we proposed to adopt some of the statutory definitions, as well as some other provisions of section 1877, virtually unchanged from what the statute provided. To establish these rules in our regulations, we proposed to create a new subpart J under 42 CFR part 411 and to make conforming changes as discussed below.

1. Scope

We proposed to cite section 1877 as the statutory authority for the rule.

2. Definitions

In section 411.351, we proposed to establish definitions of certain terms based on definitions or descriptions given in section 1877: compensation arrangement, employee, fair market value, financial relationship, group practice, interested investor, investor, referral, and remuneration. In addition, we proposed to add other definitions: entity, immediate family member or a member of a physician's immediate family, practice, and referring physician.

For purposes of identifying financial relationships that may trigger the statutory prohibition on referrals under Medicare, we proposed to adopt the description of ownership and investment interests and compensation arrangements contained in sections 1877(a)(2) and (h)(1). We also proposed to include indirect financial relationships in the statutory prohibition on referrals under Medicare.

3. General Prohibition on Referrals

In section 411.353(a), we proposed that, unless permitted under an exception, a physician who has a financial relationship with an entity (or who has an immediate family member who has a financial relationship with an entity) may not make a referral to that entity for the furnishing of clinical laboratory services covered under Medicare beginning January 1, 1992. (Note that we are providing a 30-day delay of the effective date for the provisions of this final rule with comment. However, this does not delay the effective date for any of the provisions in the final rule that only reiterate the language in section 1877 of the Social Security Act. These provisions are effective according to their statutory effective dates. The effective date for this final rule with comment is, in essence, the effective date for those parts of the rule that interpret the statute.)

To inform the public of what entities we would consider entities that perform clinical laboratory services and, therefore, subject to the provisions of section 1877 and to the regulation, we referenced existing section 493.2, which defines a "laboratory."

We proposed, in section 411.353(b), that an entity that furnishes clinical laboratory services under a prohibited referral may not bill the Medicare program or any individual, third party payer, or other entity.

In section 411.353(c), we provided that we would not pay for a clinical laboratory service that is furnished under a prohibited referral, and we proposed, in section 411.353(d), to require an entity that collects payment for a laboratory service performed under a prohibited referral to refund all collected amounts on a timely basis.

4. Exceptions That Apply to Specific Services

In accordance with section 1877(b), we proposed, in section 411.355, that the prohibition on clinical laboratory referrals would not apply in the following circumstances:

• If a physician service is provided personally by (or under the direct personal supervision of) another physician in the same group practice as the referring physician.

• If an in-office ancillary service is performed personally by the referring physician, a physician who is a member of the same group practice as the referring physician, or a nonphysician employee of the referring physician or group practice who is personally supervised by the referring or group practice physician and—

+ The in-office ancillary service is performed either in a building where the referring physician (or another physician who is a member of the same group practice) furnishes physicians' services unrelated to the furnishing of clinical laboratory services; or in a building that is used by the group practice for centrally furnishing the group's clinical laboratory services; and

+ The in-office ancillary service is billed by the physician who performed or supervised the laboratory service; by the group practice in which the physician is a member; or by an entity that is wholly owned by the physician or physician's group practice.

• If the services are furnished to prepaid health plan enrollees by one of the following organizations: (1) A health maintenance organization or a competitive medical plan in accordance with a contract with us under section 1876; (2) a health care prepayment plan in accordance with an agreement with us to furnish the services to Medicare beneficiaries under section 1833(a)(1)(A); or (3) an organization that is receiving payments on a prepaid basis for the enrollees under a demonstration project under section 402(a) of the Social Security Amendments of 1967 (42 U.S.C. 1395b–1) or under section 222(a) of the Social Security Amendments of 1972 (42 U.S.C. 1395b– 1 note).

We also proposed, in section 411.355(a), to use an existing definition of "physicians' services" but cited an incorrect cross reference to that definition. The cross-reference should have been to section 410.20 rather than section 411.20(a). Existing section 410.20 describes physicians' services and specifies the professionals who are considered to be "physicians" if they are authorized under State law to practice and if they act within the scope of their licenses.

5. Exceptions for Certain Ownership or Investment Interests

a. Publicly Traded Securities

We proposed, in section 411.357(a), that the prohibition on referrals would not apply to a physician's referrals if the financial relationship between the physician (or the physician's immediate family member) and the entity results from the ownership of certain investment securities. We proposed that the securities must be purchased by the physician (or immediate family member) on terms generally available to the public and be in a corporation that meets specific criteria.

b. Specific Providers

In section 411.357(b)(1), we proposed that the prohibition on referrals would not apply to a laboratory that is located in a rural area if certain criteria are met.

To supplement the statutory provision excepting services furnished in a rural laboratory, we proposed two requirements intended to address the possibility that this exception would be misused. First, we proposed to require, when physician owners or investors make referrals to a laboratory located in a rural area, that the tests be performed directly by the laboratory on its premises. We stated that, if referral to another laboratory is necessary, the test must be billed by the laboratory that performs the test. Second, we proposed to require that the majority of the tests referred to the rural laboratory be referred by physicians who have office practices in a rural area. (For this purpose, as indicated earlier, we proposed a definition of "practice.")

We proposed, in section 411.357(b)(2) and (b)(3), that the prohibition on referrals would not apply if the ownership or investment interest is in—

A hospital located in Puerto Rico; or