

PROPOSED STARK REGULATORY UPDATES

The attorneys at Bass, Berry & Sims have provided the following redlined document outlining the proposed textual changes to the current Stark regulations.

Title 42: Public Health

[PART 411-EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT](#)

Subpart J-Financial Relationships Between Physicians and Entities Furnishing Designated Health Services

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§411.350 Scope of subpart.

(a) This subpart implements section 1877 of the Act, which generally prohibits a physician from making a referral under Medicare for designated health services to an entity with which the physician or a member of the physician's immediate family has a financial relationship.

(b) This subpart does not provide for exceptions or immunity from civil or criminal prosecution or other sanctions applicable under any State laws or under Federal law other than section 1877 of the

Act. For example, although a particular arrangement involving a physician's financial relationship with an entity may not prohibit the physician from making referrals to the entity under this subpart, the arrangement may nevertheless violate another provision of the Act or other laws administered by HHS, the Federal Trade Commission, the Securities and Exchange Commission, the Internal Revenue Service, or any other Federal or State agency.

(c) This subpart requires, with some exceptions, that certain entities furnishing covered services under Medicare report information concerning ownership, investment, or compensation arrangements in the form, in the manner, and at the times specified by CMS.

(d) This subpart does not alter an individual's or entity's obligations under—

(1) The rules regarding reassignment of claims (§424.80);

(2) The rules regarding purchased diagnostic tests (§414.50);

(3) The rules regarding payment for services and supplies incident to a physician's professional services (§410.26); or

(4) Any other applicable Medicare laws, rules, or regulations.

§411.351 Definitions.

[The definitions in this subpart apply only for purposes of section 1877 of the Act and this subpart.](#) As used in this subpart, unless the context indicates otherwise:

Centralized building means all or part of a building, including, for purposes of this subpart only, a mobile vehicle, van, or trailer that is owned or leased on a full-time basis (that is, 24 hours per day, 7 days per week, for a term of not less than 6 months) by a group practice and that is used exclusively by the group practice. Space in a building or a mobile vehicle, van, or trailer that is shared by more than one group practice, by a group practice and one or more solo practitioners, or by a group practice and another provider or supplier (for example, a diagnostic imaging facility) is not a centralized building for purposes of this subpart. This provision does not preclude a group practice from providing services to other providers or suppliers (for example, purchased diagnostic tests) in the group practice's centralized building. A group practice may have more than one centralized building.

Clinical laboratory services means the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings, including procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body, as specifically identified by the List of CPT/HCPCS Codes. All services so identified on the List of CPT/HCPCS Codes are clinical laboratory services for purposes of this subpart. Any service not specifically identified as a clinical laboratory service on the List of CPT/HCPCS Codes is not a clinical laboratory service for purposes of this subpart.

[Commercially reasonable means that the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.](#)

Consultation means a professional service furnished to a patient by a physician if the following conditions are satisfied:

(1) The physician's opinion or advice regarding evaluation or management or both of a specific medical problem is requested by another physician.

(2) The request and need for the consultation are documented in the patient's medical record.

(3) After the consultation is provided, the physician prepares a written report of his or her findings, which is provided to the physician who requested the consultation.

(4) With respect to radiation therapy services provided by a radiation oncologist, a course of radiation treatments over a period of time will be considered to be pursuant to a consultation, provided that the radiation oncologist communicates with the referring physician on a regular basis about the patient's course of treatment and progress.

[Cybersecurity means the process of protecting information by preventing, detecting, and responding to cyberattacks.](#)

Designated health services (DHS) means any of the following services (other than those provided as emergency physician services furnished outside of the U.S.), as they are defined in this section:

(1)(i) Clinical laboratory services.

(ii) Physical therapy, occupational therapy, and outpatient speech-language pathology services.

(iii) Radiology and certain other imaging services.

(iv) Radiation therapy services and supplies.

(v) Durable medical equipment and supplies.

(vi) Parenteral and enteral nutrients, equipment, and supplies.

(vii) Prosthetics, orthotics, and prosthetic devices and supplies.

(viii) Home health services.

(ix) Outpatient prescription drugs.

(x) Inpatient and outpatient hospital services.

(2) Except as otherwise noted in this subpart, the term "designated health services" or DHS means only DHS payable, in whole or in part, by Medicare. DHS do not include services that are reimbursed by Medicare as part of a composite rate (for example, SNF Part A payments or ASC services identified at §416.164(a)), except to the extent that services listed in paragraphs (1)(i) through (1)(x) of this definition are themselves payable through a composite rate (for example, all services provided as home health services or inpatient and outpatient hospital services are DHS). [For services furnished to inpatients by a hospital, a service is not a designated health service payable, in whole or in part, by Medicare if the furnishing of the service does not affect the amount of Medicare's payment to the hospital under the Acute Care Hospital Inpatient Prospective Payment System \(IPPS\).](#)

~~Does not violate the anti-kickback statute, as used in this subpart only, means that the particular arrangement—~~

~~(1)(i) Meets a safe harbor under the anti-kickback statute, as set forth at §1001.952 of this title; “Exceptions”;~~

~~(ii) Has been specifically approved by the OIG in a favorable advisory opinion issued to a party to the particular arrangement (for example, the entity furnishing DHS) with respect to the particular arrangement (and not a similar arrangement), provided that the arrangement is conducted in accordance with the facts certified by the requesting party and the opinion is otherwise issued in accordance with part 1008 of this title, “Advisory Opinions by the OIG”; or~~

~~(iii) Does not violate the anti-kickback provisions in section 1128B(b) of the Act.~~

~~(2) For purposes of this definition, a favorable advisory opinion means an opinion in which the OIG opines that—~~

~~(i) The party's specific arrangement does not implicate the anti-kickback statute, does not constitute prohibited remuneration, or fits in a safe harbor under §1001.952 of this title; or~~

~~(ii) The party will not be subject to any OIG sanctions arising under the anti-kickback statute (for example, under sections 1128A(a)(7) and 1128(b)(7) of the Act) in connection with the party's specific arrangement.~~

Downstream contractor means a “first tier contractor” as defined at §1001.952(t)(2)(iii) or a “downstream contractor” as defined at §1001.952(t)(2)(i).

Durable medical equipment (DME) and supplies has the meaning given in section 1861(n) of the Act and §414.202 of this chapter.

Electronic health record means a repository ~~of consumer health status~~that includes electronic health information ~~in computer processable form used for clinical diagnosis and treatment for a broad array of clinical conditions;~~that—

(1) Is transmitted by or maintained in electronic media; and

(2) Relates to the past, present, or future health or condition of an individual or the provision of health care to an individual.

Employee means any individual who, under the common law rules that apply in determining the employer-employee relationship (as applied for purposes of section 3121(d)(2) of the Internal Revenue Code of 1986), is considered to be employed by, or an employee of, an entity. (Application of these common law rules is discussed in 20 CFR 404.1007 and 26 CFR 31.3121(d)-1(c).)

Entity means—

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

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

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

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

(3) For purposes of this subpart, "entity" does not include a physician's practice when it bills Medicare for the technical component or professional component of a diagnostic test for which the anti-markup provision is applicable in accordance with §414.50 of this chapter and Pub. 100-04, Medicare Claims Processing Manual, Chapter 1, Section 30.2.9.

~~— Fair market value means the value in arm's-length transactions, consistent with the general market value. "General market value" means the price that an asset would bring as the result of bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement. Usually, the fair market price is the price at which bona fide sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in bona fide service agreements with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals. With respect to rentals and leases described in §411.357(a), (b), and (l) (as to equipment leases only), "fair market value" means the value of rental property for general commercial purposes (not taking into account its intended use). In the case of a lease of space, this value may not be adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor when the lessor is a potential source of patient referrals to the lessee. For purposes of this definition, a rental payment does not take into account intended use if it takes into account costs incurred by the lessor in developing or upgrading the property or maintaining the property or its improvements.~~

Fair market value means—

(1) General. The value in an arm's-length transaction, with like parties and under like circumstances, of like assets or services, consistent with the general market value of the subject transaction.

(2) Rental of equipment. With respect to the rental of equipment, the value in an arm's-length transaction, with like parties and under like circumstances, of rental property for general commercial purposes (not taking into account its intended use), consistent with the general market value of the subject transaction.

(3) Rental of office space. With respect to the rental of office space, the value in an arm's-length transaction, with like parties and under like circumstances, of rental property for general commercial

purposes (not taking into account its intended use), without adjustment to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee, and consistent with the general market value of the subject transaction.

General market value means—

(1) General. The price that assets or services would bring as the result of bona fide bargaining between the buyer and seller in the subject transaction on the date of acquisition of the assets or at the time the parties enter into the service arrangement.

(2) Rental of equipment or office space. The price that rental property would bring as the result of bona fide bargaining between the lessor and the lessee in the subject transaction at the time the parties enter into the rental arrangement.

Home health services means the services described in section 1861(m) of the Act and part 409, subpart E of this chapter.

Hospital means any entity that qualifies as a “hospital” under section 1861(e) of the Act, as a “psychiatric hospital” under section 1861(f) of the Act, or as a “critical access hospital” under section 1861(mm)(1) of the Act, and refers to any separate legally organized operating entity plus any subsidiary, related entity, or other entities that perform services for the hospital's patients and for which the hospital bills. However, a “hospital” does not include entities that perform services for hospital patients “under arrangements” with the hospital.

HPSA means, for purposes of this subpart, an area designated as a health professional shortage area under section 332(a)(1)(A) of the Public Health Service Act for primary medical care professionals (in accordance with the criteria specified in part 5 of this title).

Immediate family member or member of a physician's immediate family means husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

“Incident to” services or services “incident to” means those services and supplies that meet the requirements of section 1861(s)(2)(A) of the Act, §410.26 of this chapter, and Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15, Sections 60, 60.1, 60.2, 60.3, and 60.4

Inpatient hospital services means those services defined in section 1861(b) of the Act and §409.10(a) and (b) of this chapter and include inpatient psychiatric hospital services listed in section 1861(c) of the Act and inpatient critical access hospital services, as defined in section 1861(mm)(2) of the Act. “Inpatient hospital services” do not include emergency inpatient services provided by a hospital located outside of the U.S. and covered under the authority in section 1814(f)(2) of the Act and part 424, subpart H of this chapter, or emergency inpatient services provided by a nonparticipating hospital within the U.S., as authorized by section 1814(d) of the Act and described in part 424, subpart G of this chapter. “Inpatient hospital services” also do not include dialysis furnished by a hospital that is not certified to provide end-stage renal dialysis (ESRD) services under subpart U of part 405 of this chapter. “Inpatient hospital services” include services that are furnished either by the hospital directly or under arrangements made by the hospital with others. “Inpatient hospital services” do not include professional services performed by physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, and certified registered nurse anesthetists and qualified

psychologists if Medicare reimburses the services independently and not as part of the inpatient hospital service (even if they are billed by a hospital under an assignment or reassignment).

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

Interoperable means–

(1) Able to securely exchange data with and use data from other health information technology without special effort on the part of the user;

(2) Allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and

(3) Does not constitute information blocking as defined in section 3022 of the Public Health Service Act.

Isolated financial transaction–(1) Isolated financial transaction means a transaction involving a single payment between two or more persons or a transaction that involves integrally related installment payments, provided that–

(i) The total aggregate payment is fixed before the first payment is made and does not take into account the volume or value of referrals or other business generated by the physician; and

(ii) The payments are immediately negotiable, guaranteed by a third party, secured by a negotiable promissory note, or subject to a similar mechanism to ensure payment even in the event of default by the purchaser or obligated party.

(2) An isolated financial transaction includes a one-time sale of property or a practice, or similar one-time transaction, but does not include a single payment for multiple or repeated services (such as a payment for services previously provided but not yet compensated).

Laboratory means an entity furnishing biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Entities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.

List of CPT/HCPCS Codes means the list of CPT and HCPCS codes that identifies those items and services that are DHS under section 1877 of the Act or that may qualify for certain exceptions under section 1877 of the Act. It is updated annually, as published in the FEDERAL REGISTER, and is posted on the CMS [Web site](http://www.cms.hhs.gov/PhysicianSelfReferral/11_List_of_Codes.asp#TopOfPage) [website](http://www.cms.hhs.gov/PhysicianSelfReferral/11_List_of_Codes.asp#TopOfPage) at http://www.cms.hhs.gov/PhysicianSelfReferral/11_List_of_Codes.asp#TopOfPage.

Locum tenens physician (or substitute physician) **is means** a physician who substitutes in exigent circumstances for another physician, in accordance with section 1842(b)(6)(D) of the Act and Pub. 100-04, Medicare Claims Processing Manual, Chapter 1, Section 30.2.11.

Member of the group or member of a group practice means, for purposes of this subpart, a direct or indirect physician owner of a group practice (including a physician whose interest is held by his or her individual professional corporation or by another entity), a physician employee of the group practice (including a physician employed by his or her individual professional corporation that has an equity interest in the group practice), a *locum tenens* physician (as defined in this section), or an on-call physician while the physician is providing on-call services for members of the group practice. A physician is a member of the group during the time he or she furnishes "patient care services" to the group as defined in this section. An independent contractor or a leased employee is not a member of the group (unless the leased employee meets the definition of an "employee" under this §411.351).

Outpatient hospital services means the therapeutic, diagnostic, and partial hospitalization services listed under sections 1861(s)(2)(B) and (s)(2)(C) of the Act; outpatient services furnished by a psychiatric hospital, as defined in section 1861(f) of the Act; and outpatient critical access hospital services, as defined in section 1861(mm)(3) of the Act. "Outpatient hospital services" do not include emergency services furnished by nonparticipating hospitals and covered under the conditions described in section 1835(b) of the Act and subpart G of part 424 of this chapter. "Outpatient hospital services" include services that are furnished either by the hospital directly or under arrangements made by the hospital with others. "Outpatient hospital services" do not include 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 they are billed by a hospital under an assignment or reassignment).

Outpatient prescription drugs means all drugs covered by Medicare Part B or D, except for those drugs that are "covered ancillary services," as defined at §416.164(b) of this chapter, for which separate payment is made to an ambulatory surgical center.

Parenteral and enteral nutrients, equipment, and supplies means the following services (including all HCPCS level 2 codes for these services):

(1) *Parenteral nutrients, equipment, and supplies*, meaning 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, as described in Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Section 180.2, as amended or replaced from time to time; and

(2) *Enteral nutrients, equipment, and supplies*, meaning 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, as described in Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Section 180.2.

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

Physical therapy, occupational therapy, and outpatient speech-language pathology services means those particular services so identified on the List of CPT/HCPCS Codes. All services so identified on the List of CPT/HCPCS Codes are physical therapy, occupational therapy, and outpatient speech-language pathology services for purposes of this subpart. Any service not specifically identified as physical therapy, occupational therapy or outpatient speech-language pathology on the List of CPT/HCPCS Codes is not a physical therapy, occupational therapy, or outpatient speech-language pathology service for purposes of this subpart. The list of codes identifying physical therapy, occupational therapy, and outpatient speech-language pathology services for purposes of this regulation includes the following:

(1) *Physical therapy services*, meaning those outpatient physical therapy services described in section 1861(p) of the Act that are covered under Medicare Part A or Part B, regardless of who provides them, if the services include—

(i) Assessments, function tests, and measurements of strength, balance, endurance, range of motion, and activities of daily living;

(ii) Therapeutic exercises, massage, and use of physical medicine modalities, assistive devices, and adaptive equipment; or

(iii) Establishment of a maintenance therapy program for an individual whose restoration potential has been reached; however, maintenance therapy itself is not covered as part of these services.

(2) *Occupational therapy services*, meaning those services described in section 1861(g) of the Act that are covered under Medicare Part A or Part B, regardless of who provides them, if the services include—

(i) Teaching of compensatory techniques to permit an individual with a physical or cognitive impairment or limitation to engage in daily activities;

(ii) Evaluation of an individual's level of independent functioning;

(iii) Selection and teaching of task-oriented therapeutic activities to restore sensory-integrative function; or

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

(3) *Outpatient speech-language pathology services*, meaning those services as described in section 1861(l)(2) of the Act that are for the diagnosis and treatment of speech, language, and cognitive disorders that include swallowing and other oral-motor dysfunctions.

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

Physician in the group practice means a member of the group practice, as well as an independent contractor physician during the time the independent contractor is furnishing patient care services (as defined in this section) 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. The contract must contain the same restrictions on compensation that apply to members of the group

practice under §411.352(g) (or the contract must satisfy the requirements of the personal service arrangements exception in §411.357(d)), and the independent contractor's arrangement with the group practice must comply with the reassignment rules in §424.80(b)(2) of this chapter (see also Pub. 100-04, Medicare Claims Processing Manual, Chapter 1, Section 30.2.7, as amended or replaced from time to time). Referrals from an independent contractor who is a physician in the group practice are subject to the prohibition on referrals in §411.353(a), and the group practice is subject to the limitation on billing for those referrals in §411.353(b).

Physician incentive plan means any compensation arrangement between an entity (or downstream contractor) and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services furnished with respect to individuals enrolled with the entity.

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

Plan of care means the establishment by a physician of a course of diagnosis or treatment (or both) for a particular patient, including the ordering of services.

Professional courtesy means the provision of free or discounted health care items or services to a physician or his or her immediate family members or office staff.

Prosthetics, Orthotics, and Prosthetic Devices and Supplies means the following services (including all HCPCS level 2 codes for these items and services that are covered by Medicare):

(1) *Orthotics*, meaning leg, arm, back, and neck braces, as listed in section 1861(s)(9) of the Act.

(2) *Prosthetics*, meaning artificial legs, arms, and eyes, as described in section 1861(s)(9) of the Act.

(3) *Prosthetic devices*, meaning devices (other than a dental device) listed in section 1861(s)(8) of the Act 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*, meaning supplies that are necessary for the effective use of a prosthetic device (including supplies directly related to colostomy care).

Radiation therapy services and supplies means those particular services and supplies, including (effective January 1, 2007) therapeutic nuclear medicine services and supplies, so identified on the List of CPT/HCPCS Codes. All services and supplies so identified on the List of CPT/HCPCS Codes are radiation therapy services and supplies for purposes of this subpart. Any service or supply not specifically identified as radiation therapy services or supplies on the List of CPT/HCPCS Codes is not a radiation therapy service or supply for purposes of this subpart. The list of codes identifying radiation therapy services and supplies is based on section 1861(s)(4) of the Act and §410.35 of this chapter.

Radiology and certain other imaging services means those particular services so identified on the List of CPT/HCPCS Codes. All services identified on the List of CPT/HCPCS Codes are radiology and certain other imaging services for purposes of this subpart. Any service not specifically identified as radiology and certain other imaging services on the List of CPT/HCPCS Codes is not a radiology or certain other imaging service for purposes of this subpart. The list of codes identifying radiology and certain other imaging services includes the professional and technical components of any diagnostic

test or procedure using x-rays, ultrasound, computerized axial tomography, magnetic resonance imaging, nuclear medicine (effective January 1, 2007), or other imaging services. All codes identified as radiology and certain other imaging services are covered under section 1861(s)(3) of the Act and §§410.32 and 410.34 of this chapter, but do not include—

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

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

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

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

(3) Radiology and certain other imaging services that are “covered ancillary services,” as defined at §416.164(b), for which separate payment is made to an ASC.

Referral—

(1) Means either of the following:

(i) Except as provided in paragraph (2) of this definition, the request by a physician for, or ordering of, or the certifying or recertifying of the need for, any designated health service for which payment may be made under Medicare Part B, including a request for a consultation with another physician and any test or procedure ordered by or to be performed by (or under the supervision of) that other physician, but not including any designated health service personally performed or provided by the referring physician. A designated health service is not personally performed or provided by the referring physician if it is performed or provided by any other person, including, but not limited to, the referring physician's employees, independent contractors, or group practice members.

(ii) Except as provided in paragraph (2) of this definition, a request by a physician that includes the provision of any designated health service for which payment may be made under Medicare, the establishment of a plan of care by a physician that includes the provision of such a designated health service, or the certifying or recertifying of the need for such a designated health service, but not including any designated health service personally performed or provided by the referring physician. A designated health service is not personally performed or provided by the referring physician if it is performed or provided by any other person including, but not limited to, the referring physician's employees, independent contractors, or group practice members.

(2) Does not include a request by a pathologist for clinical diagnostic laboratory tests and pathological examination services, by a radiologist for diagnostic radiology services, and by a radiation oncologist for radiation therapy or ancillary services necessary for, and integral to, the provision of radiation therapy, if—

(i) The request results from a consultation initiated by another physician (whether the request for a consultation was made to a particular physician or to an entity with which the physician is affiliated); and

(ii) The tests or services are furnished by or under the supervision of the pathologist, radiologist, or radiation oncologist, or under the supervision of a pathologist, radiologist, or radiation oncologist, respectively, in the same group practice as the pathologist, radiologist, or radiation oncologist.

(3) Can be in any form, including, but not limited to, written, oral, or electronic.

[\(4\) A referral is not an item or service for purposes of section 1877 of the Act and this subpart.](#)

Referring physician means a physician who makes a referral as defined in this section or who directs another person or entity to make a referral or who controls referrals made by another person or entity. A referring physician and the professional corporation of which he or she is a sole owner are the same for purposes of this subpart.

Remuneration means any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind, except that the following are not considered remuneration for purposes of this section:

(1) The forgiveness of amounts owed for inaccurate tests or procedures, mistakenly performed tests or procedures, or the correction of minor billing errors.

(2) The furnishing of items, devices, or supplies ~~(not including surgical items, devices, or supplies)~~ that are, in fact, used solely for one or more of the following purposes:

(i) Collecting specimens for the entity furnishing the items, devices or supplies;

(ii) Transporting specimens for the entity furnishing the items, devices or supplies;

(iii) Processing specimens for the entity furnishing the items, devices or supplies;

(iv) Storing specimens for the entity furnishing the items, devices or supplies;

(v) Ordering tests or procedures for the entity furnishing the items, devices or supplies; or

(vi) Communicating the results of tests or procedures for the entity furnishing the items, devices or supplies.

(3) A payment made by an insurer or a self-insured plan (or a subcontractor of the insurer or self-insured plan) to a physician to satisfy a claim, submitted on a fee-for-service basis, for the furnishing of health services by that physician to an individual who is covered by a policy with the insurer or by the self-insured plan, if—

(i) The health services are not furnished, and the payment is not made, under a contract or other arrangement between the insurer or the self-insured plan (or a subcontractor of the insurer or self-insured plan) and the physician;

(ii) The payment is made to the physician on behalf of the covered individual and would otherwise be made directly to the individual; and

(iii) The amount of the payment is set in advance, does not exceed fair market value, and is not determined in any manner that takes into account ~~directly or indirectly~~ the volume or value of any referrals.

Rural area means an area that is not an urban area as defined at §412.62(f)(1)(ii) of this chapter.

Same building means a structure with, or combination of structures that share, a single street address as assigned by the U.S. Postal Service, excluding all exterior spaces (for example, lawns, courtyards, driveways, parking lots) and interior loading docks or parking garages. For purposes of this section, the “same building” does not include a mobile vehicle, van, or trailer.

Specialty hospital means a subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Act) that is primarily or exclusively engaged in the care and treatment of one of the following:

- (1) Patients with a cardiac condition;
- (2) Patients with an orthopedic condition;
- (3) Patients receiving a surgical procedure; or

(4) Any other specialized category of services that the Secretary designates as inconsistent with the purpose of permitting physician ownership and investment interests in a hospital. A “specialty hospital” does not include any hospital—

(1) Determined by the Secretary to be in operation before or under development as of November 18, 2003;

(2) For which the number of physician investors at any time on or after such date is no greater than the number of such investors as of such date;

(3) For which the type of categories described above is no different at any time on or after such date than the type of such categories as of such date;

(4) For which any increase in the number of beds occurs only in the facilities on the main campus of the hospital and does not exceed 50 percent of the number of beds in the hospital as of November 18, 2003, or 5 beds, whichever is greater; and

(5) That meets such other requirements as the Secretary may specify.

[Target patient population means an identified patient population selected by a value-based enterprise or its VBE participants based on legitimate and verifiable criteria that—](#)

[\(1\) Are set out in writing in advance of the commencement of the value-based arrangement; and](#)

[\(2\) Further the value-based enterprise’s value-based purpose\(s\).](#)

Transaction means an instance or process of two or more persons or entities doing business. ~~An isolated financial transaction means one involving a single payment between two or more persons or entities or a transaction that involves integrally related installment payments provided that—~~

~~(1) The total aggregate payment is fixed before the first payment is made and does not take into account, directly or indirectly, the volume or value of referrals or other business generated by the referring physician; and~~

~~(2) The payments are immediately negotiable or are guaranteed by a third party, or secured by a negotiable promissory note, or subject to a similar mechanism to ensure payment even in the event of default by the purchaser or obligated party.~~

Value-based activity—(1) Means any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise:

(i) The provision of an item or service;

(ii) The taking of an action; or

(iii) The refraining from taking an action.

(2) The making of a referral is not a value-based activity.

Value-based arrangement means an ~~arrangement for the provision of at least one value-based activity for a target patient population between or among—~~

(1) The value-based enterprise and one or more of its VBE participants; or

(2) VBE participants in the same value-based enterprise.

Value-based enterprise (VBE) means two or more VBE participants—

(1) Collaborating to achieve at least one value-based purpose;

(2) Each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise;

(3) That have an accountable body or person responsible for financial and operational oversight of the value-based enterprise; and

(4) That have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s).

Value-based purpose means—

(1) Coordinating and managing the care of a target patient population;

(2) Improving the quality of care for a target patient population;

(3) Appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a target patient population; or

(4) Transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

VBE participant means an individual or entity that engages in at least one value-based activity as part of a value-based enterprise.

§411.352 Group practice.

For purposes of this subpart, a group practice is a physician practice that meets the following conditions:

(a) *Single legal entity.* The group practice must consist of a single legal entity operating primarily for the purpose of being a physician group practice in any organizational form recognized by the State in which the group practice achieves its legal status, including, but not limited to, a partnership, professional corporation, limited liability company, foundation, nonprofit corporation, faculty practice plan, or similar association. The single legal entity may be organized by any party or parties, including, but not limited to, physicians, health care facilities, or other persons or entities (including, but not limited to, physicians individually incorporated as professional corporations). The single legal entity may be organized or owned (in whole or in part) by another medical practice, provided that the other medical practice is not an operating physician practice (and regardless of whether the medical practice meets the conditions for a group practice under this section). For purposes of this subpart, a single legal entity does not include informal affiliations of physicians formed substantially to share profits from referrals, or separate group practices under common ownership or control through a physician practice management company, hospital, health system, or other entity or organization. A group practice that is otherwise a single legal entity may itself own subsidiary entities. A group practice operating in more than one State will be considered to be a single legal entity notwithstanding that it is composed of multiple legal entities, provided that—

(1) The States in which the group practice is operating are contiguous (although each State need not be contiguous to every other State);

(2) The legal entities are absolutely identical as to ownership, governance, and operation; and

(3) Organization of the group practice into multiple entities is necessary to comply with jurisdictional licensing laws of the States in which the group practice operates.

(b) *Physicians.* The group practice must have at least two physicians who are members of the group (whether employees or direct or indirect owners), as defined at §411.351.

(c) *Range of care.* Each physician who is a member of the group, as defined at §411.351, must furnish substantially the full range of patient care services that the physician routinely furnishes, including medical care, consultation, diagnosis, and treatment, through the joint use of shared office space, facilities, equipment, and personnel.

(d) *Services furnished by group practice members.* (1) Except as otherwise provided in paragraphs (d)(3), (d)(4), (d)(5), and (d)(6) of this section, substantially all of the patient care services of the physicians who are members of the group (that is, at least 75 percent of the total patient care services of the group practice members) must be furnished through the group and billed under a billing number assigned to the group, and the amounts received must be treated as receipts of the group. *Patient care services* must be measured by one of the following:

(i) The total time each member spends on patient care services documented by any reasonable means (including, but not limited to, time cards, appointment schedules, or personal diaries). (For example, if a physician practices 40 hours a week and spends 30 hours a week on patient care services for a group practice, the physician has spent 75 percent of his or her time providing patient care services for the group.)

(ii) Any alternative measure that is reasonable, fixed in advance of the performance of the services being measured, uniformly applied over time, verifiable, and documented.

(2) The data used to calculate compliance with this *substantially all* test and related supportive documentation must be made available to the Secretary upon request.

(3) The *substantially all* test set forth in paragraph (d)(1) of this section does not apply to any group practice that is located solely in a HPSA, as defined at §411.351.

(4) For a group practice located outside of a HPSA (as defined at §411.351), any time spent by a group practice member providing services in a HPSA should not be used to calculate whether the group practice has met the *substantially all* test, regardless of whether the member's time in the HPSA is spent in a group practice, clinic, or office setting.

(5) During the *start up* period (not to exceed 12 months) that begins on the date of the initial formation of a new group practice, a group practice must make a reasonable, good faith effort to ensure that the group practice complies with the *substantially all* test requirement set forth in paragraph (d)(1) of this section as soon as practicable, but no later than 12 months from the date of the initial formation of the group practice. This paragraph (d)(5) does not apply when an existing group practice admits a new member or reorganizes.

(6)(i) If the addition to an existing group practice of a new member who would be considered to have relocated his or her medical practice under §411.357(e)(2) would result in the existing group practice not meeting the *substantially all* test set forth in paragraph (d)(1) of this section, the group practice will have 12 months following the addition of the new member to come back into full compliance, provided that—

(A) For the 12-month period the group practice is fully compliant with the *substantially all* test if the new member is not counted as a member of the group for purposes of §411.352; and

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

(ii) This paragraph (d)(6) does not apply when an existing group practice reorganizes or admits a new member who is not relocating his or her medical practice.

(e) *Distribution of expenses and income.* The overhead expenses of, and income from, the practice must be distributed according to methods that are determined before the receipt of payment for the services giving rise to the overhead expense or producing the income. Nothing in this section prevents a group practice from adjusting its compensation methodology prospectively, subject to restrictions on the distribution of revenue from DHS under §411.352(i).

(f) *Unified business.* (1) The group practice must be a unified business having at least the following features:

(i) Centralized decision-making by a body representative of the group practice that maintains effective control over the group's assets and liabilities (including, but not limited to, budgets, compensation, and salaries); and

(ii) Consolidated billing, accounting, and financial reporting.

(2) Location and specialty-based compensation practices are permitted with respect to revenues derived from services that are not DHS and may be permitted with respect to revenues derived from DHS under §411.352(i).

(g) *Volume or value of referrals.* No physician who is a member of the group practice directly or indirectly receives compensation based on the volume or value of his or her referrals, except as provided in §411.352(i).

(h) *Physician-patient encounters.* Members of the group must personally conduct no less than 75 percent of the physician-patient encounters of the group practice.

(i) *Special rules for ~~productivity bonuses and profit shares~~ and productivity bonuses.* (1) ~~Overall profits. (i) Notwithstanding paragraph (g) of this section, a~~ physician in the group practice may be paid a share of overall profits of the group, ~~provided that the share is not determined in any manner that is indirectly related to the volume or value of referrals of DHS by the physician. A physician in the group practice may be paid a productivity bonus based on services that he or she has personally performed, or services "incident to" such personally performed services, or both, provided that the bonus is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physician (except that the bonus may directly relate to the volume or value of DHS referrals by the physician if the referrals are for services "incident to" the physician's personally performed services).~~ the physician's referrals.

(2) Overall profits means the ~~group's entire~~ profits derived from ~~DHS payable by Medicare or Medicaid or the profits derived from DHS payable by Medicare or Medicaid~~ all the designated health services of any component of the group ~~practice~~ that consists of at least five physicians, ~~which may include all physicians in the group. If there are fewer than five physicians in the group, overall profits means the profits derived from all the designated health services of the group.~~

(iii) Overall profits ~~should~~ must be divided in a reasonable and verifiable manner ~~that is not directly related to the volume or value of the physician's referrals of DHS.~~ The share of overall profits will be deemed not to relate directly to the volume or value of referrals if one of the following conditions is met:

(i) ~~The group's~~ Overall profits are divided per capita (for example, per member of the group or per physician in the group).

(ii) ~~Revenues~~ Overall profits derived from ~~DHS~~ designated health services are distributed based on the distribution of the group's ~~practice's~~ revenues attributed to services that are not ~~DHS~~ designated health services and would not be considered designated health services if they were payable by ~~any Federal health care program or private payer~~ Medicare.

(iii) ~~Revenues~~ derived from ~~DHS~~ designated health services constitute less than 5 percent of the group's ~~practice's~~ total revenues, and the ~~allocated~~ portion of those revenues distributed to each physician in the group ~~practice~~ constitutes 5 percent or less of his or her total compensation from the group.

(2) Productivity bonuses. (i) Notwithstanding paragraph (g) of this section, a physician in the group may be paid a productivity bonus based on services that he or she has personally performed, or services "incident to" such personally performed services, that is indirectly related to the volume or value of the physician's referrals (except that the bonus may directly relate to the volume or value of referrals by the physician if the referrals are for services "incident to" the physician's personally performed services).

(3ii) A productivity bonus must be calculated in a reasonable and verifiable manner ~~that is not directly related to the volume or value of the physician's referrals of DHS~~. A productivity bonus will be deemed not to relate directly to the volume or value of referrals ~~of DHS~~ if one of the following conditions is met:

(iA) The productivity bonus is based on the physician's total patient encounters or the relative value units (RVUs) personally performed by the physician. (The methodology for establishing RVUs is set forth in §414.22 of this chapter.)

~~(ii) The bonus is based on the allocation of the physician's compensation attributable to services that are not DHS payable by any Federal health care program or private payer.~~

(B) The services on which the productivity bonus is based are not designated health services and would not be considered designated health services if they were payable by Medicare.

~~(iiiC) Revenues derived from DHS designated health services are less than 5 percent of the group's practice's total revenues, and the ~~allocated~~ portion of those revenues distributed to each physician in the group ~~practice~~ constitutes 5 percent or less of his or her total compensation from the group ~~practice~~.~~

(3) Value-based enterprise participation. Profits from designated health services that are directly attributable to a physician's participation in a value-based enterprise, as defined in §411.351, are distributed to the participating physician.

(4) Supporting documentation. Supporting documentation verifying the method used to calculate the profit share or productivity bonus under paragraphs (i)(1), (2), and (3) of this section, and the resulting amount of compensation, must be made available to the Secretary upon request.

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

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

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

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

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

~~(ii) Where the noncompliance is due to the payment of excess compensation, the date on which all excess compensation is returned by the party that received it to the party that paid it and the financial relationship satisfies all of the requirements of an applicable exception; or~~

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

~~(i) The compensation arrangement between the entity and the referring physician fully complies with an applicable exception in this subpart except with respect to the signature requirement of the exception; and~~

~~(ii) The parties obtain the required signature(s) within 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant and the compensation arrangement otherwise complies with all criteria of the applicable exception.~~

~~(2) [Reserved]~~

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

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

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

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

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

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

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

(1) An ownership or investment interest includes, but is not limited to, stock, stock options other than those described in §411.354(b)(3)(ii), partnership shares, limited liability company memberships, as well as loans, bonds, or other financial instruments that are secured with an entity's property or revenue or a portion of that property or revenue.

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

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

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

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

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

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

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

(vi) A titular ownership or investment interest that excludes the ability or right to receive the financial benefits of ownership or investment, including, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment; or

(vii) An interest in an entity that arises from an employee stock ownership plan (ESOP) that is qualified under Internal Revenue Code section 401(a).

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

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

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

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

or investment interest (through any number of intermediary ownership or investment interests) in the entity furnishing the DHS.

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

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

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

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

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

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

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

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

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

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

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

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

(iii) The entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) receives aggregate compensation that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS.

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

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

(3)(i) For purposes of paragraphs (c)(1)(ii) and (c)(2)(iv) of this section, a physician who “stands in the shoes” of his or her physician organization is deemed to have the same compensation arrangements (with the same parties and on the same terms) as the physician organization. When applying the exceptions in §§411.355 and 411.357 to arrangements in which a physician stands in the shoes of his or her physician organization, the “parties to the arrangements” are considered to be—

(A) With respect to a signature requirement, the physician organization and any physician who “stands in the shoes” of the physician organization as required under paragraph (c)(1)(ii) or (c)(2)(iv)(A) of this section; and

(B) With respect to all other requirements of the exception, including the relevant referrals and other business generated between the parties, the entity furnishing DHS and the physician organization (including all members, employees, and independent contractor physicians).

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

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

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

(C) Do not apply to a physician whose ownership or investment interest is titular only. A titular ownership or investment interest is an ownership or investment interest that excludes the ability or right to receive the financial benefits of ownership or investment, including, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment.

(iii) An arrangement structured to comply with an exception in §411.357 (other than §411.357(p)), but which would otherwise qualify as an indirect compensation arrangement under this paragraph as of August 19, 2008, need not be restructured to satisfy the requirements of §411.357(p) until the expiration of the original term or current renewal term of the arrangement.

(4) Exceptions applicable to indirect compensation arrangements. (i) General. Except as provided in this paragraph (c)(4) of this section, only the exceptions at §§411.355 and 411.357(p) are applicable to indirect compensation arrangements.

(ii) Special rule for indirect compensation arrangements involving value-based arrangements. When an unbroken chain described in paragraph (c)(2)(i) of this section includes a value-based arrangement (as defined in §411.351) to which the physician (or the physician organization in whose shoes the physician stands under this paragraph) is a direct party, only the exceptions at §§411.355, 411.357(p), and 411.357(aa) are applicable to the indirect compensation arrangement.

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

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

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

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

(4) Alf a physician's compensation from under a bona fide employment or under a relationship, personal service arrangement, or managed care contract or other arrangement for personal services may be is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, ~~provided that the compensation arrangement meets~~ all of the following conditions: ~~The compensation arrangement:~~ must be met.

(i) ~~Is~~The compensation, or a formula for determining the compensation, is set in advance for the ~~term~~duration of the arrangement. Any changes to the compensation (or the formula for determining the compensation) must be made prospectively.

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

(iii) The compensation arrangement ~~o~~therwise complies with an applicable exception ~~under~~at §§411.355 or §411.357.

(iv) The compensation arrangement ~~e~~complies with both of the following conditions:

(A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties.

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

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

(5)(i) Compensation from an entity furnishing designated health services to a physician (or immediate family member of the physician) takes into account the volume or value of referrals only if—

(A) The formula used to calculate the physician's (or immediate family member's) compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the number or value of the physician's referrals to the entity; or

(B) There is a predetermined, direct correlation between the physician's prior referrals to the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined.

(ii) Compensation from an entity furnishing designated health services to a physician (or immediate family member of the physician) takes into account the volume or value of other business generated only if—

(A) The formula used to calculate the physician's (or immediate family member's) compensation includes other business generated by the physician for the entity as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the physician's generation of other business for the entity; or

(B) There is a predetermined, direct correlation between the other business previously generated by the physician for the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined.

(iii) For purposes of applying this paragraph (d)(5), a positive correlation between two variables exists when one variable decreases as the other variable decreases, or one variable increases as the other variable increases.

(iv) This paragraph (d)(5) applies only to section 1877 of the Act.

(6)(i) Compensation from a physician (or immediate family member of the physician) to an entity furnishing designated health services takes into account the volume or value of referrals only if–

(A) The formula used to calculate the entity's compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the entity's compensation that negatively correlates with the number or value of the physician's referrals to the entity; or

(B) There is a predetermined, direct correlation between the physician's prior referrals to the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined.

(ii) Compensation from a physician (or immediate family member of the physician) to an entity furnishing designated health services takes into account the volume or value of other business generated only if–

(A) The formula used to calculate the entity's compensation includes other business generated by the physician for the entity as a variable, resulting in an increase or decrease in the entity's compensation that negatively correlates with the physician's generation of other business for the entity; or

(B) There is a predetermined, direct correlation between the other business previously generated by the physician for the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined.

(iii) For purposes of applying this paragraph (d)(6), a negative correlation between two variables exists when one variable increases as the other variable decreases, or when one variable decreases as the other variable increases.

(iv) This paragraph (d)(6) applies only to section 1877 of the Act.

(e) *Special rule on compensation arrangements–(1) Application.* This paragraph (e) applies only to compensation arrangements as defined in section 1877 of the Act and this subpart.

(2) *Writing requirement.* In the case of any requirement in this subpart for a compensation arrangement to be in writing, such requirement may be satisfied by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties.

(3) *Special rule on writing and signature requirements.* In the case of any requirement in this subpart for a compensation arrangement to be in writing and signed by the parties, the writing requirement or the signature requirement is satisfied if–

(i) The compensation arrangement between the entity and the referring physician fully complies with an applicable exception in this subpart except with respect to the writing or signature requirement of the exception; and

(ii) The parties obtain the required writing(s) or signature(s) within 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant with the requirements of the applicable exception.

§411.355 General exceptions to the referral prohibition related to both ownership/investment and compensation.

The prohibition on referrals set forth in §411.353 does not apply to the following types of services:

(a) *Physician services.* (1) Physician services as defined in §410.20(a) of this chapter that are furnished—

(i) Personally by another physician who is a member of the referring physician's group practice or is a physician in the same group practice (as defined at §411.351) as the referring physician; or

(ii) 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 defined at §411.351) as the referring physician, provided that the supervision complies with all other applicable Medicare payment and coverage rules for the physician services.

(2) For purposes of paragraph (a) of this section, “physician services” include only those “incident to” services (as defined at §411.351) that are physician services under §410.20(a) of this chapter.

(b) *In-office ancillary services.* Services (including certain items of durable medical equipment (DME), as defined in paragraph (b)(4) of this section, and infusion pumps that are DME (including external ambulatory infusion pumps), but excluding all other DME and parenteral and enteral nutrients, equipment, and supplies (such as infusion pumps used for PEN)), that meet the following conditions:

(1) They are furnished personally by one of the following individuals:

(i) The referring physician.

(ii) A physician who is a member of the same group practice as the referring physician.

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

(2) They are furnished in one of the following locations:

(i) The same building (as defined at §411.351), but not necessarily in the same space or part of the building, in which all of the conditions of paragraph (b)(2)(i)(A), (b)(2)(i)(B), or (b)(2)(i)(C) of this section are satisfied:

(A)(1) The referring physician or his or her group practice (if any) has an office that is normally open to the physician's or group's patients for medical services at least 35 hours per week; and

(2) The referring physician or one or more members of the referring physician's group practice regularly practices medicine and furnishes physician services to patients at least 30 hours per week. The 30 hours must include some physician services that are unrelated to the furnishing of DHS payable

by Medicare, any other Federal health care payer, or a private payer, even though the physician services may lead to the ordering of DHS; or

(B)(1) The patient receiving the DHS usually receives physician services from the referring physician or members of the referring physician's group practice (if any);

(2) The referring physician or the referring physician's group practice owns or rents an office that is normally open to the physician's or group's patients for medical services at least 8 hours per week; and

(3) The referring physician regularly practices medicine and furnishes physician services to patients at least 6 hours per week. The 6 hours must include some physician services that are unrelated to the furnishing of DHS payable by Medicare, any other Federal health care payer, or a private payer, even though the physician services may lead to the ordering of DHS; or

(C)(1) The referring physician is present and orders the DHS during a patient visit on the premises as set forth in paragraph (b)(2)(i)(C)(2) of this section or the referring physician or a member of the referring physician's group practice (if any) is present while the DHS is furnished during occupancy of the premises as set forth in paragraph (b)(2)(i)(C)(2) of this section;

(2) The referring physician or the referring physician's group practice owns or rents an office that is normally open to the physician's or group's patients for medical services at least 8 hours per week; and

(3) The referring physician or one or more members of the referring physician's group practice regularly practices medicine and furnishes physician services to patients at least 6 hours per week. The 6 hours must include some physician services that are unrelated to the furnishing of DHS payable by Medicare, any other Federal health care payer, or a private payer, even though the physician services may lead to the ordering of DHS.

(ii) A centralized building (as defined at §411.351) that is used by the group practice for the provision of some or all of the group practice's clinical laboratory services.

(iii) A centralized building (as defined at §411.351) that is used by the group practice for the provision of some or all of the group practice's DHS (other than clinical laboratory services).

(3) They are billed by one of the following:

(i) The physician performing or supervising the service.

(ii) The group practice of which the performing or supervising physician is a member under a billing number assigned to the group practice.

(iii) The group practice if the supervising physician is a "physician in the group practice" (as defined at §411.351) under a billing number assigned to the group practice.

(iv) An entity that is wholly owned by the performing or supervising physician or by that physician's group practice under the entity's own billing number or under a billing number assigned to the physician or group practice.

(v) An independent third party billing company acting as an agent of the physician, group practice, or entity specified in paragraphs (b)(3)(i) through (b)(3)(iv) of this section under a billing number assigned to the physician, group practice, or entity, provided that the billing arrangement meets the requirements of §424.80(b)(5) of this chapter. For purposes of this paragraph (b)(3), a group practice may have, and bill under, more than one Medicare billing number, subject to any applicable Medicare program restrictions.

(4) For purposes of paragraph (b) of this section, DME covered by the in-office ancillary services exception means canes, crutches, walkers and folding manual wheelchairs, and blood glucose monitors, that meet the following conditions:

(i) The item is one that a patient requires for the purpose of ambulating, a patient uses in order to depart from the physician's office, or is a blood glucose monitor (including one starter set of test strips and lancets, consisting of no more than 100 of each). A blood glucose monitor may be furnished only by a physician or employee of a physician or group practice that also furnishes outpatient diabetes self-management training to the patient.

(ii) The item is furnished in a building that meets the "same building" requirements in the in-office ancillary services exception as part of the treatment for the specific condition for which the patient-physician encounter occurred.

(iii) The item is furnished personally by the physician who ordered the DME, by another physician in the group practice, or by an employee of the physician or the group practice.

(iv) A physician or group practice that furnishes the DME meets all DME supplier standards set forth in §424.57(c) of this chapter.

(v) ~~The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission~~[\[Reserved\]](#).

(vi) All other requirements of the in-office ancillary services exception in paragraph (b) of this section are met.

(5) A designated health service is "furnished" for purposes of paragraph (b) of this section in the location where the service is actually performed upon a patient or where an item is dispensed to a patient in a manner that is sufficient to meet the applicable Medicare payment and coverage rules.

(6) *Special rule for home care physicians.* In the case of a referring physician whose principal medical practice consists of treating patients in their private homes, the "same building" requirements of paragraph (b)(2)(i) of this section are met if the referring physician (or a qualified person accompanying the physician, such as a nurse or technician) provides the DHS contemporaneously with a physician service that is not a designated health service provided by the referring physician to the patient in the patient's private home. For purposes of paragraph (b)(5) of this section only, a private home does not include a nursing, long-term care, or other facility or institution, except that a patient may have a private home in an assisted living or independent living facility.

(7) *Disclosure requirement for certain imaging services.* (i) With respect to magnetic resonance imaging, computed tomography, and positron emission tomography services identified as "radiology and certain other imaging services" on the List of CPT/HCPCS Codes, the referring physician must provide written notice to the patient at the time of the referral that the patient may receive the same services from a person other than one described in paragraph (b)(1) of this section. Except as set forth in paragraph (b)(7)(ii) of this section, the written notice must include a list of at least 5 other suppliers

(as defined in §400.202 of this chapter) that provide the services for which the individual is being referred and which are located within a 25-mile radius of the referring physician's office location at the time of the referral. 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.

(ii) 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. Provision of the written list of alternate suppliers will not be required if no other suppliers provide the services for which the individual is being referred within the 25-mile radius.

(c) *Services furnished by an organization (or its contractors or subcontractors) to enrollees.* Services furnished by an organization (or its contractors or subcontractors) to enrollees of one of the following prepaid health plans (not including services provided to enrollees in any other plan or line of business offered or administered by the same organization):

(1) An HMO or a CMP in accordance with a contract with CMS under section 1876 of the Act and part 417, subparts J through M of this chapter.

(2) A health care prepayment plan in accordance with an agreement with CMS under section 1833(a)(1)(A) of the Act and part 417, subpart U of this chapter.

(3) An organization that is receiving payments on a prepaid basis for Medicare enrollees through a demonstration project under section 402(a) of the Social Security Amendments of 1967 (42 U.S.C. 1395b-1) or under section 222(a) of the Social Security Amendments of 1972 (42 U.S.C. 1395b-1 note).

(4) A qualified HMO (within the meaning of section 1310(d) of the Public Health Service Act).

(5) A coordinated care plan (within the meaning of section 1851(a)(2)(A) of the Act) offered by [an Medicare Advantage](#) organization in accordance with a contract with CMS under section 1857 of the Act and part 422 of this chapter.

(6) A MCO contracting with a State under section 1903(m) of the Act.

(7) A prepaid inpatient health plan (PIHP) or prepaid ambulance health plan (PAHP) contracting with a State under part 438 of this chapter.

(8) A health insuring organization (HIO) contracting with a State under part 438, subpart D of this chapter.

(9) An entity operating under a demonstration project under sections 1115(a), 1915(a), 1915(b), or 1932(a) of the Act.

(d) [Reserved]

(e) *Academic medical centers.* (1) Services provided by an academic medical center if all of the following conditions are met:

(i) The referring physician—

(A) Is a *bona fide* employee of a component of the academic medical center on a full-time or substantial part-time basis. (A “component” of an academic medical center means an affiliated medical school, faculty practice plan, hospital, teaching facility, institution of higher education, departmental professional corporation, or nonprofit support organization whose primary purpose is supporting the teaching mission of the academic medical center.) The components need not be separate legal entities;

(B) Is licensed to practice medicine in the State(s) in which he or she practices medicine;

(C) Has a *bona fide* faculty appointment at the affiliated medical school or at one or more of the educational programs at the accredited academic hospital (as defined at §411.355(e)(3)); and

(D) Provides either substantial academic services or substantial clinical teaching services (or a combination of academic services and clinical teaching services) for which the faculty member receives compensation as part of his or her employment relationship with the academic medical center. Parties should use a reasonable and consistent method for calculating a physician's academic services and clinical teaching services. A physician will be deemed to meet this requirement if he or she spends at least 20 percent of his or her professional time or 8 hours per week providing academic services or clinical teaching services (or a combination of academic services or clinical teaching services). A physician who does not spend at least 20 percent of his or her professional time or 8 hours per week providing academic services or clinical teaching services (or a combination of academic services or clinical teaching services) is not precluded from qualifying under this paragraph (e)(1)(i)(D).

(ii) The compensation paid to the referring physician must meet all of the following conditions:

(A) The total compensation paid by each academic medical center component to the referring physician is set in advance.

(B) In the aggregate, the compensation paid by all academic medical center components to the referring physician does not exceed fair market value for the services provided.

(C) The total compensation paid by each academic medical center component is not determined in [any](#) manner that takes into account the volume or value of [any](#) referrals or other business generated by the referring physician within the academic medical center.

[\(D\) If any compensation paid to the referring physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the requirements of §411.354\(d\)\(4\).](#)

(iii) The academic medical center must meet all of the following conditions:

(A) All transfers of money between components of the academic medical center must directly or indirectly support the missions of teaching, indigent care, research, or community service.

(B) The relationship of the components of the academic medical center must be set forth in one or more written agreements or other written documents that have been adopted by the governing body of each component. If the academic medical center is one legal entity, this requirement will be satisfied if transfers of funds between components of the academic medical center are reflected in the routine financial reports covering the components.

(C) All money paid to a referring physician for research must be used solely to support *bona fide* research or teaching and must be consistent with the terms and conditions of the grant.

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

(2) The “academic medical center” for purposes of this section consists of—

(i) An accredited medical school (including a university, when appropriate) or an accredited academic hospital (as defined at §411.355(e)(3));

(ii) One or more faculty practice plans affiliated with the medical school, the affiliated hospital(s), or the accredited academic hospital; and

(iii) One or more affiliated hospitals in which a majority of the physicians on the medical staff consists of physicians who are faculty members and a majority of all hospital admissions is made by physicians who are faculty members. The hospital for purposes of this paragraph (e)(2)(iii) may be the same hospital that satisfies the requirement of paragraph (e)(2)(i) of this section. For purposes of this paragraph, a faculty member is a physician who is either on the faculty of the affiliated medical school or on the faculty of one or more of the educational programs at the accredited academic hospital. In meeting this paragraph (e)(2)(iii), faculty from any affiliated medical school or accredited academic hospital education program may be aggregated, and residents and non-physician professionals need not be counted. Any faculty member may be counted, including courtesy and volunteer faculty. For purposes of determining whether the majority of physicians on the medical staff consists of faculty members, the affiliated hospital must include or exclude all individual physicians with the same class of privileges at the affiliated hospital (for example, physicians holding courtesy privileges).

(3) An accredited academic hospital for purposes of this section means a hospital or a health system that sponsors four or more approved medical education programs.

(f) *Implants furnished by an ASC.* Implants furnished by an ASC, including, but not limited to, cochlear implants, intraocular lenses, and other implanted prosthetics, implanted prosthetic devices, and implanted DME that meet the following conditions:

(1) The implant is implanted by the referring physician or a member of the referring physician's group practice in an ASC that is certified by Medicare under part 416 of this chapter and with which the referring physician has a financial relationship.

(2) The implant is implanted in the patient during a surgical procedure paid by Medicare to the ASC as an ASC procedure under §416.65 of this chapter.

~~(3) The arrangement for the furnishing of the implant does not violate the anti-kickback statute (section 1128B(b) of the Act)~~[\[Reserved\]](#).

~~(4) All billing and claims submission for the implants does not violate any Federal or State law or regulation governing billing or claims submission~~[\[Reserved\]](#).

(5) The exception set forth in this paragraph (f) does not apply to any financial relationships between the referring physician and any entity other than the ASC in which the implant is furnished to, and implanted in, the patient.

(g) *EPO and other dialysis-related drugs.* EPO and other dialysis-related drugs that meet the following conditions:

(1) The EPO and other dialysis-related drugs are furnished in or by an ESRD facility. For purposes of this paragraph, “EPO and other dialysis-related drugs” means certain outpatient prescription drugs that are required for the efficacy of dialysis and identified as eligible for this exception on the List of CPT/HCPCS Codes; and “furnished” means that the EPO or dialysis-related drugs are administered to a patient in the ESRD facility or, in the case of EPO or Aranesp (or equivalent drug identified on the List of CPT/HCPCS Codes) only, are dispensed by the ESRD facility for use at home.

~~(2) The arrangement for the furnishing of the EPO and other dialysis-related drugs does not violate the anti-kickback statute (section 1128B(b) of the Act)~~[\[Reserved\]](#).

~~(3) All billing and claims submission for the EPO and other dialysis-related drugs does not violate any Federal or State law or regulation governing billing or claims submission~~[\[Reserved\]](#).

(4) The exception set forth in this paragraph does not apply to any financial relationship between the referring physician and any entity other than the ESRD facility that furnishes the EPO and other dialysis-related drugs to the patient.

(h) *Preventive screening tests, immunizations, and vaccines.* Preventive screening tests, immunizations, and vaccines that meet the following conditions:

(1) The preventive screening tests, immunizations, and vaccines are subject to CMS-mandated frequency limits.

~~(2) The arrangement for the provision of the preventive screening tests, immunizations, and vaccines does not violate the anti-kickback statute (section 1128B(b) of the Act)~~[\[Reserved\]](#).

~~(3) All billing and claims submission for the preventive screening tests, immunizations, and vaccines does not violate any Federal or State law or regulation governing billing or claims submission~~[\[Reserved\]](#).

(4) The preventive screening tests, immunizations, and vaccines must be covered by Medicare and must be listed as eligible for this exception on the List of CPT/HCPCS Codes.

(i) *Eyeglasses and contact lenses following cataract surgery.* Eyeglasses and contact lenses that are covered by Medicare when furnished to patients following cataract surgery that meet the following conditions:

(1) The eyeglasses or contact lenses are provided in accordance with the coverage and payment provisions set forth in §§410.36(a)(2)(ii) and 414.228 of this chapter, respectively.

~~(2) The arrangement for the furnishing of the eyeglasses or contact lenses does not violate the anti-kickback statute (section 1128B(b) of the Act)~~[\[Reserved\]](#).

~~(3) All billing and claims submission for the eyeglasses or contact lenses does not violate any Federal or State law or regulation governing billing or claims submission.~~

(j) *Intra-family rural referrals.* (1) Services provided pursuant to a referral from a referring physician to his or her immediate family member or to an entity furnishing DHS with which the immediate family member has a financial relationship, if all of the following conditions are met:

(i) The patient who is referred resides in a rural area as defined at §411.351 of this subpart;

(ii) Except as provided in paragraph (j)(1)(iii) of this section, in light of the patient's condition, no other person or entity is available to furnish the services in a timely manner within 25 miles of or 45 minutes transportation time from the patient's residence;

(iii) In the case of services furnished to patients where they reside (for example, home health services or DME), no other person or entity is available to furnish the services in a timely manner in light of the patient's condition; and

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

(2) The referring physician or the immediate family member must make reasonable inquiries as to the availability of other persons or entities to furnish the DHS. However, neither the referring physician nor the immediate family member has any obligation to inquire as to the availability of persons or entities located farther than 25 miles of or 45 minutes transportation time from (whichever test the referring physician utilized for purposes of paragraph (j)(1)(ii)) the patient's residence.

§411.356 Exceptions to the referral prohibition related to ownership or investment interests.

For purposes of §411.353, the following ownership or investment interests do not constitute a financial relationship:

(a) *Publicly traded securities.* Ownership of investment securities (including shares or bonds, debentures, notes, or other debt instruments) that at the time the DHS referral was made could be purchased on the open market and that meet the requirements of paragraphs (a)(1) and (2) of this section.

(1) They are either—

(i) Listed for trading on the New York Stock Exchange, the American Stock Exchange, or any regional exchange in which quotations are published on a daily basis, or foreign securities listed on a recognized foreign, national, or regional exchange in which quotations are published on a daily basis;

(ii) Traded under an automated interdealer quotation system operated by the National Association of Securities Dealers; or

(iii) Listed for trading on an electronic stock market or over-the-counter quotation system in which quotations are published on a daily basis and trades are standardized and publicly transparent.

(2) They are in a corporation that had stockholder equity exceeding \$75 million at the end of the corporation's most recent fiscal year or on average during the previous 3 fiscal years. "Stockholder equity" is the difference in value between a corporation's total assets and total liabilities.

(b) *Mutual funds.* Ownership of shares in a regulated investment company as defined in section 851(a) of the Internal Revenue Code of 1986, if the company had, at the end of its most recent fiscal year, or on average during the previous 3 fiscal years, total assets exceeding \$75 million.

(c) *Specific providers.* Ownership or investment interest in the following entities, for purposes of the services specified:

(1) A rural provider, in the case of DHS furnished in a rural area (as defined at §411.351 of this subpart) by the provider. A “rural provider” is an entity that furnishes substantially all (not less than 75 percent) of the DHS that it furnishes to residents of a rural area and, for the 18-month period beginning on December 8, 2003 (or such other period as Congress may specify), is not a specialty hospital, and in the case where the entity is a hospital, the hospital meets the requirements of §411.362 no later than September 23, 2011.

(2) A hospital that is located in Puerto Rico, in the case of DHS furnished by such a hospital.

(3) A hospital that is located outside of Puerto Rico, in the case of DHS furnished by such a hospital, if—

(i) The referring physician is authorized to perform services at the hospital;

(ii) Effective for the 18-month period beginning on December 8, 2003 (or such other period as Congress may specify), the hospital is not a specialty hospital;

(iii) The ownership or investment interest is in the entire hospital and not merely in a distinct part or department of the hospital; and

(iv) The hospital meets the requirements described in §411.362 not later than September 23, 2011.

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

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

(a) *Rental of office space.* Payments for the use of office space made by a lessee to a lessor if the arrangement meets the following requirements:

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

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

(3) The space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease arrangement and is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any person or entity related to the lessor), except that the lessee may make payments for the use of space consisting of common areas if the payments do not exceed the lessee's pro rata share of expenses for the space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using the common areas. [For purposes of this paragraph \(a\), exclusive use means that the lessee \(and any other lessees of the same office space\) uses the office space to the exclusion of the lessor \(or any person or entity related to the lessor\). The lessor \(or any person or entity related to the lessor\) may not be an invitee of the lessee to use the office space.](#)

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

(5) The rental charges over the term of the lease arrangement are not determined–

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

(ii) Using a formula based on–

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

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

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

(7) If the lease arrangement expires after a term of at least 1 year, a holdover lease arrangement immediately following the expiration of the lease arrangement satisfies the requirements of paragraph (a) of this section if the following conditions are met:

(i) The lease arrangement met the conditions of paragraphs (a)(1) through (6) of this section when the arrangement expired;

(ii) The holdover lease arrangement is on the same terms and conditions as the immediately preceding arrangement; and

(iii) The holdover lease arrangement continues to satisfy the conditions of paragraphs (a)(1) through (6) of this section.

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

(1) The lease arrangement is set out in writing, is signed by the parties, and specifies the equipment it covers.

(2) The equipment leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease arrangement and is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any person or entity related to the lessor). [For purposes of this paragraph \(b\), exclusive use means that the lessee \(and any other lessees of the same equipment\) uses the equipment to the exclusion of the lessor \(or any person or entity related to the lessor\). The lessor \(or any person or entity related to the lessor\) may not be an invitee of the lessee to use the equipment.](#)

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

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

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

(ii) Using a formula based on—

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

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

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

(6) If the lease arrangement expires after a term of at least 1 year, a holdover lease arrangement immediately following the expiration of the lease arrangement satisfies the requirements of paragraph (b) of this section if the following conditions are met:

(i) The lease arrangement met the conditions of paragraphs (b)(1) through (5) of this section when the arrangement expired;

(ii) The holdover lease arrangement is on the same terms and conditions as the immediately preceding lease arrangement; and

(iii) The holdover lease arrangement continues to satisfy the conditions of paragraphs (b)(1) through (5) of this section.

(c) *Bona fide employment relationships.* Any amount paid by an employer to a physician (or immediate family member) who has a *bona fide* employment relationship with the employer for the provision of services if the following conditions are met:

(1) The employment is for identifiable services.

(2) The amount of the remuneration under the employment is—

(i) Consistent with the fair market value of the services; and

(ii) Except as provided in paragraph (c)(4) of this section, is not determined in [any](#) manner that takes into account ~~(directly or indirectly)~~ the volume or value of ~~any~~ referrals by the referring physician.

(3) The remuneration is provided under an arrangement that would be commercially reasonable even if no referrals were made to the employer.

(4) Paragraph (c)(2)(ii) of this section does not prohibit payment of remuneration in the form of a productivity bonus based on services performed personally by the physician (or immediate family member of the physician).

[\(5\) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the requirements of §411.354\(d\)\(4\).](#)

(d) *Personal service arrangements.* (1) *General*—Remuneration from an entity under an arrangement or multiple arrangements to a physician or his or her immediate family member, or to a group practice, including remuneration for specific physician services furnished to a nonprofit blood center, if the following conditions are met:

(i) Each arrangement is set out in writing, is signed by the parties, and specifies the services covered by the arrangement.

(ii) The arrangement(s) covers all of the services to be furnished by the physician (or an immediate family member of the physician) to the entity. This requirement is met if all separate arrangements between the entity and the physician and the entity and any family members incorporate each other by reference or if they cross-reference a master list of contracts that is maintained and updated centrally and is available for review by the Secretary upon request. The master list must be maintained in a manner that preserves the historical record of contracts. A physician or family member can “furnish” services through employees whom they have hired for the purpose of performing the services; through a wholly-owned entity; or through *locum tenens* physicians (as defined at §411.351, except that the regular physician need not be a member of a group practice).

(iii) The aggregate services covered by the arrangement do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement(s).

(iv) The duration of each arrangement is at least 1 year. To meet this requirement, if an arrangement is terminated with or without cause, the parties may not enter into the same or substantially the same arrangement during the first year of the original arrangement.

(v) The compensation to be paid over the term of each arrangement is set in advance, does not exceed fair market value, and, except in the case of a physician incentive plan (as defined [at](#) in §411.351 [of this subpart](#)), is not determined in [a](#) [any](#) manner that takes into account the volume or value of [any](#) referrals or other business generated between the parties.

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

(vii) If the arrangement expires after a term of at least 1 year, a holdover arrangement immediately following the expiration of the arrangement satisfies the requirements of paragraph (d) of this section if the following conditions are met:

(A) The arrangement met the conditions of paragraphs (d)(1)(i) through (vi) of this section when the arrangement expired;

(B) The holdover arrangement is on the same terms and conditions as the immediately preceding arrangement; and

(C) The holdover arrangement continues to satisfy the conditions of paragraphs (d)(1)(i) through (vi) of this section.

[\(viii\) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the requirements of §411.354\(d\)\(4\).](#)

(2) *Physician incentive plan exception.* In the case of a physician incentive plan (as defined at §411.351) between a physician and an entity (or downstream contractor), the compensation may be

determined in [any](#) manner (through a withhold, capitation, bonus, or otherwise) that takes into account ~~directly or indirectly~~ the volume or value of ~~any~~ referrals or other business generated between the parties, if the plan meets the following requirements:

(i) No specific payment is made directly or indirectly under the plan to a physician or a physician group as an inducement to reduce or limit medically necessary services furnished with respect to a specific individual enrolled with the entity.

(ii) Upon request of the Secretary, the entity provides the Secretary with access to information regarding the plan (including any downstream contractor plans), in order to permit the Secretary to determine whether the plan is in compliance with paragraph (d)(2) of this section.

(iii) In the case of a plan that places a physician or a physician group at substantial financial risk as defined at §422.208, the entity or any downstream contractor (or both) complies with the requirements concerning physician incentive plans set forth in §422.208 and §422.210 of this chapter.

[\(iv\) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the requirements of §411.354\(d\)\(4\).](#)

(e) *Physician recruitment.* (1) Remuneration provided by a hospital to recruit a physician that is paid directly to the physician and that is intended to induce the physician to relocate his or her medical practice to the geographic area served by the hospital in order to become a member of the hospital's medical staff, if all of the following conditions are met:

(i) The arrangement is set out in writing and signed by both parties;

(ii) The arrangement is not conditioned on the physician's referral of patients to the hospital;

(iii) The amount of remuneration under the arrangement is not determined in [any](#) manner that takes into account ~~(directly or indirectly)~~ the volume or value of ~~any~~ actual or anticipated referrals by the physician or other business generated between the parties; and

(iv) The physician is allowed to establish staff privileges at any other hospital(s) and to refer business to any other entities (except as referrals may be restricted under an employment or services arrangement that complies with §411.354(d)(4)).

(2)(i) The "geographic area served by the hospital" is the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 75 percent of its inpatients. The geographic area served by the hospital may include one or more zip codes from which the hospital draws no inpatients, provided that such zip codes are entirely surrounded by zip codes in the geographic area described above from which the hospital draws at least 75 percent of its inpatients.

(ii) With respect to a hospital that draws fewer than 75 percent of its inpatients from all of the contiguous zip codes from which it draws inpatients, the "geographic area served by the hospital" will be deemed to be the area composed of all of the contiguous zip codes from which the hospital draws its inpatients.

(iii) *Special optional rule for rural hospitals.* In the case of a hospital located in a rural area (as defined at §411.351), the "geographic area served by the hospital" may also be the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 90 percent of its inpatients. If the hospital draws fewer than 90 percent of its inpatients from all of the contiguous zip

codes from which it draws inpatients, the “geographic area served by the hospital” may include noncontiguous zip codes, beginning with the noncontiguous zip code in which the highest percentage of the hospital's inpatients resides, and continuing to add noncontiguous zip codes in decreasing order of percentage of inpatients.

(iv) A physician will be considered to have relocated his or her medical practice if the medical practice was located outside the geographic area served by the hospital and—

(A) The physician moves his or her medical practice at least 25 miles and into the geographic area served by the hospital; or

(B) The physician moves his medical practice into the geographic area served by the hospital, and the physician's new medical practice derives at least 75 percent of its revenues from professional services furnished to patients (including hospital inpatients) not seen or treated by the physician at his or her prior medical practice site during the preceding 3 years, measured on an annual basis (fiscal or calendar year). For the initial “start up” year of the recruited physician's practice, the 75 percent test in the preceding sentence will be satisfied if there is a reasonable expectation that the recruited physician's medical practice for the year will derive at least 75 percent of its revenues from professional services furnished to patients not seen or treated by the physician at his or her prior medical practice site during the preceding 3 years.

(3) The recruited physician will not be subject to the relocation requirement of this paragraph, provided that he or she establishes his or her medical practice in the geographic area served by the recruiting hospital, if—

(i) He or she is a resident or physician who has been in practice 1 year or less;

(ii) He or she was employed on a full-time basis for at least 2 years immediately prior to the recruitment arrangement by one of the following (and did not maintain a private practice in addition to such full-time employment):

(A) A Federal or State bureau of prisons (or similar entity operating one or more correctional facilities) to serve a prison population;

(B) The Department of Defense or Department of Veterans Affairs to serve active or veteran military personnel and their families; or

(C) A facility of the Indian Health Service to serve patients who receive medical care exclusively through the Indian Health Service; or

(iii) The Secretary has deemed in an advisory opinion issued under section 1877(g) of the Act that the physician does not have an established medical practice that serves or could serve a significant number of patients who are or could become patients of the recruiting hospital.

(4) In the case of remuneration provided by a hospital to a physician either indirectly through payments made to another physician practice, or directly to a physician who joins a physician practice, the following additional conditions must be met:

(i) The writing in paragraph (e)(1) of this section is also signed by the physician practice [if the remuneration is provided indirectly to the physician through payments made to the physician practice and the physician practice does not pass directly through to the physician all of the remuneration from the hospital.](#)

(ii) Except for actual costs incurred by the physician practice in recruiting the new physician, the remuneration is passed directly through to or remains with the recruited physician.

(iii) In the case of an income guarantee of any type made by the hospital to a recruited physician who joins a physician practice, the costs allocated by the physician practice to the recruited physician do not exceed the actual additional incremental costs attributable to the recruited physician. With respect to a physician recruited to join a physician practice located in a rural area or HPSA, if the physician is recruited to replace a physician who, within the previous 12-month period, retired, relocated outside of the geographic area served by the hospital, or died, the costs allocated by the physician practice to the recruited physician do not exceed either—

(A) The actual additional incremental costs attributable to the recruited physician; or

(B) The lower of a *per capita* allocation or 20 percent of the practice's aggregate costs.

(iv) Records of the actual costs and the passed-through amounts are maintained for a period of at least 6 years and made available to the Secretary upon request.

(v) The remuneration from the hospital under the arrangement is not determined in any manner that takes into account ~~(directly or indirectly)~~ the volume or value of any actual or anticipated referrals by the recruited physician or the physician practice (or any physician affiliated with the physician practice) receiving the direct payments from the hospital.

(vi) The physician practice may not impose on the recruited physician practice restrictions that unreasonably restrict the recruited physician's ability to practice medicine in the geographic area served by the hospital.

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

(5) Recruitment of a physician by a hospital located in a rural area (as defined at §411.351) to an area outside the geographic area served by the hospital is permitted under this exception if the Secretary determines in an advisory opinion issued under section 1877(g) of the Act that the area has a demonstrated need for the recruited physician and all other requirements of this paragraph (e) are met.

(6)(i) This paragraph (e) applies to remuneration provided by a federally qualified health center or a rural health clinic in the same manner as it applies to remuneration provided by a hospital, ~~provided that the arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.~~

(ii) The "geographic area served" by a federally qualified health center or a rural health clinic is the area composed of the lowest number of contiguous or noncontiguous zip codes from which the federally qualified health center or rural health clinic draws at least 90 percent of its patients, as determined on an encounter basis. The geographic area served by the federally qualified health center or rural health clinic may include one or more zip codes from which the federally qualified health center or rural health clinic draws no patients, provided that such zip codes are entirely surrounded by zip codes in the geographic area described above from which the federally qualified health center or rural health clinic draws at least 90 percent of its patients.

(f) *Isolated transactions.* Isolated financial transactions, such as a one-time sale of property or a practice, if all of the following conditions are met:

(1) The amount of remuneration under the isolated financial transaction is–

(i) Consistent with the fair market value of the isolated financial transaction; and

(ii) Not determined in any manner that takes into account (~~directly or indirectly~~) the volume or value of ~~any~~ referrals by the referring physician or other business generated between the parties.

(2) The remuneration is provided under an arrangement that would be commercially reasonable even if the physician made no referrals to the entity.

(3) There are no additional transactions between the parties for 6 months after the isolated financial transaction, except for transactions that are specifically excepted under the other provisions in §411.355 through §411.357 and except for commercially reasonable post-closing adjustments that do not take into account (~~directly or indirectly~~) the volume or value of referrals or other business generated by the referring physician.

(g) ~~Certain arrangements with hospitals~~ Remuneration unrelated to the provision of designated health services. Remuneration provided by a hospital to a physician if the remuneration does not relate, ~~directly or indirectly, to the furnishing of DHS. To qualify as “unrelated,” remuneration must be wholly unrelated to the furnishing of DHS and must not in any way take into account the volume or value of a physician's referrals~~ to the provision of designated health services. Remuneration does not relate to the ~~furnishing of DHS~~ provision of designated health services if it–

~~(1) Is an item, service, or cost that could be allocated in whole or in part to Medicare or Medicaid under cost-reporting principles;~~

~~(2) Is furnished, directly or indirectly, explicitly or implicitly, in a selective, targeted, preferential, or conditioned manner to medical staff or other persons in a position to make or influence referrals; or~~

~~(3) Otherwise~~ The remuneration is not determined in any manner that takes into account the volume or value of the physician's referrals ~~or other business generated by the referring physician;~~ and

(2) The remuneration is for an item or service that is not related to the provision of patient care services.

(3) For purposes of this paragraph (g):

(i) Items that are related to the provision of patient care services include, but are not limited to, any item, supply, device, equipment, or space that is used in the diagnosis or treatment of patients and any technology that is used to communicate with patients regarding patient care services.

(ii) A service is deemed to be not related to the provision of patient care services if the service could be provided by a person who is not a licensed medical professional.

(h) *Group practice arrangements with a hospital*. An arrangement between a hospital and a group practice under which DHS are furnished by the group but are billed by the hospital if the following conditions are met:

(1) With respect to services furnished to an inpatient of the hospital, the arrangement is pursuant to the provision of inpatient hospital services under section 1861(b)(3) of the Act.

(2) The arrangement began before, and has continued in effect without interruption since, December 19, 1989.

(3) With respect to the DHS covered under the arrangement, at least 75 percent of these services furnished to patients of the hospital are furnished by the group under the arrangement.

(4) The arrangement is in accordance with a written agreement that specifies the services to be furnished by the parties and the compensation for services furnished under the agreement.

(5) The compensation paid over the term of the agreement is consistent with fair market value, and the compensation per unit of service is fixed in advance and is not determined in any manner that takes into account the volume or value of any referrals or other business generated between the parties.

(6) The compensation is provided in accordance with an agreement that would be commercially reasonable even if no referrals were made to the entity.

(7) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the requirements of §411.354(d)(4).

(i) *Payments by a physician.* Payments made by a physician (or his or her immediate family member)–

(1) To a laboratory in exchange for the provision of clinical laboratory services; or

(2) To an entity as compensation for any other items or services ~~that~~

(i) That are furnished at a price that is consistent with fair market value; ~~and that are not specifically excepted by another provision in §§411.355 through 411.357 (including, but not limited to, §411.357~~

(ii) To which the exceptions in paragraphs (a) through (h) of this section are not applicable.

~~(13). "Services" in this context~~ For purposes of this paragraph (i), "services" means services of any kind (not merely those defined as "services" for purposes of the Medicare program in §400.202 of this chapter).

(j) *Charitable donations by a physician.* *Bona fide* charitable donations made by a physician (or immediate family member) to an entity if all of the following conditions are satisfied:

(1) The charitable donation is made to an organization exempt from taxation under the Internal Revenue Code (or to a supporting organization);

(2) The donation is neither solicited, nor offered, in any manner that takes into account the volume or value of referrals or other business generated between the physician and the entity; and

~~(3) The donation arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.~~

(k) *Nonmonetary compensation.* (1) Compensation from an entity in the form of items or services (not including cash or cash equivalents) that does not exceed an aggregate of \$300 per calendar year,

as adjusted for inflation in accordance with paragraph (k)(2) of this section, if all of the following conditions are satisfied:

(i) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician.

(ii) The compensation may not be solicited by the physician or the physician's practice (including employees and staff members).

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

(2) The annual aggregate nonmonetary compensation limit in this paragraph (k) is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index–Urban All Items (CPI-U) for the 12-month period ending the preceding September 30. CMS displays after September 30 each year both the increase in the CPI-U for the 12-month period and the new nonmonetary compensation limit on the physician self-referral [Web site](http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPI-U_Updates.asp)~~website~~ at http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPI-U_Updates.asp.

(3) Where an entity has inadvertently provided nonmonetary compensation to a physician in excess of the limit (as set forth in paragraph (k)(1) of this section), such compensation is deemed to be within the limit if–

(i) The value of the excess nonmonetary compensation is no more than 50 percent of the limit; and

(ii) The physician returns to the entity the excess nonmonetary compensation (or an amount equal to the value of the excess nonmonetary compensation) by the end of the calendar year in which the excess nonmonetary compensation was received or within 180 consecutive calendar days following the date the excess nonmonetary compensation was received by the physician, whichever is earlier.

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

(4) In addition to nonmonetary compensation up to the limit described in paragraph (k)(1) of this section, an entity that has a formal medical staff may provide one local medical staff appreciation event per year for the entire medical staff. Any gifts or gratuities provided in connection with the medical staff appreciation event are subject to the limit in paragraph (k)(1).

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

(1) The arrangement is in writing, signed by the parties, and covers only identifiable items ~~or~~ services, [office space, or equipment](#), all of which are specified in writing.

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

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

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

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

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

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

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

(7) The arrangement satisfies the requirements of §411.354(d)(4) in the case of—

(i) Remuneration to the physician that is conditioned on the physician's referrals to a particular provider, practitioner, or supplier; or

(ii) Remuneration paid to the group of physicians that is conditioned on one of the group's physician's referrals to a particular provider, practitioner, or supplier.

(m) *Medical staff incidental benefits.* Compensation in the form of items or services (not including cash or cash equivalents) from a hospital to a member of its medical staff when the item or service is used on the hospital's campus, if all of the following conditions are met:

(1) The compensation is offered to all members of the medical staff practicing in the same specialty (but not necessarily accepted by every member to whom it is offered) and is not offered in ~~a~~any manner that takes into account the volume or value of referrals or other business generated between the parties.

(2) Except with respect to identification of medical staff on a hospital ~~Web site~~website or in hospital advertising, the compensation is provided only during periods when the medical staff members are making rounds or are engaged in other services or activities that benefit the hospital or its patients.

(3) The compensation is provided by the hospital and used by the medical staff members only on the hospital's campus. Compensation, including, but not limited to, internet access, pagers, or two-way

radios, used away from the campus only to access hospital medical records or information or to access patients or personnel who are on the hospital campus, as well as the identification of the medical staff on a hospital ~~Web site~~[website](#) or in hospital advertising, meets the “on campus” requirement of this paragraph (m).

(4) The compensation is reasonably related to the provision of, or designed to facilitate directly or indirectly the delivery of, medical services at the hospital.

(5) The compensation is of low value (that is, less than \$25) with respect to each occurrence of the benefit (for example, each meal given to a physician while he or she is serving patients who are hospitalized must be of low value). The \$25 limit in this paragraph (m)(5) is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index–Urban All Items (CPI-U) for the 12 month period ending the preceding September 30. CMS displays after September 30 each year both the increase in the CPI-U for the 12 month period and the new limits on the physician self-referral ~~Web site~~[website](http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPI-U_Updates.asp) at http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPI-U_Updates.asp.

(6) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties.

~~(7) The compensation arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission~~[\[Reserved\]](#).

(8) Other facilities and health care clinics (including, but not limited to, federally qualified health centers) that have *bona fide* medical staffs may provide compensation under this paragraph (m) on the same terms and conditions applied to hospitals under this paragraph (m).

(n) *Risk-sharing arrangements.* Compensation pursuant to a risk-sharing arrangement (including, but not limited to, withholds, bonuses, and risk pools) between a MCO or an IPA and a physician (either directly or indirectly through a subcontractor) for services provided to enrollees of a health plan; ~~provided that the arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.~~ For purposes of this paragraph (n), “health plan” and “enrollees” have the meanings set forth in §1001.952(l) of this title.

(o) *Compliance training.* Compliance training provided by an entity to a physician (or to the physician's immediate family member or office staff) who practices in the entity's local community or service area, provided that the training is held in the local community or service area. For purposes of this paragraph (o), “compliance training” means training regarding the basic elements of a compliance program (for example, establishing policies and procedures, training of staff, internal monitoring, or reporting); specific training regarding the requirements of Federal and State health care programs (for example, billing, coding, reasonable and necessary services, documentation, or unlawful referral arrangements); or training regarding other Federal, State, or local laws, regulations, or rules governing the conduct of the party for whom the training is provided. For purposes of this paragraph, “compliance training” includes programs that offer continuing medical education credit, provided that compliance training is the primary purpose of the program.

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

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

(ii) Compensation for the rental of office space or equipment may not be determined using a formula based on—

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

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

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

~~(3) The compensation arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.~~

(q) *Referral services.* Remuneration that meets all of the conditions set forth in §1001.952(f) of this title.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) Were part of a medically underserved population.

(B) For the initial coverage period (not to exceed 1 year), the requirements of paragraph (r)(2)(ix)(A) of this section will be satisfied if the physician certifies that he or she has a reasonable expectation that at least 75 percent of the physician's obstetrical patients treated under the coverage of the malpractice insurance will–

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

(2) Be part of a medically underserved population.

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

(3) For purposes of paragraph (r)(2) of this section, *costs of malpractice insurance premiums* means:

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

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

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

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

(s) *Professional courtesy.* Professional courtesy (as defined at §411.351) offered by an entity with a formal medical staff to a physician or a physician's immediate family member or office staff if all of the following conditions are met:

(1) The professional courtesy is offered to all physicians on the entity's bona fide medical staff or in such entity's local community or service area, and the offer does not take into account the volume or value of referrals or other business generated between the parties;

(2) The health care items and services provided are of a type routinely provided by the entity;

(3) The entity has a professional courtesy policy that is set out in writing and approved in advance by the entity's governing body;

(4) The professional courtesy is not offered to a physician (or immediate family member) who is a Federal health care program beneficiary, unless there has been a good faith showing of financial need; and

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

(t) *Retention payments in underserved areas—(1) Bona fide written offer.* Remuneration provided by a hospital directly to a physician on the hospital's medical staff to retain the physician's medical practice in the geographic area served by the hospital (as defined in paragraph (e)(2) of this section), if all of the following conditions are met:

(i) The physician has a *bona fide* firm, written recruitment offer or offer of employment from a hospital, academic medical center (as defined at §411.355(e)), or physician organization (as defined at §411.351) that is not related to the hospital making the payment, and the offer specifies the remuneration being offered and requires the physician to move the location of his or her medical practice at least 25 miles *and* outside of the geographic area served by the hospital making the retention payment.

(ii) The requirements of §411.357(e)(1)(i) through §411.357(e)(1)(iv) are satisfied.

(iii) Any retention payment is subject to the same obligations and restrictions, if any, on repayment or forgiveness of indebtedness as the written recruitment offer or offer of employment.

(iv) The retention payment does not exceed the lower of—

(A) The amount obtained by subtracting the physician's current income from physician and related services from the income the physician would receive from comparable physician and related services in the written recruitment or employment offer, provided that the respective incomes are determined using a reasonable and consistent methodology, and that they are calculated uniformly over no more than a 24-month period; or

(B) The reasonable costs the hospital would otherwise have to expend to recruit a new physician to the geographic area served by the hospital to join the medical staff of the hospital to replace the retained physician.

(v) The requirements of paragraph (t)(3) are satisfied.

(2) *Written certification from physician.* Remuneration provided by a hospital directly to a physician on the hospital's medical staff to retain the physician's medical practice in the geographic area served by the hospital (as defined in paragraph (e)(2) of this section), if all of the following conditions are met:

(i) The physician furnishes to the hospital before the retention payment is made a written certification that the physician has a *bona fide* opportunity for future employment by a hospital, academic medical center (as defined at §411.355(e)), or physician organization (as defined at §411.351) that requires the physician to move the location of his or her medical practice at least 25 miles and outside the geographic area served by the hospital. The certification contains at least the following—

(A) Details regarding the steps taken by the physician to effectuate the employment opportunity;

(B) Details of the physician's employment opportunity, including the identity and location of the physician's future employer or employment location or both, and the anticipated income and benefits (or a range for income and benefits);

(C) A statement that the future employer is not related to the hospital making the payment;

(D) The date on which the physician anticipates relocating his or her medical practice outside of the geographic area served by the hospital; and

(E) Information sufficient for the hospital to verify the information included in the written certification.

(ii) The hospital takes reasonable steps to verify that the physician has a *bona fide* opportunity for future employment that requires the physician to relocate outside the geographic area served by the hospital.

(iii) The requirements of §411.357(e)(1)(i) through §411.357(e)(1)(iv) are satisfied.

(iv) The retention payment does not exceed the lower of—

(A) An amount equal to 25 percent of the physician's current annual income (averaged over the previous 24 months), using a reasonable and consistent methodology that is calculated uniformly; or

(B) The reasonable costs the hospital would otherwise have to expend to recruit a new physician to the geographic area served by the hospital to join the medical staff of the hospital to replace the retained physician.

(v) The requirements of paragraph (t)(3) are satisfied.

(3) Remuneration provided under paragraph (t)(1) or (t)(2) must meet the following additional requirements:

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

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

(ii) The hospital does not enter into a retention arrangement with a particular referring physician more frequently than once every 5 years.

(iii) The amount and terms of the retention payment are not altered during the term of the arrangement in any manner that takes into account the volume or value of referrals or other business generated by the physician.

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

(4) The Secretary may waive the relocation requirement of paragraphs (t)(1) and (t)(2) of this section for payments made to physicians practicing in a HPSA or an area with demonstrated need for the physician through an advisory opinion issued in accordance with section 1877(g)(6) of the Act, if the retention payment arrangement otherwise complies with all of the conditions of this paragraph.

(5) This paragraph (t) applies to remuneration provided by a federally qualified health center or a rural health clinic in the same manner as it applies to remuneration provided by a hospital.

(u) *Community-wide health information systems.* Items or services of information technology provided by an entity to a physician that allow access to, and sharing of, electronic health care records and any complementary drug information systems, general health information, medical alerts, and related information for patients served by community providers and practitioners, in order to enhance the community's overall health, provided that—

(1) The items or services are available as necessary to enable the physician to participate in a community-wide health information system, are principally used by the physician as part of the community-wide health information system, and are not provided to the physician in any manner that takes into account the volume or value of referrals or other business generated by the physician;

(2) The community-wide health information systems are available to all providers, practitioners, and residents of the community who desire to participate; and

~~(3) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.~~

(v) *Electronic prescribing items and services.* Nonmonetary remuneration (consisting of items and services in the form of hardware, software, or information technology and training services) necessary and used solely to receive and transmit electronic prescription information, if all of the following conditions are met:

(1) The items and services are provided by a—

(i) Hospital to a physician who is a member of its medical staff;

(ii) Group practice (as defined at §411.352) to a physician who is a member of the group (as defined at §411.351); or

(iii) PDP sponsor or MA organization to a prescribing physician.

(2) The items and services are provided as part of, or are used to access, an electronic prescription drug program that meets the applicable standards under Medicare Part D at the time the items and services are provided.

(3) The donor (or any person on the donor's behalf) does not take any action to limit or restrict the use or compatibility of the items or services with other electronic prescribing or electronic health records systems.

(4) For items or services that are of the type that can be used for any patient without regard to payer status, the donor does not restrict, or take any action to limit, the physician's right or ability to use the items or services for any patient.

(5) Neither the physician nor the physician's practice (including employees and staff members) makes the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.

(6) Neither the eligibility of a physician for the items or services, nor the amount or nature of the items or services, is determined in a manner that takes into account the volume or value of referrals or other business generated between the parties.

(7) The arrangement is set forth in a written agreement that—

(i) Is signed by the parties;

(ii) Specifies the items and services being provided and the donor's cost of the items and services; and

(iii) Covers all of the electronic prescribing items and services to be provided by the donor. This requirement is met if all separate agreements between the donor and the physician (and the donor and any family members of the physician) incorporate each other by reference or if they cross-reference a master list of agreements that is maintained and updated centrally and is available for review by the Secretary upon request. The master list must be maintained in a manner that preserves the historical record of agreements.

(8) The donor does not have actual knowledge of, and does not act in reckless disregard or deliberate ignorance of, the fact that the physician possesses or has obtained items or services equivalent to those provided by the donor.

(w) *Electronic health records items and services*. Nonmonetary remuneration (consisting of items and services in the form of software or information technology and training services, [including certain cybersecurity software and services](#)) necessary and used predominantly to create, maintain, transmit, ~~or~~ receive, [or protect](#) electronic health records, if all of the following conditions are met:

(1) The items and services are provided to a physician by an entity (as defined at §411.351) that is not a laboratory company.

(2) The software is interoperable (as defined in §411.351) at the time it is provided to the physician. For purposes of this paragraph (w), software is deemed to be interoperable if, on the date it is provided to the physician, it ~~has been~~ certified by a certifying body authorized by the National Coordinator for Health Information Technology to ~~an edition of the~~ electronic health record certification criteria identified in the then-applicable version of 45 CFR part 170.

(3) The donor (or any person on the donor's behalf) does not ~~take any action to limit or restrict the use, compatibility, or interoperability of the~~ engage in a practice constituting information blocking, as defined in section 3022 of the Public Health Service Act, in connection with the donated items or services ~~with other electronic prescribing or electronic health records systems (including, but not limited to, health information technology applications, products, or services).~~

(4) Before receipt of the items and services, the physician pays 15 percent of the donor's cost for the items and services. The donor (or any party related to the donor) does not finance the physician's payment or loan funds to be used by the physician to pay for the items and services.

(5) Neither the physician nor the physician's practice (including employees and staff members) makes the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.

(6) Neither the eligibility of a physician for the items or services, nor the amount or nature of the items or services, is determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties. For purposes of this paragraph (w), the determination is deemed not to directly take into account the volume or value of referrals or other business generated between the parties if any one of the following conditions is met:

(i) The determination is based on the total number of prescriptions written by the physician (but not the volume or value of prescriptions dispensed or paid by the donor or billed to the program);

(ii) The determination is based on the size of the physician's medical practice (for example, total patients, total patient encounters, or total relative value units);

(iii) The determination is based on the total number of hours that the physician practices medicine;

(iv) The determination is based on the physician's overall use of automated technology in his or her medical practice (without specific reference to the use of technology in connection with referrals made to the donor);

(v) The determination is based on whether the physician is a member of the donor's medical staff, if the donor has a formal medical staff;

(vi) The determination is based on the level of uncompensated care provided by the physician; or

(vii) The determination is made in any reasonable and verifiable manner that does not directly take into account the volume or value of referrals or other business generated between the parties.

(7) The arrangement is set forth in a written agreement that—

(i) Is signed by the parties;

(ii) Specifies the items and services being provided, the donor's cost of the items and services, and the amount of the physician's contribution; and

(iii) Covers all of the electronic health records items and services to be provided by the donor. This requirement is met if all separate agreements between the donor and the physician (and the donor and any family members of the physician) incorporate each other by reference or if they cross-reference a master list of agreements that is maintained and updated centrally and is available for review by the Secretary upon request. The master list must be maintained in a manner that preserves the historical record of agreements.

(8) The donor does not have actual knowledge of, and does not act in reckless disregard or deliberate ignorance of, the fact that the physician possesses or has obtained items or services equivalent to those provided by the donor.

(9) For items or services that are of the type that can be used for any patient without regard to payer status, the donor does not restrict, or take any action to limit, the physician's right or ability to use the items or services for any patient.

(10) The items and services do not include staffing of physician offices and are not used primarily to conduct personal business or business unrelated to the physician's medical practice.

~~(11) [Reserved]~~

~~(12) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.~~

~~(13) The transfer of the items or services occurs and all conditions in this paragraph (w) are satisfied on or before December 31, 2021.~~

(x) Assistance to compensate a nonphysician practitioner.

(1) Remuneration provided by a hospital to a physician to compensate a nonphysician practitioner to provide [NPP](#) patient care services, if all of the following conditions are met:

(i) The arrangement—

~~(iA) The arrangement is~~ set out in writing and signed by the hospital, the physician, and the nonphysician practitioner; ~~and~~

(B) Commences before the physician (or the physician organization in whose shoes the physician stands under §411.354(c)) enters into the compensation arrangement described in paragraph (x)(1)(vi)(A) of this section.

(ii) The arrangement is not conditioned on—

(A) The physician's referrals to the hospital; or

(B) The nonphysician practitioner's [NPP](#) referrals to the hospital.

(iii) The remuneration from the hospital—

(A) Does not exceed 50 percent of the actual compensation, signing bonus, and benefits paid by the physician to the nonphysician practitioner during a period not to exceed the first 2 consecutive years of the compensation arrangement between the nonphysician practitioner and the physician (or the physician organization in whose shoes the physician stands); and

(B) Is not determined in any manner that takes into account ~~(directly or indirectly)~~ the volume or value of ~~any~~ actual or anticipated ~~referrals by~~—

(1) ~~The~~Referrals by the physician (or any physician in the physician's practice) or other business generated between the parties; or

(2) ~~The~~NPP referrals by the nonphysician practitioner (or any nonphysician practitioner in the physician's practice) or other business generated between the parties.

(iv) The compensation, signing bonus, and benefits paid to the nonphysician practitioner by the physician does not exceed fair market value for the NPP patient care services furnished by the nonphysician practitioner to patients of the physician's practice.

(v) The nonphysician practitioner has not, within 1 year of the commencement of his or her compensation arrangement with the physician (or the physician organization in whose shoes the physician stands under §411.354(c))—

(A) ~~Practiced~~Furnished NPP patient care services in the geographic area served by the hospital; or

(B) Been employed or otherwise engaged to provide NPP patient care services by a physician or a physician organization that has a medical practice site located in the geographic area served by the hospital, regardless of whether the nonphysician practitioner furnished NPP patient care services at the medical practice site located in the geographic area served by the hospital.

(vi)(A) The nonphysician practitioner has a compensation arrangement directly with the physician or the physician organization in whose shoes the physician stands under §411.354(c); and

(B) Substantially all of the NPP patient care services that the nonphysician practitioner furnishes to patients of the physician's practice are primary care services or mental health care services.

(vii) The physician does not impose practice restrictions on the nonphysician practitioner that unreasonably restrict the nonphysician practitioner's ability to provide NPP patient care services in the geographic area served by the hospital.

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

(2) Records of the actual amount of remuneration provided under paragraph (x)(1) of this section by the hospital to the physician, and by the physician to the nonphysician practitioner, must be maintained for a period of at least 6 years and made available to the Secretary upon request.

(3) For purposes of this paragraph (x), "nonphysician practitioner" means a physician assistant as defined in section 1861(aa)(5) of the Act, a nurse practitioner or clinical nurse specialist as defined in section 1861(aa)(5) of the Act, a certified nurse-midwife as defined in section 1861(gg) of the Act, a clinical social worker as defined in section 1861(hh) of the Act, or a clinical psychologist as defined in §410.71(d) of this subchapter.

(4) For purposes of this paragraph (x), the following terms have the meanings indicated.

(i) “NPP patient care services” means direct patient care services furnished by a nonphysician practitioner that address the medical needs of specific patients or any task performed by a nonphysician practitioner that promotes the care of patients of the physician or physician organization with which the nonphysician practitioner has a compensation arrangement.

~~(4) For purposes of paragraphs (x)(1)(ii)(B) and (x)(1)(iii)(B)(2) of this section,~~ “(ii) “NPP referral” means a request by a nonphysician practitioner that includes the provision of any designated health service for which payment may be made under Medicare, the establishment of any plan of care by a nonphysician practitioner that includes the provision of such a designated health service, or the certifying or recertifying of the need for such a designated health service, but does not include any designated health service personally performed or provided by the nonphysician practitioner.

(5) For purposes of paragraph (x)(1) of this section, “geographic area served by the hospital” has the meaning set forth in paragraph (e)(2) of this section.

(6) For purposes of paragraph (x)(1) of this section, a “compensation arrangement” between a physician (or the physician organization in whose shoes the physician stands under §411.354(c) and a nonphysician practitioner—

(i) Means an employment, contractual, or other arrangement under which remuneration passes between the parties; and

(ii) Does not include a nonphysician practitioner's ownership or investment interest in a physician organization.

(7)(i) This paragraph (x) may be used by a hospital, federally qualified health center, or rural health clinic only once every 3 years with respect to the same referring physician.

(ii) Paragraph (x)(7)(i) of this section does not apply to remuneration provided by a hospital, federally qualified health center, or rural health clinic to a physician to compensate a nonphysician practitioner to provide NPP patient care services if—

(A) The nonphysician practitioner is replacing a nonphysician practitioner who terminated his or her employment or contractual arrangement to provide NPP patient care services with the physician (or the physician organization in whose shoes the physician stands) within 1 year of the commencement of the employment or contractual arrangement; and

(B) The remuneration provided to the physician is provided during a period that does not exceed 2 consecutive years as measured from the commencement of the compensation arrangement between the nonphysician practitioner who is being replaced and the physician (or the physician organization in whose shoes the physician stands).

(8)(i) This paragraph (x) applies to remuneration provided by a federally qualified health center or a rural health clinic in the same manner as it applies to remuneration provided by a hospital.

(ii) The “geographic area served” by a federally qualified health center or a rural health clinic has the meaning set forth in paragraph (e)(6)(ii) of this section.

(y) *Timeshare arrangements.* Remuneration provided under an arrangement for the use of premises, equipment, personnel, items, supplies, or services if the following conditions are met:

(1) The arrangement is set out in writing, signed by the parties, and specifies the premises, equipment, personnel, items, supplies, and services covered by the arrangement.

(2) The arrangement is between a physician (or the physician organization in whose shoes the physician stands under §411.354(c) and—

(i) A hospital; or

(ii) Physician organization of which the physician is not an owner, employee, or contractor.

(3) The premises, equipment, personnel, items, supplies, and services covered by the arrangement are used—

(i) Predominantly for the provision of evaluation and management services to patients; and

(ii) On the same schedule.

(4) The equipment covered by the arrangement is—

(i) Located in the same building where the evaluation and management services are furnished;

(ii) Not used to furnish designated health services other than those incidental to the evaluation and management services furnished at the time of the patient's evaluation and management visit; and

(iii) Not advanced imaging equipment, radiation therapy equipment, or clinical or pathology laboratory equipment (other than equipment used to perform CLIA-waived laboratory tests).

(5) The arrangement is not conditioned on the referral of patients by the physician who is a party to the arrangement to the hospital or physician organization of which the physician is not an owner, employee, or contractor.

(6) The compensation over the term of the arrangement is set in advance, consistent with fair market value, and not determined—

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

(ii) Using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services provided while using the premises, equipment, personnel, items, supplies, or services covered by the arrangement; or

(B) Per-unit of service fees that are not time-based, to the extent that such fees reflect services provided to patients referred by the party granting permission to use the premises, equipment, personnel, items, supplies, or services covered by the arrangement to the party to which the permission is granted.

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

~~(8) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act) or any Federal or State law or regulation governing billing or claims submission~~[\[Reserved\]](#).

(9) The arrangement does not convey a possessory leasehold interest in the office space that is the subject of the arrangement.

(z) Limited remuneration to a physician—(1) Remuneration from an entity to a physician for the provision of items or services provided by the physician to the entity that does not exceed an aggregate of \$3,500 per calendar year, as adjusted for inflation in accordance with paragraph (z)(2) of this section, if all of the following conditions are satisfied:

(i) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the physician.

(ii) The compensation does not exceed the fair market value of the items or services.

(iii) The arrangement is commercially reasonable.

(iv) Compensation for the lease of office space or equipment is not determined using a formula based on—

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

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

(v) Compensation for the use of premises, equipment, personnel, items, supplies, or services is not determined using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services provided while using the premises, equipment, personnel, items, supplies, or services covered by the arrangement; or

(B) Per-unit of service fees that are not time-based, to the extent that such fees reflect services provided to patients referred by the party granting permission to use the premises, equipment, personnel, items, supplies, or services covered by the arrangement to the party to which the permission is granted.

(2) The annual remuneration limit in this paragraph (z) is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index—Urban All Items (CPI-U) for the 12-month period ending the preceding September 30. CMS displays after September 30 each year both the increase in the CPI-U for the 12-month period and the new remuneration limit on the physician self-referral website at http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPI-U_Updates.asp.

(aa) Arrangements that facilitate value-based health care delivery and payment.

(1) Full financial risk—Remuneration paid under a value-based arrangement, as defined in §411.351, if the following conditions are met:

(i) The value-based enterprise is at full financial risk (or is contractually obligated to be at full financial risk within the 6 months following the commencement of the value-based arrangement) during the entire duration of the value-based arrangement.

(ii) The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.

(iii) The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.

(iv) The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.

(v) If remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement satisfies the requirements of §411.354(d)(4)(iv).

(vi) Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.

(vii) For purposes of this paragraph (aa), "full financial risk" means that the value-based enterprise is financially responsible on a prospective basis for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time. For purposes of this paragraph (aa), "prospective basis" means that the value-based enterprise has assumed financial responsibility for the cost of all patient care items and services covered by the applicable payor prior to providing patient care items and services to patients in the target patient population.

(2) Value-based arrangements with meaningful downside financial risk to the physician—Remuneration paid under a value-based arrangement, as defined in §411.351, if the following conditions are met:

(i) The physician is at meaningful downside financial risk for failure to achieve the value-based purpose(s) of the value-based enterprise during the entire duration of the value-based arrangement.

(ii) A description of the nature and extent of the physician's downside financial risk is set forth in writing.

(iii) The methodology used to determine the amount of the remuneration is set in advance of the undertaking of value-based activities for which the remuneration is paid.

(iv) The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.

(v) The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.

(vi) The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.

(vii) If remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement satisfies the requirements of §411.354(d)(4)(iv).

(viii) Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.

(ix) For purposes of this paragraph (aa), "meaningful downside financial risk" means that the physician—

(A) Is responsible to pay the entity no less than 25 percent of the value of the remuneration the physician receives under the value-based arrangement; or

(B) Is financially responsible to the entity on a prospective basis for the cost of all or a defined set of patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time.

(3) Value-based arrangements—Remuneration paid under a value-based arrangement, as defined in §411.351, if the following conditions are met:

(i) The arrangement is set forth in writing and signed by the parties. The writing includes a description of—

(A) The value-based activities to be undertaken under the arrangement;

(B) How the value-based activities are expected to further the value-based purpose(s) of the value-based enterprise;

(C) The target patient population for the arrangement;

(D) The type or nature of the remuneration;

(E) The methodology used to determine the remuneration; and

(F) The performance or quality standards against which the recipient will be measured, if any.

(ii) The performance or quality standards against which the recipient will be measured, if any, are objective and measurable, and any changes to the performance or quality standards must be made prospectively and set forth in writing.

(iii) The methodology used to determine the amount of the remuneration is set in advance of the undertaking of value-based activities for which the remuneration is paid.

(iv) The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.

(v) The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.

(vi) The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.

(vii) If the remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement satisfies the requirements of §411.354(d)(4)(iv).

(viii) Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.

(bb) Cybersecurity technology and related services—(1) Nonmonetary remuneration (consisting of certain types of technology and services), if all of the following conditions are met:

(i) The technology and services are necessary and used predominantly to implement, maintain, or reestablish cybersecurity.

(ii) Neither the eligibility of a physician for the technology or services, nor the amount or nature of the technology or services, is determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties.

(iii) Neither the physician nor the physician's practice (including employees and staff members) makes the receipt of technology or services, or the amount or nature of the technology or services, a condition of doing business with the donor.

(iv) The arrangement is documented in writing.

(2) For purposes of this paragraph (bb), "technology" means any software or other types of information technology other than hardware.

§411.361 Reporting requirements.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, all entities furnishing services for which payment may be made under Medicare must submit information to CMS or to the Office of Inspector General (OIG) concerning their reportable financial relationships (as defined in paragraph (d) of this section), in the form, manner, and at the times that CMS or OIG specifies.

(b) *Exception.* The requirements of paragraph (a) of this section do not apply to entities that furnish 20 or fewer Part A and Part B services during a calendar year, or to any Medicare covered services furnished outside the United States.

(c) *Required information.* The information requested by CMS or OIG can include the following:

(1) The name and unique physician identification number (UPIN) or the national provider identifier (NPI) of each physician who has a reportable financial relationship with the entity.

(2) The name and UPIN or NPI of each physician who has an immediate family member (as defined at §411.351) who has a reportable financial relationship with the entity.

(3) The covered services furnished by the entity.

(4) With respect to each physician identified under paragraphs (c)(1) and (c)(2) of this section, the nature of the financial relationship (including the extent or value of the ownership or investment interest or the compensation arrangement) as evidenced in records that the entity knows or should know about in the course of prudently conducting business, including, but not limited to, records that the entity is already required to retain to comply with the rules of the Internal Revenue Service and the Securities and Exchange Commission and other rules of the Medicare and Medicaid programs.

(d) *Reportable financial relationships.* For purposes of this section, a reportable financial relationship is any ownership or investment interest, as defined at §411.354(b) or any compensation arrangement, as defined at §411.354(c), except for ownership or investment interests that satisfy the exceptions set forth in §411.356(a) or §411.356(b) regarding publicly traded securities and mutual funds.

(e) *Form and timing of reports.* Entities that are subject to the requirements of this section must submit the required information, upon request, within the time period specified by the request. Entities are given at least 30 days from the date of the request to provide the information. Entities must retain the information, and documentation sufficient to verify the information, for the length of time specified by the applicable regulatory requirements for the information, and, upon request, must make that information and documentation available to CMS or OIG.

(f) *Consequences of failure to report.* Any person who is required, but fails, to submit information concerning his or her financial relationships in accordance with this section is subject to a civil money penalty of up to \$10,000 as adjusted annually under 45 CFR part 102 for each day following the deadline established under paragraph (e) of this section until the information is submitted. Assessment of these penalties will comply with the applicable provisions of part 1003 of this title.

(g) *Public disclosure.* Information furnished to CMS or OIG under this section is subject to public disclosure in accordance with the provisions of part 401 of this chapter.

§411.362 Additional requirements concerning physician ownership and investment in hospitals.

(a) *Definitions.* For purposes of this section—

Baseline number of operating rooms, procedure rooms, and beds means the number of operating rooms, procedure rooms, and beds for which the applicable hospital or high Medicaid facility is licensed as of March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of such date, but does have a provider agreement in effect on December 31, 2010, the date of effect of such agreement).

External data source means a data source that—

- (1) Is generated, maintained, or under the control of a State Medicaid agency;
- (2) Is reliable and transparent;
- (3) Maintains data that, for purposes of the process described in paragraph (c) of this section, are readily available and accessible to the requesting hospital, comparison hospitals, and CMS; and
- (4) Maintains or generates data that, for purposes of the process described in paragraph (c) of this section, are accurate, complete, and objectively verifiable.

Main campus of the hospital means "campus" as defined at §413.65(a)(2).

Ownership or investment interest means for purposes of this section, a direct or indirect ownership or investment interest in a hospital.

(1) A direct ownership or investment interest in a hospital exists if the ownership or investment interest in the hospital is held without any intervening persons or entities between the hospital and the owner or investor.

(2) An indirect ownership or investment interest in a hospital exists if—

(i) Between the owner or investor and the hospital there exists an unbroken chain of any number (but no fewer than one) of persons or entities having ownership or investment interests; and

(ii) The hospital has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the owner or investor has some ownership or investment interest (through any number of intermediary ownership or investment interests) in the hospital.

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

Physician owner or investor means a physician (or immediate family member of the physician) with a direct or an indirect ownership or investment interest in the hospital.

Procedure room means a room in which catheterizations, angiographies, angiograms, and endoscopies are performed, except such term shall not include an emergency room or department (exclusive of rooms in which catheterizations, angiographies, angiograms, and endoscopies are performed).

Public advertising for the hospital means any public communication paid for by the hospital that is primarily intended to persuade individuals to seek care at the hospital.

(b) *General requirements.* (1) *Physician ownership and provider agreement.* The hospital had physician ownership or investment on December 31, 2010; and a provider agreement under section 1866 of the Act in effect on that date.

(2) *Prohibition on facility expansion.* The hospital may not increase the number of operating rooms, procedure rooms, and beds beyond that for which the hospital is licensed on March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of this date, but does have a provider agreement in effect on December 31, 2010, the effective date of such agreement), unless an exception is granted pursuant to paragraph (c) of this section.

(3) *Disclosure of conflicts of interest.* (i) At such time and in such manner as specified by CMS, the hospital must submit an annual report to CMS containing a detailed description of the identity of each owner or investor in the hospital and the nature and extent of all ownership and investment interests in the hospital.

(ii) The hospital must—

(A) Require each referring physician owner or investor who is a member of the hospital's medical staff to agree, as a condition of continued medical staff membership or admitting privileges, to provide 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. Disclosure must be required by a time that permits the patient to make a meaningful decision regarding the receipt of care.

(B) Not condition any physician ownership or investment interests either directly or indirectly on the physician owner or investor making or influencing referrals to the hospital or otherwise generating business for the hospital.

(C) Disclose on any public ~~Web-site~~[website](#) for the hospital and in any public advertising for the hospital that the hospital is owned or invested in by physicians. Any language that would put a reasonable person on notice that the hospital may be physician-owned would be deemed a sufficient statement of physician ownership or investment. For purposes of this section, a public ~~Web-site~~[website](#) for the hospital does not include, by way of example: social media ~~Web-~~[websites](#); electronic patient payment portals; electronic patient care portals; and electronic health information exchanges.

(4) *Ensuring bona fide investment.* The hospital satisfies the following criteria:

(i) The percentage of the total value of the ownership or investment interests held in the hospital, or in an entity whose assets include the hospital, by physician owners or investors in the aggregate does not exceed such percentage as of March 23, 2010.

(ii) Any ownership or investment interests that the hospital offers to a physician owner or investor are not offered on more favorable terms than the terms offered to a person who is not a physician owner or investor.

(iii) The hospital (or any owner or investor in the hospital) does not directly or indirectly provide loans or financing for any investment in the hospital by a physician owner or investor.

(iv) The hospital (or any owner or investor in the hospital) does not directly or indirectly guarantee a loan, make a payment toward a loan, or otherwise subsidize a loan, for any individual physician owner or investor or group of physician owners or investors that is related to acquiring any ownership or investment interest in the hospital.

(v) Ownership or investment returns are distributed to each owner or investor in the hospital in an amount that is directly proportional to the ownership or investment interest of such owner or investor in the hospital.

(vi) Physician owners and investors do not receive, directly or indirectly, any guaranteed receipt of or right to purchase other business interests related to the hospital, including the purchase or lease of any property under the control of other owners or investors in the hospital or located near the premises of the hospital.

(vii) The hospital does not offer a physician owner or investor the opportunity to purchase or lease any property under the control of the hospital or any other owner or investor in the hospital on more favorable terms than the terms offered to an individual who is not a physician owner or investor.

(5) *Patient safety.* The hospital satisfies the following criteria:

(i) If the hospital does not have a physician available on the premises to provide services during all hours in which the hospital is providing services to the patient, the hospital must disclose this information to the patient. Before providing services to the patient, the hospital must receive a signed acknowledgment from the patient stating that the patient understands that a physician may not be present during all hours services are furnished to the patient.

(ii) The hospital must have the capacity to provide assessment and initial treatment for all patients, and the ability to refer and transfer patients to hospitals with the capability to treat the needs of the patient that the hospital is unable to address. For purposes of this paragraph, the hospital inpatient stay or outpatient visit begins with the provision of a package of information regarding scheduled preadmission testing and registration for a planned hospital admission for inpatient care or an outpatient service.

(6) *Prohibition on conversion from an ambulatory surgery center.* The hospital must not have been converted from an ambulatory surgical center to a hospital on or after March 23, 2010.

(c) *Criteria for an individual hospital seeking an exception to the prohibition on facility expansion—*
(1) *General.* An applicable hospital or high Medicaid facility may request an exception from the prohibition on facility expansion up to once every 2 years from the date of a CMS decision on the hospital's most recent request.

(2) *Criteria for applicable hospital.* An applicable hospital is a hospital that satisfies all of the following criteria:

(i) *Population increase.* Is located in a county that has a percentage increase in population that is at least 150 percent of the percentage increase in population of the State in which the hospital is located during the most recent 5-year period for which data are available as of the date that the hospital submits its request. To calculate State and county population growth, a hospital must use Bureau of the Census estimates.

(ii) *Medicaid inpatient admissions.* Has an annual percent of total inpatient admissions under Medicaid that is equal to or greater than the average percent with respect to such admissions for all hospitals located in the county in which the hospital is located during the most recent 12-month period for which data are available as of the date that the hospital submits its request. For purposes of this paragraph, the most recent 12-month period for which data are available means the most recent 12-month period for which the data source used contains all data from the requesting hospital and each hospital located in the same county as the requesting hospital.

(A) Until such time that the Healthcare Cost Report Information System (HCRIS) contains sufficiently complete inpatient Medicaid discharge data, a hospital may use filed Medicare hospital cost report data or data from an external data source (as defined in paragraph (a) of this section) to estimate its annual percent of total inpatient admissions under Medicaid and the average percent with respect to such admissions for all hospitals located in the county in which the hospital is located.

(B) On or after such date that the Secretary determines that HCRIS contains sufficiently complete inpatient Medicaid discharge data, a hospital may use only filed Medicare hospital cost report data to estimate its annual percent of total inpatient admissions under Medicaid and the average percent with respect to such admissions for all hospitals located in the county in which the hospital is located.

(iii) *Nondiscrimination.* Does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries.

(iv) *Average bed capacity.* Is located in a State in which the average bed capacity in the State is less than the national average bed capacity during the most recent fiscal year for which HCRIS, as of the date that the hospital submits its request, contains data from a sufficient number of hospitals to determine a State's average bed capacity and the national average bed capacity. CMS will provide on its [Web-sitewebsite](#) State average bed capacities and the national average bed capacity. For purposes of this paragraph (c)(2)(iv), "sufficient number" means the number of hospitals, as determined by CMS that would ensure that the determination under this paragraph (c)(2)(iv) would not materially change after additional hospital data are reported.

(v) *Average bed occupancy.* Has an average bed occupancy rate that is greater than the average bed occupancy rate in the State in which the hospital is located during the most recent fiscal year for which HCRIS, as of the date that the hospital submits its request, contains data from a sufficient number of hospitals to determine the requesting hospital's average bed occupancy rate and the relevant State's average bed occupancy rate. A hospital must use filed hospital cost report data to determine its average bed occupancy rate. CMS will provide on its [Web-sitewebsite](#) State average bed occupancy rates. For purposes of this paragraph (c)(2)(v), "sufficient number" means the number of hospitals, as determined by CMS that would ensure that the determination under this paragraph (c)(2)(v) would not materially change after additional hospital data are reported.

(3) *Criteria for high Medicaid facility.* A high Medicaid facility is a hospital that satisfies all of the following criteria:

(i) *Sole hospital.* Is not the sole hospital in the county in which the hospital is located.

(ii) *Medicaid inpatient admissions.* With respect to each of the 3 most recent 12-month periods for which data are available as of the date the hospital submits its request, has an annual percent of total inpatient admissions under Medicaid that is estimated to be greater than such percent with respect to such admissions for any other hospital located in the county in which the hospital is located. For purposes of this paragraph, the most recent 12-month period for which data are available means the most recent 12-month period for which the data source used contains all data from the requesting hospital and every hospital located in the same county as the requesting hospital.

(A) Until such time that the Healthcare Cost Report Information System (HCRIS) contains sufficiently complete inpatient Medicaid discharge data, a hospital may use filed Medicare hospital cost report data or data from an external data source (as defined in paragraph (a) of this section) to estimate its annual percentage of total inpatient admissions under Medicaid and the annual percentages of total inpatient admissions under Medicaid for every other hospital located in the county in which the hospital is located.

(B) On or after such date that the Secretary determines that HCRIS contains sufficiently complete inpatient Medicaid discharge data, a hospital may use only filed Medicare hospital cost report data to estimate its annual percentage of total inpatient admissions under Medicaid and the annual percentages of total inpatient admissions under Medicaid for every other hospital located in the county in which the hospital is located.

(iii) *Nondiscrimination.* Does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries.

(4) *Procedure for submitting a request.*

(i) A hospital must either mail an original and one copy of the written request to CMS or submit the request electronically to CMS. If a hospital submits the request electronically, the hospital must mail an original hard copy of the signed certification set forth in paragraph (c)(4)(iii) of this section to CMS.

(ii) A request must include the following information:

(A) The name, address, National Provider Identification number(s) (NPI), Tax Identification Number(s) (TIN), and CMS Certification Number(s) (CCN) of the hospital requesting an exception.

(B) The county in which the hospital requesting an exception is located.

(C) The name, title, address, and daytime telephone number of a contact person who will be available to discuss the request with CMS on behalf of the hospital.

(D) A statement identifying the hospital as an applicable hospital or high Medicaid facility and a detailed explanation with supporting documentation regarding whether and how the hospital satisfies each of the criteria for an applicable hospital or high Medicaid facility. The request must state that the hospital does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries.

(E) Documentation supporting the hospital's calculations of its baseline number of operating rooms, procedure rooms, and beds; the hospital's number of operating rooms, procedure rooms, and beds for which the hospital is licensed as of the date that the hospital submits a request for an exception; and the additional number of operating rooms, procedure rooms, and beds by which the hospital requests to expand.

(iii) A request must include the following certification signed by an authorized representative of the hospital: "With knowledge of the penalties for false statements provided by 18 U.S.C. 1001, I certify that all of the information provided in the request and all of the documentation provided with the request is true and correct to the best of my knowledge and belief." An authorized representative is the chief executive officer, chief financial officer, or other comparable officer of the hospital.

(5) *Community input and timing of complete request.* Upon submitting a request for an exception and until the hospital receives a CMS decision, the hospital must disclose on any public [Web site](#) [website](#) for the hospital that it is requesting an exception and must also provide actual notification that it is requesting an exception, in either electronic or hard copy form, directly to hospitals whose data are part of the comparisons in paragraphs (c)(2)(ii) and (c)(3)(ii) of this section. Individuals and entities in the hospital's community may provide input with respect to the hospital's request no later than 30 days after CMS publishes notice of the hospital's request in the FEDERAL REGISTER. Such input must take the form of written comments. The written comments must be either mailed or submitted electronically to CMS. If CMS receives written comments from the community, the hospital has 30 days after CMS notifies the hospital of the written comments to submit a rebuttal statement.

(i) If only filed Medicare hospital cost report data are used in the hospital's request, the written comments, and the hospital's rebuttal statement—

(A) A request will be deemed complete at the end of the 30-day comment period if CMS does not receive written comments from the community.

(B) A request will be deemed complete at the end of the 30-day rebuttal period, regardless of whether the hospital submits a rebuttal statement, if CMS receives written comments from the community.

(ii) If data from an external data source are used in the hospital's request, the written comments, or the hospital's rebuttal statement—

(A) A request will be deemed complete no later than 180 days after the end of the 30-day comment period if CMS does not receive written comments from the community.

(B) A request will be deemed complete no later than 180 days after the end of the 30-day rebuttal period, regardless of whether the hospital submits a rebuttal statement, if CMS receives written comments from the community.

(6) A permitted increase under this section—

(i) May not result in the number of operating rooms, procedure rooms, and beds for which the hospital is licensed exceeding 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds; and

(ii) May occur only in facilities on the hospital's main campus.

(7) *Publication of final decisions.* Not later than 60 days after receiving a complete request, CMS will publish the final decision in the FEDERAL REGISTER.

(8) *Limitation on review.* There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the process under this section (including the establishment of such process).

§411.370 Advisory opinions relating to physician referrals.

(a) *Period during which CMS accepts requests.* The provisions of §411.370 through §411.389 apply to requests for advisory opinions that are submitted to CMS during any time period in which CMS is required by law to issue the advisory opinions described in this subpart.

(b) *Matters that qualify for advisory opinions and who may request one.* Any individual or entity may request a written advisory opinion from CMS concerning whether a physician's referral relating to designated health services (other than clinical laboratory services) is prohibited under section 1877 of the Act. In the advisory opinion, CMS determines whether a business arrangement described by the parties to that arrangement appears to constitute a “financial relationship” (as defined in section 1877(a)(2) of the Act) that could potentially restrict a physician's referrals, and whether the arrangement or the designated health services at issue appear to qualify for any of the exceptions to the referral prohibition described in section 1877 of the Act.

(1) The request must involve an existing arrangement or one into which the requestor, in good faith, specifically plans to enter. The planned arrangement may be contingent upon the party or parties receiving a favorable advisory opinion. CMS does not consider, for purposes of an advisory opinion, requests that present a general question of interpretation, pose a hypothetical situation, or involve the activities of third parties.

(2) The requestor must be a party to the existing or proposed arrangement.

(c) *Matters not subject to advisory opinions.* CMS does not address through the advisory opinion process—

(1) Whether the fair market value was, or will be, paid or received for any goods, services, or property; and

(2) Whether an individual is a *bona fide* employee within the requirements of section 3121(d)(2) of the Internal Revenue Code of 1986.

(d) *Facts subject to advisory opinions.* CMS considers requests for advisory opinions that involve applying specific facts to the subject matter described in paragraph (b) of this section. Requestors must include in the advisory opinion request a complete description of the arrangement that the requestor is undertaking, or plans to undertake, as described in §411.372.

(e) *Requests that will not be accepted.* CMS does not accept an advisory opinion request or issue an advisory opinion if—

(1) The request is not related to a named individual or entity;

(2) CMS is aware that the same, or substantially the same, course of action is under investigation, or is or has been the subject of a proceeding involving the Department of Health and Human Services or another governmental agency; or

(3) CMS believes that it cannot make an informed opinion or could only make an informed opinion after extensive investigation, clinical study, testing, or collateral inquiry.

(f) *Effects of an advisory opinion on other Governmental authority.* Nothing in this part limits the investigatory or prosecutorial authority of the OIG, the Department of Justice, or any other agency of the Government. In addition, in connection with any request for an advisory opinion, CMS, the OIG, or the Department of Justice may conduct whatever independent investigation it believes appropriate.

§411.372 Procedure for submitting a request.

(a) *Format for a request.* A party or parties must submit a request for an advisory opinion to CMS according to the instructions specified on the CMS [Web site](#)~~website~~.

(b) *Information CMS requires with all submissions.* The request must include the following:

(1) The name, address, telephone number, and Taxpayer Identification Number of the requestor.

(2) The names and addresses, to the extent known, of all other actual and potential parties to the arrangement that is the subject of the request.

(3) The name, title, address, and daytime telephone number of a contact person who will be available to discuss the request with CMS on behalf of the requestor.

(4) A complete and specific description of all relevant information bearing on the arrangement, including—

(i) A complete description of the arrangement that the requestor is undertaking, or plans to undertake, including: the purpose of the arrangement; the nature of each party's (including each entity's) contribution to the arrangement; the direct or indirect relationships between the parties, with an emphasis on the relationships between physicians involved in the arrangement (or their immediate family members who are involved) and any entities that provide designated health services; the types

of services for which a physician wishes to refer, and whether the referrals will involve Medicare or Medicaid patients;

(ii) Complete copies of all relevant documents or relevant portions of documents that affect or could affect the arrangement, such as personal services or employment contracts, leases, deeds, pension or insurance plans, financial statements, or stock certificates (or, if these relevant documents do not yet exist, a complete description, to the best of the requestor's knowledge, of what these documents are likely to contain);

(iii) Detailed statements of all collateral or oral understandings, if any; and

(iv) Descriptions of any other arrangements or relationships that could affect CMS's analysis.

(5) Complete information on the identity of all entities involved either directly or indirectly in the arrangement, including their names, addresses, legal form, ownership structure, nature of the business (products and services) and, if relevant, their Medicare and Medicaid provider numbers. The requestor must also include a brief description of any other entities that could affect the outcome of the opinion, including those with which the requestor, the other parties, or the immediate family members of involved physicians, have any financial relationships (either direct or indirect, and as defined in section 1877(a)(2) of the Act and §411.351), or in which any of the parties holds an ownership or control interest as defined in section 1124(a)(3) of the Act.

(6) A discussion of the specific issues or questions the requestor would like CMS to address including, if possible, a description of why the requestor believes the referral prohibition in section 1877 of the Act might or might not be triggered by the arrangement and which, if any, exceptions to the prohibition the requestor believes might apply. The requestor should attempt to designate which facts are relevant to each issue or question raised in the request and should cite the provisions of law under which each issue or question arises.

(7) An indication of whether the parties involved in the request have also asked for or are planning to ask for an advisory opinion on the arrangement in question from the OIG under section 1128D(b) of the Act (42 U.S.C. 1320a-7d(b)) and whether the arrangement is or is not, to the best of the requestor's knowledge, the subject of an investigation.

(8) The certification(s) described in §411.373. The certification(s) must be signed by—

(i) The requestor, if the requestor is an individual;

(ii) The chief executive officer, or comparable officer, of the requestor, if the requestor is a corporation;

(iii) The managing partner of the requestor, if the requestor is a partnership; or

(iv) A managing member, if the requestor is a limited liability company.

(9) A check or money order payable to CMS in the amount described in §411.375(a).

(c) *Additional information CMS might require.* If the request does not contain all of the information required by paragraph (b) of this section, or, if either before or after accepting the request, CMS believes it needs more information in order to render an advisory opinion, it may request whatever additional information or documents it deems necessary. Additional information must be provided in

writing, signed by the same person who signed the initial request (or by an individual in a comparable position), and be certified as described in §411.373.

§411.373 Certification.

(a) Every request must include the following signed certification: "With knowledge of the penalties for false statements provided by 18 U.S.C. 1001 and with knowledge that this request for an advisory opinion is being submitted to the Department of Health and Human Services, I certify that all of the information provided is true and correct, and constitutes a complete description of the facts regarding which an advisory opinion is sought, to the best of my knowledge and belief."

(b) If the advisory opinion relates to a proposed arrangement, in addition to the certification required by paragraph (a) of this section, the following certification must be included and signed by the requestor: "The arrangement described in this request for an advisory opinion is one into which [the requestor], in good faith, plans to enter." This statement may be made contingent on a favorable advisory opinion, in which case the requestor should add one of the following phrases to the certification:

(1) "if CMS issues a favorable advisory opinion."

(2) "if CMS and the OIG issue favorable advisory opinions."

§411.375 Fees for the cost of advisory opinions.

(a) *Initial payment.* Parties must include with each request for an advisory opinion submitted through December 31, 1998, a check or money order payable to CMS for \$250. For requests submitted after this date, parties must include a check or money order in this amount, unless CMS has revised the amount of the initial fee in a program issuance, in which case, the requestor must include the revised amount. This initial payment is nonrefundable.

(b) *How costs are calculated.* Before issuing the advisory opinion, CMS calculates the costs the Department has incurred in responding to the request. The calculation includes the costs of salaries, benefits, and overhead for analysts, attorneys, and others who have worked on the request, as well as administrative and supervisory support for these individuals.

(c) *Agreement to pay all costs.* (1) By submitting the request for an advisory opinion, the requestor agrees, except as indicated in paragraph (c)(3) of this section, to pay all costs the Department incurs in responding to the request for an advisory opinion.

(2) In its request for an advisory opinion, the requestor may designate a triggering dollar amount. If CMS estimates that the costs of processing the advisory opinion request have reached or are likely to exceed the designated triggering dollar amount, CMS notifies the requestor.

(3) If CMS notifies the requestor that the actual or estimated cost of processing the request has reached or is likely to exceed the triggering dollar amount, CMS stops processing the request until the requestor makes a written request for CMS to continue. If CMS is delayed in processing the request for an advisory opinion because of this procedure, the time within which CMS must issue an advisory opinion is suspended until the requestor asks CMS to continue working on the request.

(4) If the requestor chooses not to pay for CMS to complete an advisory opinion, or withdraws the request, the requestor is still obligated to pay for all costs CMS has identified as costs it incurred in processing the request for an advisory opinion, up to that point.

(5) If the costs CMS has incurred in responding to the request are greater than the amount the requestor has paid, CMS, before issuing the advisory opinion, notifies the requestor of any additional amount that is due. CMS does not issue an advisory opinion until the requestor has paid the full amount that is owed. Once the requestor has paid CMS the total amount due for the costs of processing the request, CMS issues the advisory opinion. The time period CMS has for issuing advisory opinions is suspended from the time CMS notifies the requestor of the amount owed until the time CMS receives full payment.

(d) *Fees for outside experts.* (1) In addition to the fees identified in this section, the requestor also must pay any required fees for expert opinions, if any, from outside sources, as described in §411.377.

(2) The time period for issuing an advisory opinion is suspended from the time that CMS notifies the requestor that it needs an outside expert opinion until the time CMS receives that opinion.

§411.377 Expert opinions from outside sources.

(a) CMS may request expert advice from qualified sources if CMS believes that the advice is necessary to respond to a request for an advisory opinion. For example, CMS may require the use of accountants or business experts to assess the structure of a complex business arrangement or to ascertain a physician's or immediate family member's financial relationship with entities that provide designated health services.

(b) If CMS determines that it needs to obtain expert advice in order to issue a requested advisory opinion, CMS notifies the requestor of that fact and provides the identity of the appropriate expert and an estimate of the costs of the expert advice. As indicated in §411.375(d), the requestor must pay the estimated cost of the expert advice.

(c) Once CMS has received payment for the estimated cost of the expert advice, CMS arranges for the expert to provide a prompt review of the issue or issues in question. CMS considers any additional expenses for the expert advice, beyond the estimated amount, as part of the costs CMS has incurred in responding to the request, and the responsibility of the requestor, as described in §411.375(c).

§411.378 Withdrawing a request.

The party requesting an advisory opinion may withdraw the request before CMS issues a formal advisory opinion. This party must submit the withdrawal in writing to the same address as the request, as indicated in §411.372(a). Even if the party withdraws the request, the party must pay the costs the Department has expended in processing the request, as discussed in §411.375. CMS reserves the right to keep any request for an advisory opinion and any accompanying documents and information, and to use them for any governmental purposes permitted by law.

§411.379 When CMS accepts a request.

(a) Upon receiving a request for an advisory opinion, CMS promptly makes an initial determination of whether the request includes all of the information it will need to process the request.

(b) Within 15 working days of receiving the request, CMS–

- (1) Formally accepts the request for an advisory opinion;
- (2) Notifies the requestor about the additional information it needs; or
- (3) Declines to formally accept the request.

(c) If the requestor provides the additional information CMS has requested, or otherwise resubmits the request, CMS processes the resubmission in accordance with paragraphs (a) and (b) of this section as if it were an initial request for an advisory opinion.

(d) Upon accepting the request, CMS notifies the requestor by regular U.S. mail of the date that CMS formally accepted the request.

(e) The 90-day period that CMS has to issue an advisory opinion set forth in §411.380(c) does not begin until CMS has formally accepted the request for an advisory opinion.

§411.380 When CMS issues a formal advisory opinion.

(a) CMS considers an advisory opinion to be issued once it has received payment and once the opinion has been dated, numbered, and signed by an authorized CMS official.

(b) An advisory opinion contains a description of the material facts known to CMS that relate to the arrangement that is the subject of the advisory opinion, and states CMS's opinion about the subject matter of the request based on those facts. If necessary, CMS includes in the advisory opinion material facts that could be considered confidential information or trade secrets within the meaning of 18 U.S.C. 1095.

(c)(1) CMS issues an advisory opinion, in accordance with the provisions of this part, within 90 days after it has formally accepted the request for an advisory opinion, or, for requests that CMS determines, in its discretion, involve complex legal issues or highly complicated fact patterns, within a reasonable time period.

(2) If the 90th day falls on a Saturday, Sunday, or Federal holiday, the time period ends at the close of the first business day following the weekend or holiday;

(3) The 90-day period is suspended from the time CMS'

(i) Notifies the requestor that the costs have reached or are likely to exceed the triggering amount as described in §411.375(c)(2) until CMS receives written notice from the requestor to continue processing the request;

(ii) Requests additional information from the requestor until CMS receives the additional information;

(iii) Notifies the requestor of the full amount due until CMS receives payment of this amount; and

(iv) Notifies the requestor of the need for expert advice until CMS receives the expert advice.

(d) After CMS has notified the requestor of the full amount owed and has received full payment of that amount, CMS issues the advisory opinion and promptly mails it to the requestor by regular first class U.S. mail.

§411.382 CMS's right to rescind advisory opinions.

Any advice CMS gives in an opinion does not prejudice its right to reconsider the questions involved in the opinion and, if it determines that it is in the public interest, to rescind or revoke the opinion. CMS provides notice to the requestor of its decision to rescind or revoke the opinion so that the requestor and the parties involved in the requestor's arrangement may discontinue any course of action they have taken in accordance with the advisory opinion. CMS does not proceed against the requestor with respect to any action the requestor and the involved parties have taken in good faith reliance upon CMS's advice under this part, provided—

(a) The requestor presented to CMS a full, complete and accurate description of all the relevant facts; and

(b) The parties promptly discontinue the action upon receiving notice that CMS had rescinded or revoked its approval, or discontinue the action within a reasonable “wind down” period, as determined by CMS.

§411.384 Disclosing advisory opinions and supporting information.

(a) Advisory opinions that CMS issues and releases in accordance with the procedures set forth in this subpart are available to the public.

(b) Promptly after CMS issues an advisory opinion and releases it to the requestor, CMS makes available a copy of the advisory opinion for public inspection during its normal hours of operation and on the CMS ~~Web site~~[website](#).

(c) Any predecisional document, or part of such predecisional document, that is prepared by CMS, the Department of Justice, or any other Department or agency of the United States in connection with an advisory opinion request under the procedures set forth in this part is exempt from disclosure under 5 U.S.C. 552, and will not be made publicly available.

(d) Documents submitted by the requestor to CMS in connection with a request for an advisory opinion are available to the public to the extent they are required to be made available by 5 U.S.C. 552, through procedures set forth in 45 CFR part 5.

(e) Nothing in this section limits CMS's obligation, under applicable laws, to publicly disclose the identity of the requesting party or parties, and the nature of the action CMS has taken in response to the request.

§411.386 CMS's advisory opinions as exclusive.

The procedures described in this subpart constitute the only method by which any individuals or entities can obtain a binding advisory opinion on the subject of a physician's referrals, as described in §411.370. CMS has not and does not issue a binding advisory opinion on the subject matter in §411.370, in either oral or written form, except through written opinions it issues in accordance with this subpart.

§411.387 Parties affected by advisory opinions.

An advisory opinion issued by CMS does not apply in any way to any individual or entity that does not join in the request for the opinion. Individuals or entities other than the requestor(s) may not rely on an advisory opinion.

§411.388 When advisory opinions are not admissible evidence.

The failure of a party to seek or to receive an advisory opinion may not be introduced into evidence to prove that the party either intended or did not intend to violate the provisions of sections 1128, 1128A or 1128B of the Act.

§411.389 Range of the advisory opinion.

(a) An advisory opinion states only CMS's opinion regarding the subject matter of the request. If the subject of an advisory opinion is an arrangement that must be approved by or is regulated by any other agency, CMS's advisory opinion cannot be read to indicate CMS's views on the legal or factual issues that may be raised before that agency.

(b) An advisory opinion that CMS issues under this part does not bind or obligate any agency other than the Department. It does not affect the requestor's, or anyone else's, obligations to any other agency, or under any statutory or regulatory provision other than that which is the specific subject matter of the advisory opinion.