendment of office space and equipment leases apply to personal services arrangements.

5. The compensation is set in advance and, except for physician incentive plans, does not take into account the volume or value of referrals or other business generated between the parties.

6. The services do not involve the counseling or promotion of an unlawful business arrangement or other activity.

B. Physician Incentive Plans

1. Certain payments are permitted between a physician and an entity or a downstream subcontractor.
   a. This permits physicians to use a wholly owned company to provide contracted services under the exception.

2. With regard to the incorporation-by-reference requirement, the exception permits either incorporation of other agreements or cross-referencing to a master list of contracts maintained centrally and in a manner that preserves the historical record (i.e., updating should not erase past records).

XXIV. Exceptions for Recruitment and Retention

A. General principles.
1. Focuses on relocation of the recruited physician's medical practice, rather than the physician's residence.

2. Permits cross-town recruitment of residents and physicians who have been in medical practice less than one year without regard to any change in the location of their practice, because they are deemed to not have an established practice.
   
a. CMS describes "cross-town recruitment of an established physician's practice from a competitor hospital" as "potentially abusive."

3. Permits recruitment by federally qualified health centers ("FQHCs") in addition to hospitals.
   
a. CMS specifically refused to include other DHS entities, such as home health agencies or nursing homes, because they could pose a "risk of abuse."

4. Permits recruitment payments made through existing medical groups under certain conditions.

5. Permits limited retention payments to physicians with practices in HPSAs.

6. Modifies language regarding recruited physician maintaining staff privileges at other hospitals.
   
a. CMS indicates that original intent was to avoid recruitment payment being used to lock physicians into using the recruiting hospital, except for separate employment or contractual arrangements.
   
b. CMS enters the fray over economic credentialing by noting that "reasonable credentialing restrictions on physicians becoming competitors of a hospital would not violate this condition."

B. Requirements of the Recruitment Exception

1. Hospital (or FQHC) may make recruitment payment directly to a physician if the following conditions are met:
   
a. Recruited physicians must relocate their practice from outside the hospital’s Geographic Service Area (“GSA”) to inside the hospital’s GSA.
Requires recruited physicians to move their medical practice 25 miles or have a new medical practice that derives at least 75% of its revenues from professional services furnished to patients not seen or treated by the physician during the proceeding three years.

Greater latitude was extended to physicians who, for two years immediately prior to recruitment, had no separate private practice and were employed on a full-time basis to serve patients of

- federal or state prisons;
- the Department of Defense or Department of Veterans Affairs; and
- Indian Health Services facilities

(1) CMS provided flexibility under the “zip code rules” for defining the hospital’s GSA. The basic rule is that the hospital’s GSA is the lowest number of contiguous zip codes from which the hospital draws at least 75% of its inpatients. With regard to relocating a physician to a zip code “hole” that would not otherwise be part of the hospital’s GSA, the zip code hole rule applies, this rule is available where no inpatients reside in the zip code, but the zip code is entirely surrounded by zip codes in the GSA.

(2) CMS created an exception in circumstances in which all of a hospital’s contiguous zip codes do not account for 75% of the inpatients. CMS created an alternative zip code rule for certain rural hospitals to allow them to use certain non-contiguous zip codes.

(3) CMS clarified that a hospital may use any configuration of zip codes that meets the regulatory requirements at the time the parties enter into the recruitment arrangement. CMS added that a hospital may use different zip code configurations for each recruitment arrangement even if the arrangements are entered into on the same date.

b. Arrangement is set out in writing and signed by the parties.

c. Arrangement is not conditioned on physician's referral of patients to the hospital.
(1) CMS has identified "cost, cross-coverage, and professional expertise" as legitimate reasons why a physician would relocate.

(2) For several years, the overhead costs that could be allocated to a recruited physician were limited to “actual, additional incremental costs” attributed to the recruited physician. However, CMS eventually added some flexibility where physicians are relocating into a practice in a rural area or HPSA to replace a physician who has left the practice within 12 months because the physician retired, relocated outside the hospital’s GSA, or died. In such cases, a per capita allocation of overhead may be used so long as it does no exceed 20% of the practice’s aggregate cost.

d. Amount of recruitment payment is not determined (directly or indirectly) based on the volume or value of actual or anticipated referrals.

(1) Hospitals may impose reasonable credentialing restrictions on physicians whom they recruit, provided they do not take into account “in any way” the volume or nature of referrals or other business generated.

- This leaves open the question of whether hospitals may impose minimum procedure requirements for quality of care purposes. CMS specifically refused to take a position on economic credentialing.

e. Recruited physician is allowed to establish staff privileges at any other hospital and to refer business to any other entities (except as otherwise permitted under employment arrangement, services contract, or potentially economic credentialing).

(1) Non-compete clauses are permitted to the extent that they do not “unreasonably restrict the recruited physician’s ability to practice medicine” in the hospital’s GSA. CMS indicated that liquidated damages provisions would be acceptable so long as the amount was not unreasonable or otherwise had a substantial effect on the physician remaining in the hospital’s GSA. CMS clarified [in Q & A 8884] that this exception may be available to the hospital, for the provision of recruitment assistance to a resident it has trained, upon completion of the residency. The resident need not relocate a medical practice provided he establishes
his own medical practice in the geographic area served by the recruiting hospital. The resident must, however, become a member of the hospital’s medical staff.

(2) CMS recognizes that often residents do not join the organized medical staff of the training hospital until their training is complete and they can practice without supervision. Having “privileges” or “permission” to provide patient care services only under the supervision of an attending physician is not necessarily the same as “being a member of the medical staff.” To the extent a resident is not considered to be part of the hospital’s organized medical staff, this exception would be available. All of the requirements of an exception must be satisfied in order for remuneration to comply with the physician self-referral rules. CMS points out, however, that this discussion is limited to residents and any activities that occur within the scope of their training programs. If a resident moonlights, he may be a member of the organized medical staff at which he moonlights.

(3) If the resident’s privileges terminate (e.g., pursuant to a provision in the medical staff bylaws or pursuant to the resident’s employment contract) at the end of his residency and the resident, now physician, is not considered a member of the medical staff, the hospital may use this exception to provide a recruitment payment to the physician provided all the requirements of the exception are satisfied at the time of the arrangement. CMS cautions that this answer is contingent upon:

(i) the coterminous nature of the medical staff membership having been established prior to the parties entering into the recruitment arrangement; and

(ii) consideration provided by either party pursuant to the recruitment arrangement not occurring until after the termination of the physician’s medical staff membership as a resident

2. Additional conditions must be met to allow recruitment payment to be made (i) indirectly through another physician or group practice or (ii) directly to physician to join an existing physician or group practice.
a. Written agreement is signed by party to whom payments are directly made.

b. Remuneration must be passed directly through to and remain with recruited physician, except actual costs incurred by the physician or group practice.

c. In the case of an income guarantee, the costs allocated by the physician or group practice to the recruited physician may not exceed the actual additional incremental costs attributable to the recruited physician.

d. Records of actual costs and passed through amounts must be maintained for at least five years.

e. Remuneration may not take into account the volume or value of referrals by the recruited physician, the group practice, or any physician in the group practice.

f. Physician or group practice may not impose additional practice restrictions on the recruited physicians (e.g., a noncompete agreement), except those related to quality of care.

g. Arrangement may not violate the antikickback statute.

h. Arrangement may not violate any federal or state law or regulation governing billing or claims submission.

3. CMS does not believe the fair market value exception can apply to recruitment arrangements.

C. Requirements of the Retention Exception

1. Hospital (or FQHC) may make retention payment directly to a physician if the following conditions are met:

a. Physician is on the hospital's medical staff.

b. Payment is to retain the physician's medical practice in the geographic area served by the hospital (the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 75% of its inpatients).

c. Geographic area served by the hospital is:

(1) A HPSA (without regard for the physician's specialty) or
An area with a demonstrated need for the physician as determined through a Stark advisory opinion.

d. Arrangement is set out in writing and signed by the parties.

e. Arrangement is not conditioned on physician's referral of patients to the hospital.

f. Amount of the retention payment is not determined (directly or indirectly) based on the volume or value of actual or anticipated referrals.

(1) Retention payments may take into account physician’s experience, training and length of service in the area.

(2) CMS expresses concern about not "protecting payments to physicians in bidding wars between hospitals."

(3) CMS has emphasized that retention exception "does not protect payments made indirectly to a retained physician via another person or entity, including a physician practice."

g. Physician is allowed to establish staff privileges at any other hospital and to refer business to any other entities (except as otherwise permitted under employment arrangement, services contract, or economic credentialing).

h. Physician has a bona fide opportunity for future employment. The physician must provide written certification to support the bona fide opportunity. In addition, the hospital must take reasonable steps to verify that the employment opportunity requires the physician to relocate outside of the hospital’s GSA.

i. Retention payment is limited to the lower of:

(1) Amount obtained by subtracting (i) the physician's current income from physician and related services from (ii) the income the physician would receive from comparable services in the bona fide recruitment offer over no more than 24 months; or

(2) Reasonable costs of hospital recruiting a physician who is new to the hospital’s GSA to replace the retained physician.
j. Any retention payment is subject to the same obligations and restrictions, if any, on repayment or forgiveness of indebtedness as the bona fide recruitment offer.

k. The hospital may not enter into a retention arrangement with a particular referring physician more frequently than once every five years.

l. The amount and terms of the retention payment may not be altered during the term of the arrangement in any way that takes into account the volume or value of referrals.

m. The arrangement otherwise complies with all of the conditions of this section.

n. Arrangement may not violate the anti-kickback statute.

o. Arrangement may not violate any federal or state law or regulation governing billing or claims submission.

XXV. Isolated Transaction Exception

A. Requirements for Exception

1. Remuneration must be:

a. Consistent with fair market value.

b. Not determined in a manner taking into account the volume or value of referrals or business generated between the parties

c. Commercially reasonable

2. The parties may not enter into additional transactions for six months.

a. Post-closing adjustments permitted within six months of the date of sale if they are commercially reasonable and do not take into account the volume or value of referrals or business generated by the referring physician.

3. The definition of transaction includes installment sales within the definition of isolated transaction provided that:

a. Total aggregate payment is set before the first payment is made.
b. Payment does not take into account referrals or other business generated by the referring physician.

c. Outstanding balance is secured by negotiable promissory note or similar mechanism.

XXVI. Exception for Remuneration Unrelated to Provision of DHS

A. Requirements for Exception

1. Remuneration provided by a hospital to a physician

   a. Does not apply to remuneration from entities other than hospitals.

2. Remuneration is related to DHS if it:

   a. Is an item/service/cost allocated to Medicare under cost reporting principles.

   b. Is furnished directly, indirectly, explicitly, or implicitly in a selective, targeted, preferential, or conditioned manner to medical staff or potential referral sources.

   c. Otherwise takes into account the volume/value of referrals or other business of referring physician.

B. Exception is narrowly interpreted to apply only when remuneration is wholly unrelated to DHS; therefore, practical use of this exception is limited.

XXVII. Exception for Payments Made by a Physician for Items and Services

A. Requirements for Exception

1. To a laboratory in exchange for clinical laboratory services or furnished at a price that is consistent with fair market value, and that are not specifically excepted under another provision in sections 411.355 through 411.357.

XXVIII. Exception for Charitable Donations by Physician

A. Requirements for Exception

1. Bona fide charitable donations made by a physician to an entity must be:

   a. Made to a tax-exempt organization.
b. Neither solicited, nor made, in a manner that takes into account the volume or value of referrals.

2. The donation must not otherwise violate the antikickback statute or any other federal or state law or regulation governing billing or claims submission.

B. Broad-based solicitations not targeted specifically at physicians (e.g., sales of charity ball tickets or general fund-raising campaigns) qualify under this exception.

XXIX. Exception for Non-monetary Compensation

A. Requirements for Exception

1. Items or services (not cash or cash equivalent).

2. Does not exceed aggregate of $355.

   a. Maximum value to be updated annually for inflation based on CPI-U and displayed on the CMS physician self-referral website.

   b. Inflation update to be made as soon as possible after September 30th each year.

   c. If an entity inadvertently exceeds the threshold, the physician may repay amounts exceeding the aggregate cap. The amount repaid may not exceed 50% of the limit. The physician must repay the excess amounts within the earlier of the same calendar year the amounts were provided or 180 days. The repayment provision may only be used once per referring physician every three years.

3. Does not take into account volume or value of referrals or other business.


5. Arrangement does not violate antikickback statute.

6. Entities with formal medical staffs to provide one “local medical staff appreciation event” per year that does not count toward the non-monetary compensation limits. The provision does not apply to laboratories because they do not have formal medical staffs.

XXX. Fair Market Value Exception
A. Applies to any compensation resulting from an arrangement between an entity and a physician or group. Applies to payments made by physicians to an entity and by an entity to physicians.

B. May be used even if another exception could apply, but all of the requirements of the other exception are not met.

C. Requirements for Exception

1. Arrangement is in writing, signed by the parties and covers only identifiable items or services.

2. Written agreement specifies the timeframe for the arrangement.
   a. Can be any period of time, provided that the parties only enter into one arrangement during the course of one year.
   b. An arrangement for less than one year can be renewed if the terms do not change.

3. Written agreement specifies the compensation to be provided
   a. The compensation must be set in advance.
   b. Must be consistent with fair market value.
      - Fair market value can be per click or per use, but not a percentage.
   c. Cannot be determined in any way that takes into account the volume or value of referrals or any other business generated by the referring physician.
   d. Compensation for the rental of equipment may not be determined using a formula based on: (1) a percentage of the revenue raised, earned, billed, collected or otherwise attributable to the service performed or business generated through the use of the equipment; or (2) per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred between the parties.

4. Arrangement involves a transaction that is commercially reasonable and furthers the legitimate business purposes of the parties.

5. Arrangement meets a safe harbor under the anti-kickback statute or has received a favorable advisory opinion.
6. Services do not involve the counseling or promotion of a business arrangement that violates any other federal or state law.

D. Methodology for valuing physician services within lease arrangements found within fair market value definition.

1. Rentals and leases
   a. Fair market value means value for general commercial purposes (not accounting for intended use).
   b. Such value may not be adjusted to reflect the additional value of lessee's proximity or convenience to lessor when lessor is a potential referral source to lessee.

E. There are a range of methods may be appropriate for determining fair market value but good faith reliance on a proper valuation does not establish the ultimate issue of the accuracy of the valuation.

XXXI. Exception for Medical Staff Incidental Benefits

A. Requirements for Exception
   1. Items or services (not cash or cash equivalents).
   2. From a hospital, or other facility or health care clinic that has a bona fide medical staff, to a member of the medical staff.
   3. Item or service must be used on hospital's campus.
   4. Offered to all medical staff members, practicing in the same specialty, without regard to referrals.
   5. Offered only when medical staff members are engaged in services for hospital, except with respect to identification of medical staff on hospital website or in hospital advertising.
      a. Electronic or Internet items or services and dedicated pagers or two-way radios are covered by exception.
      b. Dedicated computers or other technology for use in connection with hospital services provided to hospital patients are covered by exception.
   6. Compensation is reasonably related (directly or indirectly) to delivery of medical services.
7. Compensation less than $30 for each occurrence (adjusted for inflation).

8. Compensation not determined in any manner that takes into account the volume or value of referrals.

9. Compensation does not violate anti-kickback statute.

XXXII. Exception for Compliance Training

A. Requirements for Exception

1. Provided by an entity that provides DHS to a physician (or a physician's immediate family member or a physician's office staff).

2. Provided to physician practices in entity's local community or service area.

3. Training is held in the local community or service area.

4. Subject matter of compliance training.
   a. Basic elements of a compliance program.
   b. Requirements of federal health care programs (i.e., billing, coding, reasonable and necessary services, documentation, unlawful referral arrangements).
   c. Other federal, state, or local laws, regulations, or rules governing conduct of those for whom training is provided.
   d. Training may include courses were CME credit is available if compliance training is the primary purpose.
   e. Compliance training may be provided online.

XXXIII. Exception for Professional Courtesy

Professional courtesy is defined as free or discounted health care items or services to a physician or his or her immediate family members or office staff.

A. Requirements for Exception

1. Professional courtesy is offered to all physicians on the entity's bona fide medical staff or in the local community or service area without regard to volume or value of referrals.
2. Health care items and services are of a type routinely provided by the entity.

3. Entity's professional courtesy policy is set out in writing and approved in advance by entity's governing body.

4. Professional courtesy is not offered to a physician (or immediate family member) who is a federal health care program beneficiary without good faith showing of financial need.

5. If professional courtesy involves whole or partial reduction of any coinsurance obligation, the insurer must be informed in writing.

6. Arrangement does not violate the anti-kickback statute.

7. Arrangement does not violate any federal or state law or regulation governing billing or claims submission.

B. General Observations

1. CMS indicates that most commenters supported the creation of a professional courtesy exception and several submitted specific proposal.

2. CMS observes that “free or discounted ‘professional courtesy' to physicians and their family members is a longstanding tradition and remains a widespread practice.”

3. CMS notes that professional courtesy discounts can be offered under the employment exception.

4. In response to concerns that professional courtesy not be required, CMS establishes that nothing in these regulations should be construed as requiring or encouraging professional courtesy arrangements.

5. CMS warns that some professional courtesy arrangements may violate the anti-kickback statute or the civil monetary penalty provisions against inducements to beneficiaries.

6. CMS notes that private insurance may have concerns about professional courtesy in the form of coinsurance waivers.

7. Regulation purports to encompass free or discounted items or services provided to physician's office staff as professional courtesy.
a. It is unclear, however, why such free or discounted items or services, which involve no physician financial relationship, would even implicate the Stark statute.

b. The benefit would appear to go to the individual office staff, not the physician.

XXXIV. Exception for Community-wide Health Information Systems

A. Applies to items or services of information technology provided by an entity to a physician to participate in a community-wide health information system (i.e., access and sharing of electronic health care records).

B. Requirements for Exception

1. Items or services are designed to allow a physician to have access to, or share, electronic health care records and any complementary drug information systems, general health information, medical alerts, and related information.

2. The items or services must be:

   a. Available as necessary to enable the physician to participate in the community-wide information system.

   b. Principally used by the physician as part of the community-wide health information system.

   c. Not provided to the physician in any manner that takes into account the volume or value of referrals.

3. The community-wide health information systems must be available to all providers, practitioners, and residents of the community who desire to participate.

4. The arrangement may not otherwise violate the antikickback statute or any other federal or state law or regulation governing billing or claims submission.

XXXV. Electronic Prescribing Items and Services

A. A DHS entity may provide physicians with electronic prescribing items and services (i.e., hardware, software, or information technology and training services) without creating a financial relationship under Stark.

B. Requirements of exception:
1. The electronic prescribing items and services must be provided by:
   a. a hospital to a physician who is a member of its medical staff;
   b. a group practice to a physician who is a member of the group; or
   c. a PDP sponsor or MA organization to a prescribing physician.

2. The items and services must be provided as part of, or for the purposes of accessing, an electronic prescription drug program that meets the Medicare Part D standards.

3. The donor may not limit or restrict the items’ use or compatibility with other electronic prescribing or electronic health records systems.

4. The donor may not restrict a physician’s ability to use the items or services for any patient. For example, where possible, the donor only permits the physician to use the items or service with respect to patients with one particular medical service payer.

5. The donor must not know of, or act in deliberate ignorance of, the fact that the physician has received similar items or services.¹

6. A physician’s eligibility to receive the items or services, and the amount or nature of such items or services, are not determined in a manner that takes into account the volume or value of referrals or other business generated between the parties.

7. The arrangement between the donor and physician must be in writing and signed by the parties as well as specify all items and services provided and the donor’s cost of such. If there are separate agreements, such agreements must incorporate each other by reference or be listed on an updated master list.

XXXVI. Electronic Health Records Items and Services

A. A DHS entity may provide items and services necessary and used predominantly to create, maintain, transmit, or receive electronic health records (i.e., software, or information technology and training services) to physicians without creating a financial relationship under Stark.²

B. Requirements of the exception.

¹ 42 C.F.R. § 411.357(v)(3)(4)&(8)
² 42 C.F.R. § 411.357(w)
1. The software must be interoperable at the time it is provided.

   (a) “Interoperable” means able to communicate and exchange data accurately, effectively, securely and consistently with different information technology systems, software applications, and network, in various settings; and exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered;

   (b) Software is “deemed” interoperable if a certifying body approved by CMS certified the software as interoperable no more than 12 months prior to the date it is provided to the physician.

2. The items and services must not include staffing of physician offices and may not be used primarily to conduct personal business or business unrelated to the physician’s medical practice.

3. Electronic health record software must contain electronic prescribing capability, either through an electronic prescribing component or the ability to interface with the physician’s existing electronic prescribing system that meets the applicable Medicare Part D standards.

4. The donor may not limit or restrict the use, compatibility or interoperability of the items or services with other electronic prescribing or electronic health records systems.

5. In addition, the donor may not restrict a physician’s ability to use the items or services for a patient based on the patient’s medical service payer. The donor must not know of, or act in deliberate ignorance of, the fact that the physician has received similar items or services.

6. The physician must pay 15% of the donor’s costs before receiving the items or services and the donor must not finance, or loans the physician funds for, this payment. The physician, or physician’s practice, must not make the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.

7. A physician’s eligibility to receive the items or services and the amount or nature of such, must not be determined in a manner that takes into account the volume or value of referrals or other business generated between the parties. Such requirement will be met if the determination meets one of the following criteria:

   - It is based on the total number of prescriptions written by the physician, but not the volume or value of prescriptions dispensed or paid by the donor or billed to the Medicare program;
• It is based on the size of the physician’s medical practice (e.g., total patients, total patient encounters, or total relative value units);
• It is based on the total number of hours the physician practices medicine;
• It is based on the physician’s overall use of automated technology in his or her medical practice;
• It is based on whether the physician is a member of the donor’s medical staff, if the donor has a formal medical staff;
• It is based on the level of uncompensated care provided by the physician; or
• It is made in any reasonable and verifiable manner that does not directly relate take into account the volume or value of referrals or other business generated between the parties.\(^3\)

8. The arrangement must be in writing and signed by the parties as well as specify all items and services provided, the donor’s cost of such and the physician’s contribution towards the cost.

   (a) If the total items and services provided are addressed in separate agreements, such must incorporate each other by reference or must be listed on an updated master list.

9. The arrangement must not violate the anti-kickback statute. The transfer of all items or services must occur and all conditions of the exception must be met by December 31, 2013.

XXXVII. Exception for Certain Arrangements Involving Temporary Noncompliance

A. Requirements for Exception

1. The arrangement must have

   a. Fully complied with another exception for 180 calendar days preceding date of noncompliance.

\(^3\) 42 C.F.R. § 411.357(w)(6)
b. Fallen out of compliance for reasons beyond entity's control and entity has taken steps to rectify compliance.

c. Otherwise complied with anti-kickback statute and applicable laws and regulations.

2. Exception only applies to DHS performed during temporary period and noncompliance may not exceed 90 days.

3. Exception may be used only once every three years by same referring physician.

C. Arrangements that previously complied with the exceptions for non-monetary compensation or incidental medical staff benefits are not eligible for protection

D. CMS suggests that the entity contemporaneously document reasons for noncompliance and efforts to rectify compliance.

XXXVIII. Alternative Method of Compliance

1. Purpose is to relieve some of the unintended consequences of the Stark statute’s strict liability.

2. Written agreements that are missing signatures may be corrected within 30 days if the error is non-inadvertent and within 90 days if the error is inadvertent, all the while remaining protected by the applicable exception.

3. In order to benefit from this rule, an agreement must otherwise be compliant with all other elements of the applicable exception. A physician may only take advantage of this rule once in a three year period.

XXXIX. Anti-kickback Safe Harbors

A. No “wholesale importation of the anti-kickback safe harbors” into exceptions applicable to the prohibition against referrals.

B. However, remuneration that meets all of the conditions of the following safe harbors are excepted from the prohibition against referrals:

1. Referral services

2. Obstetrical malpractice insurance subsidies.
a. In the FY 2009 IPPS final rule, CMS added another alternative through which arrangements for obstetrical malpractice insurance subsidies can remain compliant with the Stark statute. This new alternative allows hospitals, federally qualified health centers and rural health clinics to provide obstetrical malpractice insurance subsidies to a physician that routinely engages in obstetrics as part of a medical practice. Such practice must be located in either (1) a primary care Health Professional Shortage Area (HPSA), a rural area, or an area with demonstrated need as determined in an advisory opinion, or (2) an area comprised of patients at least 75% of whom live in a medically underserved area or are part of a medically underserved population. This provision became effective on October 1, 2008.

XL. Reporting Requirements

A. All entities, except those furnishing 20 or fewer Part A or B services in a calendar year, must submit certain information concerning reportable financial relationships to CMS or the OIG when requested.

1. Reportable financial relationships include any ownership or investment interest and compensation arrangements except such relationships that fit an exception.

2. Reportable information would include the name and UPIN of each physician who has a reportable financial relationship with the entity and the nature of the relationship.

3. Annual reports of financial relationships requirements

C. Failure to report may result in assessment of a civil money penalty of up to $10,000 for each day of noncompliance.

XLI. The Period Of Disallowance

A. The period of disallowance resulting from the submission of Medicare claims where there has been a Stark violation ends

1. when the arrangement comes into compliance, if the non-compliance does not relate to compensation;

2. the date when the excess remuneration is returned, if the non-compliance relates to excess compensation; or
3. the date on which additional money is paid, if non-compliance relates to insufficient payment.

B. A period of disallowance may end earlier based on the specific facts and circumstances of a situation.

XLII. Burden Of Proof

A. The burden of proof on the provider-claimant (not the government) when a provider administratively appeals a Stark claim denial. In addition, while the burden of production is initially on the claimant, that burden may shift to the government to prove that the requirement of an exception was not met.

XLIII. Self-Referral Disclosure Protocol

A. Section 6409 of the Patient Protection and Affordable Health Care Act, Pub. L. No. 111-148 (Mar. 23, 2010) (“ACA”) instructed the HHS Secretary, in cooperation with the OIG, to develop and implement a self-referral disclosure protocol (“SRDP”) for actual and potential Stark violations. Secretary is authorized to compromise and reduce penalties due and owing for violation of the Stark Law under the SRDP.


C. When a disclosure made according to the SRDP is received by CMS (and confirmed via return email) obligations under Section 6402 of ACA, if applicable, will be suspended until a settlement agreement is reached or a disclosing entity is removed (or removes itself) from the SRDP. Section 6402 of the ACA requires that all overpayments be reported and returned by the later of: (i) 60 days after the date on which the overpayment was identified; or (ii) the date any corresponding cost report is due. The SRDP suspends this timeframe, allowing disclosing parties additional time to investigate potentially complicated issues.

D. Effective September 23, 2010, disclosing entities with current corporate integrity agreements (CIAs) or certification of compliance agreements (CCAs) with the OIG must disclose a reportable event solely related to a Stark issue to CMS utilizing the SDRP, with a copy to the disclosing party’s OIG monitor.

D. Generally, the SRDP mirrors the well-known OIG Protocol. Although it is specifically limited to “actual or potential violations of the self-referral law,” the SRDP has many similar features:

1. Disclosing parties must provide CMS all relevant information, including names, dates, identification numbers, and a detailed description of the issue,
its discovery, investigation, resolution, and any corrective actions (including the restructuring of the disclosed arrangement).

2. Parties who are already subject to a government inquiry (including investigations, audits, or routine oversight activities) are not automatically precluded from the SRDP, although they must notify CMS of any ongoing investigations of which they are aware.

3. As a condition of remaining in the SRDP, disclosing parties must agree not to appeal any overpayment assessed as a part of a settlement agreement.

4. CMS is not bound to resolve a disclosure in any particular fashion or for any specific amount (CMS will not, for instance, agree to reduce a claimed overpayment by any specified percentage) although it will look to the mitigation factors provided in the Accountable Care Act:
   - The nature and extent of the improper legal practice;
   - The timeliness of self-disclosure;
   - The cooperation in providing additional information relating to the disclosure;
   - The litigation risk associated with the matter disclosed; and
   - The financial position of the disclosing party.

   Any reduction based on these factors will be based on an individual appraisal of the facts and circumstances of each disclosed violation.

5. CMS may treat matters discovered outside the scope of the matter initially disclosed as outside the SRDP.

6. To remain in the SRDP, parties are expected to cooperate fully with CMS’s verification process.

7. Parties must provide a description of any notices, if applicable, provided to other government agencies (such as the SEC or IRS).

8. Parties may not include any repayments as part of their SRDP submission, and may not make repayments during CMS’s verification without CMS’s permission. Parties are encouraged, however, to place reserved payments in an interest bearing escrow account to ensure adequate resources remain available at settlement. CMS also notes that amounts collected from individuals billed in violation of Stark must be refunded to those individuals on a timely basis. The SRDP does not explicitly state how such repayment will occur in connection with a compromised settlement.

E. CMS has also added some requirements which break with the OIG format:

1. Disclosures under the SRDP must be filed electronically, via email to 1877SRDP@CMS.HHS.GOV. In addition, an original and one copy must be
mailed to the Division of Technical Payment Policy. Following receipt of an electronic submission, CMS will send an email acknowledgement. (It is this email acknowledgement that begins the tolling of the 60-day repayment period in section 6402 of the ACA). CMS will then review the submission and send a letter to the disclosing party either accepting or rejecting the disclosure. Notably, there is no time frame for CMS to provide notice of acceptance or rejection.

2. Disclosing party must provide a detailed description as to why the party believes a violation of Stark has occurred, including a “complete legal analysis” of the application of the Stark law to the matter being disclosed. This analysis should also include a description of any exception the party believes is, or may be, applicable and which elements of that exception are and are not met.

3. Disclosing party must provide a statement as to whether the party has a “history of similar conduct, or…any prior criminal, civil, and regulatory enforcement actions (including payment suspensions)….”

4. Disclosing party must provide details regarding the existence and “adequacy” of any pre-existing compliance plan.

5. SRDP notes specifically that cooperation with CMS will require access to all “supporting documents without the assertion of privileges or limitations…..”

6. SRDP requires that a detailed financial analysis be submitted along with the initial disclosure (this varies from the OIG Protocol, which provides for a self-assessment after the scope of the non-compliance has been identified). This financial analysis must include the full amount, itemized by year, that is actually or potentially due and owing based upon the applicable look back period. The SRDP defines the look back period as the “time during which the disclosing party may not have been in compliance” with the Stark Law. The financial analysis must also include: (1) a description of the calculation methodology used and an explanation as to whether, and how, estimates were used; (2) the total amount of remuneration a physician(s) received as a result during the “look back” period; and (3) a summary of any auditing activity undertaken and documents relied upon.

7. SRDP notes specifically that it is separate from the Advisory Opinion process, and that parties may not use both processes simultaneously.

E. Following submission (and acceptance) of a disclosure into the SRDP, CMS will begin its verification process. Parties are required to fully cooperate with CMS during the verification process in order to remain in the SRDP. Specifically, CMS notes that it expects to receive documents and information requested “without the need to resort to compulsory methods.” Where CMS determines it needs new information, however, it will provide a disclosing party at least 30 days in which to produce it. Failure to cooperate could lead to removal from the SRDP. Where a
party is removed, removes itself, or is initially rejected from the SRDP, CMS notes the reopening rules at 42 C.F.R. §§ 405.980 through 405.986 “shall” apply.

F. Upon review of the disclosing party’s submission, CMS will coordinate with the OIG and DOJ. If warranted, CMS states that it may use such submission to prepare a recommendation to the OIG and DOJ for resolution of False Claims Act, civil monetary penalty or other liability.