

## 42 C.F.R. § 411.351

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### Definitions.

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

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

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

*Commercially reasonable* means that the particular arrangement furthers a legitimate business purpose of the parties 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
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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—

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