

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 their ownership, investment, or compensation arrangements in the form, manner, and at the times specified by CMS.

[66 FR 952, Jan. 4, 2001]

§ 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 definition 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 (for example, a diagnostic imaging facility) is not a centralized building for purposes of this rule. This provision does not preclude a group practice from providing services to other providers (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 CPT and HCPCS codes posted on the CMS web site, <http://www.cms.gov>, (and in annual updates published in the FEDERAL REGISTER and posted on the CMS web site), except as specifically excluded on the CMS web site and in annual updates. All services identified on the CMS web site and in annual updates are clinical laboratory services for purposes of these regulations. Any service not specifically identified on the CMS web site, as amended from time to time and published in the FEDERAL REGISTER, is not a clinical laboratory service for purposes of these regulations.

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.

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(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 these regulations, the term “designated health services (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 (that is, all services provided as home health services or inpatient and outpatient hospital services are DHS).

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 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. For purposes of this definition, 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 is the person or entity to which CMS makes payment for

the DHS, directly or upon assignment on the patient’s behalf, except that if the person or entity has reassigned its right to payment to an employer pursuant to §424.80(b)(1) of this chapter; a facility pursuant to §424.80(b)(2) of this chapter; or a health care delivery system, including clinics, pursuant to §424.80(b)(3) of this chapter (other than a health care delivery system that is a health plan (as defined in §1000.952(1) 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), the person or entity furnishing DHS is the person or entity to which payment has been reassigned. Provided further, that 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 is the entity furnishing DHS for any services provided by such supplier.

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. With respect to the rentals and leases described in §411.357(a) and (b), “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 section, 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.

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 “rural primary care 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 and section 2050 of the Medicare Carriers Manual (CMS Pub. 14-3), Part 3—Claims Process. (Those wishing to subscribe to program manuals should contact either the Government Printing Office (GPO) or the National Technical Information Service (NTIS) at the following addresses: Superintendent of Documents,

Government Printing Office, ATTN: New Orders, P.O. Box 371954, Pittsburgh, PA 15250-7954, Telephone (202) 512-1800, Fax number (202) 512-2250 (for credit card orders); or National Technical Information Service, Department of Commerce, 5825 Port Royal Road, Springfield, VA 22161, Telephone (703) 487-4630. In addition, individual manual transmittals and Program Memoranda can be purchased from NTIS. Interested parties should identify the transmittal(s) they want. GPO or NTIS can give complete details on how to obtain the publications they sell. Additionally, all manuals are available at the following Internet address: <http://www.hcfa.gov/pubforms/progman.htm>.)

Inpatient hospital services means those services as defined in section 1861(b) of the Act and §409.10(a) and (b) of this chapter and includes inpatient psychiatric hospital services listed in section 1861(c) of the Act and inpatient rural primary care 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. These 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 a hospital provides for its patients that are furnished either by the hospital or by others under arrangements with the hospital. “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 Used to Describe Certain Designated Health Services Under the Physician Referral Provisions (Section 1877 of the Social Security Act) means the list of certain designated health services under section 1877 of the Act initially posted on the CMS web site and updated annually thereafter in an addendum to the physician fee schedule final rule and on the CMS web site.

Member of the group means, for purposes of this rule, 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. “*Locum tenens* physician” means a physician who substitutes (that is, “stands in the shoes”) in exigent circumstances for a regular physician who is a member of the group, 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.

Outpatient hospital services means the therapeutic, diagnostic, and partial hospitalization services listed under sections 1861(s)(2)(B) and (C) of the Act; outpatient services furnished by a psychiatric hospital, as defined in section 1861(f) of the Act; and outpatient rural primary care hospital services, as defined in section 1861(mm)(3) of the Act. Emergency services covered in non-participating hospitals are excluded under the conditions described in section 1835(b) of the Act and subpart G of part 424 of this chapter. “Outpatient hospital services” includes services that a hospital provides for its patients that are furnished either by the hospital or by others under arrangements with the hospital. “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 nutriment to a patient with permanent, severe pathology of the alimentary tract that does not allow absorption of sufficient nutrients to maintain strength commensurate with the patient’s general condition, as described in section 65–10 of the Medicare Coverage Issues Manual (CMS Pub. 6); 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).

Patient care services means any tasks 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 identified by the CPT and HCPCS codes on the CMS web site (and in annual updates published in the FEDERAL REGISTER). All services identified on the CMS web site and in annual updates are physical therapy, occupational therapy, and speech-language pathology services for purposes of these regulations. Any service not specifically identified on the CMS web site, as amended from time to time and published in the FEDERAL REGISTER, is not a physical therapy, occupational therapy, or speech-language pathology service for purposes of these regulations. The list of codes identifying physical therapy, occupational therapy, and speech-language pathology services for purposes of these regulations 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) to 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 fits 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). Referrals from an independent contractor who is a physician in the group 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 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.

Prosthetics, Orthotics, and Prosthetic Devices and Supplies means the following services (including all HCPCS level 2 codes for these 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 identified by the CPT and HCPCS codes on the CMS web site and in annual updates published in the FEDERAL REGISTER. All services identified on the CMS web site and in annual updates are *radiation therapy services and supplies* for purposes of these regulations. Any service not specifically identified on the CMS web site, as amended from time to time and published in the FEDERAL REGISTER, is not a *radiation therapy service or supply* for purposes of these regulations. The list

of codes for radiation therapy services and supplies identified on the CMS web site and in annual updates 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 identified by the CPT and HCPCS codes on the CMS web site and in annual updates published in the FEDERAL REGISTER (except as otherwise specifically excluded on the CMS web site and in annual updates). All services identified on the CMS web site and in annual updates are *radiology and certain other imaging services* for purposes of these regulations. Any service not specifically identified on the CMS web site, as amended from time to time and published in the FEDERAL REGISTER, is not a *radiology or certain other imaging service* for purposes of these regulations. The list of *radiology and certain other imaging services* set forth on the CMS web site and in annual updates 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 ultrasonic 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, and performed during, nonradiological medical procedures; and

(3) 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.

(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.

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 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 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 parking garages. For purposes of this rule, the "same building" does not include a mobile vehicle, van, or trailer.

[66 FR 952, Jan. 4, 2001]

§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 formed primarily for the purpose of