

the physician or a member of the physician's immediate family has a financial relationship.

(b) This subpart does not provide for exceptions or immunity from civil or criminal prosecution or other sanctions applicable under any State laws or under Federal law other than section 1877 of the Act. For example, although a particular arrangement involving a physician's financial relationship with an entity may not prohibit the physician from making referrals to the entity under this subpart, the arrangement may nevertheless violate another provision of the Act or other laws administered by HHS, the Federal Trade Commission, the Securities and Exchange Commission, the Internal Revenue Service, or any other Federal or State agency.

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

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

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

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

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

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

[85 FR 77656, Dec. 2, 2020]

§ 411.351 Definitions.

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

Centralized building means all or part of a building, including, for purposes of this subpart only, a mobile vehicle, van, or trailer that is owned or leased on a full-time basis (that is, 24 hours per day, 7 days per week, for a term of not less than 6 months) by a group practice and that is used exclusively by the group practice. Space in a building

or a mobile vehicle, van, or trailer that is shared by more than one group practice, by a group practice and one or more solo practitioners, or by a group practice and another provider or supplier (for example, a diagnostic imaging facility) is not a centralized building for purposes of this subpart. This provision does not preclude a group practice from providing services to other providers or suppliers (for example, purchased diagnostic tests) in the group practice's centralized building. A group practice may have more than one centralized building.

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

Commercially reasonable means that the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.

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

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

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

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

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

Cybersecurity means the process of protecting information by preventing, detecting, and responding to cyberattacks.

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

- (1)(i) Clinical laboratory services.
- (ii) Physical therapy, occupational therapy, and outpatient speech-language pathology services.
- (iii) Radiology and certain other imaging services.
- (iv) Radiation therapy services and supplies.
- (v) Durable medical equipment and supplies.
- (vi) Parenteral and enteral nutrients, equipment, and supplies.
- (vii) Prosthetics, orthotics, and prosthetic devices and supplies.
- (viii) Home health services.
- (ix) Outpatient prescription drugs.
- (x) Inpatient and outpatient hospital services.

(2) Except as otherwise noted in this subpart, the term "designated health services" or DHS means only DHS payable, in whole or in part, by Medicare. DHS do not include services that are paid by Medicare as part of a composite rate (for example, SNF Part A payments or ASC services identified at §416.164(a)), except to the extent that services listed in paragraphs (1)(i) through (1)(x) of this definition are themselves payable under a composite rate (for example, all services provided

as home health services or inpatient and outpatient hospital services are DHS). For services furnished to inpatients by a hospital, a service is not a designated health service payable, in whole or in part, by Medicare if the furnishing of the service does not increase the amount of Medicare's payment to the hospital under any of the following prospective payment systems (PPS):

- (i) Acute Care Hospital Inpatient (IPPS);
- (ii) Inpatient Rehabilitation Facility (IRF PPS);
- (iii) Inpatient Psychiatric Facility (IPF PPS); or
- (iv) Long-Term Care Hospital (LTCH PPS).

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

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

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

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

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

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

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

Downstream contractor means a "first tier contractor" as defined at §1001.952(t)(2)(iii) of this title or a

“downstream contractor” as defined at § 1001.952(t)(2)(i) of this title.

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

Electronic health record means a repository of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinical conditions.

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

Entity means—

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

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

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

(2) A health plan, MCO, PSO, or IPA that employs a supplier or operates a facility that could accept reassignment from a supplier under § 424.80(b)(1) and

(b)(2) of this chapter, with respect to any DHS provided by that supplier.

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

Fair market value means—

(1) *General*. The value in an arm’s-length transaction, consistent with the general market value of the subject transaction.

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

(3) *Rental of office space*. With respect to the rental of office space, the value in an arm’s-length transaction of rental property for general commercial purposes (not taking into account its intended use), without adjustment to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee, and consistent with the general market value of the subject transaction.

General market value means—

(1) *Assets*. With respect to the purchase of an asset, the price that an asset would bring on the date of acquisition of the asset as the result of *bona fide* bargaining between a well-informed buyer and seller that are not otherwise in a position to generate business for each other.

(2) *Compensation*. With respect to compensation for services, the compensation that would be paid at the time the parties enter into the service arrangement as the result of *bona fide* bargaining between well-informed parties that are not otherwise in a position to generate business for each other.

(3) *Rental of equipment or office space.* With respect to the rental of equipment or the rental of office space, the price that rental property would bring at the time the parties enter into the rental arrangement as the result of *bona fide* bargaining between a well-informed lessor and lessee that are not otherwise in a position to generate business for each other.

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

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

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

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

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

Inpatient hospital services means those services defined in section 1861(b) of the Act and §409.10(a) and (b) of this chapter and include inpatient psychiatric hospital services listed in section 1861(c) of the Act and inpatient

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

Interoperable means—

(1) Able to securely exchange data with and use data from other health information technology; and

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

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

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

(ii) The payments are immediately negotiable, guaranteed by a third

party, secured by a negotiable promissory note, or subject to a similar mechanism to ensure payment even in the event of default by the purchaser or obligated party.

(2) An isolated financial transaction includes a one-time sale of property or a practice, single instance of forgiveness of an amount owed in settlement of a *bona fide* dispute, or similar one-time transaction, but does not include a single payment for multiple or repeated services (such as payment for services previously provided but not yet compensated).

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

List of CPT/HCPCS Codes means the list of CPT and HCPCS codes that identifies those items and services that are DHS under section 1877 of the Act or that may qualify for certain exceptions under section 1877 of the Act. It is updated annually and posted on the CMS website at <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/ListofCodes>.

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

Member of the group or member of a group practice means, for purposes of this subpart, a direct or indirect physician owner of a group practice (including a physician whose interest is held by his or her individual professional

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

Outpatient hospital services means the therapeutic, diagnostic, and partial hospitalization services listed under sections 1861(s)(2)(B) and (s)(2)(C) of the Act; outpatient services furnished by a psychiatric hospital, as defined in section 1861(f) of the Act; and outpatient critical access hospital services, as defined in section 1861(mm)(3) of the Act. “Outpatient hospital services” do not include emergency services furnished by nonparticipating hospitals and covered under the conditions described in section 1835(b) of the Act and subpart G of part 424 of this chapter. “Outpatient hospital services” include services that are furnished either by the hospital directly or under arrangements made by the hospital with others. “Outpatient hospital services” do not include professional services performed by physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, certified registered nurse anesthetists, and qualified psychologists if Medicare reimburses the services independently and not as part of the outpatient hospital service (even if they are billed by a hospital under an assignment or reassignment).

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

Parenteral and enteral nutrients, equipment, and supplies means the following

services (including all HCPCS level 2 codes for these services):

(1) *Parenteral nutrients, equipment, and supplies*, meaning those items and supplies needed to provide nutriment to a patient with permanent, severe pathology of the alimentary tract that does not allow absorption of sufficient nutrients to maintain strength commensurate with the patient's general condition, as described in Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Section 180.2, as amended or replaced from time to time; and

(2) *Enteral nutrients, equipment, and supplies*, meaning items and supplies needed to provide enteral nutrition to a patient with a functioning gastrointestinal tract who, due to pathology to or nonfunction of the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with his or her general condition, as described in Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Section 180.2.

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

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

patient speech-language pathology service for purposes of this subpart. The list of codes identifying physical therapy, occupational therapy, and outpatient speech-language pathology services for purposes of this regulation includes the following:

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

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

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

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

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

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

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

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

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

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

Physician has the meaning set forth in section 1861(r) of the Act. A physician and the professional corporation

of which he or she is a sole owner are the same for purposes of this subpart.

Physician in the group practice means a member of the group practice, as well as an independent contractor physician during the time the independent contractor is furnishing patient care services (as defined in this section) for the group practice under a contractual arrangement directly with the group practice to provide services to the group practice's patients in the group practice's facilities. The contract must contain the same restrictions on compensation that apply to members of the group practice under §411.352(g) (or the contract must satisfy the requirements of the personal service arrangements exception in §411.357(d)), and the independent contractor's arrangement with the group practice must comply with the reassignment rules in §424.80(b)(2) of this chapter (see also Pub. L. 100–04, Medicare Claims Processing Manual, Chapter 1, Section 30.2.7, as amended or replaced from time to time). Referrals from an independent contractor who is a physician in the group practice are subject to the prohibition on referrals in §411.353(a), and the group practice is subject to the limitation on billing for those referrals in §411.353(b).

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

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

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

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

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

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

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

(3) *Prosthetic devices*, meaning devices (other than a dental device) listed in section 1861(s)(8) of the Act that replace all or part of an internal body organ, including colostomy bags, and one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens.

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

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

Radiology and certain other imaging services means those particular services so identified on the List of CPT/HCPCS Codes. All services identified on the List of CPT/HCPCS Codes are radiology and certain other imaging services for purposes of this subpart. Any service not specifically identified as radiology and certain other imaging services on the List of CPT/HCPCS Codes is not a radiology or certain other imaging service for purposes of this subpart. The list of codes identifying radiology and certain other imaging services includes the professional and technical components of any diagnostic test or procedure using x-rays, ultrasound, computerized axial tomography, magnetic resonance imaging, nuclear medicine (effective January 1, 2007), or

other imaging services. All codes identified as radiology and certain other imaging services are covered under section 1861(s)(3) of the Act and §§410.32 and 410.34 of this chapter, but do not include—

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

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

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

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

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

Referral—

(1) Means either of the following:

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

(ii) Except as provided in paragraph (2) of this definition, a request by a physician that includes the provision of any designated health service for which payment may be made under Medicare, the establishment of a plan of care by a physician that includes the

provision of such a designated health service, or the certifying or recertifying of the need for such a designated health service, but not including any designated health service personally performed or provided by the referring physician. A designated health service is not personally performed or provided by the referring physician if it is performed or provided by any other person including, but not limited to, the referring physician’s employees, independent contractors, or group practice members.

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

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

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

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

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

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

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

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

(2) The furnishing of items, devices, or supplies that are, in fact, used solely for one or more of the following purposes:

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

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

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

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

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

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

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

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

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

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

Rural area means an area that is not an urban area as defined at § 412.64(b) of this chapter.

Rural emergency hospital has the meaning set forth in section 1861(kkk)(2) of the Act and § 419.91 of this chapter.

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

Specialty hospital means:

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

(i) Patients with a cardiac condition;

(ii) Patients with an orthopedic condition;

(iii) Patients receiving a surgical procedure; or

(iv) 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.

(2) A “specialty hospital” does not include any hospital—

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

(ii) 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;

(iii) 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;

(iv) 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

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

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

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

(2) Further the value-based enterprise’s value-based purpose(s).

Transaction means an instance of two or more persons or entities doing business.

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

- (1) The provision of an item or service;
- (2) The taking of an action; or
- (3) The refraining from taking an action.

Value-based arrangement means an arrangement for the provision of at least one value-based activity for a target patient population to which the only parties are—

- (1) The value-based enterprise and one or more of its VBE participants; or
- (2) VBE participants in the same value-based enterprise.

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

- (1) Collaborating to achieve at least one value-based purpose;
- (2) Each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise;
- (3) That have an accountable body or person responsible for the financial and operational oversight of the value-based enterprise; and
- (4) That have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s).

Value-based purpose means any of the following:

- (1) Coordinating and managing the care of a target patient population;
- (2) Improving the quality of care for a target patient population;
- (3) Appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a target patient population; or
- (4) Transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

VBE participant means a person or entity that engages in at least one value-

based activity as part of a value-based enterprise.

[85 FR 77656, Dec. 2, 2020, as amended at 86 FR 65667, Nov. 19, 2021; 87 FR 72285, Nov. 23, 2022]

§411.352 Group practice.

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

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

- (1) The States in which the group practice is operating are contiguous (although each State need not be contiguous to every other State);
- (2) The legal entities are absolutely identical as to ownership, governance, and operation; and