List of Subjects in 42 CFR Part 411

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

42 CFR part 411 is amended as set forth below:

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

1. The authority citation for part 411 is revised to read as follows:

Authority: Secs. 1102, 1834, 1842(l), 1861, 1862, 1871, 1877, and 1879 of the Social Security Act (42 U.S.C. 1302, 1395m, 1395u(l), 1395x, 1395y, 1395hh, 1395nn, and 1395pp).

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

§ 411.1 Basis and scope.

- (a) Statutory basis. 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 Federal providers or agencies (sections 1814(c) and 1835(d)), by hospitals and physicians outside the United States (sections 1814(f) and 1862(a)(4)), and by hospitals and SNFs of the Indian Health Service (section 1880). Section 1877 sets forth limitations on referrals and payment for clinical laboratory services furnished by entities with which the referring physician (or an immediate family member of the referring physician) has a financial relationship.
- 3. Section 411.350 is revised to read as follows:

§ 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 clinical laboratory 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 items or services under Part A or Part B report information concerning their ownership, investment, or compensation arrangements in the form, manner, and at the times specified by

4. New §§ 411.351, 411.353, 411.355 through 411.357, and 411.360 are added to read as follows:

§ 411.351 Definitions.

As used in this subpart, unless the context indicates otherwise:

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. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body.

Compensation arrangement means any arrangement involving any remuneration, direct or indirect, between a physician (or a member of a physician's immediate family) and an entity.

Direct supervision means supervision by a physician who is present in the office suite and immediately available to provide assistance and direction throughout the time services are being performed.

Employee means any individual who, under the usual 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 at 20 CFR 404.1007 and 26 CFR 31.3121(d)–1(c).)

Entity means a sole proprietorship, trust, corporation, partnership, foundation, not-for-profit corporation, or unincorporated association.

Fair market value means the value in arm's-length transactions, consistent with the general market value. With respect to rentals or leases, 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.

Financial relationship refers to a direct or indirect relationship between a physician (or a member of a physician's immediate family) and an entity in which the physician or family member has—

- (1) An ownership or investment interest that exists in the entity through equity, debt, or other means and includes an interest in an entity that holds an ownership or investment interest in any entity providing laboratory services; or
- (2) A compensation arrangement with the entity.

Group practice means a group of two or more physicians, legally organized as a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association, that meets the following conditions:

- (1) Each physician who is a *member* of the group, as defined in this section, furnishes 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.
- (2) Except as provided in paragraphs (2)(i) and (2)(ii) of this definition, 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) are furnished through the group and billed in the name of the group and the amounts received are treated as receipts of the group. "Patient care services" are measured by the total patient care time each member spends on these services. For example, if a physician practices 40 hours a week and spends 30 hours on patient care services for a group practice, the physician has spent 75 percent of his or her time providing countable patient care services.
- (i) The "substantially all" test does not apply to any group practice that is located solely in an HPSA, as defined in this section, and
- (ii) For group practices located outside of an HPSA (as defined in this section) any time spent by group practice members providing services in an HPSA should not be used to calculate whether the group practice located outside the HPSA has met the "substantially all" test, regardless of whether the members' time in the HPSA