preamble and the regulations established as a result of the publication of this final rule with comment period are in the context of referrals for clinical laboratory services and address only those provisions of section 1877 that are effective as of January 1, 1992.

Even though we will cover the designated health services under a separate proposed rule, this final rule with comment will affect how we review referrals involving any of the designated health services. The statute groups clinical laboratory services together with all other designated health services beginning on January 1, 1995. Generally, the prohibition in the statute and the exceptions are drafted so that they apply equally to situations involving referrals for any of the designated health services, including referrals for clinical laboratory services. As a result, we believe that a majority of our interpretations in this final rule with comment will apply to the other designated health services.

Until we publish a rule covering the designated health services, we intend to rely on our language and interpretations in this final rule when reviewing referrals for the designated health services in appropriate cases. We believe appropriate cases are those in which our interpretations of the statute clearly apply equally to referrals for clinical laboratory services and other designated health services. For example, we have defined the term "immediate family member" for purposes of this final rule with comment. We will be guided by this definition when we review referrals for the designated health services.

The following discussion covers the basic prohibition in section 1877 and fundamental concepts and definitions, while it highlights the changes to section 1877 made by OBRA '93, as amended by SSA '94, that relate to clinical laboratory services and that became effective on January 1, 1992.

## 1. General Prohibition

The prohibition of certain referrals is contained at section 1877(a)(1) of the Act. The provisions of that section remained unchanged by OBRA '93 until January 1, 1995. With certain exceptions, section 1877(a)(1)(A)prohibits a physician from making a referral to an entity for the furnishing of clinical laboratory services, for which Medicare would otherwise pay, if the physician (or a member of the physician's immediate family) has a financial relationship with that entity. ("Financial relationship," as described by the Act, is discussed under I.D.4, below.) Further, section 1877(a)(1)(B)

prohibits an entity from presenting or causing to be presented a Medicare claim or bill to any individual, third party payor, or other entity for clinical laboratory services furnished under a prohibited referral.

## 2. Definition of Referral

The definition of "referral," as it relates to clinical laboratory services, was not changed by OBRA '93. Section 1877(h)(5) specifies that the following requests constitute a referral:

• For physicians' services, the request by a physician for an item or service for which payment may be made under Medicare Part B, including the request by a physician 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).

• For other items, the request or establishment of a plan of care by a physician that includes the furnishing of clinical laboratory services.

Under section 1877(h)(5)(C), however, a referral does not include a request by a pathologist for clinical diagnostic laboratory tests and pathological examination services if the services are furnished by (or under the supervision of) the pathologist as a result of a consultation requested by another physician.

3. Definitions of Compensation Arrangement and Remuneration

The predecessor provision of section 1877(h)(1) (that is, section 1877(h)(1) as it read before the enactment of OBRA '93) defines a "compensation arrangement" as any arrangement involving any remuneration between a physician (or an immediate family member) and an entity. It defines "remuneration" to include any remuneration, directly or indirectly, overtly or covertly, in cash or in kind. OBRA '93 amends section 1877(h)(1) by adding paragraph (h)(1)(C) to enumerate certain exceptions to the above definition of compensation arrangement. Paragraph (h)(1)(C) specifies that a compensation arrangement does not include the following types of remuneration:

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

• The provision of items, devices, or supplies that are used solely to—

+ Collect, transport, process, or store specimens for the entity providing the item, device, or supply; or

+ Order or communicate the results of tests or procedures for the entity.

• 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—

+ 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;

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

+ 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; and

+ The payment meets other requirements the Secretary may impose by regulation as needed to protect against Medicare program or patient abuse.

## 4. Financial Relationships

Under OBRA '93, section 1877(a)(2) continues to describe a financial relationship between a physician (or an immediate family member of a physician) and an entity as being an ownership or investment interest in the entity or a compensation arrangement between a physician (or immediate family member) and the entity. The statute also continues to provide that an ownership or investment interest may be established through equity, debt, or other means. (Note that effective for referrals made on or after January 1, 1995, OBRA '93 provides that an ownership or investment interest also includes an interest in an entity that holds an ownership or investment interest in any entity furnishing the clinical laboratory service or other designated health services.)

5. General Exceptions to the Prohibition on Physician Referrals

Section 1877(b) provides for general exceptions to the prohibition on referrals. (General exceptions are exceptions that apply to both ownership/investment and compensation.) Because these exceptions frequently refer to a "group practice," we begin our discussion of the exceptions by describing "group practice" as defined by the statute at section 1877(h)(4).

Until January 1, 1995, OBRA '93 continued to define "group practice" as a group of two or more physicians legally organized as a partnership,