

industry has asked for “bright-line” rules and new regulatory exceptions for nonabusive arrangements.

We believe it is impracticable and not in the public interest to offer what would essentially constitute a third opportunity to comment on much of the material in this rule and thereby delay finalizing useful exceptions and the many “bright-line” rules necessary either to protect the Medicare program from fraud and abuse or permit nonabusive arrangements. We have already issued a proposed rule, major portions of which were finalized upon publication of the Phase I final rule with comment period and became effective on January 4, 2002. This interim final rule responds to public comments received on the January 1998 proposed rule as well as public comments received on Phase I. Phase I comments necessarily informed our rulemaking with respect to finalizing the remainder of the January 1998 proposed rule because those comments addressed definitions and other matters that apply throughout the regulatory scheme. To publish yet another proposed rule on this matter would prevent affected parties from using important new or expanded exceptions. Even if we were able to finalize a proposed rule in an expedited fashion, the inability to use the new or expanded exceptions could expose DHS entities to significant financial liability for otherwise nonabusive relationships. Moreover, the public will not be denied the opportunity to comment on this rule because we are publishing it as an interim final rule with comment period. In accordance with section 902 of MMA, we are obligated to consider comments on this interim final rule and publish a final rule addressing those comments within three years.

In the Phase I preamble, we informed the public that we intended to publish a second final rule with comment period (Phase II) that would address the remainder of the proposed rule as well as comments on Phase I. The additional regulatory definitions and new regulatory exceptions in Phase II are inextricably intertwined with the Phase I final rule. The industry has patiently and eagerly awaited the publication of a single, comprehensive Phase II regulation that would provide the guidance and finality necessary for physicians and health care providers to structure their financial relationships in a manner that assures each party's compliance with the statutory prohibition. It would be contrary to the public interest to upset expectations by publishing another proposed rule thereby denying affected parties the

clarity and finality they expected to obtain with this rule. In addition, to extract a significant portion of the material in this interim final rule (much, if not all, of which will not be controversial) and to publish it separately in another proposed rule would thwart our efforts to present the unified and complete regulatory scheme necessary to support both compliance and enforcement efforts.

In addition, further delay could disrupt or hinder our programmatic objective of improving beneficiaries' access to care. For instance, this interim final rule with comment period creates a new exception for certain payments made by a hospital or federally qualified health center to a physician to retain the physician's medical practice in a health professional shortage area. In addition, this interim final rule creates an exception for intra-family rural referrals and obstetrical malpractice insurance subsidies. Beneficiary access to care in underserved or rural areas is a critical programmatic objective. It is not in the public interest to delay finalizing the new exceptions designed to serve this purpose.

For the reasons explained above, we find good cause to waive notice of proposed rulemaking and to issue this rule as an interim final rule with comment period.

In accordance with the provisions of Executive Order 12866, Phase II of this rulemaking was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 411

Kidney diseases, Medicare, Physician referral, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare.

■ For the reasons set forth in the preamble, CMS amends 42 CFR chapter IV as set forth below:

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 1. The authority citation for part 411 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A—General Exclusions and Exclusion of Particular Services

■ 2. In § 411.1, paragraph (a) is republished to read as follows:

§ 411.1 Basis and scope.

(a) *Statutory basis.* Sections 1814(a) and 1835(a) of the Act require that a physician certify or recertify a patient's need for home health services but, in general, prohibit a physician from certifying or recertifying the need for services if the services will be furnished by an HHA in which the physician has a significant ownership interest, or with which the physician has a significant financial or contractual relationship. Sections 1814(c), 1835(d), and 1862 of the Act exclude from Medicare payment certain specified services. The Act provides special rules for payment of services furnished by the following: Federal providers or agencies (sections 1814(c) and 1835(d)); hospitals and physicians outside of the U.S. (sections 1814(f) and 1862(a)(4)); and hospitals and SNFs of the Indian Health Service (section 1880 of the Act). Section 1877 of the Act sets forth limitations on referrals and payment for designated health services furnished by entities with which the referring physician (or an immediate family member of the referring physician) has a financial relationship.

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

■ 3. The heading for subpart J is revised as set forth above, and subpart J is revised to read as follows:

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

Sec.

- 411.350 Scope of subpart.
- 411.351 Definitions.
- 411.352 Group practice.
- 411.353 Prohibition on certain referrals by physicians and limitations on billing.
- 411.354 Financial relationship, compensation, and ownership or investment interest.
- 411.355 General exceptions to the referral prohibition related to both ownership/investment and compensation.
- 411.356 Exceptions to the referral prohibition related to ownership or investment interests.
- 411.357 Exceptions to the referral prohibition related to compensation arrangements.
- 411.361 Reporting requirements.

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

§ 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 Part A or Part B report information concerning ownership, investment, or compensation arrangements in the form, in the manner, and at the times specified by CMS.

§ 411.351 Definitions.

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.

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 and/or management 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 the radiation oncologist communicates with the referring physician on a regular basis about the patient's course of treatment and progress.

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) Clinical laboratory services.

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

(3) Radiology and certain other imaging services.

(4) Radiation therapy services and supplies.

(5) Durable medical equipment and supplies.

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

(7) Prosthetics, orthotics, and

prosthetic devices and supplies.

(8) Home health services.

(9) Outpatient prescription drugs.

(10) Inpatient and outpatient hospital services.

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, ambulatory surgical center services or SNF Part A payments), except to the extent the services listed in paragraphs (1) through (10) 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).

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

(1) Meets a safe harbor under the anti-kickback statute in § 1001.952 of this title, "Exceptions";

(2) Has been specifically approved by the OIG in a favorable advisory opinion issued to a party to the particular arrangement (e.g., 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

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

A favorable advisory opinion for purposes of this definition means an opinion in which the OIG opines that—

(1) 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

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

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

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, not-for-profit 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 to which CMS makes payment for the DHS, directly or upon assignment on the patient's behalf; or

(ii) Is the person or entity to which the right to payment for the DHS has been reassigned pursuant to § 424.80(b)(1) (employer), (b)(2) (facility), or (b)(3) (health care delivery system) of this chapter (other than a health care delivery system that is a health plan (as defined in § 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 pursuant to § 424.80(b)(1) and (b)(2) of this chapter, with respect to any designated health services provided by that supplier.

(3) For purposes of this subpart, "entity" does not include a physician's practice when it bills Medicare for a diagnostic test in accordance with § 414.50 of this chapter (Physician billing for purchased diagnostic tests) and section 3060.4 of the Medicare Carriers Manual (Purchased diagnostic tests), as amended or replaced from time to time.

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.

An hourly payment for a physician's personal services (that is, services performed by the physician personally and not by employees, contractors, or others) shall be considered to be fair market value if the hourly payment is established using either of the following two methodologies:

(1) The hourly rate is less than or equal to the average hourly rate for emergency room physician services in the relevant physician market, provided there are at least three hospitals providing emergency room services in the market.

(2) The hourly rate is determined by averaging the 50th percentile national compensation level for physicians with the same physician specialty (or, if the specialty is not identified in the survey, for general practice) in at least four of the following surveys and dividing by 2,000 hours. The surveys are:

- Sullivan, Cotter & Associates, Inc.—Physician Compensation and Productivity Survey
- Hay Group—Physicians Compensation Survey
- Hospital and Healthcare Compensation Services—Physician Salary Survey Report
- Medical Group Management Association—Physician Compensation and Productivity Survey
- ECS Watson Wyatt—Hospital and Health Care Management Compensation Report
- William M. Mercer—Integrated Health Networks Compensation Survey

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 means those services that meet the requirements of section 1861(s)(2)(A) of the Act, 42 CFR § 410.26, and section 2050 of the Medicare Carriers (CMS Pub. 14–3), Part 3—Claims Process, as amended or replaced from time to time.

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).

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 designated health services 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 at <http://www.cms.gov/medlearn/refphys.asp>.

Locum tenens physician means a physician who substitutes (that is, “stands in the shoes”) in exigent circumstances for a physician, in accordance with applicable reassignment rules and regulations, including section 3060.7 of the Medicare Carriers Manual (CMS Pub. 14–3), Part 3—Claims Process, as amended or replaced from time to time.

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 prescription drugs covered by Medicare Part B.

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 nutrition 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 section 65–10 of the Medicare Coverage Issues Manual (CMS Pub. 6), 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 section 65–10 of the Medicare Coverage Issues Manual (CMS Pub. 6), as amended or replaced from time to time.

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

(1) *Physical therapy services*, meaning those outpatient physical therapy services (including speech-language pathology services) described at 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;

(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; or

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

(2) *Occupational therapy services*, meaning those services described at 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.

Physician means a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor, as defined in section 1861(r) of the Act.

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 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 fit in the personal services exception in § 411.357(d)), and the independent contractor's arrangement with the group practice must comply with the reassignment rules at § 424.80(b)(3) of this chapter (see also section 3060.3 of the Medicare Carriers Manual (CMS Pub. 14-3), Part 3—Claims Process, 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 subcontractor) 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.

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 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, but does not include nuclear medicine procedures.

Radiology and certain other imaging 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 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, or other imaging services, computerized axial tomography, or magnetic resonance imaging, as covered under section 1861(s)(3) of the Act and § 410.32 and § 410.34 of this chapter but does 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 procedures that are integral to the performance of a

nonradiological medical procedure and performed—

(i) During the nonradiological medical procedure; or

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

(3) Diagnostic nuclear medicine procedures.

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, 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.

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 used solely to collect, transport, process, or store specimens for the entity furnishing the items, devices, or supplies or are used solely to order or communicate the results of tests or procedures for the entity.

(3) A payment made by an insurer or a self-insured plan (or a subcontractor of the insurer or plan) to a physician to satisfy a claim, submitted on a fee-for-service basis, for the furnishing of health services by that physician 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 plan (or a subcontractor of the insurer or 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 a manner that takes into account directly or indirectly the volume or value of any referrals.

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)) that is primarily or exclusively engaged in the care and treatment of one of the following: Patients with a cardiac condition; patients with an orthopedic condition; patients receiving a surgical procedure; or 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.

Transaction means an instance or process of two or more persons or entities doing business. An isolated 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, secured by a negotiable promissory note, or subject to a similar mechanism to assure payment even in the event of default by the purchaser or obligated party. § 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, not-for-profit 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 in § 411.351.

(c) *Range of care*. Each physician who is a member of the group, as defined in § 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 an HPSA, as defined in § 411.351.

(4) For a group practice located outside of an HPSA (as defined in § 411.351), any time spent by a group practice member providing services in an 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 practice under § 411.457(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 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 referrals by the physician, 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 rule for productivity bonuses and profit shares.* (1) A physician in a group practice may be paid a share of overall profits of the group, or a productivity bonus based on services that he or she has personally

performed (including services "incident to" those personally performed services as defined in § 411.351), provided that the share or bonus is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physician.

(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 of any component of the group practice that consists of at least five physicians. Overall profits should 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 profits are divided per capita (for example, per member of the group or per physician in the group).

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

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

(3) A productivity bonus should 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:

(i) The bonus is based on the physician's total patient encounters or relative value units (RVUs). (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.

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

(4) Supporting documentation verifying the method used to calculate the profit share or productivity bonus under paragraphs (i)(2) and (i)(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.* 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.

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

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

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

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

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

a claim or bill for a designated health service if—

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

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

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

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

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

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

§ 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) 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. (3) 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 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 a retirement plan;

(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); or

(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).

(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) *Indirect ownership or investment interest.* (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 act 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.

(1) 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" in § 411.351. (However, any other portion of the arrangement may still constitute a compensation arrangement.)

(2) *Indirect compensation arrangement.* 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

otherwise reflects, 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 § 411.354(d)(2) or (d)(3). 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 otherwise reflects, 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 otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS.

(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 will be considered "set in advance" if the aggregate compensation, a time-based or per unit of service based (whether per-use or per-service) amount, or a specific formula for calculating the compensation is set in an agreement between the parties before the furnishing of the items or services for which the compensation is to be paid. The formula for determining the compensation must be set forth in sufficient detail so that it can be objectively verified, and the formula may not be changed or modified during the course of the agreement in any manner that reflects 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) will be

deemed not to take into account "the volume or value of referrals" if the compensation is fair market value for services or items actually provided and does not vary during the course of the compensation agreement in any manner that takes into account referrals of DHS.

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

(4) A physician's compensation from a *bona fide* employer or under a managed care or other contract may be conditioned on the physician's referrals to a particular provider, practitioner, or supplier, so long as the compensation arrangement—

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

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

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

(iv) Complies with the following conditions:

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

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

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

contract. § 411.355 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 in § 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, "incident to" services include only those "incident to" services (as defined in § 411.351) that are physician services under § 410.20(a) of this chapter.

(3) All other "incident to" services (for example, diagnostic tests, physical therapy) are outside the scope of paragraph (a) of this section.

(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 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 in § 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 in § 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 in § 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 the billing arrangement meets the requirements of § 424.80(b)(6) 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 purposes of ambulating, 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 located 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.

(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.

(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 organization in accordance with a contract with CMS under section 1857 of the Act and part 422 of this chapter.

(6) A managed care organization (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; 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 total compensation paid by all academic medical center components to the referring physician is set in advance and, in the aggregate, does not exceed fair market value for the services provided, and is not determined in a 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.

(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 written agreement(s) or other written document(s) 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 hospital(s) 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 are 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 provision, 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.

(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 a Medicare-certified ASC (under part 416 of this chapter) 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.

(3) The arrangement for the furnishing of the implant does not violate the anti-kickback statute (section 1128B(b) of the Act).

(4) All billing and claims submission for the implants does not violate any Federal or State law or regulation governing billing or claims submission.

(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 furnished in or by an ESRD facility.* 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 (g): "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).

(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.

(4) The exception set forth in this paragraph (g) 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).

(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.

(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).

(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 in § 411.356(c)(1);

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

(iii) In the case of services furnished to patients where they reside (for example, home health services or in-home 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 from 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 (a)(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; or

(ii) Traded under an automated interdealer quotation system operated

by the National Association of Securities Dealers.

(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 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. A rural area for purposes of this paragraph (c)(1) is an area that is not an urban area as defined in § 412.62(f)(1)(ii) of this chapter.

(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; and

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

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

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

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

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

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

(3) The space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any person or entity related to the lessor), except that the lessee may make payments for the use of space consisting of common areas if the payments do not exceed the lessee's pro rata share of expenses for the space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using the common areas.

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

(5) The rental charges over the term of the agreement are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

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

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

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

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

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

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

(4) The rental charges over the term of the agreement are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

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

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

(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 a 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 agreement 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).

(d) *Personal service arrangements.* (1) *General*—Remuneration from an entity under an arrangement or multiple arrangements to a physician, an immediate family member of the physician, 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 will be 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 should 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 in § 411.351, except that the regular physician need not be a member of a group practice).

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

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

(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, is not determined in a 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 State or Federal law.

(2) *Physician incentive plan exception.* In the case of a physician incentive plan (as defined in § 411.351) between a physician and an entity (or downstream subcontractor), the compensation may be determined in a 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 subcontractor 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 in § 422.208, the entity (and/or any downstream contractor) complies with the requirements concerning physician incentive plans set forth at § 422.208 and § 422.210 of this chapter.

(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 hospital does not determine (directly or indirectly) the amount of the remuneration to the physician based on 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 a separate employment or services contract that complies with § 411.354(d)(4)).

(2) 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. A physician will be considered to have relocated his or her medical practice if—

(i) The physician moves his or her medical practice at least 25 miles; or

(ii) 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) Residents and physicians who have been in practice 1 year or less will not be subject to the relocation requirement of this paragraph, except that the recruited resident or physician must establish his or her medical practice in the geographic area served by the hospital.

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

(i) The written agreement in § 411.357(e)(1) is also signed by the party to whom the payments are directly made;

(ii) Except for actual costs incurred by the physician or 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 made by the hospital to a recruited physician who joins a physician or physician practice, the costs allocated by the physician or physician practice to the recruited physician do not exceed the actual additional incremental costs attributable to the recruited physician;

(iv) Records of the actual costs and the passed through amounts are maintained for a period of at least 5 years and made available to the Secretary upon request;

(v) The remuneration from the hospital under the arrangement is not to be determined in a 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 or physician practice may not impose additional practice restrictions on the recruited physician other than conditions related to quality of care; and

(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) This paragraph (e) applies to remuneration provided by a federally qualified health center in the same manner as it applies to remuneration provided by a hospital, so long as 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.

(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 transaction is—

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

(ii) Not determined in a 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 agreement that would be commercially reasonable even if the physician made no referrals.

(3) There are no additional transactions between the parties for 6 months after the isolated 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 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. Remuneration relates to the furnishing of DHS 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 takes into account the volume or value of referrals or other business generated by the referring physician.

(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 a 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.

(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 are furnished at a price that is consistent with fair market value, and that are not specifically excepted under another provision in § 411.355 through § 411.357 (including, but not limited to, § 411.357(l)). “Services” in this context means services of any kind (not just those defined as “services” for purposes of the Medicare program in § 400.202).

(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 made, 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) *Non-monetary compensation up to \$300.* (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 year, 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 \$300 limit in this paragraph (k) will be 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 intends to display as soon as possible after September 30 each year, both the increase in the CPI-U for the 12-month period and the new non-monetary compensation limit on the physician self-referral Web site: <http://cms.hhs.gov/medlearn/refphys.asp>.

(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 by the physician (or an immediate family member) or group of physicians to the entity, if the arrangement is set forth in an agreement that meets the following conditions:

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

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

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

(4) The arrangement would be commercially reasonable (taking into account the nature and scope of the

transaction) and furthers the legitimate business purposes of the parties.

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

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

(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 provided to all members of the medical staff practicing in the same specialty (but not necessarily accepted by every member to whom it is offered) without regard to 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 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 or in hospital advertising, will meet 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) will be 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 intends to display as soon as possible 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:

<http://cms.hhs.gov/medlearn/refphys.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.

(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 managed care organization or an independent physicians' association 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 ascribed to those terms 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 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, reporting); specific training regarding the requirements of Federal and State health care programs (for example, billing, coding, reasonable and necessary services, documentation, 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 (but not including continuing medical education).

(p) *Indirect compensation arrangements.* Indirect compensation

arrangements, as defined in § 411.354(c)(2), if all of the following conditions are satisfied:

(1) 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 value or volume of referrals or other business generated by the referring physician for the entity furnishing DHS.

(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 a written contract, 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 to the referring physician that meets all of the conditions set forth in § 1001.952(o) of this title.

(s) *Professional courtesy.* Professional courtesy (as defined in § 411.351) offered by an entity 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 the entity's local community or service area without regard to 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's professional courtesy policy 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;

(5) If the professional courtesy involves any whole or partial reduction of any coinsurance obligation, the insurer is informed in writing of the reduction; and

(6) 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) Remuneration provided by a hospital or federally qualified health center directly to a physician on the hospital's or federally qualified health center's medical staff to retain the physician's medical practice in the geographic area served by the hospital or federally qualified health center (as defined in paragraph (e)(2) of this section), if all of the following conditions are met:

(i) Paragraphs 411.357(e)(1)(i) through 411.357(e)(1)(iv) are satisfied;

(ii) The geographic area served by the hospital or federally qualified health center is a HPSA (regardless of the physician's specialty) or is an area with demonstrated need for the physician as determined by the Secretary in an advisory opinion issued according to section 1877(g)(6) of the Act;

(iii) The physician has a *bona fide* firm, written recruitment offer from a hospital or federally qualified health center that is not related to the hospital or the federally qualified health center making the payment, and the offer specifies the remuneration being offered and would require the physician to move the location of his or her practice at least 25 miles *and* outside of the geographic area served by the hospital or federally qualified health center making the retention payment;

(iv) The retention payment is limited to the lower of—

(A) The amount obtained by subtracting (1) the physician's current income from physician and related services from (2) the income the physician would receive from comparable physician and related services in the *bona fide* recruitment 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 or federally qualified health center would otherwise have to expend to recruit a new physician to the geographic area served by the hospital or federally qualified health center in order to join the medical staff of the hospital or federally qualified health center to replace the retained physician;

(v) Any retention payment is subject to the same obligations and restrictions, if any, on repayment or forgiveness of indebtedness as the *bona fide* recruitment offer;

(vi) The hospital or federally qualified health center does not enter into a retention arrangement with a particular referring physician more frequently than once every 5 years and 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;

(vii) The arrangement otherwise complies with all of the conditions of this section; and

(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.

(2) The Secretary may waive the relocation requirement of paragraph (t)(1) 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 according to section 1877(g)(6) of the Act, if the retention payment arrangement otherwise complies with all of the conditions of this paragraph.

(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. § 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) of each physician who has a reportable financial relationship with the entity.

(2) The name and UPIN of each physician who has an immediate family member (as defined in § 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 and/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 in § 411.354(b) or any compensation arrangement, as defined in § 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 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.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 1. The authority citation for part 424 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart B—Certification and Plan of Treatment Requirements

■ 2. In § 424.22, paragraph (d) is republished to read as set forth below.

§ 424.22 Requirements for home health services.

* * * * *

(d) *Limitation on the performance of certification and plan of treatment functions.* The need for home health services to be provided by an HHA may not be certified or recertified, and a plan of treatment may not be established and reviewed, by any physician who has a financial relationship, as defined in § 411.351 of this chapter, with that HHA, unless the physician's relationship meets one of the exceptions in section 1877 of the Act, which sets forth general exceptions to the referral prohibition related to both ownership/investment and compensation; exceptions to the referral prohibition related to ownership or investment interests; and exceptions to the referral prohibition related to compensation arrangements.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare-Hospital Insurance; and Program No. 93.774, Medicare-Supplementary Medical Insurance Program)

Dated: February 13, 2003.

Thomas A. Scully,
Administrator, Centers for Medicare & Medicaid Services.

Dated: October 23, 2003.

Tommy G. Thompson,
Secretary.

Note: The following attachment will not appear in the Code of Federal Regulations.

Attachment—List of CPT¹/HCPCS Codes for Purposes of Section 1877 of the Social Security Act—Effective July 26, 2004

Clinical Laboratory Services

Include CPT codes for all clinical laboratory services in the 80000 series, except EXCLUDE CPT codes for the following blood component collection services:

86890 Autologous blood process
86891 Autologous blood, op salvage
86927 Plasma, fresh frozen
86930 Frozen blood prep
86931 Frozen blood thaw
86932 Frozen blood freeze/thaw
86945 Blood product/irradiation
86950 Leukocyte transfusion
86965 Pooling blood platelets
86985 Split blood or products

Include the following CPT and HCPCS level 2 codes for other clinical laboratory services:

0010T TB test, gamma interferon
0023T Phenotype drug test, hiv 1
0026T Measure remnant lipoproteins
0030T Antiprothrombin antibody
0041T Detect ur infect agnt w/cpas
0043T Co expired gas analysis
0058T Cryopreservation, ovary tiss
0059T Cryopreservation, oocyte
G0001 Drawing blood for specimen
G0027 Semen analysis
G0103 Psa, total screening
G0107 CA screen; fecal blood test
G0123 Screen cerv/vag thin layer
G0124 Screen c/v thin layer by MD
G0141 Scr c/v cyto, autosys and md
G0143 Scr c/v cyto, thinlayer, rescr
G0144 Scr c/v cyto, thinlayer, rescr
G0145 Scr c/v cyto, thinlayer, rescr
G0147 Scr c/v cyto, automated sys
G0148 Scr c/v cyto, autosys, rescr
G0306 CBC/diffwbc w/o platelet
G0307 CBC without platelet
G0328 Fecal blood scrn immunoassay
P2028 Cephalin flocculation test
P2029 Congo red blood test
P2033 Blood thymol turbidity
P2038 Blood mucoprotein
P3000 Screen pap by tech w md supv
P3001 Screening pap smear by phys
P9612 Catheterize for urine spec
P9615 Urine specimen collect mult
Q0111 Wet mounts/ w preparations
Q0112 Potassium hydroxide preps
Q0113 Pinworm examinations
Q0114 Fern test
Q0115 Post-coital mucous exam

¹CPT codes and descriptions only are copyright 2003 American Medical Association. All rights are reserved and applicable FARS/DFARS clauses apply.

Physical Therapy, Occupational Therapy, and Speech-Language Pathology

Include the following CPT codes for the physical therapy/occupational therapy/speech-language pathology services in the 97000 series:

97001 Pt evaluation
97002 Pt re-evaluation
97003 Ot evaluation
97004 Ot re-evaluation
97010 Hot or cold packs therapy
97012 Mechanical traction therapy
97016 Vasopneumatic device therapy
97018 Paraffin bath therapy
97020 Microwave therapy
97022 Whirlpool therapy
97024 Diathermy treatment
97026 Infrared therapy
97028 Ultraviolet therapy
97032 Electrical stimulation
97033 Electric current therapy
97034 Contrast bath therapy
97035 Ultrasound therapy
97036 Hydrotherapy
97039 Physical therapy treatment
97110 Therapeutic exercises
97112 Neuromuscular reeducation
97113 Aquatic therapy/exercises
97116 Gait training therapy
97124 Massage therapy
97139 Physical medicine procedure
97140 Manual therapy
97150 Group therapeutic procedures
97504 Orthotic training
97520 Prosthetic training
97530 Therapeutic activities
97532 Cognitive skills development
97533 Sensory integration
97535 Self care mngmt training
97537 Community/work reintegration
97542 Wheelchair mngmt training
97545 Work hardening
97546 Work hardening add-on
97601 Wound(s) care, selective
97602 Wound(s) care, nonselective
97703 Prosthetic checkout
97750 Physical performance test
97755 Assistive technology assess
97799 Physical medicine procedure

Include CPT codes for physical therapy/occupational therapy/speech-language pathology services not in the 97000 series:

64550 Apply neurostimulator
90901 Biofeedback train, any meth
90911 Biofeedback peri/uro/rectal
92507 Speech/hearing therapy
92508 Speech/hearing therapy
92526 Oral function therapy
92597 Oral speech device eval
92607 Ex for speech device rx, 1hr
92608 Ex for speech device rx addl
92609 Use of speech device service
92610 Evaluate swallowing function
92611 Motion fluoroscopy/swallow
92612 Endoscopy swallow tst (fees)
92614 Laryngoscopic sensory test
92616 Fees w/laryngeal sense test
93797 Cardiac rehab
93798 Cardiac rehab/monitor
94667 Chest wall manipulation
94668 Chest wall manipulation
95831 Limb muscle testing, manual
95832 Hand muscle testing, manual
95833 Body muscle testing, manual
95834 Body muscle testing, manual

95851	Range of motion measurements	71010	Chest x-ray	73080	X-ray exam of elbow
95852	Range of motion measurements	71015	Chest x-ray	73090	X-ray exam of forearm
96000	Motion analysis, video/3d	71020	Chest x-ray	73092	X-ray exam of arm, infant
96001	Motion test w/ft press meas	71021	Chest x-ray	73100	X-ray exam of wrist
96002	Dynamic surface emg	71022	Chest x-ray	73110	X-ray exam of wrist
96003	Dynamic fine wire emg	71023	Chest x-ray and fluoroscopy	73120	X-ray exam of hand
96105	Assessment of aphasia	71030	Chest x-ray	73130	X-ray exam of hand
96110	Developmental test, lim	71034	Chest x-ray and fluoroscopy	73140	X-ray exam of finger(s)
96111	Developmental test, extend	71035	Chest x-ray	73200	Ct upper extremity w/o dye
96115	Neurobehavior status exam	71100	X-ray exam of ribs	73201	Ct upper extremity w/dye
0029T	Magnetic tx for incontinence	71101	X-ray exam of ribs/chest	73202	Ct uppr extremity w/o & w/dye
	Include HCPCS level 2 codes for the	71110	X-ray exam of ribs	73206	Ct angio upr extrm w/o & w/dye
	following physical therapy/occupational	71111	X-ray exam of ribs/chest	73218	MRI upper extremity w/o dye
	therapy/speech-language pathology services:	71120	X-ray exam of breastbone	73219	MRI upper extremity w/dye
G0279	Excorp shock tx, elbow epi	71130	X-ray exam of breastbone	73220	MRI uppr extremity w/o & w/dye
G0280	Excorp shock tx other than	71250	Ct thorax w/o dye	73221	MRI joint upr extrem w/o dye
G0281	Elec stim unattend for press	71260	Ct thorax w/dye	73222	MRI joint upr extrem w/dye
G0283	Elec stim other than wound	71270	Ct thorax w/o & w/dye	73223	MRI joint upr extr w/o & w/dye
		71275	Ct angiography, chest	73500	X-ray exam of hip
		71550	Mri chest w/o dye	73510	X-ray exam of hip
		71551	Mri chest w/dye	73520	X-ray exam of hips
		71552	Mri chest w/o & w/dye	73540	X-ray exam of pelvis & hips
		71555	Mri angio chest w or w/o dye	73550	X-ray exam of thigh
		72010	X-ray exam of spine	73560	X-ray exam of knee, 1 or 2
		72020	X-ray exam of spine	73562	X-ray exam of knee, 3
		72040	X-ray exam of neck spine	73564	X-ray exam, knee, 4 or more
		72050	X-ray exam of neck spine	73565	X-ray exam of knees
		72052	X-ray exam of neck spine	73590	X-ray exam of lower leg
		72069	X-ray exam of trunk spine	73592	X-ray exam of leg, infant
		72070	X-ray exam of thoracic spine	73600	X-ray exam of ankle
		72072	X-ray exam of thoracic spine	73610	X-ray exam of ankle
		72074	X-ray exam of thoracic spine	73620	X-ray exam of foot
		72080	X-ray exam of trunk spine	73630	X-ray exam of foot
		72090	X-ray exam of trunk spine	73650	X-ray exam of heel
		72100	X-ray exam of lower spine	73660	X-ray exam of toe(s)
		72110	X-ray exam of lower spine	73700	Ct lower extremity w/o dye
		72114	X-ray exam of lower spine	73701	Ct lower extremity w/dye
		72120	X-ray exam of lower spine	73702	Ct lwr extremity w/o & w/dye
		72125	Ct neck spine w/o dye	73706	Ct angio lwr extr w/o & w/dye
		72126	Ct neck spine w/dye	73718	MRI lower extremity w/o dye
		72127	Ct neck spine w/o & w/dye	73719	MRI lower extremity w/dye
		72128	Ct chest spine w/o dye	73720	MRI lwr extremity w/o & w/dye
		72129	Ct chest spine w/dye	73721	MRI jnt of lwr extre w/o dye
		72130	Ct chest spine w/o & w/dye	73722	MRI joint of lwr extr w/dye
		72131	Ct lumbar spine w/o dye	73723	MRI joint lwr extr w/o & w/dye
		72132	Ct lumbar spine w/dye	73725	Mr ang lwr ext w or w/o dye
		72133	Ct lumbar spine w/o & w/dye	74000	X-ray exam of abdomen
		72141	Mri neck spine w/o dye	74010	X-ray exam of abdomen
		72142	Mri neck spine w/dye	74020	X-ray exam of abdomen
		72146	Mri chest spine w/o dye	74022	X-ray exam series, abdomen
		72147	Mri chest spine w/dye	74150	Ct abdomen w/o dye
		72148	Mri lumbar spine w/o dye	74160	Ct abdomen w/dye
		72149	Mri lumbar spine w/dye	74170	Ct abdomen w/o & w/dye
		72156	Mri neck spine w/o & w/dye	74175	Ct angio abdom w/o & w/dye
		72157	Mri chest spine w/o & w/dye	74181	MRI abdomen w/o dye
		72158	Mri lumbar spine w/o & w/dye	74182	MRI abdomen w/dye
		72170	X-ray exam of pelvis	74183	MRI abdomen w/o & w/dye
		72190	X-ray exam of pelvis	74185	MRI angio, abdom w or w/o dye
		72191	Ct angiograph pelv w/o & w/dye	74210	Contrst x-ray exam of throat
		72192	Ct pelvis w/o dye	74220	Contrast x-ray, esophagus
		72193	Ct pelvis w/dye	74230	Cine/vid x-ray, throat/esoph
		72194	Ct pelvis w/o & w/dye	74240	X-ray exam, upper gi tract
		72195	Mri pelvis w/o dye	74241	X-ray exam, upper gi tract
		72196	Mri pelvis w/dye	74245	X-ray exam, upper gi tract
		72197	Mri pelvis w/o & w/dye	74246	Contrst x-ray uppr gi tract
		72198	Mr angio pelvis w/o & w/dye	74247	Contrst x-ray uppr gi tract
		72200	X-ray exam sacroiliac joints	74249	Contrst x-ray uppr gi tract
		72202	X-ray exam sacroiliac joints	74250	X-ray exam of small bowel
		72220	X-ray exam of tailbone	74290	Contrast x-ray, gallbladder
		73000	X-ray exam of collar bone	74291	Contrast x-rays, gallbladder
		73010	X-ray exam of shoulder blade	74710	X-ray measurement of pelvis
		73020	X-ray exam of shoulder	75552	Heart mri for morph w/o dye
		73030	X-ray exam of shoulder	75553	Heart mri for morph w/dye
		73050	X-ray exam of shoulders	75554	Cardiac MRI/function
		73060	X-ray exam of humerus	75555	Cardiac MRI/limited study
		73070	X-ray exam of elbow	75635	Ct angio abdominal arteries

76000 Fluoroscope examination
 76006 X-ray stress view
 76010 X-ray, nose to rectum
 76020 X-rays for bone age
 76040 X-rays, bone evaluation
 76061 X-rays, bone survey
 76062 X-rays, bone survey
 76065 X-rays, bone evaluation
 76066 Joint survey, single view
 76070 Ct bone density, axial
 76071 Ct bone density, peripheral
 76075 DEXA, axial skeleton study
 76076 DEXA, peripheral study
 76078 Radiographic absorptiometry
 76082 Computer mammogram add-on
 76083 Computer mammogram add-on
 76090 Mammogram, one breast
 76091 Mammogram, both breasts
 76092 Mammogram, screening
 76093 Magnetic image, breast
 76094 Magnetic image, both breasts
 76100 X-ray exam of body section
 76101 Complex body section x-ray
 76102 Complex body section x-rays
 76120 Cine/video x-rays
 76125 Cine/video x-rays add-on
 76150 X-ray exam, dry process
 76370 Ct scan for therapy guide
 76375 3d/holograph reconstr add-on
 76380 CAT scan follow-up study
 76400 Magnetic image, bone marrow
 76499 Radiographic procedure
 76506 Echo exam of head
 76511 Echo exam of eye
 76512 Echo exam of eye
 76513 Echo exam of eye, water bath
 76514 Echo exam of eye, thickness
 76516 Echo exam of eye
 76519 Echo exam of eye
 76536 Us Exam of head and neck
 76604 Us exam, chest, b-scan
 76645 Us exam, breast(s)
 76700 Us exam, abdom, complete
 76705 Echo exam of abdomen
 76770 Us exam abdo back wall, comp
 76775 Us exam abdo back wall, lim
 76778 Us exam kidney transplant
 76800 Us exam, spinal canal
 76801 Ob us < 14 wks, single fetus
 76802 Ob us < 14 wks, add'l fetus
 76805 Ob us >= 14 wks, sngl fetus
 76810 Ob us >= 14 wks, addl fetus
 76811 Ob us, detailed, sngl fetus
 76812 Ob us, detailed, addl fetus
 76815 Ob us, limited, fetus(s)
 76816 Ob us, follow-up, per fetus
 76818 Fetal biophys profile w/nst
 76819 Fetal biophys profil w/o nst
 76825 Echo exam of fetal heart
 76826 Echo exam of fetal heart
 76827 Echo exam of fetal heart
 76828 Echo exam of fetal heart
 76856 Us exam, pelvic, complete
 76857 Us exam, pelvic, limited
 76870 Us exam, scrotum
 76880 Us exam, extremity
 76885 Us exam infant hips, dynamic
 76886 Us exam infant hips, static
 76970 Ultrasound exam follow-up
 76977 Us bone density measure
 76999 Echo examination procedure

Include the following CPT codes for echocardiography and vascular ultrasound:

93303 Echo transthoracic
 93304 Echo transthoracic
 93307 Echo exam of heart

93308 Echo exam of heart
 93320 Doppler echo exam, heart [if used in conjunction with 93303-93308]
 93321 Doppler echo exam, heart [if used in conjunction with 93303-93308]
 93325 Doppler color flow add-on [if used in conjunction with 93303-93308]
 93875 Extracranial study
 93880 Extracranial study
 93882 Extracranial study
 93886 Intracranial study
 93888 Intracranial study
 93922 Extremity study
 93923 Extremity study
 93924 Extremity study
 93925 Lower extremity study
 93926 Lower extremity study
 93930 Upper extremity study
 93931 Upper extremity study
 93965 Extremity study
 93970 Extremity study
 93971 Extremity study
 93975 Vascular study
 93976 Vascular study
 93978 Vascular study
 93979 Vascular study
 93980 Penile vascular study
 93981 Penile vascular study
 93990 Doppler flow testing

Include the following CPT and HCPCS level 2 codes:

51798 Us urine capacity measure
 78350 Bone mineral, single photon
 91110 Gi tract capsule endoscopy
 0028T DEXA body composition study
 0042T Ct perfusion w/contrast, cbf
 G0130 Single energy x-ray study
 G0202 Screening mammography digital
 G0204 Diagnostic mammography digital
 G0206 Diagnostic mammography digital
 G0288 Recon, CTA for surg plan
 R0070 Transport portable x-ray
 R0075 Transport port x-ray multipl

Radiation Therapy Services and Supplies

Include the following codes in the CPT 70000 series:

77261 Radiation therapy planning
 77262 Radiation therapy planning
 77263 Radiation therapy planning
 77280 Set radiation therapy field
 77285 Set radiation therapy field
 77290 Set radiation therapy field
 77295 Set radiation therapy field
 77299 Radiation therapy planning
 77300 Radiation therapy dose plan
 77301 Radiotherapy dose plan, imrt
 77305 Teletx isodose plan simple
 77310 Teletx isodose plan intermed
 77315 Teletx isodose plan complex
 77321 Special teletx port plan
 77326 Brachytx isodose calc simp
 77327 Brachytx isodose calc interm
 77328 Brachytx isodose plan compl
 77331 Special radiation dosimetry
 77332 Radiation treatment aid(s)
 77333 Radiation treatment aid(s)
 77334 Radiation treatment aid(s)
 77336 Radiation physics consult
 77370 Radiation physics consult
 77399 External radiation dosimetry
 77401 Radiation treatment delivery
 77402 Radiation treatment delivery
 77403 Radiation treatment delivery
 77404 Radiation treatment delivery
 77406 Radiation treatment delivery

77407 Radiation treatment delivery
 77408 Radiation treatment delivery
 77409 Radiation treatment delivery
 77411 Radiation treatment delivery
 77412 Radiation treatment delivery
 77413 Radiation treatment delivery
 77414 Radiation treatment delivery
 77416 Radiation treatment delivery
 77417 Radiology port film(s)
 77418 Radiation tx delivery, imrt
 77427 Radiation tx management, x5
 77431 Radiation therapy management
 77432 Stereotactic radiation trmt
 77470 Special radiation treatment
 77499 Radiation therapy management
 77520 Proton trmt, simple w/o comp
 77522 Proton trmt, simple w/comp
 77523 Proton trmt, intermediate
 77525 Proton treatment, complex
 77600 Hyperthermia treatment
 77605 Hyperthermia treatment
 77610 Hyperthermia treatment
 77615 Hyperthermia treatment
 77620 Hyperthermia treatment
 77750 Infuse radioactive materials
 77761 Apply intrcav radiat simple
 77762 Apply intrcav radiat interm
 77763 Apply intrcav radiat compl
 77776 Apply interstit radiat simpl
 77777 Apply interstit radiat inter
 77778 Apply interstit radiat compl
 77781 High intensity brachytherapy
 77782 High intensity brachytherapy
 77783 High intensity brachytherapy
 77784 High intensity brachytherapy
 77789 Apply surface radiation
 77790 Radiation handling
 77799 Radium/radioisotope therapy

Include the following CPT and HCPCS level 2 codes classified elsewhere:

31643 Diag bronchoscope/catheter
 50559 Renal endoscopy/radiotracer
 55859 Percut/needle insert, pros
 61770 Incise skull for treatment
 61793 Focus radiation beam
 92974 Cath place, cardio brachytx
 G0173 Stereo radiosurgery, complete
 G0242 Multisource photon ster plan
 G0243 Multisour photon stero treat
 G0251 Linear acc based stero radio
 G0338 Linear accelerator stero pln
 G0339 Robot lin-radsurg com, first
 G0340 Robt lin-radsurg fractx 2-5

EPO and Other Dialysis-Related Drugs

The physician self-referral prohibition does not apply to the following codes for EPO and other dialysis-related drugs furnished in or by an ESRD facility if the conditions in § 411.355(g) are satisfied:

J0630 Calcitonin salmon injection
 J0636 Inj calcitriol per 0.1 mcg
 J0895 Deferoxamine mesylate inj
 J1270 Injection, doxercalciferol
 J1750 Iron dextran
 J1756 Iron sucrose injection
 J1955 Inj levocarnitine per 1 gm
 J2501 Paricalcitol
 J2916 Na ferric gluconate complex
 J2993 Reteplase injection
 J2995 Inj streptokinase /250000 IU
 J2997 Alteplase recombinant
 J3364 Urokinase 5000 IU injection
 P9041 Albumin (human), 5%, 50ml
 P9045 Albumin (human), 5%, 250ml
 P9046 Albumin (human), 25%, 20ml

P9047 Albumin (human), 25%, 50ml
 Q4054 Darbepoetin alfa, esrd use
 Q4055 Epoetin alfa, esrd use

*Preventive Screening Tests, Immunizations
 and Vaccines*

The physician self-referral prohibition does not apply to the following tests if they are performed for screening purposes and satisfy the conditions in § 411.355(h):

76083 Computer mammogram add-on
 76092 Mammogram, screening
 G0103 Psa, total screening
 G0107 CA screen; fecal blood test

G0123 Screen cerv/vag thin layer
 G0124 Screen c/v thin layer by MD
 G0141 Scr c/v cyto, autosys and md
 G0143 Scr c/v cyto, thinlayer, rescr
 G0144 Scr c/v cyto, thinlayer, rescr
 G0145 Scr c/v cyto, thinlayer, rescr
 G0147 Scr c/v cyto, automated sys
 G0148 Scr c/v cyto, autosys, rescr
 G0202 Screening mammographydigital
 G0328 Fecal blood scrn immunoassay
 P3000 Screen pap by tech w md supv
 P3001 Screening pap smear by phys

The physician self-referral prohibition does not apply to the following immunization and

vaccine codes if they satisfy the conditions in § 411.355(h):

90655 Flu vaccine, 6–35 mo, im
 90657 Flu vaccine, 6–35 mo, im
 90658 Flu vaccine, 3 yrs, im
 90732 Pneumococcal vaccine
 90740 Hepb vacc, ill pat dose im
 90743 Hep b vacc, adol, 2 dose im
 90744 Hepb vacc ped/adol 3 dose im
 90746 Hepb vaccine, adult, im
 90747 Hepb vacc, ill pat 4 dose im

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