is spent in a group practice, clinic, or office setting.

(3) The practice expenses and income are distributed in accordance with methods previously determined. In the case of faculty practice plans associated with a hospital, institution of higher education, or medical school that has an approved medical residency training program in which faculty practice plan physicians perform specialty and professional services, both within and outside the faculty practice, as well as perform other tasks such as research, this definition applies only to those services that are furnished within the faculty practice plan.

Hospital means any separate legally organized operating entity plus any subsidiary, related, or other entities that perform services for the hospital's patients and for which the hospital bills. A "hospital" does not include entities that perform services for hospital patients "under arrangements" with the hospital.

HPSA means, for purposes of this regulation, 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 42 CFR part 5, appendix A, part I—Geographic Areas). In addition, with respect to dental, mental health, vision care, podiatric, and pharmacy services, an HPSA means an area designated as a health professional shortage area under section 332(a)(1)(A) of the Public Health Service Act for dental professionals, mental health professionals, vision care professionals, podiatric professionals, and pharmacy professionals, respectively.

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

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.

Members of the group means physician partners and full-time and part-time physician contractors and employees during the time they furnish services to patients of the group practice that are furnished through the group and are billed in the name of the group.

Patient care services means any tasks performed by a group practice member that address the medical needs of specific patients, regardless of whether they involve direct patient encounters. They can include, for example, the services of physicians who do not directly treat patients, time spent by a physician consulting with other physicians, or time spent reviewing laboratory tests.

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 items or services.

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, any item or 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.

(ii) Except as provided in paragraph
(2) of this definition, a request by a physician that includes the provision of laboratory services or the establishment of a plan of care by a physician that includes the provision of laboratory services.

(2) Does not include a request by a pathologist for clinical diagnostic laboratory tests and pathological examination services if—

(i) The request is part of a consultation initiated by another physician; and

(ii) The tests or services are furnished by or under the supervision of the pathologist.

Referring physician means a physician (or group practice) who makes a referral as defined in this section.

Remuneration means any payment, discount, forgiveness of debt, or other benefit made directly or indirectly, overtly or covertly, in cash or in kind, except that the following are not considered remuneration:

(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 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-forservice 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.

Transaction means an instance or process of two or more persons doing business. An *isolated transaction* is one involving a single payment between two or more persons. A transaction that involves long-term or installment payments is not considered an isolated transaction.

§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 financial relationship with an entity, or who has an immediate family member who has a financial relationship with the entity, may not make a referral to that entity for the furnishing of clinical laboratory services for which payment otherwise may be made under Medicare.

(b) *Limitations on billing.* An entity that furnishes clinical laboratory services under 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