

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 411

[BPD-674-FC]

RIN: 0938-AF40

Medicare Program; Physician Financial Relationships With, and Referrals to, Health Care Entities That Furnish Clinical Laboratory Services and Financial Relationship Reporting Requirements

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period provides that, if a physician or a member of a physician's immediate family has a financial relationship with an entity, the physician may not make referrals to the entity for the furnishing of clinical laboratory services under the Medicare program, except under specified circumstances. It contains revisions to our proposal of March 11, 1992, based on comments submitted by the public. Further, it incorporates the new expansions and exceptions created by the Omnibus Budget Reconciliation Act of 1993 and the amendments in the Social Security Act Amendments of 1994 (SSA '94), that are related to referrals for clinical laboratory services and have a retroactive effective date of January 1, 1992.

In addition, we are responding to comments received on the interim final rule with comment period (published on December 3, 1991) that set forth Medicare reporting requirements for the submission by certain health care entities of information about their relationships with physicians. That document implemented the reporting requirements of section 1877(f) of the Social Security Act. This rule revises those requirements to incorporate the amendments to section 1877(f) made by SSA '94, to apply to any further reporting we may require.

EFFECTIVE DATES: The regulations are effective September 13, 1995.

Comment Date: Comments on the new provisions added by the Omnibus Budget Reconciliation Act of 1993 and any changes in section 1877 that resulted from the Social Security Act Amendments of 1994 will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on October 13, 1995.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following

address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPD-674-FC, P.O. Box 26688, Baltimore, MD 21207.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses: Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C-5-09-26, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code BPD-674-FC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309-G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690-7890).

For comments that relate to information collection requirements, mail a copy of the comments to: Allison Herron Eydt, HCFA Desk Officer, Office of Information and Regulatory Affairs, Room 3001, New Executive Office Building, Washington, DC 20503.

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FOR FURTHER INFORMATION CONTACT: Betty Burrier, (410) 786-0191.

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I. Legislation and Regulations—Chronological Background

In section 6204 of the Omnibus Budget Reconciliation Act of 1989 (OBRA '89) (Public Law 101-239, enacted on December 19, 1989), the Congress added a provision to the Social Security Act (the Act) that governs whether physicians who have financial relationships (or who have immediate family members with financial relationships) with a health care entity can refer Medicare patients to that entity for clinical laboratory services. This provision was amended by section 4207(e) of the Omnibus Budget

Reconciliation Act of 1990 (OBRA '90) (Public Law 101-508, enacted on November 5, 1990); section 13562 of the Omnibus Budget Reconciliation Act of 1993 (OBRA '93) (Public Law 103-66, enacted on August 10, 1993); and section 152 of the Social Security Act Amendments of 1994 (SSA '94) (Public Law 103-432, enacted on October 31, 1994). As discussed below, we published an interim final rule in 1991 concerning financial relationship reporting requirements, and we published a proposed rule in 1992 concerning physician referrals to clinical laboratories.

A. OBRA '89

Section 6204 of OBRA '89 added section 1877, "Limitation on Certain Physician Referrals," to the Act. (Unless otherwise indicated, all references below to various sections of the law are references to the Act.) In general, section 1877 as added by OBRA '89 prohibits a physician with a financial relationship with an entity that furnishes clinical laboratory services (or a physician with an immediate family member who has such a relationship) from making a referral to that entity for clinical laboratory services for which Medicare would pay. It also prohibits the entity from billing Medicare, an individual, a third-party payor, or other entity for an item or service furnished as a result of a prohibited referral. Additionally, it requires a refund of any amount collected from an individual as the result of a billing for an item or service furnished under a prohibited referral. The statute provides for certain exceptions to the prohibition.

B. OBRA '90

Section 4207(e) of OBRA '90 amended certain provisions of section 1877 to clarify definitions and reporting requirements relating to physician ownership and referral and to provide an additional exception to the prohibition.

C. Federal Register Documents

On December 3, 1991, we published an interim final rule in the **Federal Register**, at 56 FR 61374, that set forth reporting requirements under the Medicare program for health care entities furnishing clinical laboratory services (and certain other services as discussed below) to submit information about their relationships with physicians. On March 11, 1992, we published a proposed rule in the **Federal Register**, at 57 FR 8588, that proposed regulations concerning the provisions of section 1877, as amended by OBRA '90, concerning physician

referrals to clinical laboratories. Although we summarize the provisions of the interim final rule and proposed rule in section II of this document, readers may want to refer to the interim final rule and proposed rule for additional information on the statutory provisions as amended by OBRA '90 and for the specifics of our proposals.

D. OBRA '93 and SSA '94

Section 13562 of OBRA '93 included extensive revisions to section 1877. Some of the revisions simply elaborate on or amend existing law, while others institute entirely new provisions. With regard to referrals for clinical laboratory services, some of the provisions of OBRA '93 have a prospective effective date of January 1, 1995, while others have a retrospective effective date of January 1, 1992. Most dramatically, section 13562 extends section 1877 to cover 10 additional designated health services, beginning with referrals made after December 31, 1994.

In addition, section 13624 added paragraph (r) to section 1903. This section extends certain provisions of section 1877 to the Medicaid program effective on or after December 31, 1994. That is, this section prohibits Medicaid payments to a State for designated health services furnished on the basis of a referral that would result in the denial of payment under Medicare if Medicare provided for coverage of the service to the same extent and under the same terms and conditions as under the State plan. This section also provides that the reporting requirements under 1877(f) and the civil money penalty provisions for failure to report information under section 1877(g)(5) apply to entities that furnish services covered under the Medicaid program in the same manner as they apply to entities that furnish Medicare covered services.

SSA '94 amended the reporting requirements that entities providing Medicare (and now Medicaid) items and services have to meet for purposes of the referral prohibition, changed some of the designated health services, and altered the effective date provisions in OBRA '93. The changes in the effective date provisions have altered the dates on which some of the provisions relating to referrals for clinical laboratory services go into effect prior to January 1, 1995. These changes have been reflected in this final rule.

A separate notice of proposed rulemaking will be published to address those provisions of OBRA '93 that relate to designated health services (including clinical laboratory services) and that become effective January 1, 1995. In other words, the discussion in this

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-for-service 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,

professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association, that meets the following conditions:

- Each physician member of the group furnishes substantially the full range of services that the physician routinely furnishes, including medical care, consultation, diagnosis, or treatment, through the joint use of shared office space, facilities, equipment, and personnel.
- Substantially all of the services of the physician members of the group are furnished through the group, are billed in the name of the group, and amounts so received are treated as receipts of the group.
- The overhead expenses of and the income from the practice are distributed in accordance with methods previously determined. (OBRA '93 eliminates the requirement that the methods be previously determined by members of the group.)
- The group practice complies with all other standards established by the Secretary in regulations.

In addition, OBRA '93 amended section 1877(h)(4). The predecessor provision of section 1877(h)(4) provided that, in the case of a faculty practice plan associated with a hospital with an approved medical residency training program in which physician members may furnish a variety of different specialty services and furnish professional services both within and outside the group, as well as perform other tasks such as research, the conditions contained in the definition of "group practice" apply only with respect to the services furnished within the faculty practice plan. OBRA '93 added, as an addition to a faculty practice plan associated with a hospital, a faculty practice plan associated with an institution of higher education or a medical school.

(Note that OBRA '93 makes other changes to the definition of group practice that will become effective January 1, 1995.)

a. Exception—Physicians' Services

Section 1877(b)(1) continues to specify that the prohibition does not apply to services furnished on a referral basis if the services are physicians' services, as defined in section 1861(q), furnished personally by (or under the personal supervision of) another physician in the same group practice (as defined in section 1877(h)(4)) as the referring physician.

b. Exception—In-Office Ancillary Services

Section 1877(b)(2) continues to specify that the prohibition does not

apply to referrals for certain in-office ancillary services. Both the predecessor provisions and current provisions of section 1877(b)(2) contain requirements that must be met in order for the exception to apply. These requirements concern who may furnish the services, where the services are furnished, and how the services must be billed.

Who May Furnish the Services

Under the predecessor provisions of section 1877(b)(2)(A)(i), the services had to be personally furnished by the referring physician, a physician who was a member of the same group as the referring physician, or individuals employed by the physician or group practice and who were personally supervised by the physician or by another physician in the group practice. OBRA '93 amends this provision to require that the individual performing the service be *directly* supervised by the physician or by another physician in the group practice and dropped the employment requirement.

Where the Services May Be Furnished

The predecessor provision of section 1877(b)(2)(A)(ii) required that the services be furnished in either of the following:

- A building in which 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.
- In the case of a referring physician who is a member of a group practice, in another building that is used by the group practice for the centralized provision of the group's clinical laboratory services.

OBRA '93 amended this provision to require, in the group practice situation, that the building be used for the provision of some or all of the group's clinical laboratory services. That is, this provision no longer requires that the provision of laboratory services be centralized at that site.

The statute contains an undesignated paragraph at the end of the group practice location requirements that reads as follows: "unless the Secretary determines other terms and conditions under which the provision of such services does not present a risk of program or patient abuse, * * *"

We believe that, because of the way the paragraph is indented, how it applies to the in-office ancillary services exception is ambiguous. It could apply to all of paragraph (b)(2)(A)(ii) or apply to only paragraph (b)(2)(A)(ii)(II). If it applies to all of paragraph (b)(2)(A)(ii), it would affect both solo and group

practitioners. If it applies to only paragraph (b)(2)(A)(ii)(II), it would affect only group practices.

The Conference Report that accompanied OBRA '93 (H. Rep. No. 213, 103rd Cong., 1st Sess. 810 (1993)) points out that the conference agreement includes an exception for clinical laboratory services provided by a group practice that has multiple office locations. The Report also says that the conferees expect that the Secretary will publish regulations specifying other terms and conditions under which group practices may qualify for a group practice exception to the general prohibition. Arguably, the Congress had only group practices in mind in drafting the provision at issue. Therefore, we believe that the undesignated paragraph applies to only paragraph (b)(2)(A)(ii)(II), which concerns the site requirements as they relate to a group practice.

In addition, this paragraph could be read to mean that the Secretary is allowed to *liberalize* the circumstances in paragraph (b)(2)(A)(ii)(II) (the building/location requirements) if she determines that there are other, additional "terms and conditions" under which an entity can provide services without presenting a risk of program or patient abuse. In this case, the interpretation would not appear redundant with the undesignated paragraph that follows at the end of section 1877(b)(2)(B), which authorizes the Secretary to impose additional "requirements" for application of the in-office exception.

We could also interpret "other terms and conditions" as including any different terms or conditions, whether they are more restrictive or more liberal, that the Secretary may add to the list in paragraph (b)(2)(A)(ii) or in (b)(2)(A)(ii)(II). However, more restrictive conditions could make the two undesignated paragraphs redundant.

Alternatively, the paragraph following section 1877(b)(2)(A)(ii)(II)(bb) could be read to mean that the circumstances in (b)(2)(A)(ii) must be met for the exception to apply unless the Secretary determines *other* terms and conditions under which there will be no patient or program abuse, and which should be substituted for the list of conditions in (b)(2)(A)(ii). We do not believe that this reading would conflict with the paragraph that follows section 1877(b)(2)(B), because the Secretary could then still add more requirements to the list of those in paragraph (b)(2)(A)(ii) (with (b)(2)(A)(ii) now consisting of the Secretary's substitutions). Therefore, it is our

interpretation that this paragraph is intended to provide for the possibility of a liberalization of the conditions as described in section 1877(b)(2)(A)(ii)(II). At this time, we are not imposing any additional terms or conditions for the application of this provision, and we solicit comments on this issue.

Billing

Section 1877(b)(2)(B) continues to require that the ancillary services be billed by one of the following:

- The physician performing or supervising the services.
- A group practice of which the performing or supervising physician is a member.
- An entity that is wholly owned by the physician or group practice.

(Note that, effective January 1, 1995, the statutory definition of group practice requires that a group practice bill under a billing number assigned to the group.)

c. Exception—Certain Prepaid Health Plans

Section 1877(b)(3) continues to specify that the prohibition on referrals does not apply to services furnished to their enrollees by Medicare-contracting health maintenance organizations (HMOs), Medicare-contracting competitive medical plans (CMPs), and prepaid health care organizations under a contract or agreement with us. OBRA '93 expands the exception to apply it to services furnished to their enrollees by Federally-qualified HMOs. (The Federally-qualified HMOs are not required to have a contract or agreement with us in order for the exception to apply.)

d. Exception—Hospital Financial Relationship Unrelated to the Provision of Clinical Laboratory Services

Before the enactment of OBRA '93, section 1877(b)(4) provided a general exception to the prohibition in the case of a financial relationship with a hospital if the financial relationship did not relate to the provision of clinical laboratory services. OBRA '93 omitted this general exception, replacing it with section 1877(e)(4). Section 1877(e)(4) provides that remuneration from a hospital to a physician that is unrelated to the provision of clinical laboratory services does not constitute compensation that would trigger the prohibition on referrals. However, SSA '94 revised the effective date provision in section 13562(b)(2)(B) of OBRA '93. This effective date provision now states that section 1877(b)(4) continues to apply until January 1, 1995 as it was in effect before OBRA '93.

e. Other Exceptions

Section 1877(b) (currently at (b)(4)) continues to authorize the Secretary to provide in regulations for additional exceptions for financial relationships, beyond those specified in the statute, if she determines they do not pose a risk of Medicare program or patient abuse.

6. Exceptions Applicable Only to Financial Relationships Consisting of Ownership or Investment Interests

OBRA '93 continues to provide that certain ownership or investment interests do not constitute a "financial relationship" for purposes of the section 1877 prohibition on referrals.

a. Exception—Certain Investment Securities and Shares

Before OBRA '93, section 1877(c) contained an exception for ownership of investment securities, provided they were purchased on terms generally available to the public and were in a corporation that was (1) listed for trading on various specified stock exchanges and (2) had, at the end of the corporation's most recent fiscal year, total assets exceeding \$100 million. These provisions were reflected in the proposed rule.

OBRA '93 has modified this provision in several ways. First, investment securities no longer have to be those purchased on terms generally available to the public; they must only be those which "may be purchased" on terms generally available to the public. Second, the securities can be those listed on additional exchanges, including any regional exchange in which quotations are published on a daily basis, or foreign securities listed on a recognized foreign, national, or regional exchange in which quotations are published on a daily basis.

Third, the investment securities no longer have to be in a corporation with \$100 million in total assets at the end of a fiscal year; now the holdings of the corporation must be measured in terms of "stockholder equity," and the amount has been modified from \$100 million to \$75 million. This amount can now either be measured at the end of the most recent fiscal year or based on the corporation's average during the previous 3 fiscal years.

Finally, OBRA '93 extends the exception to apply to mutual funds, exempting ownership of shares in a regulated investment company as defined in section 851(a) of the Internal Revenue Code of 1986, if the company had, at the end of its most recent fiscal year, or on average during the previous 3 fiscal years, total assets exceeding \$75 million.

Under the effective date provisions of OBRA '93, the amended version of section 1877(c) was not effective until January 1, 1995. SSA '94 revised the effective date provision to make the amended version of section 1877(c) effective retroactively to January 1, 1992; however, the revised effective date provision states that, prior to January 1, 1995, the amended section 1877(c) does not apply to any securities of a corporation that meets the requirements of section 1877(c)(2) as they appeared prior to OBRA '93. Section 1877(c)(2), prior to OBRA '93, contained the requirement that a corporation have \$100 million in total assets. This final rule reflects the amended version of section 1877(c). It also specifies that, until January 1, 1995, ownership of investment securities in a corporation with \$100 million in total assets can also qualify for the exception.

b. Exception—Ownership or Investment Interest in Certain Health Care Facilities

Section 1877(d) continues to provide additional exceptions to the prohibition on physician referrals for an ownership or investment interest of a physician (or an immediate family member of the physician) in three types of facilities:

- A hospital located in Puerto Rico.
- A laboratory located in a rural area (that is, an area outside of a Metropolitan Statistical Area as defined in section 1886(d)(2)(D)).
- A hospital outside of Puerto Rico if the referring physician is authorized to perform services at the hospital and the ownership or investment interest is in the hospital itself (and not merely in a subdivision of the hospital).

(Note that OBRA '93 contains changes to the above provisions that became effective on January 1, 1995. These extend the exceptions to designated health services and modify the exception for rural providers. Before OBRA '93, the exception applied if the laboratory furnishing the services is in a rural area (as defined in section 1886(d)(2)(D)). The statute now provides that the exception applies in the case of designated health services furnished in a rural area (as defined in section 1886(d)(2)(D)) by an entity, if substantially all of the designated health services furnished by the entity are furnished to individuals residing in the rural area.

7. Exceptions Applicable Only to Financial Relationships Consisting of Certain Compensation Arrangements

Section 1877(e) continues to provide that certain compensation arrangements are not considered a "financial

relationship" for purposes of the prohibition on physician referrals.

a. Exception—Rental of Office Space

OBRA '93 amends the exception in section 1877(e)(1) for payments made by a lessee to a lessor for the use of office space, but delayed the effective date of the amendments until January 1, 1995. Section 152(c) of SSA '94 amends the effective date provision for OBRA '93 to eliminate this delay. The amended version of this exception now contains a requirement that the rented space not exceed that which is reasonable and necessary for the legitimate business purposes of the lease and that the space be used exclusively by the lessee during the lease. In addition, the exception now allows a lessee to pay for common areas shared with other occupants. Specifically, this provision states that payments made by a lessee to a lessor for the use of a premises do not constitute a compensation arrangement that would trigger the prohibition on referrals if the following conditions are met:

- The lease is set out in writing, signed by the parties, and specifies the premises covered by the lease.
- The space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee, except that the lessee may make payments for the use of space consisting of common areas if these payments do not exceed the lessee's pro rata share of expenses for that space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using the common areas.
- The lease provides for a term of rental or lease for at least 1 year.
- The rental charges over the term of the lease are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of referrals or other business generated between the parties.
- The lease would be commercially reasonable even if no referrals were made between the parties.
- The lease meets any other requirements the Secretary may impose by regulation as needed to protect against program or patient abuse.

b. Exception—Rental of Equipment

OBRA '93 added a new provision, section 1877(e)(1)(B), effective January 1992, that excepts from the definition of compensation arrangements payments made by a lessee of equipment to the

lessor of the equipment for the use of the equipment if the following conditions are met:

- The lease is set out in writing, signed by the parties, and specifies the equipment covered by the lease.
- The equipment rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the rental or lease and is used exclusively by the lessee when being used by the lessee.
- The lease provides for a term of rental or lease of at least 1 year.
- The rental charges over the term of the lease are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.
- The lease would be commercially reasonable even if no referrals were made between the parties.
- The lease meets any other requirements the Secretary may impose by regulation as needed to protect against Medicare program or patient abuse.

c. Exception—Bona Fide Employment Relationship

The predecessor provision of section 1877(e)(2) provided that an arrangement between a hospital and a physician (or the physician's immediate family member) for the employment of the physician (or family member) or for the provision of administrative services would not trigger the prohibition on referrals if certain conditions (detailed in the March 1992 proposed rule) were met. OBRA '93 amended this exception to make it applicable to any bona fide employment relationship with any employer that meets the same conditions.

d. Exception—Personal Service Arrangements

The predecessor provision of section 1877(e)(3) provided that remuneration from service arrangements with entities (other than hospitals) does not constitute a compensation arrangement for purposes of the prohibition on referrals if certain conditions (detailed in the March 1992 proposed rule) are met. This exception was limited to an arrangement for one of five specific types of services. OBRA '93 amended this provision to specify that remuneration from any entity under any kind of personal service arrangement (including remuneration for specific physicians' services furnished to a nonprofit blood center) would not constitute compensation that would

trigger the prohibition on referrals if the following conditions are met:

- The arrangement is set out in writing, signed by the parties, and specifies the services covered by the arrangement.
- The arrangement covers all of the services to be furnished by the physician (or immediate family member of the physician) to the entity.
- The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement.
- The term of the arrangement is for at least 1 year.
- The compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value and, except in the case of a physician incentive plan (as described below), is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.
- The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.
- The arrangement meets any other requirements the Secretary may impose by regulation as needed to protect against Medicare program or patient abuse.

Section 1877(e)(3)(B) provides that, in the case of a physician incentive plan between a physician and an entity, the compensation may be determined in a manner (through a withhold, capitation, bonus, or otherwise) that takes into account, directly or indirectly, the volume or value of any referrals or other business generated between the parties if the plan meets the following requirements:

- No specific payment is made (directly or indirectly) under the plan to a physician or a physician group as an inducement to reduce or limit medically necessary services provided with respect to a specific individual enrolled with the entity.
- If the plan places a physician or a physician group at substantial financial risk as determined by the Secretary under section 1876(i)(8)(A)(ii), the plan complies with any requirements the Secretary may impose under that section.

In addition, section 1877(e)(3)(B)(i)(III) requires the entity, upon request by the Secretary, to provide access to descriptive information regarding the plan, in order to permit the Secretary to determine whether the plan is in compliance with the requirements listed above.

Section 1877(e)(3)(B)(ii) defines a "physician incentive plan" as 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 provided with respect to individuals enrolled with the entity.

On December 14, 1992, we published, at 57 FR 59024, our proposed rule on physician incentive plans. Because there may be entities that were not affected by the proposed rule at the time it was published but are now affected, we plan to publish the final rule with a 60-day comment period so that these newly-affected entities have an opportunity to comment.

As the result of section 152(c) of SSA '94, until January 1, 1995, the provisions in section 1877(e)(3) do not apply to any arrangements that meet the requirements of subsection (e)(2) or (e)(3) of section 1877 of the Act before they were amended by OBRA '93.

e. Exception—Remuneration Unrelated to Provision of Clinical Laboratory Services

Before OBRA '93, section 1877(b)(4) provided an exception for financial relationships (ownership/investment interests or compensation arrangements) with a hospital unrelated to the provision of clinical lab services. OBRA '93 omits this exception, but replaces it with section 1877(e)(4), which excepts remuneration provided by a hospital to a physician if it is unrelated to the provision of clinical laboratory services. Section 152(c) of SSA '94 amends section 13562(b)(2)(B) of OBRA '93 to reinstate, until January 1, 1995, section 1877(b)(4) as it appeared before OBRA '93.

f. Exception—Physician Recruitment

OBRA '93 retains, at section 1877(e)(5), the provision previously at section 1877(e)(4). The provision provides that remuneration from a hospital to a physician to induce the physician to relocate to the area serviced by the hospital in order to be a member of the hospital's medical staff does not constitute a compensation arrangement for purposes of the prohibition on referrals if certain conditions (detailed in the March 1992 proposed rule) are met.

g. Exception—Isolated Transaction

OBRA '93 retains, at section 1877(e)(6), the provision previously at section 1877(e)(5). The provision provides that an isolated financial transaction, such as a one-time sale of property or (as added by OBRA '93) a practice, is not considered to be a

compensation arrangement for purposes of the prohibition on referrals if certain conditions (detailed in the March 1992 proposed rule) are met.

h. Salaried Physicians in a Group Practice

OBRA '93 removed, effective January 1, 1992, the provision previously at section 1877(e)(6). That provision had specified that a compensation arrangement involving payment by a group practice of the salary of a physician member of the group practice did not constitute a compensation arrangement that would trigger the prohibition on referrals.

i. Exception—Certain Group Practice Arrangements With a Hospital

OBRA '93 added a new section 1877(e)(7) that provides, effective January 1, 1992, that an arrangement between a hospital and group under which clinical laboratory services are furnished by the group but are billed by the hospital does not constitute a compensation arrangement for purposes of the prohibition on referrals if the following conditions are met:

- With respect to the services furnished to a hospital inpatient, the arrangement is in accordance with the provision of inpatient hospital services under section 1861(b)(3).
- The arrangement began before December 19, 1989, and has continued in effect without interruption since that date.
- With respect to the clinical laboratory services covered under the arrangement, substantially all of these services furnished to patients of the hospital are furnished by the group under the arrangement.
- The arrangement is set out in a written agreement that specifies the services to be furnished by the parties and the amount of compensation.
- The compensation paid over the term of the agreement is consistent with fair market value, and the compensation per unit of services is fixed in advance and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

• The compensation is provided under an agreement that would be commercially reasonable even if no referrals were made to the entity.

• The arrangement between the parties meets any other requirements the Secretary may impose by regulation as needed to protect against Medicare program or patient abuse.

j. Exception—Payments by a Physician for Items and Services

OBRA '93 added a new section 1877(e)(8), which provides that the following do not constitute compensation arrangements for purposes of the prohibition on referrals:

- Payments made by a physician to a laboratory in exchange for the provision of clinical laboratory services.
- Payments made by a physician to an entity as compensation for items or services other than clinical laboratory services if the items or services are furnished at fair market value.

8. Sections 1877(f) and 1877(g)

SSA '94 amends the provisions of section 1877(f), which concern reporting requirements. This section requires each entity providing covered items or services for which payment may be made under Medicare to provide the Secretary with information concerning the entity's ownership, investment, and (as added by SSA '94) compensation arrangements including (1) the covered items and services furnished by the entity and (2) the names and unique physician identification numbers of all physicians with an ownership or investment interest (as described in section 1877(a)(2)(A)) in or a compensation arrangement (as described in section 1877(a)(2)(B)) with the entity, or whose immediate relatives have such an ownership or investment interest in or who have such a compensation relationship with the entity. OBRA '93 retained the provisions of section 1877(g), which concern sanctions.

9. Other Definitions

OBRA '93 amended section 1877(h)(5) and (6) to remove the definitions for "investor" and "interested investor, disinterested investor," effective January 1, 1992.

II. Published Federal Register Documents

A. Provisions of the Proposed Rule—Physician Ownership of, and Referrals to, Health Care Entities That Furnish Clinical Laboratory Services

As stated earlier, on March 11, 1992, we published in the **Federal Register** a proposed rule that set forth our proposal for establishing in regulations the provisions of section 1877, as amended by OBRA '90, that relate to physician referrals to clinical laboratories. Section 1877 is very specific. For the most part, we believed the definitions set forth in section 1877(h) were detailed and therefore did not require extensive elaboration in regulations. Accordingly,

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

A hospital located outside of Puerto Rico if one of two specified conditions is met concerning the nature of the ownership.

6. Exceptions Related to Compensation Arrangements

We proposed to add section 411.359 to specify that, for purposes of the referral prohibition, certain compensation arrangements (as defined in the proposed rule) would not constitute a financial relationship if they involve—

- Rental or lease of office space;
- Certain employment and service arrangements with hospitals;
- Certain arrangements connected with physician recruitment;
- Certain isolated financial transactions;
- Certain service arrangements with entities other than hospitals;
- Salaried physicians in a group practice; and
- Other arrangements with hospitals if the arrangement does not relate to furnishing clinical laboratory services.

B. Provisions of the Interim Final Rule With Comment Period—Reporting Requirements for Financial Relationships Between Physicians and Health Care Entities That Furnish Selected Items and Services

The interim final rule with comment period (published December 3, 1991) listed reporting requirements under the Medicare program for the submission by certain health care entities of information about their financial relationships with physicians. It implemented section 1877(f), which includes the requirement that entities furnishing Medicare covered items or services provide us with information concerning their ownership or investment arrangements. (The rule extended the reporting to include compensation arrangements, not just ownership and investment interests.) The December 1991 interim final rule also provided notice of our decision to waive the requirements of section 1877(f) with respect to certain entities that do not furnish clinical laboratory services.

The information submitted was to include at least the name and unique physician identification number (UPIN) of each physician who had a financial relationship with the entity, the name and UPIN of each physician who had an immediate relative who had a financial relationship with the entity and, with respect to each physician identified, the nature of the financial relationship (including the extent and/or value of the ownership or investment interest or the

compensation arrangement, if we requested it).

Any person who, although required to, failed to submit the required information was subject to a civil money penalty of not more than \$10,000 for each day of the period beginning on the day following the applicable deadline established until the information was submitted.

In addition, the interim final rule discussed our decision to waive the reporting requirements for all entities (other than those providing clinical laboratory services) in States other than the minimum number of 10 specified in the statute. In the 10 States we selected, the reporting requirements were waived for entities other than the 6 types enumerated in the statute and section 411.361(c). The waiver represented a balance between our need to obtain sufficient ownership information for meaningful use in developing a statistical profile required by the Congress in section 6204(f) of OBRA '89, as amended by section 4207(e)(4) of OBRA '90, and in evaluating the need for future legislative, policy, or operational actions, and the need to minimize the administrative time and cost involved in collecting and analyzing the information. We believe that by collecting the information from the enumerated entities in the minimum number of 10 States, we satisfied these congressional and administrative needs.

In determining the States in which a blanket waiver would not be granted, we selected 10 States that represented approximately 42 percent of the physicians who bill the Medicare program for items and services furnished to beneficiaries. Medicare contractors servicing all providers and suppliers in the 10 selected States process approximately 40 percent of all Medicare claims. Services provided by the six types of entities specified in the statute account for a significant proportion of Medicare expenditures and represent a cross-section of Medicare covered services. Therefore, we decided to waive the requirements of section 1877(f) with respect to entities (other than those providing clinical laboratory services) in all States except the following: Arkansas, California, Connecticut, Florida, Michigan, Ohio, Pennsylvania, South Carolina, Texas, and West Virginia. These States were selected because they represent: A mix of rural (West Virginia), urban (Florida), and mixed urban/rural States (Ohio, Texas); a variety of claims/bills volume, from very small (Arkansas) to very large (Pennsylvania); and, a geographic spread from north (Michigan) to south

(South Carolina) as well as both coasts (from California to Connecticut).

Note that while the effect of section 1877(f) of the Act and section 6204(f) of OBRA '89 was to require the Secretary to submit to the Congress a statistical profile within 90 days after each calendar quarter, section 4207(e)(4) of OBRA '90 amended OBRA '89 to require only one statistical profile, which was due by June 30, 1992. Clinical laboratory entities reported information about financial relationships with physicians as part of a survey conducted in the fall of 1991, and we used this data in the required statistical profile.

Section 1877(f) authorizes the Secretary to gather information from any entity providing covered items or services in such form, manner, and at such time as she specifies. Thus, the Secretary can again require entities to report whenever she deems it appropriate for purposes of enforcing the referral prohibition in section 1877. Section 152(a) of SSA '94 amended section 1877(f), altering the rules for future reporting. The provision now requires entities to report not only their ownership arrangements with physicians, but also their investment and compensation arrangements. Section 152(a) also eliminated the Secretary's authority to waive the reporting requirements for certain states or services. The Secretary, however, continues to have the right to determine that an entity is not subject to the reporting requirements because it provides Medicare-covered services very infrequently. In addition, the reporting requirements still do not apply to designated health services furnished outside the United States. The effective date of the amendments to section 1877(f) is the date of enactment of SSA '94, that is, October 31, 1994.

III. Principles for Developing This Final Rule With Comment Period

In this final rule with comment, we are adopting the provisions of our March 1992 proposed rule, changed as appropriate to address the comments on the proposed rule and the new requirements relating to clinical laboratory services contained in OBRA '93, as amended by SSA '94, that have a retroactive effective date of January 1, 1992. OBRA '93 provides several exceptions that were not in previous legislation. In some cases, these new exceptions address suggestions received through public comment on the March 1992 proposed rule. It is our intention that this final rule with comment reflect, to the extent possible, the comments on the proposed rule and the new, but retroactive, requirements of OBRA '93,

as amended by SSA '94. This final rule with comment also revises the provisions of the December 1991 interim final rule to incorporate the amendments to section 1877(f) made by SSA '94, to apply to any future reporting that we require.

To address the provisions of section 1877 that are effective on January 1, 1995, as provided by OBRA '93, we plan to publish regulations in addition to this one. We will publish a proposed rule to interpret any retroactive provisions contained in OBRA '93 that we believe allow us to exercise discretion in their implementation. In this final rule, we have, in general, only reiterated the new, but retroactive, statutory provisions, incorporating them into our proposals. We have interpreted the new provisions only in the few instances in which it was necessary to do so in order to allow the statute to be implemented at all.

The proposed rule will also cover those provisions of section 1877 concerning physician referrals for clinical laboratory services that became effective on January 1, 1995, as well as those covering the other designated health services (all of which are effective for referrals made on or after January 1, 1995). Finally, we plan to publish a final rule that will address any comments received on this final rule with comment and the new proposed rule.

We are including in this final rule the OBRA '93 provisions related to the following:

- The in-office ancillary services exception.
 - The rental of equipment exception.
 - The rental of office space exception.
 - The bona fide employment relationships exception.
 - The personal services and physician incentive plan exception.
 - The exception concerning remuneration unrelated to the provision of clinical laboratory services.
- The change in the isolated transactions exception.
- The exception concerning certain group practice arrangements with a hospital.
 - The exception for payments by a physician for items and services.
 - All changes in definitions in 1877(h) that have a retroactive effective date (compensation arrangement, remuneration, group practice).

IV. Analysis of and Responses to Public Comments on the Proposed Rule—Physician Ownership of, and Referrals to, Health Care Entities That Furnish Clinical Laboratory Services

In response to the publication in the **Federal Register** of the proposed rule on March 11, 1992, we received 299 timely public comments. The comments came from a wide variety of correspondents including professional associations and societies, health care workers, law firms, third party health insurers, hospitals, and private individuals. We screened each commenter's letter and grouped like or related comments. Some comments were identical, indicating that the commenters had submitted form letters. After associating like comments, we placed them in categories based on subject matter or based on the portion of the regulations affected and then reviewed the comments. All comments relating to general subjects, such as the format of the regulations, were similarly reviewed.

This process identified areas of the proposed regulation that we needed to review in terms of their effect on policy, consistency, or clarity of the rules.

We have presented all comments and responses in, for the most part, the order in which the issues appeared in the March 1992 proposed rule.

Note: We have found it necessary to change the designation of some sections from what was proposed. We have prepared a table, which appears at the end of this preamble, that relates the requirements in this final rule to the correlative proposed sections from which they evolved. If OBRA '93 provisions resulted in significant change, we so identify OBRA '93 as the source. This table is intended merely to assist parties who may be interested in comparing specific provisions as proposed or as contained in OBRA '93 to those of the final rule with comment. It does not supplant the more detailed discussion in this preamble. Unless otherwise indicated, citations in the responses that follow are to the sections as they are designated by this final rule with comment.

A. General

1. Purpose of Final Rule

Comment: One commenter requested that the Secretary ensure that the final rule is cast so that its purpose is clear; that is, the rule should be presented so as to support the idea that the ethical delivery of quality, medically necessary care is fundamental to preserving the integrity of medical practice in general as well as the Medicare program in particular.

Response: We share the commenter's view. We believe that section 1877 was enacted out of concern over the findings of various studies that physicians who

have a financial relationship with a laboratory entity order more clinical laboratory tests for their Medicare patients than physicians who do not have a financial relationship. There have been at least 10 studies conducted over the past few years that concluded that patients of physicians who have financial relationships with health care suppliers receive a greater number of health care services from those suppliers than do patients generally.

To the extent that section 1877 and this final rule protect against this practice, the Medicare program and its beneficiaries are well served. Therefore, to the extent that physicians and providers of clinical laboratory services change their financial relationships and behavior to comply with provisions of section 1877 and, in turn, reduce overutilization of laboratory services, we believe that this change will have a positive effect on other health insurance programs. One of our prime goals is to ensure that our rules carry out the Congress' mandate in a manner that is in the best interest of all individuals who may be affected by the rules.

2. Delay of Effective Date

Comment: Several commenters requested that we delay the effective date of the final rule. One commenter recommended a 60-day delay, another recommended not less than 90 days, and yet another commenter requested not less than 120 days from the date of publication in the **Federal Register** and that application of the regulation should be prospective only.

Response: We usually provide for a 30-day delay in the effective date of a final rule. This delay is offered so that affected parties have the opportunity to change their practices, if necessary, to comply with the requirements of the final rule. While we understand that the goal behind the commenters' suggestions is to provide sufficient time for parties affected by this final rule to make arrangements to comply with its requirements, we do not believe that an additional delay in the effective date would be beneficial. This is so primarily because, in this rule, we are establishing additional exceptions from the prohibition on referrals based upon public comments. In addition, we plan to publish a subsequent final regulation that will address any comments received on this regulation.

3. Delay of Enforcement Provisions

Comment: One commenter requested that the Secretary indicate that the enforcement of the prohibition on referrals begin no earlier than the effective date of this rule. As a result of

this suggestion, any physician who is out of compliance with section 1877 before that effective date would be held harmless under the final rule.

Another commenter requested that we postpone the implementation of sanctions, at the very least, until 90 days after the final rule has been issued.

Response: Section 1877(g) of the Act sets forth several enforcement provisions that apply to prohibited referrals for clinical laboratory services and to prohibited claims for payment for these services.

- Section 1877(g)(1) provides for denial of Medicare payment for a clinical laboratory service furnished as the result of a prohibited referral.

- Under section 1877(g)(2), if a person collects any amounts that were billed for services furnished under a prohibited referral, a timely refund of each amount is required.

- Section 1877(g)(3) authorizes the imposition of civil money penalties of not more than \$15,000 for each such service and possible exclusion from the Medicare and other programs for any person that presents, or causes to be presented, a bill or a claim for a clinical laboratory service that the person knows or should know was unlawfully referred or for which a refund has not been made.

- Under section 1877(g)(4), civil money penalties of not more than \$100,000 for each arrangement or scheme and possible exclusion from participation in the Medicare and other programs are authorized in cases in which a physician or an entity enters into a circumvention arrangement or scheme (such as a cross-referral arrangement) that the physician or entity knows or should know has a principal purpose of ensuring referrals by the physician to a particular entity that would be unlawful under section 1877 if made directly. (See the final rule with comment published by the Office of Inspector General on March 31, 1995 (60 FR 16580) for further information. That rule addresses sections 1877(g)(3) and (g)(4).)

The first commenter appears to be suggesting that these statutory enforcement provisions should not be applied until the effective date of this final rule and that a physician who is not in compliance with the provisions of the statute at the time the final rule is published should be held harmless until the effective date of the final rule. The second commenter suggested a 90-day delay in application of any sanctions following publication of the final rule.

We disagree with these suggestions. First, many of the provisions of section

1877 of the Act were effective on January 1, 1992, by operation of law. These provisions are, for the most part, self-implementing. This rule incorporates into regulations statutory requirements that are already in effect, clarifying or interpreting certain provisions, and exercising the Secretary's authority to promulgate additional exceptions through regulations. Even though the requirements of this final rule are effective later than the effective date of the statute, we cannot postpone the statutory effective date. Nonetheless, any sanctions that can be applied only as a result of the clarification or interpretation of the statute specified in this rule will, of course, be applied prospectively, beginning with the effective date of this rule.

Section 1877(f) of the Act sets forth certain reporting requirements with which entities were to comply by October 1, 1991. Under this authority, we conducted a survey in the fall of 1991 concerning physician ownership in, and compensation arrangements with, entities furnishing clinical laboratory services. Based on data gathered from that survey, Medicare carriers have already been denying some claims for laboratory services furnished by a laboratory that is independent of a physician's office and that are furnished in violation of the prohibition on referrals. Similarly, the Office of the Inspector General could impose sanctions if, for example, a clinical laboratory has failed to refund an amount that it collected for a service furnished as the result of a referral if the laboratory knew the referral was prohibited.

4. Good Faith Standard

Comment: One commenter suggested that the final rule have either a good faith standard or a provision that the statute will not be violated unless the physician or the laboratory has actual knowledge of a prohibited referral. The commenter requested that the final rule specify the scope of the inquiry required and define the extent of the duty imposed upon laboratories and physicians to determine the relationship of persons that would affect their ability to refer laboratory work or to accept a referral.

Response: It is important to emphasize that the statute and this rule do not prohibit financial relationships that exist or might be established between physicians and entities providing clinical laboratory services. What is prohibited are certain referrals for clinical laboratory testing of Medicare patients. The statute itself, at

section 1877(a)(2), describes "financial relationship" for purposes of determining whether a referral is prohibited. And, as discussed above, section 1877(g) specifies several sanctions that may be applied if a physician or an entity billing for a Medicare covered clinical laboratory service violates the statute's requirements. Thus, unless an exception applies, the statute operates automatically under its own terms to prohibit referrals for Medicare-covered clinical laboratory services to be performed by an entity with which the physician or an immediate family member of the physician has a financial relationship.

We understand that this commenter is advocating adoption of a policy that would hold harmless a physician or laboratory if there is no intention on the part of either to seek an advantage from an ownership interest or compensation arrangement. The commenter is also concerned that a physician or a laboratory may be unintentionally involved in a relationship that would call the physician's referrals into question. Similarly, a laboratory may be unaware that it has a relationship with a referring physician's relatives that would cause the prohibition to apply. However, the statutory prohibition against referrals in such situations applies because of the existence of the financial relationship, not because of the intent of the physician or laboratory or because there is actual knowledge of the relationship. It is the responsibility of physicians and laboratory entities to take whatever steps are necessary to ensure that they do not violate Federal law.

5. Physician Ownership of Health Care Facilities

Comment: One major national medical organization indicated that it believed ownership of health care facilities by referring physicians is an issue that should be addressed, and it supported the proposed rule. It believed there is increased evidence that, when physicians have a financial relationship with an entity, the relationship adversely affects patient care and adds to the cost of health care in the United States. Therefore, the organization believed that physicians should not have a direct or indirect financial interest in diagnostic or therapeutic facilities to which they refer patients, and it indicated support for legislation and regulations that would eliminate this conflict of interest by prohibiting such ownership arrangements in health care.

Response: We agree with this commenter. As stated earlier, recent studies have concluded that there is a higher level of utilization of services when physicians refer patients to entities with which they have a financial relationship. As mentioned in the preamble to the proposed rule (57 FR 8589), a report from the Office of the Inspector General to the Congress established that at least 25 percent of the nearly 4500 independent clinical laboratories are owned in whole or in part by referring physicians. The same report found that Medicare patients of referring physicians who own or invest in independent clinical laboratories received 45 percent more clinical laboratory services than all Medicare patients. ("Financial Arrangements Between Physicians and Health Care Businesses," May 1989, page 18). A study published in "Medical Care" (Vol. 32, No. 2) in February 1994 found that a review of clinical laboratory practices in Florida lends support to the contentions of critics that physician joint ventures (health care businesses that physicians own, but where they do not practice or directly provide services) result in increased use of services and higher charges to consumers. Utilization, measured as the number of billable laboratory procedures per patient, is significantly higher in facilities owned by referring physicians. Although the study reported only negligible differences in charges per procedure (compared to nonphysician-owned facilities), it found that higher utilization rates resulted in significantly higher gross and net revenue per patient. Furthermore, the study found that differences in average production costs per patient in physician-owned and nonphysician-owned facilities were not significant. The net result is that physician joint ventures are far more profitable than comparable nonphysician joint ventures. The study results, which included laboratory services furnished to both private and publicly insured patients, corroborate previous evidence of higher use of laboratory procedures among Medicare and Medicaid patients treated by referring physician investors.

Many States have enacted or are considering regulations that would affect physician referrals to entities with which the physicians have financial relationships. For example, New Jersey implemented regulations that effectively prohibit physicians from referring patients to facilities they own. Physicians who do not comply with the regulations are subject to sanctions under the State's physicians practice

law. Furthermore, in OBRA '93 the Congress has extended application of the prohibition on referrals to other types of health care services and health care entities.

6. Process for Amending Regulations

Comment: One commenter indicated that we should maintain an expedited process for amending the regulations and issuing clarifications. The commenter pointed out that, despite a careful review of the proposed regulations, it is not possible to identify all of the unintended consequences of applying the proposed regulations to particular laboratory arrangements. The commenter believed that unless we respond quickly to issue clarifications and correct such problems when identified, inappropriate regulations can disrupt the delivery of, and limit patient access to, quality clinical laboratory services.

Response: We understand and appreciate the commenter's desire to feel secure about the requirements of the law. We make all possible efforts to publish final rules as quickly as possible and to amend the regulations expeditiously if clarifications or changes are needed and can be accomplished through rulemaking. In addition, we keep our regional offices and the Medicare contractors informed through manual instructions of technical changes that can be made without rulemaking. The contractors, in turn, advise the physicians and laboratory entities in their service areas of such changes. In regard to inquiries about particular laboratory arrangements, our regulations do not provide for the issuance of formal advisory opinions of any kind pertaining to section 1877 or any other section of the law for which we are responsible. We receive a large volume of correspondence from the public, and we do respond to general questions about the contents of our regulations and manuals. We, however, do not have the authority and will not attempt to interpret the applicability of these physician self-referral provisions to situations posed in correspondence. Our advice must, of necessity, continue to be general.

7. Evolution of Group Practices

Comment: Before the enactment of section 1877 of the Act, the Medicare program did not have a statutory definition of "group practice," nor any detailed body of law developed through regulations or manual instructions to define or otherwise recognize a group practice as a provider entity. One commenter indicated that we should recognize the significance of this

rulemaking to the development and evolution of group practices in this country.

The commenter expressed hope that regulations will recognize the diversity of business structures within the group practice field and accommodate nonabusive arrangements for the provision of clinical laboratory services based on the substance of the arrangements, not merely their form.

The commenter also indicated that we should be mindful of the significance of this rule to the competitive "playing field" in health care. It was stated that, as medical group practices evolve into larger and more full-service providers of a wide range of physician ancillary and other health care products and services, they are furnishing many items and services that have traditionally been furnished by inpatient institutions or independent suppliers. The commenter also expressed hope that nothing in the final rule will prohibit group practices from performing services for other physicians' patients or other providers assuming, of course, that the referring source does not have a prohibited financial arrangement with the group. The commenter applauded us for proposing a rule that does not force groups to choose between serving their own patients and those of otherwise unrelated physicians.

Response: In publishing these final regulations, it is not our intent to obstruct the efforts of an association of physicians to qualify as a group practice under the definition in section 1877(h)(4) and therefore qualify for the in-office ancillary services exception set forth in section 1877(b)(2) of the Act and described in § 411.355(b). If a group of physicians meets the definition of a "group practice" under section 1877(h), it could also be eligible for the exception for physicians' services in section 1877(b)(1) and possibly the exception in section 1877(e)(7) for certain arrangements between a hospital and a group practice. Further, we believe that, to the extent possible, we have accommodated various group practice configurations given the statutory parameters.

The point made in the last sentence of the comment, as we understand it, endorses the adoption of a policy that would enable group practice laboratories to continue to perform laboratory tests for their own patients as well as to accept laboratory referrals from physicians in the community who do not have a financial relationship with the group practice. In the responses to various comments presented below, we have clarified that the provisions of section 1877 prohibit

laboratory referrals only if a financial relationship exists between the referring physician (or an immediate family member) and the laboratory entity. In other words, the law does not prohibit a laboratory from accepting referrals from a physician who does not have a financial relationship with it. Therefore, in all situations, a group practice will be permitted to accept referrals for laboratory services from physicians in the community who do not have, or do not have an immediate family member who has, a financial relationship with the group practice or the laboratory.

8. Use of Diagnosis Code for Laboratory Billing

Comment: One commenter believed the government is being misled about the need for certain diagnostic testing. The commenter noted that self-referrals could be used by unscrupulous physicians as a means to generate income. The commenter believed a major check on this practice would be the requirement of an appropriate diagnosis code for each service billed. The commenter believed it should be the role of the Medicare carriers to monitor unnecessary testing and then to take appropriate actions so that no testing is paid for if the diagnosis code does not suggest medical need.

Response: Section 202(g) of the Medicare Catastrophic Coverage Act of 1988 (Public Law 100-360), enacted July 1, 1988, added paragraph (p) to section 1842 of the Act. Under the provisions of section 1842(p)(1), each bill or request for payment for physicians' services under Medicare Part B must include the appropriate diagnosis code "as established by the Secretary" for each item or service the Medicare beneficiary received. We fully explain the conditions and requirements of this provision in a final rule published on March 4, 1994 (59 FR 10290).

The conference report that accompanied Public Law 100-360 explained clearly the purpose of the requirement for physician diagnostic coding. After rejecting a Senate provision that would have required the use of diagnostic codes on all prescriptions, because they believed that the requirement would have been unduly burdensome on Medicare suppliers of services, the conferees agreed to require diagnostic coding for physicians' services under Part B. They explained their reasons for this requirement as follows: "This information would be available for immediate use for utilization review of physician services * * *." (H.R. Conf. Rep. No. 661, 100th Cong., 2nd Sess.

191 (1988)) The new coding requirement does not apply to bills from laboratories, except for physician laboratory services, which are described in section 405.556.

Claims submitted directly to the Medicare carrier by a clinical laboratory that is not part of a physician's office are not subject to the above requirement. The Medicare carriers, however, review claims submitted for payment to ensure that, to the extent possible, only services that are reasonable and necessary for the treatment of an illness or injury or to improve the functioning of a malformed body member are approved for payment. We agree that it would be easier for a Medicare carrier to make a medical necessity determination if the claim contained an appropriate diagnosis coding. It is clear, however, that the Congress intended to limit diagnosis coding to physicians' services. Therefore, at this time, we are unable to accept the suggestion the commenter made.

9. Referrals That Are Not Abusive

Comment: One commenter indicated that it would appear that relationships between a practitioner and an entity would not pose a risk of patient or program abuse if the relationships do not result in a return to the practitioner of monies beyond those that would be received if the physician directly furnished such laboratory tests (or other Medicare outpatient services).

The commenter suggested that it would be helpful if an exception could be established for referrals, from a physician to an entity, that are medically necessary (that is, represent legitimate claims on the Medicare program) and are not motivated by direct or indirect financial benefits that exceed fair market value accruing to the physician.

Response: The commenter appears to argue that the prohibition should not apply to a referral that is made by a physician to an entity with which he or she has a financial relationship if the service being performed is determined to be medically necessary and the physician does not realize an unacceptable financial gain as a result of the laboratory referral. The financial gain could not be larger than the fair market value of what he or she would realize if the service was performed, for example, in his or her own office and would have qualified for the in-office ancillary services exception.

Section 1862(a)(1) states, in part, that, notwithstanding any other provision of title XVIII of the Act, no payment may be made under Part A or Part B of the Medicare program for any expenses

incurred for items or services that are not reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member. In exercising their contractual responsibilities, Medicare carriers enforce this overriding coverage criterion through the use of claims screens, medical review, and other procedures. The commenter appears to believe that, because these carrier safeguards are in place, a "reasonable and necessary" exception could be established. The problem with this commenter's approach is twofold. First, section 1877 prohibits certain referrals to entities with which the referring physician or an immediate family member has a financial relationship regardless of whether the service furnished is found by a carrier to be medically necessary. Second, assessing whether a physician's referrals result in a financial gain from the relationship with a laboratory would be a very difficult and burdensome administrative process. Carriers process approximately 4 million claims for clinical laboratory services each year. It would be very costly to determine whether each claim called into question by certain referrals results in a cost benefit to the referring physician.

10. Contractor Implementation

Comment: One commenter, a Medicare contractor, indicated it had concerns with the administration of the prohibition on referrals along with the numerous exceptions that have been granted for specific services, certain ownership or investment interests, and certain compensation arrangements. The commenter anticipates that the monitoring of these various provisions will be complex and will greatly affect post-pay and systems areas.

Response: It is not clear, at this time, how significant a workload the provisions will create for carrier claims processing and fraud units. However, once this rule is published, the carriers will start performing compliance audits based on specified criteria. We do not expect that these audits will result in much increase in the carrier's workload. We do not believe that there will be any significant effect on either post-pay or systems areas.

B. Scope of Regulations

Comment: One commenter indicated that the preamble section of the proposed rule explaining what the agency believes is the regulatory scope (57 FR 8593) should be omitted. The commenter contended that it imparts no specific guidance and defines no

regulatory requirement. Furthermore, this commenter objected to the preamble reference to violations of other Federal or State law and stated that it is gratuitous to advise the regulated entity or person that compliance with section 1877 of the Act, or regulations promulgated thereunder, does not foreclose citation and adjudication under another Federal or State statutory requirement or regulation.

Response: We disagree. Sections 411.1 and 411.350, as described in the preamble of the proposed rule and as set forth in the proposed regulation, conform to regulation drafting guidelines in explaining the general content of 42 CFR part 411, subpart J. Our intent in including this information, something that is routinely done in any new HCFA regulation, is to provide the public with an outline of the regulation's substantive content.

In this case it is important as well to state what the new regulation does not provide for. Before the proposed rule was published, we received numerous inquiries indicating that the provisions of section 1877 were being confused with the anti-kickback safe harbors specified in the final rule published on July 29, 1991 (56 FR 35952). In fact, the Medicare anti-kickback statute (section 1128B(b) of the Act) and section 1877, while similar in that they address possible abuses of Medicare, are different in scope and application and, therefore, need to be distinguished. The conference report for OBRA '89 includes the following statement:

The conferees wish to clarify that any prohibition, exemption, or exception authorized under this provision in no way alters (or reflects on) the scope and application of the anti-kickback provisions in section 1128B of the Social Security Act. The conferees do not intend that this provision should be construed as affecting, or in any way interfering, [sic] with the efforts of the Inspector General to enforce current law, such as cases described in the recent Fraud Alert issued by the Inspector General. In particular, entities which would be eligible for a specific exemption would be subject to all of the provisions of current law. (H.R. Conf. Rep. No. 386, 101st Cong., 1st session 856 (1989).)

Furthermore, we believe it is our duty to inform the public that lawful conduct under sections 1128B and 1877 of the Act may not be lawful under other Federal statutes or State law or regulations. Conversely, conduct that is lawful under those other authorities may be prohibited under section 1877 and these final regulations.

C. Definitions

1. Clinical Laboratory Services

Under the proposed rule (section 411.353), "laboratory services" are considered to be any services provided by the entities described in section 493.2. The preamble to the proposed rule pointed out at 57 FR 8595 that this would include anatomical laboratory services but would not include noninvasive tests that are not considered clinical laboratory services, such as electroencephalograms or electrocardiograms. Nor would it include x-rays or diagnostic imaging services, such as mammogram and computerized axial tomography scans.

Comment: A few commenters recommended that a definition of "clinical laboratory" be included in the regulations. They suggested that, if the definition used for purposes of the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) is to be adopted, that it should be repeated in section 411.351.

One commenter indicated that the definition of clinical laboratory should state the following:

"Clinical laboratory means a facility for the 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, as described in section 493.2. Such examinations include screening procedures to determine the presence or absence of various substances or organisms in the body. Such examinations do not include noninvasive tests, such as electroencephalograms, electrocardiograms, x-rays or diagnostic imaging services, such as mammogram and computerized axial tomography services."

Response: We agree that this final regulation should contain a definition of clinical laboratory. Thus, based on the definition at section 493.2, which defines a laboratory for CLIA purposes, we are including the following in section 411.351:

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.

Comment: One commenter urged that the definition of laboratory services should include a statement that what are considered clinical laboratory services for current procedural terminology (CPT) code purposes are also considered clinical laboratory services for the purpose of these regulations. Thus, in this commenter's opinion, there would be no question about what constitutes clinical laboratory services.

Response: As mentioned in the response to the previous comment, we have defined a clinical laboratory as meaning any laboratory entity that is required to satisfy the CLIA standards in order to perform tests on human beings 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." Therefore, for the purposes of the prohibition on physician self-referral, we are defining "clinical laboratory services" at section 411.351 as follows:

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.

Given this position, the American Medical Association (the organization responsible for CPT) and the CPT publication would not be the references to define the kind of services that are regulated by the physician referral legislation. If individuals want to know what specific tests and test systems are subject to CLIA certification, they may contact the Center for Disease Control and Prevention (CDC), Public Health Service, Attention: CLIA, 1600 Clifton Road, Atlanta, GA 30333. CDC has categorized approximately 12,000 test systems, assays, and examinations for complexity using the criteria at 42 CFR 493.17. CDC publishes notices periodically in the **Federal Register** to announce additional test systems, assays, or examinations that have been categorized or recategorized since the preceding publication.

For these reasons, we do not support the sole use of CPT codes to identify

clinical laboratory services for physician referral purposes.

Comment: One commenter suggested that it would be helpful to define further what type of anatomical laboratory services are covered by the statute and which specific tests we consider to be noninvasive and not subject to the prohibition on referrals.

Response: We agree with this commenter. As mentioned in the preamble to the proposed rule (57 FR 8595), anatomical laboratory services are subject to the prohibition on physician referrals. Anatomical laboratory services (and anatomical pathology services) involve the examination of tissue, often tissue removed during surgery. As such, it appears to us that anatomical laboratory services are always invasive (that is, they involve the examination of materials derived from the human body, as described in 42 CFR 493.2).

Therefore, we believe that these tests would always be subject to CLIA and section 1877. Consequently, any physician who refers patients for these kinds of tests to a laboratory with which he or she (or a family member) has a financial relationship could be in violation of section 1877. In such a case, any of the many exceptions in section 1877 might exempt that physician's referral from the prohibition.

The commenter has also suggested that we specify which noninvasive testing is exempt from the prohibition on referrals. As mentioned in the response to the previous comment, we believe that the most appropriate way for a physician or clinical laboratory to determine if Medicare considers a diagnostic test to be a clinical laboratory test subject to the requirements of section 1877, is to find out if the test is subject to categorization under CLIA. The Medicare carriers are available to provide this information to individuals and physicians if it is not clear to a physician, other supplier, or provider of services and if they do not have available the latest compiled list of clinical laboratory test systems, assays, and examinations categorized by complexity and published by the CDC. If a test does not appear on a compiled list, a physician or laboratory should contact the CDC at the address we mentioned in the last response in order to be certain, since the lists are not yet complete.

2. Compensation Arrangement

Under the proposed rule (§ 411.351), a compensation arrangement would be any arrangement that involves any remuneration between a physician or a member of his or her immediate family

and an entity. The definition of compensation arrangement was amended by OBRA '93 to exclude certain types of remuneration (identified in section I.D.1.c. of this preamble).

Comment: One commenter indicated that the final regulations need to give a specific definition for the phrase "compensation arrangement," not simply repeat the words that the Congress has provided.

Response: The commenter did not explain why the proposed definition was perceived as insufficient. The words of the definition are specific, and we do not believe they are susceptible to misinterpretation. The definition is broad, because it covers any remuneration between a physician (or an immediate family member) and an entity, and it may be this aspect of the definition that concerned the commenter. We believe, however, that it was the intent of the Congress to include all arrangements (direct and indirect) between physicians and laboratories involving any remuneration. We believe that the statutory definition accomplishes this purpose. In the OBRA '93 amendments, the Congress retained the broad definition of "remuneration" in section 1877(h)(1)(B), but did specifically except from the term "compensation arrangement" a very limited list of arrangements involving the kinds of remuneration listed in section 1877(h)(1)(C). These changes are reflected in this final regulation.

Comment: One commenter indicated that laboratories often must enter into arrangements with physicians, who are not employed by the laboratory, for necessary services. The commenter believed that as long as certain safeguards, comparable to those applicable to arrangements between physicians and hospitals, are met, these arrangements should not be considered compensation arrangements that would prohibit the physicians from making referrals. Examples of such arrangements are (1) an arrangement to review abnormal test results when further medical consultation is required, and (2) a contract with a physician to provide various consultation services, such as reviewing anatomic pathology specimens, interpreting holter monitors or electrocardiograms, and reviewing Pap tests.

Another commenter indicated that, because of the breadth of the self-referral law, any time a laboratory makes a payment to a physician, a compensation arrangement is created. Thus, for example, if a laboratory maintains a self-insured group medical plan and pays physicians directly for

the medical services provided to its employees, it would, in this commenter's view, have a compensation arrangement with those physicians and should not accept Medicare referrals from them. The commenter suggested that these types of legitimate arrangements should not be considered compensation arrangements as long as safeguards are put into place to ensure nonabuse.

Response: What these commenters are asking for is an exception for an arrangement under which a referring physician furnishes services to a laboratory (or, alternatively, that the term compensation arrangement be defined in a manner so as not to include that arrangement). Section 1877(e)(3), as amended by OBRA '93, provides an exception for a compensation relationship in which a laboratory entity pays a physician for personal services furnished under an arrangement. Such an arrangement does not result in the physician being prohibited from making referrals to that entity if certain specific conditions (detailed in section I.D.6.d. of this preamble) are met.

In addition to the exception in section 1877(e)(3), section 1877(e)(2), as amended by OBRA '93, provides that, if a laboratory makes payments to a physician as the result of a bona fide employment relationship with the physician, that physician's referrals would not be prohibited, providing certain criteria are met.

Comment: One commenter stated that in many situations laboratories are required by State or Federal law to have particular arrangements with physicians. For example, under the new CLIA regulations (42 CFR part 493), laboratories may be required to have physicians in a number of different positions in the laboratory. The commenter believed these types of arrangements should not be considered compensation arrangements that would prohibit referrals by the physicians.

Response: As mentioned in an earlier response, it is our belief that most of these arrangements could qualify for either the exception found in section 1877(e)(2) for bona fide employment relationships or, when the physicians are not employed, section 1877(e)(3) for personal service arrangements.

Accordingly, a compensation arrangement between a laboratory and a referring physician for specific identifiable services that has all of the elements required for the subject exceptions would not cause that physician's referrals to be prohibited.

Comment: One commenter noted that laboratories routinely sell services directly to physicians who then

reimburse the laboratory for those services before marking them up to patients. The commenter did not believe that those payments should constitute a compensation arrangement.

Response: As set forth in OBRA '93, section 1877(e)(8)(A) of the Act provides a compensation-related exception for physicians who pay a laboratory in exchange for the provision of clinical laboratory services (see section 411.357(i)(1)).

The commenter has made the point that physicians routinely reimburse laboratories for services and then mark them up to patients. Under section 1833(h)(5)(A), Medicare payment for a clinical diagnostic laboratory test may be made only to the person or entity that performed or supervised the performance of the test. (This rule is subject to certain exceptions involving services furnished or supervised by a physician when payment is made to another physician in the same group practice, services performed by a laboratory at the request of another laboratory, and tests performed under arrangements made by a hospital.) As a result, physicians should generally not be able to pay a laboratory in exchange for Medicare covered laboratory services, and then mark them up to patients.

Comment: One commenter noted that many laboratories are part of large, diversified corporations (which themselves may be related to other large, diversified corporations) that provide a number of different services to physicians. These services may include pharmaceutical, billing, and waste transport services. The commenter believed that, so long as these services are provided at fair market value, there is no reason that an entity should not provide these services to physicians and also accept their Medicare referrals.

Response: As mentioned previously, if a physician is paying fair market value to the supplier entity for whatever nonlaboratory services he or she is purchasing, referrals by the physician to the laboratory should not be prohibited. However, the arrangement must meet the conditions found in new § 411.357(i).

Comment: One commenter indicated that the regulations should be clarified to expressly prohibit any arrangement under which the referring physician bills patients for clinical laboratory or anatomic pathology services that are not personally performed or supervised by the billing physician or the group practice. In particular, the commenter suggested that the prohibition should apply to arrangements under which the referring physician requires the

pathologist or independent laboratory to bill the referring physician, rather than the patient or third party payer, for any services provided by the pathologist or independent laboratory on referral by the physician. The commenter pointed out that, at the present time, the Medicare payment rules prohibit a physician from billing for certain clinical diagnostic laboratory tests performed by an independent laboratory for Medicare patients (section 1833(h)(5)(A)) but, the commenter maintained, this payment prohibition does not apply to anatomic pathology services or to clinical laboratory services performed for non-Medicare patients. Thus, the commenter concluded that the referring physician would not be prohibited from marking up the costs of anatomical tests to Medicare and for clinical laboratory and anatomical testing billed to other third party payers.

The commenter believed that an arrangement under which the referring physician charges payers for the services of a separate laboratory constitutes a compensation arrangement within the meaning of the law. The commenter added that "compensation arrangement" is defined as any arrangement "involving any remuneration." Further, the term "remuneration" is defined broadly to include direct or indirect, overt or covert, and in-cash or in-kind arrangements. The commenter believed, therefore, that an arrangement under which the referring physician can receive payment for services not personally performed or supervised by himself or herself, including payment for services for non-Medicare patients, should be found to be a compensation arrangement within the broad language of the law.

Specifically, the commenter recommended that the final regulation make clear that the definition of "compensation arrangement" encompasses any arrangement under which a referring physician bills and collects for laboratory services that are not personally performed or supervised by the physician.

Response: This commenter raised several issues: first, whether anatomical pathology services are diagnostic laboratory tests and, thus, subject to the billing requirements of section 1833(h)(5)(A); second, whether the billing requirements of that section can be applied to clinical diagnostic laboratory tests performed for non-Medicare patients; and third, whether the definitions of compensation and remuneration at section 1877(h)(1) can be broadly interpreted to include payments made to the physician for any

laboratory services he or she did not personally perform or supervise, including payment for services for non-Medicare patients. We will address each of these issues in order.

Under Medicare, the term "medical and other health services" includes, under section 1861(s)(3), the broad category of "diagnostic laboratory tests." Under section 1861(s)(16), such diagnostic laboratory tests include only those diagnostic tests performed in a laboratory that meets CLIA requirements. Anatomical pathology services are tests involving tissue examination, such as that done during surgery. We believe that any anatomical pathology tests would be diagnostic in nature and would have to be performed in a laboratory that meets CLIA requirements. As such, the tests fall squarely within the category of "diagnostic laboratory tests" and would therefore be subject to the payment rules in section 1833(h)(5)(A).

Under section 1833(h)(5)(A), payments for clinical diagnostic laboratory tests are subject to mandatory assignment. That is, with certain narrow exceptions, payment may be made only to the person or entity that performed or supervised the performance of the test. Further, under section 1842(b)(6), a carrier generally may pay assigned benefits only to the physician or other supplier that furnished the service. Thus, unless physicians are billing Medicare within the conditions found in these provisions of the law, they are billing in error.

In regard to the second issue, the language of section 1833(h)(5)(A) applies specifically to services for which payment may be made under Medicare Part B. Therefore, we agree with the commenter that the billing requirements found in the Medicare statute do not extend to non-Medicare patients.

In regard to the third issue, under section 1877(e)(8)(A), payments by a physician to a laboratory for clinical laboratory services do not constitute compensation that triggers the referral prohibition.

3. Entity

In the proposed rule (§ 411.351), we defined "entity" as a sole proprietorship, trust, corporation, partnership, foundation, not-for-profit corporation, or unincorporated association.

Comment: One commenter indicated that the statute does not define "entity" and the definition in the proposed regulations could prohibit certain nonabusive arrangements because it covers trusts, foundations, and not-for-

profit corporations. For example, a physician might own stock in a not-for-profit corporation or be a trustee of a charitable trust that operates a laboratory. The commenter suggested that this definition either be modified to contain an exception for nonabusive business entities or that the trust, foundation, and not-for-profit corporation criteria be deleted.

Response: We do not agree with this commenter. Under section 1877, unless an exception applies, any referral for clinical laboratory services is prohibited if the referring physician or a member of the physician's immediate family has a financial relationship with the entity to which the referral is made. This is so because the statute does not, in any way, limit the types of organizations covered by the referral prohibition as long as they provide clinical laboratory services. Therefore, our proposed definition of "entity" was meant to include all possible organizations and associations that provide laboratory testing. As was stated in the proposed rule, we believe that we need to define the term "entity" to ensure that the term is understood by all affected parties. Note, however, that if a trustee takes no compensation from and has no ownership interest in an entity, he or she would not have a financial relationship as defined in section 1877. Therefore, the physician would not be prohibited from referring Medicare patients to that entity. Finally, we are not aware of any situations in which a not-for-profit entity would issue stock.

4. Fair Market Value

Under the proposed rule (section 411.351), fair market value is defined to mean 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 of the lessor when the lessor is a potential source of patient referrals to the lessee. This definition is based on the definition in the statute. (OBRA '93 did not change the statutory definition.)

Comment: One commenter indicated that the statute makes it clear that lease and rental values may not be adjusted to reflect proximity to referral sources. The commenter was concerned about our statement in the preamble to the proposed rule at 57 FR 8599 that certain rental payments could be construed to

induce referrals, even if there is no explicit or implicit understanding regarding referrals. These arrangements would typically involve rental payments either substantially above or below the fair market value of the rental space. The commenter believed that there is still no adequate means to determine when an increase (or decrease) in value will be considered "substantial" and therefore viewed as suspect. The commenter agreed that an example of an abusive arrangement occurs when a physician rents space to a health care entity at a rate above what the market would ordinarily bear, and the entity agrees to the high rent because of an understanding that the physician will refer his or her patients to that entity.

The commenter pointed out that many factors influence what may be considered as "fair market value" in a normally functioning real estate market. For example, the principle that site rents vary inversely with increased travel time pervades the real estate industry. Thus, the commenter concluded, a facility that is convenient to places in which health care services are furnished, such as a laboratory adjacent to a medical building, will command higher rents than one across town.

The commenter suggested that the final rule should reflect some means of differentiating between rent and lease payments that have inherently greater values based on traditional economic factors and those that are "artificially" inflated.

Response: In using the term "substantially" in excess of or below fair market value, we were describing an example of how a rental or lease agreement could be an influence on referrals. Such an agreement could take many forms and incorporate a myriad of possible financial incentives depending on local factors that could influence the rental or lease price. We want to emphasize, however, that the definitions in the statute (section 1877(h)(3)) and regulations (§ 411.351) state that fair market value means that a rental or lease of property must be consistent with the value of the property for general commercial purposes and that a rental or lease of space may not be adjusted to reflect any additional value a lessee or lessor would attribute to the proximity or convenience of a potential source of referrals. Therefore, if the economic factor to which the commenter referred, that is, that site rents vary inversely with increased travel time, plays a part in determining the level of rent agreed to by a physician and a laboratory entity, the fair market value test set forth in the statute would

not be met. This would be the case even if the factor is a "traditional economic factor" that "pervades the real estate industry." In other words, if rent is inflated either artificially or because of its proximity to a referral source, the fair market standard would not be met and the exception would not apply.

5. Financial Relationship

In the proposed rule (section 411.351), we defined a "financial relationship" as either 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 through equity, debt, or other similar means; or
- (2) A compensation arrangement.

The OBRA '93 amendments added that, in addition to equity, debt, or other means, an ownership interest includes an interest in an entity that holds an ownership or investment interest in any entity providing clinical laboratory services. This expanded provision, however, is not applicable until January 1, 1995.

Comment: One commenter expressed strong support for the proposed policy that the prohibition would extend to physicians who are the previous owners of a laboratory, if they are paid by the new owners under an installment sales agreement that extends past January 1, 1992. The commenter indicated that such arrangements can easily be abused; that is, they raise the possibility that the previous owners would make referrals for the purpose of ensuring that the new owners continue to pay off their debt. Similarly, the commenter agreed with our statement that, if an organization related to the laboratory agrees to pay the laboratory's debt to the physician, a financial relationship is still created.

On the other hand, another commenter indicated that we should permit specific debt relationships if the following criterion is met: The debt interest is manifested by a written note that has a fixed repayment schedule unrelated in any fashion to the productivity of the debtor or any entity owned by the debtor, and the debt-equity relationship of the debtor does not exceed 4 to 1.

Another commenter recommended that physicians who remain interested investors through a debt relationship in a laboratory that they once owned not be penalized. That is, the physicians should not be subsequently regarded as having a nonexempt financial relationship with that laboratory.

Response: We agree with the first commenter. A financial relationship may exist in the form of an ownership or investment interest, which, according to the language in section 1877(a)(2), "may be through equity, debt, or other means." We did not propose any exceptions addressing situations involving debt. That is because we do not believe that there would be no risk of program or patient abuse in such circumstances. Obviously, the continued financial viability of an entity that is in debt to a potential referring physician could be of great concern to that physician. Therefore, we are not providing the exception requested.

Comment: Two commenters indicated that the term "indirect relationship," which is used to define financial relationships in proposed § 411.351, should be itself defined or deleted since there is no statutory definition of indirect relationships. According to the discussion at page 8595 of the proposed rule's preamble, "a physician would be considered to have an indirect financial relationship with a laboratory entity if he or she had an ownership interest in an entity which in turn has an ownership interest in the laboratory entity." The commenter stated that, if this is the definition we adopt, that definition should appear in § 411.351 of the final regulations; otherwise, the term should be deleted from the regulation entirely.

Response: We agree with the commenter that our interpretation of indirect ownership or investment interest should appear in the regulation. Therefore, we include it in section 411.351 of this final rule. As specified at section 1877(a)(2), financial relationships that could cause a referral to be prohibited are of two kinds. The first is an ownership or investment interest, which may be through equity, debt, or other means. The second is a compensation arrangement, which, as defined at section 1877(h)(1)(A), is any arrangement involving any remuneration (with certain narrow exceptions added by OBRA '93). "Remuneration" is defined in section 1877(h)(1)(B) as including *any remuneration*, direct or indirect, overt or covert, in cash or in kind. This is a broad concept that, we believe, encompasses compensation/remuneration obtained through an indirect financial arrangement. We further believe that an indirect relationship can occur in the ownership/investment situation as well as under a compensation arrangement. The term "indirect" appears specifically only in the definition of remuneration in section 1877(h)(1)(B), which applies

in the context of compensation arrangements. However, an ownership or investment interest as defined in section 1877(a)(2) may be through equity, debt, or *other means*. We believe that the term "other means" is broad enough to encompass an infinite variety of direct and indirect ownership or investment interests. As a result, we included the concept of an indirect ownership or investment interest in the proposed rule.

It was also our opinion that the Congress intended to cover all forms of financial relationships that may exist between a physician and a laboratory. Any other reading would allow physicians to easily circumvent the statute: they could hold ownership interests in entities furnishing clinical laboratory services by simply establishing and owning shares in holding companies or shell corporations that, in turn, own the laboratories.

The Congress has demonstrated its intention to cover situations involving indirect ownership and investment interests. As amended by OBRA '93, the language at the end of section 1877(a)(2) provides that "[a]n ownership or investment interest may be through equity, debt, or *other means*, and *includes* an interest in an entity that holds an ownership or investment interest in any entity providing the designated health service." [Emphasis added.] This provision became effective January 1, 1995. However, we believe the amended provision demonstrates that, prior to OBRA '93, an ownership or investment held through "other means" could be interpreted to *include* indirect interests.

In addition, in proposing this amendment, the Committee on Ways and Means explained that "[t]he definition of financial relationship would be modified to include *explicitly* that an interest in an entity (i.e., holding company) that holds an investment or ownership interest in another entity is a financial relationship for purposes of the referral prohibition." [Emphasis added.] (H. Rep. No. 111, 103d Cong., 1st Sess. (1993).) In other words, we believe the intent of this amendment was to explicitly list a concept that was already implicitly included in the scope of the provision. The Conference Report for OBRA '93 reveals that the House Ways and Means provision was enacted without changes. (H. Rep. No. 213, 103d Cong., 1st Sess. (1993).) For these reasons, we decline to delete the term "indirect" and intend that it be considered in determining whether particular referrals are prohibited.

6. Group Practice

Under the proposed rule (§ 411.351), a 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:

- Each physician who is a member of the group 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.
- Substantially all of the patient care services of the physicians who are members of the group (that is, at least 85 percent of the aggregate services furnished by all physician members of the group practice) are furnished through the group and are billed in the name of the group and the amounts received are treated as receipts of the group. The group practice must attest in writing that it meets this 85 percent requirement.
- The practice expenses and income are distributed in accordance with methods previously determined by members of the group.

In the case of faculty practice plans associated with hospitals that have approved medical residency programs for which plan physicians perform specialty and professional services, both within and outside the faculty practice, this definition applies only to those services that are furnished to patients of the faculty practice plan.

"Group practice" as defined in section 1877(h)(4)(A), as it reads under OBRA '93, is discussed in section II.D.1.c.4. of this preamble.

a. Threshold for "Substantially All"

Comment: A few commenters suggested that the threshold for what is "substantially all" of the services of physician members should be lowered from 85 percent to 75 percent because rural group practices would have difficulty in meeting the higher percentage. The same commenters noted that, if the threshold for group practices is not lowered, there should be a special threshold for rural group practices that may not be able to meet the 85 percent standard.

Response: The comments we received on the proposed rule have identified group practices that have partners, full and part-time physician employees, and physician contractors, who may also be either full- or part-time. All configurations of physicians must be

able to show that the statutory requirements are met and, specifically, that substantially all of the services of the members are furnished through the group. (We discuss in a later comment which physicians qualify as "members" of a group practice.) As we have mentioned previously in this preamble, it is not our intention to unnecessarily impede associations of physicians from qualifying as a group practice, and we recognize that groups that have part-time physicians may have a more difficult time qualifying than groups that have all full-time physicians.

We agree that the 85 percent criterion should be reduced to 75 percent, and we have made that change in the definition of group practice (§ 411.351). Before deciding to make this change, we considered the implications for group practices that have part-time and contractual physicians and the possibility of establishing separate standards for rural and urban locations and the changes that will be made by the OBRA '93 provision on January 1, 1995. (Beginning on January 1, 1995, members of the group must personally conduct no less than 75 percent of the physician-patient encounters of the group practice.) We accept the point of view that a standard higher than 75 percent would be difficult for many rural group practices to meet. That is because the scarcity of physicians in rural areas generally imposes varying responsibilities that cause these physicians to devote less time to a group practice than might be the case in other areas. In order to be consistent and to eliminate whatever administrative confusion might result from different standards for rural and urban areas, we are adopting the 75 percent standard for all areas.

Comment: One commenter indicated that group practices should be allowed to select the methodology for determining the 85 percent threshold; that is, 85 percent of total physician time, or 85 percent of total group income (calculated on the basis of allowed charges, etc.), or 85 percent of all physicians' services delivered—whatever method they prefer to use and are able to document.

Another commenter recommended that the Medicare allowed charges or fee schedule amounts be used as the measurement criterion for the following reasons: (1) By using such a measure, the necessary data would be readily available to Medicare carriers in the Medicare databases; (2) these measures would not impose any new record keeping obligations on physicians and group practices; and (3) if alternative measures, such as time, patients,

service, or total revenue were used, physicians and group practices would be subjected to additional burdensome record keeping requirements.

A third commenter suggested that the following conditions indicate that the criteria are met: All Medicare allowed charges or fee schedule amounts for the services furnished by all physician members of the group are furnished through the group, and billed in the name of or under a number or numbers assigned to the group practice, and the amounts received are treated as receipts of the group.

Finally, another commenter recommended that we consider (1) excluding from the formula any part-time physician who does not refer work to the laboratory for Medicare patients, and (2) revising the current 85 percent formula to provide that, so long as 85 percent of Medicare laboratory work is attributed to full-time physicians (a full-time physician being a person who bills at least 85 percent of his or her services through the group), the group practice would then be able to meet the exception.

Response: As noted, we proposed that, to meet the "substantially all" criterion, a group practice would have to be able to show that at least 85 percent of the aggregate patient care services furnished by all physician members of the group practice are furnished through the group practice. In addition, as stated in section 1877(h)(4)(B), these services must be billed in the name of the group, and receipts for the services must be treated as receipts of the group. After carefully considering the language of the statute and these comments, we decided to adopt the following approach:

We are continuing to provide that to meet the "substantially all" criterion, in the aggregate, a specific percentage of patient care services furnished by all physician members must be furnished through the group practice. As we noted in an earlier response, we are changing the percentage from 85 percent to 75 percent. The comments have revealed that there is confusion about what constitutes "patient care services" and how to measure them. To remedy this, we are clarifying in the regulation that patient care services include any tasks performed by a group practice member that address the medical needs of specific patients, whether or not they involve direct patient encounters. As a result, patient care services can involve the work of pathologists and radiologists who do not directly treat patients or a physician's time spent consulting with another physician when the patient is

not present or time spent reviewing laboratory tests.

We are also clarifying that a practice must measure patient care services by calculating the total patient care time each member spends on patient care services. We believe that this method of measuring services is an equitable one that will capture most accurately a group practice member's commitment to providing services through the practice. For example, if a member furnishes only a few services through the practice during the course of a week, but these services are surgical procedures that consume most of the physician's time that week, this fact will be reflected in the calculations.

As to the first comment, we do not believe that leaving this matter entirely to the discretion of each group practice would be feasible. It is our goal to accomplish fairness and evenhandedness across group practices by establishing a consistent and uniform approach. Leaving the matter to the discretion of each group practice would also put an additional burden on the Medicare carriers. The carriers could very well be involved in audits of group practices in the future. If we adopted the commenter's suggestion, a carrier would, on the occasion of each audit, first have to determine whether a particular method employed by a group practice is appropriate before determining whether the standard is met. Thus, we are clarifying that, to meet the substantially all criteria, 75 percent of total patient care services (measured as patient care time) of group practice physicians must be provided through the group.

It is not clear to us how using a method employing Medicare allowed charges or physician fee schedule amounts would satisfy the statutory requirements. The carriers would have this information, as the commenter stated, but section 1877(h)(4) does not say that only substantially all of a group practice's Medicare business be considered. The reference is to " * * * substantially all the services of the physicians who are members * * *." Accordingly, we believe that all services, both Medicare and non-Medicare, must be considered.

Here is an example of how our uniform total patient care time approach would work:

Ten physicians deliver services through a group practice. Eight of them devote 100 percent of their patient care time to the group practice. One devotes 80 percent, and one 10 percent. This can be illustrated as follows:

| | | |
|-----------------------------|------|---------------------|
| 8 physicians at 100% each = | 800% | |
| 1 physician at 80% = | 80% | |
| 1 physician at 10% = | 10% | |
| | 890% | divided by 10 = 89% |

Thus, in this example, 89 percent of the total of the time spent by these physicians is devoted to services billable by the group practice. The issues of group practice billing numbers and part-time physicians are discussed below.

Comment: One commenter suggested that the calculations for substantially all services be made, at the election of the practice group, with respect to either the previous fiscal year of the practice group or the previous 12-month period, which is the approach used by the safe harbor regulations. The commenter believed that a 12-month period is appropriate for this purpose in order to avoid short term fluctuations that might otherwise distort the determination.

Response: We agree that a 12-month period is appropriate for use in determining compliance with the "substantially all" criterion. We will allow a group practice (as defined in section 1877(h)(4)) to elect whether to use the calendar year, its fiscal year, or the immediately preceding 12-month period to determine whether it complies with the standard. Furthermore, we will allow any new group practice (one in which the physicians have only recently begun to practice together) or any other group practice that has been unable in the past to meet the requirements of section 1877(h)(4) (including the "substantially all" criterion) to initially look forward 12-months, as described below, to determine compliance with the standard. These groups would also be able to elect whether to use the calendar year, fiscal year, or the next 12-months. Finally, once any group has chosen whether to use its fiscal year, the calendar year, or another 12-month period, the group practice must adhere to this choice.

In new 411.360, each group practice must submit to its carrier an initial attestation that the group has met the "substantially all" criterion (75 percent of patient care time) in the 12-month period it has chosen. New group practices or other groups that wish to initially use future months to meet the "substantially all" criterion must attest that they plan to meet the criterion within whatever upcoming 12-month period they have chosen and will take

measures to ensure the standard is met. After this 12-month period is over, the group must attest that it did meet the standard during that period.

The attestation must contain a statement that the information furnished in the attestation is true and accurate and must be signed by a representative for the group. It must be mailed to the carrier within 90 days after the effective date of this final rule, that is, 120 days after the date of publication of this rule in the **Federal Register**. We are requiring this initial attestation so the carriers will be able to determine whether payment for laboratory services should be continued. After their initial attestation (whether it is retroactive or prospective), group practices must submit updated attestations to the carrier each year at the end of the period they have chosen to use to measure this standard.

If a group practice using an initial prospective period does not meet the "substantially all" criterion at the end of its chosen 12-month period, the group would not qualify as a group practice. As such, an overpayment could exist from the beginning of the period in which the group has claimed that it would meet the "substantially all" standard.

This approach does have paperwork burden implications for group practices. However, we do not believe that the burden is significant. It should be a relatively easy task for most group practice physicians to assess the amount of their patient care time that is spent on services that can be billed in the name of the group.

b. Member of a Group

Comment: Several commenters indicated that we should define more precisely what is meant by a "member" of a group practice because the "substantially all" criteria apply to physicians who are "members" of a group practice. For example, one commenter suggested that for part-time members of a group practice, only that percentage of time/services/income devoted by the member to the group should be assigned to the group for the purpose of calculating the total time/services/income of the group.

Several commenters indicated that the term "member" of the group practice should have a restrictive definition, such as one that is limited to principals of the practice, for example, shareholders, partners, or officers.

Another commenter indicated that the term "member" can be broadly interpreted to include all physician employees or even independent contractor physicians of the group

practice, and that how the term is defined can have significant impact. Yet another commenter recommended that the term "member" be defined to include physician owners as well as full- and part-time employed physicians.

One commenter recommended that the definition exclude any physician who is not a shareholder, partner, or employee of the group, or an independent contractor providing more than a certain number of hours of service per week (for example, 20 hours) for the group. The commenter stated that such a rule is supported by common sense, as it is doubtful that physicians who furnish services on a sporadic basis would consider themselves to be members of a group or qualify for the various benefits associated with being a member of the group.

On the other hand, another commenter stated that, if the term "member" is given a restrictive definition, limited to principals of the group practice, the practice will be able to circumvent the 85 percent aggregate services requirement simply by ensuring that no physician who provides substantial services outside the group becomes a principal of the group. The commenter believed that limiting the definition, however, might restrict the numbers of physicians who may supervise laboratory testing under the in-office ancillary services exception because it applies to only services furnished by or supervised by physicians who are "members" of the same group practice. The commenter also suggested that it might affect where that testing may take place. Under section 1877(b)(2)(A)(ii), testing may be done in a building in which the referring physician (or another physician member of the group practice) has a practice or in another building which is used for the centralized provision of the group's clinical laboratory services. Particularly in multi-site group practices, the referring physicians could be physician-employees or independent contractors who would not be "members." Thus, their laboratory tests would have to be performed in a building in which a member personally supervises the laboratory services. This, however, would not seriously impede the group practice, in this commenter's view, as most group practices could readily set themselves up in a manner that allows for at least one principal to be available for supervision. This commenter further stated that a broader definition of the term "member" that includes all physician employees and/or

independent contractors leads to different results. That is, it might make it more difficult for the group practice to satisfy the 85 percent aggregate services requirement in the definition, depending on the number of part-time employees and contractors. However, it would allow for almost any associated physician to make referrals and supervise the performance of laboratory services.

Response: As evidenced by the range of comments we received concerning this group member issue, whatever approach we select may not address all of the concerns raised by the commenters. Essentially, we agree that the issue of who qualifies as a "member" of a group practice raises a number of complex questions. As we understand it, group practices typically have partners, full-time physician employees, part-time physician employees, and physician contractors.

We take the position that all of these physicians can be members of a group for purposes of the group practice provisions of section 1877. We consider physician partners and full-time and part-time physician employees and contract physicians to be members during the time they furnish services to patients of the group practice that are provided through the group and are billed in the name of the group. Thus, their services would be considered in determining whether the group practice as a whole meets the requirement that substantially all of the services of physician members be furnished through the group.

Examples are as follows:

- A group practice consists of two physician partners, five full-time physician employees, two part-time physician employees, and a contractor physician who spends one morning a week at the group practice delivering specialty services. The two partners and the full-time employees practice only through the group. The two part-time employees devote 50 percent of their time to the group, and the contractor physician spends 10 percent of his or her time with the group.

| | |
|------------------------|------|
| 7 physicians at 100% = | 700% |
| 2 physicians at 50% = | 100% |
| 1 physician at 10% = | 10% |

810% divided by 10 = 81%

- In another group practice, two physician partners spend 100 percent of their patient care hours through the

group. Five part-time physician employees spend 70 percent each, and two other part-time physician employees spend 25 percent of their time at the group practice. A contractor physician devotes 10 percent.

| | |
|------------------------|------|
| 2 physicians at 100% = | 200% |
| 5 physicians at 70% = | 350% |
| 2 physicians at 25% = | 50% |
| 1 physician at 10% = | 10% |

610% divided by 10 = 61%

In these examples, using 75 percent as the threshold, the first group practice would qualify, but the second would not.

On balance, we believe this approach is the most appropriate and is neither overly restrictive nor overly permissive. It will eliminate problems that might arise for many group practices that employ physicians or contract for the services of physician specialists on a part-time basis. Because this approach is not overly restrictive, we do not believe it will obstruct rural group practices. On the other hand, as demonstrated in the above example, the inclusion of part-time physicians may cause some group practices to fail to meet the 75 percent aggregate requirement.

To clarify our position about this issue, we have included the following definition under section 411.351 ("Definitions"):

Members of the group means physician partners and full-time and part-time physician employees and physician contractors 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.

c. Individual Billing by a Group Practice Physician

Comment: A few commenters indicated that some group practices permit the physicians of the group to bill Medicare under their unique physician identification number. Under the proposed rule, they do not meet the definition of a group practice because services furnished by the group physicians are not billed in the name of the group. The commenters requested an exception for a few group practices that actually practice medicine as a group but do not qualify because of this element of the new definition of group practice.

One commenter indicated that many group practices have made a decision to have each physician bill independently and reassign benefits to the group rather than for services to be billed under the group's provider number. This decision is based on the desire of some physicians within the group to be nonparticipating physicians but only for the services billed by the group as group services. (As nonparticipating physicians, they can bill the beneficiary directly and charge for the part of the bill that is more than the Medicare approved amount, with certain limitations.) According to the commenter, the physicians would agree to bill under a group provider number except for an informal, nonregulatory position that all physician members of a group practice must make a joint decision to be either participating or nonparticipating physicians. The commenter recommended that the final rule clarify that billing in the name of the group allows for physician members of a group to make individual choices about participating or not participating in Medicare. It was suggested that such a decision could be made at a "department level" within the group practice by differentiating between specialty categories.

Response: The definition of a group practice set forth in section 1877(h)(4)(A) requires that substantially all of the services of physicians who are members of the group be provided through the group and be billed in the name of the group. (Beginning January 1, 1995, services must be billed under a billing number assigned to the group.) Under this language, an organization whose individual physicians bill in their own name does not constitute a group practice. Additionally, the services of a physician who does not bill in the group's name cannot be counted in determining whether the group practice satisfies the substantially all criteria.

We recognize that, under the in-office ancillary services exception found in section 1877(b)(2)(B), the physician who performs or supervises the performance of the services may also bill for those services. As mentioned above, however, when a physician bills in this manner, he or she is doing so as a solo practitioner and not as a member of a group practice.

Finally, when a bill is submitted in the name of the group on an assignment-related basis, it is the group that accepts assignment. A Medicare participation agreement under section 1842(h)(1) is an agreement to accept assignment in all cases. Therefore, any participation agreement with respect to services

furnished by a group must be entered into by the group and must apply to all services that the physicians furnish as members of the group.

d. Structure of a Group Practice

Comment: One commenter stated that the definition of "group practice" applies not only to professional corporations and other single entities but also to "similar associations." The commenter believed that, when a group practice is organized into two separate entities that are organizationally interrelated through common ownership, administration, or similar substantial and ongoing connections (more than merely their joint ownership of a clinical laboratory), the two entities together should qualify as a similar association under the statute, thus allowing the two entities to satisfy the group practice criteria in the aggregate.

The commenter believed that if such entities are not aggregated for purposes of the group practice definition, then the primary care entity that has the laboratory must qualify separately as a group practice. Further, under the group practice definition, as set forth in the proposed rule, this may be impossible. The commenter described a situation involving a primary care entity and a specialty care entity. These two entities share certain office space, facilities, equipment, and personnel that physicians practicing in both entities jointly use. Thus, as stated by the commenter, there are two group practices sharing a laboratory facility. The commenter believed that each physician member of these entities does furnish the full range of his or her services through the joint use of space, facilities, equipment, and personnel, and the entities allocate the costs of this use on a formulaic basis. The commenter believed the organizational structure described in this situation should meet the conditions in the statute. The commenter pointed out that the preamble to the proposed rule states that each member of the group must individually furnish substantially the full range of services he or she routinely furnishes *through the group practice*. The commenter argued that this language is contradictory to the statute, which requires that each physician who is a member furnish the full range of services *through the joint use of shared space*, etc.—not furnish the full range through the group practice. The commenter suggested that the final rule state the actual requirements.

Response: It appears to us that what the commenter is describing is a situation in which two interrelated group practices share a laboratory. The

physicians' services exception under section 1877(b)(1) allows members of the same group practice to refer Medicare patients to each other for clinical laboratory services, as long as one of the physicians either personally performs the services or personally supervises the provision of the services. Thus, section 1877(b)(1) clearly contemplates physicians *within the same* group practice, but not physicians in different group practices. The in-office ancillary exception in section 1877(b)(2) allows members of the same group practice to refer to each other as long as the physician providing or supervising the services meets the tests in section 1877(b)(2) (A) and (B) for personal performance or direct supervision, location, and billing.

To qualify for the in-office ancillary services exception, an organization of physicians must meet the definition of a "group practice" under section 1877(h)(4). Under the definition, a 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." We agree that, in including a "similar association" in the list, the Congress has provided some flexibility for different kinds of entities to qualify as group practices. Nonetheless, we also believe that the statutory definition clearly contemplates only single legal entities. We do not view two independent group practices as a single practice, just because they are organizationally interrelated through common ownership or other substantial and ongoing connections.

We believe that the statute would have explicitly allowed for a "common ownership" or "substantial connection" configuration as part of the group practice definition had the Congress intended to include it. Also, it appears to us that using the premise of common ownership or substantial connection to combine individuals and entities could lead to far-reaching exceptions to the referral prohibition that we do not believe the Congress ever intended. For example, two solo practitioners could state that they are interrelated through shared administrative services and their common ownership of a shared laboratory, thus qualifying them as a similar association.

As we explain throughout this preamble, we do not believe that a clinical laboratory that is shared by associations of physicians who do not meet the definition of a single group practice will generally qualify for the in-office ancillary services exception. However, each individual physician in

these groups might qualify separately for the exception by meeting the requirements in section 1877(b)(2). That is, the physician must personally furnish the services or directly supervise the individual(s) that are furnishing the services. Further, the services must be furnished in a building in which the referring physician furnishes physicians' services unrelated to clinical laboratory services, and the services must be billed by the physician or an entity wholly owned by the physician.

Comment: One commenter indicated that we should address the issue of group practices that may include more than one legal entity as long as the entities either are in parent-subsidiary relationships or are under common ownership and control. The commenter stated that the proposed definition of group practice requires an entity to be legally organized, and gives multiple examples of the types of legal entities typically used in group practices. The commenter believed the definition is silent on the question of whether a group practice may have more than one such legal entity under a common umbrella. For example, a "parent" professional corporation or partnership might own subsidiary entities for real estate and/or equipment ownership or for billing or ancillary services. Alternatively, rather than having a parent/subsidiary relationship, these same types of separate entities might operate jointly under the common ownership and control of a core group of physicians. These separate structures have been highly desirable for reasons related to taxation, benefits, liability, debt service capacity, etc.

Response: This commenter was concerned about groups of physicians who furnish services through a "group practice" that is composed of several legal entities. The commenter believed that such a group practice should be able to take advantage of the in-office ancillary services exception as long as the entities are in either parent-subsidiary relationships or are under common ownership and control. The commenter specifically mentioned examples in which a professional corporation might own subsidiaries for providing equipment, for billing, or for ancillary services.

The definition of "group practice" in section 1877(h)(4)(A) means a group of 2 or more physicians, legally organized as a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association. As we have said elsewhere in this preamble, we believe that the statute contemplates a group

practice that is composed of one single group of physicians who are organized into one legal entity. In short, we do not believe that a group practice can consist of two or more groups of physicians, each organized as separate legal entities.

However, we do not believe the statute precludes a single group practice (that is, one single group of physicians) from owning other legal entities for the purpose of providing services to the group practice. Thus, a group practice could wholly own a separately incorporated laboratory facility which provides laboratory services to group practice or other patients. However, because the group practice physicians have an ownership interest in the laboratory, they could be prohibited from referring to the laboratory, unless an exception applies.

The physicians could qualify for the in-office ancillary services exception, provided they meet the requirements for supervision, location, and billing. This exception does not appear to dictate any particular ownership arrangements between group practice physicians and the laboratory in which the services are provided. In fact, the billing requirement in section 1877(b)(2)(B) allows the services to be billed by the referring physician, the group practice, or an entity wholly owned by the group practice. The exception appears to anticipate that a "group practice," as defined in section 1877(h)(4), may wholly own separate legal entities for billing or for providing ancillary services.

e. Corporate Practice of Medicine

Comment: Two commenters indicated that there are legitimate physician group practice structures and relationships that may not satisfy the definition of a group practice as set forth in the proposed rule. A specific concern is with group practice organizations affiliated with hospitals that are organized in compliance with State corporate practice of medicine statutes.

In States that have these statutes, according to the commenters, only a validly-organized professional corporation or professional association can enter into employment arrangements with physicians.

One of the commenters presented an example of a group practice that is organized as a nonprofit hospital affiliated corporation that owns a clinical laboratory. The nonprofit hospital-affiliated corporation will be unable to employ the physicians; that is, a separate professional corporation must be established to employ the physicians in accordance with applicable State law. Typically, this commenter claimed,

nonprofit corporations will not qualify as the appropriate vehicle for a for-profit professional corporation or association.

The commenters believed that entities such as those described above (joint not for profit/for profit structures) that meet certain specific standards should qualify under the "similar association" language of the group practice definition. They believed that, so long as all other requirements established by the Secretary relating to appropriate standards for group practices (including the performance of services, billing practices, location of facilities, and income distribution provisions) are met, these entities do not pose a threat of abuse to the Medicare program and, as a result, they should be considered as a single group practice under the definition. To ensure that only appropriate entities qualify, one commenter suggested that (1) the separate professional corporation be organized for the sole purpose of providing medical services to the nonprofit corporation/group practice and be obligated to furnish those services exclusively to the nonprofit corporation, and (2) that the nonprofit corporation perform all other services associated with a group practice (including laboratory, billing, etc.) and employ all nonphysician staff.

Response: We believe the commenters are asking that we regard a joint structure, such as a nonprofit hospital-affiliated corporation linked with a professional corporation or association, as one group practice. This designation would allow the physicians in the professional corporation or association to refer to the nonprofit corporation's laboratory under the physicians' services or in-office ancillary services exceptions in section 1877(b).

In order to meet the definition of a group practice, there must be one identifiable legal entity. As we understand it, the clinical laboratory is owned by a nonprofit hospital-affiliated corporation but, because of the corporate practice of medicine requirements, that nonprofit corporation is unable to directly employ the physicians. As a result, the physicians are members of a separate professional corporation or association. The hospital-affiliated corporation and the professional corporation or association are separate legal entities that cannot qualify as one group practice. Also, because the hospital-affiliated corporation cannot directly employ the physicians, the exception in section 1877(e)(2) does not apply. (This exception allows referrals by a physician when there is a compensation arrangement between an entity and a

physician for the employment of the physician.)

We see one possible exception for a nonprofit corporation that is affiliated with physicians who perform certain physician services. Under section 1877(e)(3), as amended by OBRA '93, there is an exception from the prohibition on physician referrals in the case of a personal service arrangement involving remuneration from an entity to a physician, or to an immediate family member of a physician, providing—

- The arrangement is set out in writing, is signed by the parties, and specifies the services covered by the arrangement;
- The arrangement covers all of the services to be furnished by the physician (or an immediate family member of the physician) to the entity;
- The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement;
- The term of the arrangement is for at least 1 year;
- The compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value, and, except in the case of a physician incentive plan, is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties;
- The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law; and
- The arrangement meets any other requirements the Secretary imposes by regulation to protect against Medicare program or patient abuse.

If the nonprofit corporation (that owns the laboratory) and the professional corporation or association (that has physician investors) have such an arrangement, the physicians would not be prohibited from referring laboratory testing to the nonprofit corporation's laboratory.

f. Not-For-Profit Corporations

Comment: One commenter asked about the provision that permits group practices to be legally organized as not-for-profit corporations. The proposed rule defines a "group practice" as "a group of two or more physicians legally organized as * * * a not-for-profit corporation * * *." The commenter, however, stated that not all group practices organized as not-for-profit groups have physicians as their original incorporators or corporate members, nor

is this required by State law. As an example, the commenter stated that tax-exempt hospitals often have affiliated group practices, and the group practice's operating entity (to which the commenter referred as a "physician-directed clinic") might be a not-for-profit corporation separate from the tax-exempt hospital entity that employs the physicians. This arrangement does not present a potential for abuse, in the commenter's view, although it is unclear whether a not-for-profit physician-directed clinic organization affiliated with a not-for-profit hospital in this manner meets the definition of a group practice. Therefore, the commenter recommended that the final regulation recognize the arrangements.

Response: As we understand the commenter's example, a tax-exempt hospital employs physicians who are part of an affiliated not-for-profit physician-directed clinic that was originally organized by the hospital. (Under Medicare, a physician-directed clinic is one in which (1) a physician (or a number of physicians) is present to perform medical (rather than administrative) services at all times the clinic is open; (2) each patient is under the care of a clinic physician; and (3) the nonphysician services are under medical supervision. (See Medicare Carriers Manual, section 2050.4.)) Further, we understand the commenter to be making the following suggestions:

- That an entity attempting to qualify as a group practice need not have been organized (or incorporated) by physicians; that is, as long as the entity is one in which two or more physicians have been brought together as a group practice, it does not matter that the initial organizing was done by nonphysicians.
- That an entity that, in fact, is a physician-directed clinic, organized by an affiliated hospital, be permitted to qualify as a group practice.

As to the first suggestion, the commenter referred to only the regulations, but the definition of "group practice" at section 1877(h)(4) also requires that there be "two or more physicians legally organized" as a not-for-profit corporation or as one of several other specified associations. Because the statute is silent about who must actually legally organize the association or operate or control it, we believe that any individuals or entities can assume these tasks, as long as the group practice meets all of the other specific requirements in section 1877(h)(4). Thus, if a clinic (or other facility) is legally organized to include two or more physicians and provides the services of physicians, it is a group

practice, even if it is established, operated, and controlled by a nonphysician group or corporation. This would be so regardless of who employs the physicians (in the scenario presented by the commenter, the clinic physicians were employed by the hospital that established the clinic).

g. Individual Pathology Services

Comment: One commenter suggested that the proposed regulations may preclude arrangements under which a group practice retains the services of an independent pathologist to direct the group's laboratory or otherwise assist in improving the quality of laboratory services available. The commenter wrote that the group practice may not be able to satisfy the definition of a group practice laboratory for purposes of section 1877(b)(2) if it retains the services of an independent pathologist who is not considered a member of the group, but who provides medical direction to the laboratory. Second, according to the commenter, an independent pathologist affiliated with a reference laboratory may be unwilling to provide consulting services to a group practice laboratory unless the consulting arrangement is specifically excepted by the regulations. Therefore, the commenter requested that the final regulations provide that (1) a pathologist retained by a group practice on a regular, part-time basis to direct, supervise, and otherwise assist in the performance of laboratory services be considered to be a member of the group practice; and (2) the services of a pathologist serving as a laboratory consultant be included within the category of exceptions set forth in proposed Section 411.359(e)(1)(i) (that is, service arrangements with nonhospital entities).

Another commenter requested that we develop an additional exception relating to compensation arrangements involving the provision of consulting services, as opposed to the furnishing of actual testing services. The commenter suggested that the arrangement would have to be: in writing, consistent with fair market value for the consulting services provided, and not conditioned on referral of laboratory services from one party to the other or otherwise related to the volume or value of referrals for laboratory services.

Response: First, part-time or contract physicians, including independent pathologists, may be considered members of a group practice if they meet the conditions in the "member" definition in § 411.351. As indicated by the commenter, a group practice can hire a pathologist to direct, supervise, or

otherwise assist in performing laboratory tests. We agree that this is an important point because the most significant advantage of a practice meeting the group practice definition is that it qualifies the group for the in-office ancillary services exception in section 1877(b)(2). This exception applies if the referring physician or *another member* of the same group practice either performs or directly supervises the performance of the laboratory services. A group practice would not be able to use the section 1877(b)(2) in-office exception if it is a group practice member who is referring patients to the group's laboratory, but it is a nonmember pathologist who is performing or supervising the laboratory services.

The second concern of the first commenter involves an independent pathologist, who is somehow "affiliated" with an outside laboratory, who might be unwilling to provide consultation services to a group practice laboratory unless the consulting arrangement is specifically excepted from the prohibition by the regulations. Following is our analysis of such a situation.

First, the group practice laboratory is itself a laboratory entity that is compensating a pathologist (physician) for certain services the physician is providing and that relate to the group's laboratory services. We believe the pathologist could refer to the group practice laboratory if this arrangement fits within the exception in section 1877(e)(3). Section 1877(e)(3) excepts from the term "compensation arrangement" payments *from an entity to a physician* for personal services provided by the physician under an arrangement. The arrangement must meet certain criteria (for example, the arrangement must list the specific services in writing, be signed, be reasonable and necessary, and compensation must be for fair market value).

Section 1877(e)(3) does not appear to differentiate between physicians receiving compensation on the basis of whether they are independent contractors who also service other outside laboratories or whether they are employees or owners of outside laboratories.

The group practice could also be regarded as a group of physicians who may be purchasing services from an outside laboratory (if the pathologist is employed by or owns the outside laboratory). If this is the case, the compensation could instead be excepted under section 1877(e)(8). This provision excepts payments *made by a physician*

to an entity as compensation for items or services other than clinical laboratory services if they are furnished at a price that is consistent with fair market value.

If the pathologist is considered a member of the group practice and makes referrals to the outside laboratory, whether the referrals would be prohibited depends upon the nature of the pathologist's relationship with the laboratory. The referrals might not be prohibited if the pathologist is the employee of the outside laboratory. In that situation, the payment the pathologist receives from the outside laboratory would not be "compensation" under section 1877(e)(2), which exempts any amount paid by an employer to a physician who has a bona fide employment relationship with the entity for the provision of services if certain standards are met.

If the pathologist is independent but contracts with the outside laboratory, the compensation that flows from the outside laboratory to the pathologist could be excepted under section 1877(e)(3). This provision excepts remuneration from an entity under a personal service arrangement if certain standards are met.

If the pathologist owns the outside laboratory though, his or her referrals would be prohibited. That is because the pathologist would be referring to a laboratory in which he or she has an ownership interest (the section 1877(e) provisions except only compensation arrangements). Finally, if the pathologist is a member of the group practice, none of the group practice members can refer to the laboratory that is owned by the pathologist. That is because, in Section 431.351 of the proposed rule, we defined "referring physician" as a physician (or group practice) who makes a referral. Thus, any referral by one group practice member is imputed to the entire group practice.

7. Immediate Family

Under the proposed rule (§ 411.351) an "immediate family member" of a physician 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-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

Comment: Two commenters recommended that we adopt what they believed to be a more manageable definition of immediate family member. They recommended eliminating, at the very least, the references to

grandparents, grandchildren, and assorted in-laws.

One of the two commenters recommended that the definition include "natural or adoptive parent, child or sibling" and exclude the remainder of the identified relatives. In this commenter's view, the definition of immediate family reaches beyond what is intended by the statute.

Response: As we stated in the proposed rule, our proposed definition is a longstanding definition used (in § 411.12) by the Medicare program to implement section 1862(a)(11), which excludes from Medicare coverage services furnished by an immediate relative. We also explained that, in our view, the definition encompasses the range of relatives who could be in a position to influence the pattern of a physician's referrals. These commenters simply stated their opinion that the definition is overreaching, without explaining why.

For these reasons, we are retaining the definition as proposed.

Comment: One commenter suggested that when an allowable clinical laboratory service is performed as part of a medical consultation by a family member of the referring physician, we should not prohibit that referral solely because the consulting physician is related to the referring physician.

Response: Under the definition of referral in section 1877(h)(5)(A), the request by a physician for an item or service covered under 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, constitutes a "referral" by a "referring physician." The first physician has, in sending his patient to the family member, made a referral under the statute.

If the family member performs or supervises the performance of the laboratory test, it is likely that the family member has either an ownership interest in the entity that performed the test and/or is compensated by the entity for supervising or performing the test. As a result, the first physician has referred a patient for laboratory tests to an entity with which his or her immediate family member has an ownership or compensation relationship. If no exceptions apply, this makes the referral a prohibited one. If the consultant family member merely orders the laboratory test from a laboratory in which neither he or she nor the first physician has a financial interest, the referral would not be prohibited.

We also point out that section 1877(h)(5)(C) provides that if a pathologist performs a laboratory test or supervises the performance of a test that is part of a consultation requested by another physician, the furnishing of the test by the pathologist or his or her request that the test be completed (under the pathologist's supervision) is not a referral. In other words, a self-referral by a pathologist as a result of a consultation does not constitute a referral for purposes of section 1877.

Comment: One commenter is a solo practitioner whose office is located in a building owned by herself and six other physicians, one of whom is her husband. In the building, there is an independent laboratory that is owned by the group practice to which her husband belongs. The laboratory was established by the physicians in the building for the practices in the building. The commenter did not think it is right that, because her husband has an ownership interest in the laboratory, her patients should not have access to it.

Response: Unless an exception applies, it appears, on the face of it, that the commenter is correct in stating that her referrals to the independent clinical laboratory would be prohibited. Her relationships with the laboratory appear to be as follows:

- She may have been an investor in the laboratory, because she was one of the "physicians in the building" who set the laboratory up "for the practices in the building."
- She is the spouse of a member of the group practice that now owns the laboratory.
- She is part owner of the building that houses not only the laboratory, but her solo practice and her husband's group practice as well.

It appears, therefore, that this physician, in addition to being an immediate family member of what may be a partial owner of the laboratory, may also be an investor in the laboratory herself (depending on the nature of her initial involvement in setting up the laboratory and any current financial interest) and may have a compensation arrangement with the laboratory based on rentals she presumably receives as a part owner of the building. We believe, however, that her family relationship generally controls to prohibit her referrals if her husband has an ownership or investment interest in the group practice or its laboratory or if he receives unexcepted forms of compensation from the group practice.

The physician's referrals would not be prohibited on the basis of her husband's ownership interest if the laboratory qualifies as a rural laboratory under

§ 411.356(b)(1). Note that, as discussed elsewhere in the preamble, unless the group practice that owns the laboratory satisfies the definitional requirements, referrals by group practice physicians to the laboratory might also be called into question.

8. Practice

In the proposed rule (411.351), we defined a "practice" to mean an office in which the physician, as a matter of routine, sees patients for purposes of diagnosis and treatment and where patient records are kept.

Comment: One commenter indicated that many group practices provide medical services in satellite facilities where only limited medical services are offered and that the medical records of the group practice are kept in a centralized location. Thus, the commenter recommended that we clarify in the final rule that the definition of "practice" is not incorporated into the definition of "group practice."

Another commenter stated that some physicians maintain a medical practice without being tied to a particular location, such as certain hospital-based physicians and those who treat nursing home patients. These physicians use office space only to receive mail and for other administrative support functions. Such a practice, be it group or individual, does not have an office for purposes of diagnosis and treatment, or even to keep substantial amounts of medical records. The commenter believed this fact is not taken into account in the definition.

Response: We acknowledge that the commenters have raised some legitimate problems with the proposed approach and how difficult it is to determine where someone has a "practice." We are responding to these comments by creating a new, more equitable standard that is not based on the concept of a physician's "practice" (and thus eliminate the definition from the rule). We are using the new standard required by OBRA '93, which states that to qualify as a rural provider, substantially all of the clinical laboratory services furnished by the entity must be furnished to individuals residing in the rural area. As part of this standard, we are defining "substantially all" as meaning that 75 percent of the individuals to whom services are furnished reside in the rural area. Although the effective date of this provision for rural providers is January 1, 1995, we believe it is reasonable to incorporate it into this final rule.

9. Referral

In the proposed rule (§ 411.351), a "referral" means either of the following:

- 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 other than a pathologist, and any test or procedure ordered by or to be performed by (or under the supervision of) that physician; or
- If a plan of care includes the performance of clinical laboratory testing, the request or establishment of the plan of care by a physician. When a pathologist, in responding to another physician's request for a consultation, furnishes or supervises the furnishing of clinical diagnostic laboratory tests and pathological examination services, the services are not considered to have been furnished on a referral basis.

a. Pathology Referrals

Comment: Two commenters wanted the definition of "referral" to be clarified so as to exclude circumstances in which a pathologist providing professional services to one laboratory sends specimens ordered by the attending physician to a second laboratory in which the pathologist has a financial interest.

One commenter indicated that the definition should also exclude circumstances in which a pathologist recommends to an attending physician appropriate follow-up laboratory services.

Response: Under the definition of "referral" in section 1877(h)(5), a request by a pathologist for clinical diagnostic laboratory tests and pathology examination services will not be considered a referral if such laboratory services are furnished by (or under the supervision of) the pathologist as a result of a consultation requested by another physician. Thus, if the pathologist described in the first comment either performs or directly supervises the performance of the laboratory testing in the second laboratory, the request for services would not be considered a referral by the pathologist. The answer is different, however, if the pathologist sends laboratory work to a laboratory with which he or she has a financial relationship and the services are not performed by the pathologist or under his or her direct supervision. The services in this situation would be considered to have been furnished as a result of a prohibited referral, unless one of the exceptions applies. Similarly, if the pathologist sends tests to a

laboratory with which the first referring physician has a financial relationship, the referral would be prohibited, unless an exception applies. Because we recognize that there are situations in which a physician's request for a consultation with a pathologist could constitute a referral, this final rule revises the proposed definition of "referral" by removing the phrase "other than a pathologist".

We do not consider a pathologist's recommendation to the attending physician for additional testing to be a referral. That is because it is the attending physician who ultimately decides whether such testing is necessary and whether to order the additional testing and from what laboratory.

b. Plan of Care and End-Stage Renal Disease (ESRD) Patients

Comment: One commenter indicated that the proposed rule is ambiguous with regard to the "plan of care" element within the definition of "referral." At one level, the commenter believed, the language is simply unclear in that, with regard to "a plan of care that includes the performance of clinical laboratory tests," it is difficult to understand what is meant by the "request or the establishment of the plan of care by a physician." According to the commenter, this might mean that when a physician establishes a plan of care that entails laboratory testing and the facility or other individual implementing the plan of care orders those tests from a laboratory, the physician shall be considered to have made the laboratory referral. If this interpretation is correct, the commenter believed there are some issues specific to chronic hemodialysis facilities and referrals that require clarification.

The commenter wrote that hemodialysis patients receive three different classes of clinical laboratory tests:

1. Tests ordered on a patient-specific basis on account of particular clinical signs and symptoms and referred by the dialysis facility to an independent or hospital-based clinical laboratory that bills Medicare. These tests pose no interpretive problems, as the physician does, in fact, order each one individually.

2. Routine monthly testing applicable to every patient and for which payment is incorporated into the facility's dialysis composite rate.

3. Testing integral to monitoring the patient during the dialysis treatment itself, performed in the facility and not billed separately.

The commenter pointed out that every time a patient is referred to a facility for chronic renal dialysis, clinical laboratory testing from categories 2 and 3 is required on an ongoing basis as part of the overall care of the patient. If the physician's plan of care for dialysis is deemed to include these tests for purposes of this rule, the commenter believed that the practical result would be to prohibit physicians from making referrals for tests to dialysis facilities in which they have an ownership interest.

A second commenter stated that the ESRD program includes in its composite rate payment methodology most items and services related to the treatment of patients with ESRD, including hematocrit and hemoglobin tests, clotting time tests, routine diagnostic tests, and routine diagnostic laboratory tests. Thus, the commenter pointed out, the determination of whether an item or service is included under the composite rate payment is presumptive and in no way depends on the frequency with which a dialysis patient requires the item or service. The commenter recommended that the final rule, or the preamble to the final rule, explicitly exclude clinical laboratory referrals covered by ESRD from its application.

Response: Section 1877(h)(5)(B) says that "the request or establishment of a plan of care by a physician which includes the provision of [clinical laboratory services] constitutes a "referral" by a "referring physician." The commenter has pointed out that this provision, carried over into the proposed rule, is ambiguous and unclear. The statute could mean (1) that there is a referral when a physician establishes a plan of care or requests that one be established that includes laboratory services or (2) that 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 constitutes a referral. Because the comments reveal that this provision has caused confusion, we have decided to adopt the latter interpretation and have incorporated it into the regulation.

We also agree that it is not clear what technically constitutes a "plan of care." We believe that any time a physician orders any item, service, or treatment for a patient, that order is pursuant to a plan of care. If a plan of care entails laboratory testing and the facility or other individual implementing the plan orders those tests from a laboratory, the physician who established the plan of care is considered to have made the laboratory referral. In addition, as we mentioned in a previous response, the

prohibition could also apply if the individual implementing some or all of the plan of care is a consulting physician. We agree, however, that, under certain circumstances, this may cause problems when those laboratory tests are included in the ESRD composite rate. Thus, as we discuss below, we are including those laboratory tests that are paid under the ESRD composite rate as part of a new exception. We agree that the application of the composite rate constitutes a barrier to either Medicare program or patient abuse because the Medicare program will pay only a set amount to the facilities irrespective of the number and frequency of laboratory tests that are ordered.

c. Consultation Referrals

Comment: A few commenters believed that it was unnecessary for us to include in the preamble the discussion about consultations (57 FR 8595) and the responsibility of a consulting physician to not engage in a cross-referral arrangement. They believed there is no corresponding statutory or regulatory provision and that, except for a small number of truly "bad apples" practicing medicine, physicians have not and will not engage in the complicated and tortuous process of directing referrals.

One commenter was concerned that the proposed rule suggests that physicians who refer to consultants have some obligation to tie the consultant's hands when it comes to which clinical laboratories the consultant can use. The commenter believed such an obligation runs afoul of the principle of medical ethics that requires a physician to refer patients to the entity that furnishes the most efficacious service, regardless of other considerations. The commenter indicated that, in a managed care setting, it may be impossible for the attending physician to even know who the consulting physician is, much less be in a position to dictate which laboratory is selected. In sum, this commenter believed that it will be difficult in practice for physicians to determine where the prohibition ends.

Response: We do not agree with these commenters. In response to the first comment, the discussion in the proposed rule was based on the statute at section 1877(g)(4). This provision says that "any physician or other entity that enters into an arrangement or scheme (such as a cross-referral arrangement) which the physician or entity knows or should know has a principal purpose of assuring referrals by the physician to a particular entity

which, if the physician directly made referrals to such entity, would be in violation of [section 1877], shall be subject to a civil money penalty * * *."

Because the provision applies to physicians who make referrals and to "other entities," we believe that it can apply to consulting physicians who help a physician indirectly make prohibited referrals. In the preamble of the proposed rule (57 FR 8595) we stated that, if a consulting physician deems it necessary to order clinical laboratory services, those services may not be ordered from a laboratory in which the referring physician has a financial interest. We included this explanation to give the reader an example of the kinds of referrals that are prohibited under the statutory definition of "referral." Under section 1877(h)(5)(A), a request by a physician for a consultation with another physician (and any test or procedure ordered by, or to be performed by or performed under the supervision of that other physician) constitutes a referral. Thus, it is necessary for the consulting physician to be aware of any financial relationships the referring physician may have with a laboratory, in order for the referral not to be prohibited. Finally, the consulting physician is also obligated not to refer laboratory testing to an entity with which he or she has a financial relationship, unless an exception applies.

Concerning services furnished in a managed care setting, section 1877(b)(3) provides a general exception for services provided to patients enrolled in the prepaid health plans listed in that provision and in the regulations at § 411.355(c).

d. Statutory Authority

Comment: One commenter noted that the statutory definition of referral encompasses requests for any item or service for which payment may be made under Medicare Part B, but the prohibition contained in the statute is aimed at referrals for clinical laboratory services and not other referrals. Thus, in the commenter's view, the statute makes the rule somewhat confusing. That is, the behavior that the statute seeks to restrict, referrals for clinical laboratory services, is narrower in scope than the behavior of "referring" itself. Therefore, the commenter suggested that the final rule clarify that the prohibited behavior is related to clinical laboratory services.

Response: We agree that the definition of "referral" under the statute at section 1877(h)(5) is broad. In section 1877(h)(5)(A), for physicians' services, it covers a physician's request for any item or service covered under Part B of

Medicare. For other items, section 1877(h)(5)(B) covers a physician's request or establishment of a plan of care that includes furnishing clinical laboratory services. However, section 1877(a)(1)(A) specifically narrows the scope of section 1877 by describing the subset of referrals that are prohibited. Physicians were originally prohibited from making referrals to an entity for the purpose of providing clinical laboratory services. As of January 1, 1995, physicians are prohibited from making a much broader range of referrals to entities furnishing the other designated health services listed in section 1877(h)(6).

e. Hospitals and Group Practice Laboratory

Comment: One commenter believed that, if there is an "under arrangement" agreement between a hospital and a group practice for the group practice to provide laboratory services to hospital patients under section 1861(w)(1), it is the hospital and not the group practice physicians that is making a referral for the purposes of the section 1877 self-referral proscription. The commenter pointed out that, for the most part, as recognized in the proposed regulation, a physician's request for a service is tantamount to a referral to a particular service provider. If services are being furnished to hospital inpatients and outpatients, however, the commenter indicated that it is the hospital's obligation to ensure that the services be performed and to direct that the services be performed by a particular party. Thus, in the commenter's opinion, it is the hospital that is making the referral to the group practice laboratory. Consequently, the commenter recommended clarification of the definition of "referral" and "referring physician" so that it is clear that a physician's ordering of clinical laboratory services for hospital patients does not constitute a "referral" within the meaning of section 1877.

Response: The commenter believed that we should revise the definitions of "referral" and "referring physician" to make it clear that, in the situation described in the comment, it is the hospital that makes a referral to a group practice laboratory and not the group practice physicians. We disagree with this interpretation. Every referral for clinical laboratory services must originate with a physician, and the general rule in section 1877(a)(1)(A) prohibits a *physician* from making a referral to an entity with which the physician (or an immediate family member) has a financial relationship. A "referral" need not even indicate a

specific laboratory. Section 1877(h) defines a "referral" as any request by a physician for an item or service or the establishment of a plan of care that includes the provision of laboratory services.

We do not believe that the Congress intended to allow physicians to circumvent the referral prohibition by imputing their referrals to an operating entity such as a clinic, hospital, or other institution. We believe that "referring physicians" and "referrals" involve only individual physicians or groups of physicians who send a Medicare patient or specimen to a laboratory for services.

Although, in our opinion, the general prohibition applies to the situation described by the commenter, there are exceptions within the statute that could apply to allow the group practice physicians to continue to refer.

The commenter has described a situation in which group practice physicians apparently provide patient care services to hospital patients. They refer hospital patients to the group practice's laboratory; the group practice laboratory provides laboratory services for the hospital under arrangements; and Medicare pays the hospital. The referring physicians in this case are referring to a laboratory that receives compensation from the hospital (the hospital buys laboratory services under arrangements). The hospital is also apparently compensating the group physicians for patient care services. The physicians, in addition, are likely to be receiving compensation from the group practice that owns the group practice laboratory and/or they have an ownership interest in the group practice and its laboratory.

We believe that the exception in section 1877(e)(7) could apply to allow referrals based on part of this scenario. This provision says that there is no "compensation arrangement" that would trigger the prohibition in section 1877, for arrangements between a hospital and a group practice under which the group practice provides laboratory services but the hospital bills for the services, if certain criteria are met. If the arrangement meets the criteria, the group practice should be able to refer to the hospital's laboratory without violating section 1877. That is because the underlying compensation passing between the hospital (which, in essence, is purchasing services from the group practice laboratory) and the group does not trigger the prohibition.

There is, however, a complicating factor in the commenter's scenario. That is, the group practice physicians are referring to their own group practice laboratory. It is likely that these

physicians are receiving compensation from the group practice that owns the laboratory or that they own some portion of the group practice and the laboratory. The compensation or ownership interests involved here would require a separate exception in order to allow the group practice physicians to refer. The services could, for example, be excepted under the in-office ancillary services exception in section 1877(b)(2), which allows a group practice to refer to its own laboratory if certain criteria are met.

In addition, the hospital may be separately compensating the group practice physicians for patient care services, compensation that is independent of the compensation the hospital pays the group to purchase laboratory services. The compensation from the hospital, however, could be excepted under section 1877(e)(2), if there is a bona fide employment relationship between the hospital and the physicians, or section 1877(e)(3) if the hospital is paying the physicians for personal services furnished to the hospital.

10. Referring Physician

We proposed, in § 411.351, to define a "referring physician" as "a physician (or group practice) who makes a referral as defined in this section."

Comment: One commenter believed that the definition of referral is not necessary because the statute is clear as written.

Response: We incorporated this definition in the rule to make the regulations as complete and clear as possible. Furthermore, this definition interprets the statutory term to include referrals made by an individual physician as well as referrals made by a group practice.

Comment: A commenter raised the issue of a physician who owns or manages a clinic but does not function as a physician by providing care to clinic patients. The physician also owns an interest in a clinical laboratory to which clinic patients or samples are sometimes referred. The commenter believed the physician-owner should not be considered a referring physician within the meaning of the regulation when he or she does not function as a physician. The commenter also believed that, if a clinic owner is only incidentally a physician, that professional degree should play no role in setting his or her legal obligations. In the commenter's view, to include physicians who are mere owners/managers of clinics within the definition of referring physician would be arbitrary and prejudicial to them. The

commenter added that such a physician should be compared to nonphysician clinic owners or managers who are not covered by the statute or its implementing regulations. Clearly, according to the commenter, clinic owners or managers with medical degrees should have the same legal status as nonphysician owners or managers. Thus, the commenter recommended that the final regulation, or its preamble, explicitly exclude from the definition of referring physician, physician-owners who neither practice medicine nor make direct referrals to clinical laboratories.

Response: Section 1877 prohibits referrals by "physicians" and does not qualify "physicians" to exempt any subset of these individuals. Since section 1877 does not define who is a physician for purposes of that section, the usual Medicare definition of that term applies. "Physician" is defined in the statute, at section 1861(r), as a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he or she performs that function or action (including osteopathic practitioners within the scope of their practice as defined by State law). The definition also includes a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, and a chiropractor. These additional individuals qualify as "physicians" only when they are performing within the scope of their license or providing items and services that they are legally authorized to perform within their specialty. The Medicare regulations define "physicians' services" at 410.20 as those furnished by one of these individuals who is legally authorized to practice by the State and "who is acting within the scope of his or her license." Arguably then, a physician who owns or manages a clinic but does not provide any of the items or services authorized within the scope of his or her license would not be a "physician" for purposes of section 1877. However, if such an individual refers clinic patients to a particular laboratory or attempts to influence a clinic physician to make such referrals, that individual's status changes. That is, he or she has become involved in the care of particular patients and is therefore acting in the role of a physician. As a result, the provisions of section 1877 (including the provision prohibiting circumvention schemes and indirect referrals) would apply.

11. Remuneration

We proposed, in section 411.351, to define "remuneration" as "any

payment, discount, forgiveness of debt, or other benefit made directly or indirectly, overtly or covertly, in cash or in kind."

a. Discounts

Comment: Some commenters supported the concept of including discounts in the definition of remuneration. They indicated that it is not unusual for a physician with substantial Medicare business to obtain a larger discount than a physician who has no Medicare business. Discounts, in the view of these commenters, can therefore influence a physician to use a particular laboratory and, in an extreme case, the prospect of a deeper discount may even induce a physician to order unnecessary tests.

One commenter offered the opinion that the intent of the legislation is clear from the definition of "compensation arrangement," which is defined to include all forms of remuneration, direct or indirect, overt or covert, in cash or in kind.

Another commenter indicated that the existence of a discount arrangement has a strong potential to result in excessive laboratory testing, which contributes to the distressing rise in health care costs in this country.

Some commenters objected to including "discounts" in the definition of remuneration because they believed the term "discounts" is vague, overbroad, and impossible to define. In their view, the definition would be fraught with unintended adverse consequences. One commenter believed that a compensation arrangement, for the purpose of section 1877, should be created only whenever the following situation occurs: (1) Some remuneration passes from a laboratory to a physician; and (2) the prospect of remuneration gives the physician an incentive to order increased testing.

One commenter indicated that, to a certain extent, physicians receive a lower price than other payers because of the legitimate cost savings associated with physician billing.

Two commenters stated that there is nothing inherently abusive about discounts. One of the commenters believed that what gives the physician an incentive to increase his or her utilization of testing is not the discount; it is his or her ability to mark up the testing and thereby derive a profit from the transaction. The other commenter suggested that discounts be permitted if the laboratory can meet the following conditions:

- The discount is not tied to the referral of Medicare specimens to the laboratory.

- The discount is related to verifiable cost differences in handling specimens that satisfy the conditions for the discount, including cost differences due to such factors as economies of scale, lower billing and collection costs, prompt and regular payment, or reduced bad debt cost.

- The discount is available to anyone who can satisfy the requirements for the discount, for example, type of test or other objective requirement; and

- The discount is not provided to any referring physician. (We assume by this that the commenter meant that discounts a laboratory entity would make to providers of services, such as hospitals, would be permissible under these guidelines.)

Response: As discussed earlier, section 1877(e)(8)(A), as added by OBRA '93, provides that a physician may make payments to a clinical laboratory in exchange for furnishing clinical laboratory services and continue to refer Medicare patients to that laboratory. There is no requirement that the payments meet any particular pricing standards. However, when a laboratory provides a physician with a discount, it may in some cases be providing that physician with a benefit (that is, remuneration) that is separate from the payment that the physician has made to the laboratory to purchase laboratory services. Since we are not interpreting the OBRA '93 provisions in this rule, but merely reiterating them, we have not yet taken a position on how this new provision will affect discounts. We will interpret section 1877(e)(8)(A) and how it applies to discounts in the context of the proposed rule covering all of the designated health services.

In regard to discounts for items and services other than clinical laboratory services, a physician may purchase other things from a clinical laboratory besides clinical laboratory services. Section 1877(e)(8)(B) allows a physician to purchase from any entity items and services, other than laboratory services, as long as they are purchased at fair market value. Section 1877(h)(3) defines fair market value as the value in arm's-length transactions, consistent with the general market value, which would not include discounts. In light of section 1877(e)(8)(B), we are keeping "discounts" in the definition of "remuneration." As a result, discounts would remain "compensation arrangements" for discounts on items or services such as supplies or personnel or consulting services purchased by a physician from a clinical laboratory or other entity.

Comment: One commenter indicated that providing a discount to physicians

is not necessarily a means of providing them compensation. As an example, the commenter pointed out that in New York, a State that has long had a direct billing law and related regulations, discounts are passed directly on to the patient or insurance carrier. It is a market mechanism that, in the commenter's view, actually works to hold down the cost of health care. The commenter considered discounts a goal to be aimed for, not a practice to be precluded. The commenter indicated that a simple way to help hold down the cost of health care is to follow the direct billing practices established in New York or to exempt those States that already have such laws.

Response: This commenter made a good point. Nonetheless, the Medicare statute generally does not currently authorize us to impose the "direct billing" requirement found at section 1877(h)(5)(A) for laboratory services other than those furnished to Medicare patients. As we noted in an earlier response, we will address the discount issue in our proposed rule covering the designated health services.

Comment: A commenter stated that physician groups often contract with HMOs to provide medical care for HMO members and described the following situation: The physician group is paid a predetermined monthly rate per enrollee as payment in full for all outpatient medical services, including laboratory services furnished to covered enrollees. To ensure that the physician group can furnish all necessary services in an efficient and cost effective manner, the physician group typically enters into discount agreements with providers not affiliated with the group to furnish services to the HMO's patients at a discounted rate. These arrangements include laboratory services at a discounted rate.

In the commenter's view, this type of discount arrangement would not pose any risk of Medicare program or patient abuse under the following conditions:

1. The HMO does not bill the Medicare program for any Medicare patient laboratory tests performed by an outside laboratory.
2. The physician group does bill commercial insurance for tests performed but does not mark up the cost of the test; that is, the group bills the exact amount charged by the outside laboratory.
3. The discount arrangement is not, in any way, influenced by the volume of Medicare patient laboratory tests sent to the laboratory facility.
4. The discount arrangement is based upon the volume of laboratory services purchased for HMO patients.

5. An agreement to provide laboratory services to HMO patients at a specified fee or discount that is not based upon volume of Medicare referrals is revenue neutral as far as the Medicare program is concerned. In other words, the fixed discount or specified fee is established completely independently of the volume of Medicare referrals and certainly independently of the Medicare program itself.

Response: We believe that the exception set forth in sections 1877(b)(3) and section 411.355(c) applies in this situation, at least in part. Under those provisions, the prohibition on referrals does not apply to referrals for services furnished by an organization with a contract under section 1876 to an individual enrolled with the organization. (Also see 42 CFR part 417, subpart C.) This exception also applies to referrals for services furnished by organizations with health care prepayment plans that have agreements with us under section 1833(a)(1)(A) to an individual enrolled in the plan (see 42 CFR part 417, subpart D) and by organizations receiving payments on a prepaid basis for their enrollees in accordance with the terms of a demonstration project authorized 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). Also, as added by OBRA '93, this exception applies to referrals for services furnished by a qualified HMO (within the meaning of section 1310(d) of the Public Health Service Act) to its enrollees. Thus, the exception no longer requires that all HMO plans contract with Medicare in order to qualify for the exception. The exception in section 1877(b)(3) applies to all services furnished by the organizations listed in that provision, including those services furnished to enrollees by outside physician groups, which have contracted with the organizations. As we noted in earlier responses, we will address the issue of how to treat discounts under section 1877 in the proposed rule covering the designated health services.

b. Forgiveness of Debt; Other Benefits

Comment: One commenter indicated concerns with the inclusion of the term "forgiveness of debt" in the definition of remuneration. According to the commenter, there are a number of legitimate reasons why a laboratory might forgive a debt owed by a physician. For example, there might be a dispute over the correctness of a bill or over whether the physician had in

fact ordered certain tests. In such instances, a laboratory might decide to write off the debt. In contrast, the laboratory might decide to furnish services to a physician who had previously owed money to the laboratory, which the laboratory had written off. This same commenter recognized that forgiveness of debt in such a situation might be an abuse; that is, the laboratory might simply forgive an obligation owed in order to obtain continued referrals. Thus, the commenter agreed that the forgiveness of debt should be considered remuneration within the meaning of the statute, but added that the definition should distinguish between the atypical situation and routine types of write-offs.

One commenter believed that the inclusion of "other benefit" in the definition of remuneration is very broad. The commenter believed the definition could reach a variety of services that are integral to the provision of laboratory services and that enhance the quality of the services furnished. Examples of "other benefits" that might be exchanged between a physician and laboratory mentioned by the commenter are test tubes and other laboratory testing supplies, telecommunications equipment such as stand-alone printers, courier services, and educational or consultation services.

Another commenter recommended that the definition of remuneration be amended to exclude from the prohibited category those items or services that are enhancements to the quality of laboratory services and that have no value independent of the laboratory service, such as courier pickup of samples, increased frequency of pick up of samples, and electronic transmission of results.

One commenter recommended that the definition of remuneration be amended to exclude "discount, forgiveness of debt, or other benefit" and that we retain the statutory definition.

Response: Section 1877(h)(1) as amended by OBRA '93 specifies that a "compensation arrangement" does not include arrangements involving only the following kinds 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 as follows:
 - + To collect, transport, process, or store specimens for the entity providing the item, device, or supply.

+ To order or communicate the results of tests or procedures for the entity.

This provision also excepts payments made by an insurer or self-insured plan to a physician for the physician's claims under certain circumstances.

Thus, we believe that, when a laboratory writes off a debt to essentially correct the records between the parties, the exception described above would apply. However, if a laboratory has a continual pattern of disposing of the debt of its referring physicians in this manner, we might scrutinize the situation under the circumvention scheme provision (section 1877(g)(4).) Negotiations between parties about the correct amount of money owed for services delivered, resulting in a balancing of accounts, would also qualify under this exception, as well as the exchange of certain laboratory supplies, telecommunications equipment, and courier services.

One commenter mentioned that "other benefits" exchanged between a physician and a laboratory could be educational or consultation services. Section 1877(e)(3) provides that a physician who has a personal services arrangement (or an immediate family member with a personal services arrangement) with a laboratory entity (for example, to furnish consultations or educational services) may refer patients to that entity if certain conditions are met. Also, section 1877(e)(8)(B) allows a physician to make payments to any entity (including a laboratory) for items and services, other than clinical laboratory services, if the purchase is consistent with fair market value.

Because of these facts, we are retaining the proposed definition of remuneration but are explaining that certain day-to-day business transactions as listed in the statute are not included in this definition.

c. Payments

Comment: One commenter objected to including the term "payment" in the definition of remuneration. This commenter pointed out that payments frequently occur between laboratories and physicians and, in many instances, these payments do not create incentives for physicians to order increased laboratory testing. For example, in the commenter's opinion, the following situations do not create incentives for physicians to increase their laboratory referrals.

- The laboratory *pays* a physician who furnishes interpretation or consultation services such as Pap test interpretation, tissue pathology

consultations, or EKG holter monitor readings.

- A laboratory *pays* a physician a refund as a result of an overpayment or to settle a disputed claim.

- A laboratory that maintains a self-insured group medical plan for its employees *pays* a physician who furnished services to a laboratory employee.

- A laboratory *pays* a physician to be on call to come to its blood-drawing station in case of an emergency, as required by State law.

- A physician *pays* the laboratory for the provision of a nonlaboratory service that it furnishes or that is furnished by a subsidiary or related corporation, for example, billing, management or consultation services, or the provision of some other medical product or service.

Response: As stated above in response to a similar comment, section 1877(h)(1)(B) provides that, for purposes of determining whether a compensation arrangement exists, the term remuneration includes "any remuneration, directly or indirectly, overtly or covertly, in cash or in kind." One of the definitions found in the American Heritage Dictionary of the English Language for "remuneration" is "payment." Therefore, we believe we are correct in concluding that, in general, payments between a laboratory and a physician are a form of remuneration. Arrangements involving remuneration between these parties can, in turn, be characterized as "compensation arrangements." Most, if not all, of the examples provided by the commenter could now fall within specific statutory exceptions. Examples one, three, and four could be excepted under section 1877(e)(3), which excepts certain situations in which an entity pays a physician under a personal service arrangement. The second example could be remuneration that is excepted from the definition of a "compensation arrangement" under section 1877(h)(1)(A) and (C), and the fifth example could be excepted under section 1877(e)(8)(B), which excepts payments by a physician to an entity in exchange for items or services other than clinical laboratory services.

We realize that many legitimate transactions occur between laboratories and physicians. We believe that most of these will qualify for the exceptions listed above. But, in the case of continuing arrangements that provide for payment between laboratories and physicians that do not qualify for the exceptions, the prohibition applies.

D. Prohibition on Certain Referrals by Physicians and Limitations on Billing

1. Medicare Only

Comment: One commenter indicated that the final regulation concerning the prohibition should include a statement that a physician's referrals for non-Medicare patients to receive clinical laboratory services, which are not reimbursable under Medicare, are not affected by section 1877 or this rule.

Another commenter requested that the final rule confirm that the statute and the proposed rule do not apply to State Medicaid programs.

Response: In the preamble to the proposed rule (57 FR 8595), we stated that the general prohibition on referrals applies only to referrals for clinical laboratory services that would otherwise be covered by the Medicare program. Therefore, referrals for clinical laboratory services to be furnished to a physician's non-Medicare patients are not affected by section 1877. This concept is reflected in section 411.353(a) of this rule. As a result of section 13624 of OBRA '93, however, section 1877 will have an effect on the Medicaid program beginning with referrals made on or after December 31, 1994. (We plan to address this matter in a separate proposed rule.)

2. Related Parties

Comment: The preamble to the proposed rule (57 FR 8596) states that a financial relationship between a physician and an organization related to an entity that furnishes clinical laboratory services (for example, a parent or subsidiary corporation of the laboratory entity) is to be considered an indirect financial relationship with the entity.

One commenter believed that this concept needs clarification and that it would be helpful to have some "bright line" rules for what constitutes a related entity. The commenter asked several sets of questions, which, as we understand them, are as follows:

- Is the related entity concept limited to a parent/subsidiary model or will brother/sister corporations be included?
- Is the relationship between the entities to be defined in terms of a stock ownership requirement and, if so, will a threshold percentage of ownership be required?

In this regard, the commenter suggested that we may want to review the control group concepts set out in sections 414(b) and 414(c) of the Internal Revenue Code of 1986 (IRC) and to consider adopting a similar approach.

Furthermore, the commenter asked questions involving the following situations and suggested that it would be helpful to have specific examples presented in the final rule.

- Twenty-five percent of a clinical laboratory is owned by a professional corporation (P.C.) that, in turn, is owned by five physicians as equal shareholders. The P.C. also employs physicians who are not owners.

—Would a referral to the laboratory by a physician employed by the P.C. be prohibited?

—Would referrals by any of the owners of the P.C. be prohibited?

- Two of the five physician-owners of the P.C. separately own the 25 percent interest in the laboratory rather than the entire P.C.

—Would a referral to the laboratory by a physician employed by the P.C. be prohibited?

—Would a referral by one of the remaining three owners of the P.C. be prohibited?

- A company that is a general partner in a surgery center limited partnership also owns a clinical laboratory. The surgery center has as other limited partners a number of physicians. Can physicians who are limited partners refer patients to the company's laboratory?

Response: First, we want to state that it is not possible to provide specific answers to cover every possible variation of financial relationship. As noted elsewhere in this preamble, we receive a large volume of correspondence. To the extent that there is some uncertainty or confusion concerning a particular provision of the statute or regulation, we are ready to discuss the matter by telephone or in writing. We can, however, only provide our views about general questions; as mentioned previously, we cannot provide formal advisory opinions on specific circumstances.

In regard to the first set of questions, the commenter was concerned about indirect financial relationships with entities. As we explained in an earlier response, we believe that the language of the statute is intended to support indirect, as well as direct, financial relationships, as was specified in proposed section 411.351. In the preamble to the proposed rule, we stated that this would cover financial relationships with an organization related to an entity that furnishes clinical laboratory services. We gave as an example an interest in a parent or subsidiary corporation of the laboratory entity. The commenter's first question was whether the related entity concept

was limited to parent/subsidiary situations or whether brother/sister corporations would also be included.

Although the preamble gave the example of a parent or subsidiary relationship between entities, we believe that a physician can have an indirect financial relationship with a laboratory entity under any circumstances in which that physician owns some portion of an entity that has an ownership interest in the laboratory entity. This would be true regardless of whether the entities are related as parent/subsidiary or brother/sister corporations. In other words, these relationships are not the determining factor. For example, a physician's ownership interest might be in a nonlaboratory subsidiary of a parent laboratory corporation. If the physician has an ownership interest in the subsidiary without owning any portion of the parent laboratory, the physician will not be considered to have an ownership interest in the laboratory. The physician would have an ownership interest in the laboratory only if the nonlaboratory subsidiary had an ownership interest (for example, through stock or debt instruments) in the parent laboratory.

We believe the analysis is similar for brother/sister corporations or entities. Subsidiary entities that are related via a common parent may or may not have any ownership interest in each other. If a physician has an ownership interest in a subsidiary that, in turn, has an ownership interest in a brother laboratory, the physician could be regarded as having an indirect ownership interest in the laboratory. However, this would not be the case if the brother/sister corporations have no ownership relationship.

The commenter also asked whether the relationship between entities depends upon stock ownership and, if so, what threshold percentage of ownership is required. The statute in section 1877(a)(2) defines as a financial relationship any ownership interest, regardless of the manner in which the interest is held or the amount of the interest. We believe this rule applies to all ownership interests, whether they are direct or indirect.

Our analysis of corporate relationships would also involve any compensation aspects of the relationships. As we said in the preamble to the proposed rule, any financial relationship between a physician and an organization related through ownership to a laboratory entity could be covered as an indirect financial relationship with the laboratory entity. In addition, even if a physician has an

ownership interest in a corporation that has no ownership interest in a laboratory entity, the physician may gain certain financial advantages from the relationship between the nonlaboratory entity and a laboratory that could constitute compensation to the physician from the laboratory. For example, if corporations file as one affiliated company, they may pool their gains and losses for tax purposes. As a result, a physician owner could receive some benefits from the affiliation.

The commenter recommended that we adopt an approach for related entities that is similar to that of the control group concept under the IRC. Generally, under section 414(b) of the IRC, employees of all corporations that are members of a controlled group of corporations (within the meaning of section 1563(a) of the IRC) are treated as employed by a single employer. Under 414(c) of the IRC, all employees of trades or businesses (whether or not incorporated) that are under common control are treated as employed by a single employer. Furthermore, under section 1563(a) of the IRC, a controlled group of corporations generally means the following:

- A parent-subsidiary controlled group is one in which one or more chains of corporations are connected through stock ownership with a common parent corporation.
- A brother-sister controlled group is one in which two or more corporations have five or fewer persons (individuals, estates, or trusts) owning certain levels of stock and controlling certain levels of voting power of all classes of stock entitled to vote.

Since we believe that the statutory language is very broad and encompasses both direct and indirect financial relationships, we cannot accept the commenter's suggestions to use the concept of a control group. Such a concept would narrow the scope of the provisions and would, thus, be inconsistent with the statute.

The commenter raised questions about several specific scenarios. In the first, a P.C. that is owned by five physicians owns 25 percent of a clinical laboratory. The P.C. also employs physicians. Referrals by physician-owners of the P.C. to the laboratory that is owned, in part, by the P.C. would be prohibited, unless an exception applies. Clearly, these five physicians have an ownership interest in the laboratory, even though it is indirectly held through their ownership of the P.C. We also believe that referrals by physician-employees of the P.C. may be prohibited depending upon the following facts. If the P.C. is not a group practice and

employee-physicians are receiving remuneration from the owner physicians for their services as bona fide employees of the P.C., then, under section 1877(e)(2), the remuneration would not constitute a "compensation arrangement" if the (e)(2) requirements are met. The remuneration, therefore, would not subject the employee-physicians to the prohibition.

If the P.C. is a group practice, the employee physicians could be considered "members of the group." If so, the referrals of any one member of the group are imputed to the entire group. Because members who are owner physicians in the example may not be able to refer, then neither can the employees, unless an exception applies. If the P.C. is a group practice, the arrangement would need to be evaluated under the in-office ancillary services exception in section 1877(b)(2). That exception does not appear to dictate any particular ownership arrangements between group practice physicians and the laboratory in which the services are furnished. A group practice can take advantage of this exception, and members can refer to each other in the laboratory provided that the group meets the definition of a group practice under section 1877(h)(4). Under the exception in section 1877(b)(2), the services must be furnished by the referring physician or a group member or must be directly supervised by a group practice member. In addition, the services must be billed by the referring physician, the group practice, or an entity wholly owned by the group practice.

In the second scenario involving a P.C., the facts are different. Here two of the five physician-owners of the P.C. have an ownership interest in the laboratory, and this laboratory interest is separate from their ownership of the P.C. Obviously, referrals by those two physicians to the laboratory are prohibited, unless an exception applies. While additional facts surrounding this situation might lead to a different conclusion, it appears that referrals by the remaining three physician-owners of the P.C. and by physician-employees of the P.C. would probably not be prohibited. This is so because, in this case, the P.C. has no ownership interest in the laboratory and the other physicians have no ownership interest. Although the employees are perhaps indirectly compensated by the two owners, their referrals would not be prohibited if their employment arrangement meets the requirements in section 1877(e)(2). If the P.C. is a group practice, however, referrals of any member of a group practice (including

owners and employees of the practice) would be precluded, unless an exception applies, such as that in section 1877(b)(2). We stress that this conclusion is based on a minimal amount of information; the conclusion could change if it became apparent that any of the three physician owners or physician employees were receiving any income or compensation, directly or indirectly, from the laboratory. We also stress that sanctions could apply if this turns out to be a circumvention scheme.

Concerning the last question, our analysis of this situation indicates that referrals by limited partner physicians would not be prohibited as long as these physicians do not have a financial relationship with the laboratory or with the company that is a partner in the surgery center. That is, the physicians cannot have an ownership or investment interest in the laboratory itself or the company that owns the laboratory. In addition, there can be no compensation passing between the physicians and the laboratory or between the physicians and the company. When physicians and a company are partners in an enterprise such as a surgery center, their joint ownership does not necessarily mean that there is compensation or payment passing between them; they may simply both be investors. If the arrangement, however, is structured so that there is any compensation passing between the physicians and the company or the physicians and the laboratory, the physician's referrals to the laboratory would be prohibited, provided no exception applies.

Finally, we again remind the commenter that section 1877(g) sets forth sanctions that may be imposed if certain requirements of section 1877 are not met. For example, any physician who enters into an arrangement or scheme that the physician knows or should know has the principle purpose of ensuring referrals by the physician to a particular entity that, if they were made directly, would be in violation of the prohibition, would be subject to the sanctions imposed by section 1877(g).

3. Identical Ownership

Comment: One commenter suggested that group practices may own and operate a laboratory that has been set up as a separate entity. The commenter believed that this arrangement did not appear to be addressed in the proposed regulation. The commenter pointed out that often a group practice will own and operate a clinical laboratory as a separate entity for various financial, liability, and other legal reasons. This commenter believed that there does not

appear to be any potential for abuse with these arrangements as long as the separate entity is wholly owned by the group practice or as long as there is identical overlap in ownership. Consequently, the commenter requested that the final rule clarify this point.

Response: As mentioned throughout this preamble, section 1877(a) prohibits a physician who has (or whose immediate family member has) a financial relationship with an entity furnishing clinical laboratory services from referring Medicare patients to that entity unless an exception applies. The statute does not contain a specific exception for wholly-owned entities. The commenter has not provided any evidence to convince us that any entity wholly owned by a group practice is free from program or patient abuse. Thus, we disagree with the conclusion reached by this commenter.

Concerning the commenter's reference to an identical overlap in ownership, we assume the commenter means that the same physicians who own the group practice also own the laboratory. As mentioned above, we do not believe that the Congress intended to except entities that are either wholly-owned or that have an identical overlap in ownership from the referral prohibition. Therefore, unless an exception applies, the physician or group practice owners would be prohibited from referring to a laboratory in which they have an ownership interest.

We believe that in many cases the in-office ancillary services exception in section 1877(b)(2) would apply. For example, physicians in a group practice, as defined in section 1877(h)(4), can refer to a laboratory as long as the laboratory services are furnished personally by the referring physician or by another physician in the same group practice, or under the direct supervision of a physician in the same group practice; in a building that is used by the practice to furnish some or all of the group's laboratory services; and that are billed by the group practice or by an entity that is wholly owned by the group. We believe that this exception applies to any group practice that meets these requirements, regardless of who owns the laboratory, or the manner in which it is owned. Also, services furnished by a rural laboratory would be exempted, regardless of the circumstances of ownership.

4. Technical Change

Comment: One commenter recommended that the phrase "under that referral" at the end of proposed § 411.353(b) be changed to "under that

referral that is prohibited by paragraph (a)."

Response: We do not agree that this change is necessary, since "that referral" refers back to the earlier part of the sentence, which says "that is prohibited by paragraph (a) * * *."

5. Refunds

Comment: One commenter indicated that it is not unreasonable for an "entity that collects payment" to be required to make refunds in accordance with these regulations. The commenter believed, however, that the regulations provide no ability for the "entity that collects payment" to obtain the information needed to determine whether it is required to make a refund. The commenter suggested that the regulations either explicitly provide the means for the entity that collects payment to obtain the requisite referral information from the physician ordering the service or hold it harmless for refunds it does not make because it does not have the needed information.

Response: We do not agree with this comment. A laboratory is responsible for knowing with whom it has a financial relationship. Under section 1877(f) and our rule at § 411.361, laboratory entities are required, as specified by us, to provide us with information concerning their financial relationships, including ownership and compensation arrangements and including the names and unique identification numbers of all physicians with financial relationships or whose immediate relatives have financial relationships. Additionally, under the CLIA rules at § 493.634, laboratories are required to provide and update ownership information.

E. General Exceptions to Referral Prohibitions Related to Ownership and Compensation

1. Physicians' Services

We proposed that the prohibition on referrals does not apply to physicians' services that are furnished personally by (or under the direct personal supervision of) another physician in the same group practice as the referring physician.

Comment: One commenter indicated that the proposed rule states that exempt physicians' services would have to be performed in the group practice's office. The commenter questioned whether the exception should be so limited. The commenter believed that if physicians' services, as that term is defined in the proposed rule, are performed in another entity furnishing clinical laboratory services for a group

practice, the exception should apply as long as the physician performing the physicians' services and the referring physician are members of the same group practice. In other words, in the commenter's opinion, the physicians' services exception should apply regardless of whether the clinical laboratory is a group practice laboratory or a laboratory owned by another entity with which the group practice has a financial arrangement.

Response: We agree, in part, with this commenter. This exception applies to a limited number of services, that is, clinical laboratory services that are treated as physicians' services for Medicare purposes in the context of a group practice. We believe that the services can be performed anywhere and under any circumstances as long as they qualify as "physicians' services" and are personally performed or personally supervised by another group practice member and do not otherwise result in a prohibited referral. Thus, physicians' services furnished by group practice physicians do not need to be furnished in group practice offices, provided they meet the other requirements in the statute.

2. In-Office Ancillary Services

Based on the provisions of OBRA '89, we explained in the proposed rule that the prohibition on referrals would not apply to in-office ancillary services if the following conditions are met:

- The services are furnished personally by one of the following:
 - + The referring physician.
 - + A physician who is a member of the same group practice as the referring physician.
 - + Nonphysician employees of the referring physician or group practice who are personally supervised by the referring physician or by another physician in the group practice.
- The services are furnished in one of the following locations:
 - + In a building in which 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.
 - + In the case of a referring physician who is a member of a group practice, in another building that is used by the group practice for centrally furnishing the group's clinical laboratory services.
- The services are billed by one of the following:
 - + The physician performing or supervising the services.
 - + The group practice of which the referring physician is a member.

- + An entity that is wholly owned by the physician or the physician's group practice.

(As discussed later in this preamble, OBRA '93 made significant changes to the in-office ancillary services exception (section 1877(b)(2).)

a. Referrals From Physicians Who Do Not Have a Financial Relationship With the Physician or Group Practice

Comment: One commenter suggested that a significant loophole is created in the proposal by exempting from the referral prohibition certain services provided by the referring physician, under his or her direction, or under the direction of others in the same group practice. The commenter suggested that, under this proposal, a group practice could establish a laboratory in its own office and accept referrals from outside physicians not associated with the group practice. The commenter believed that the acceptance of such referrals from physicians outside the group should result in that laboratory being considered an independent clinical laboratory owned by the physicians in the group. Therefore, the commenter believed that, under the terms of section 1877, the laboratory should no longer be permitted to accept referrals from the outside.

Some other commenters believed that the exemption for in-office ancillary services was adopted with the understanding that clinical laboratory services would be limited to the physicians' or group practices' own patients. According to these commenters, the regulations implementing the legislation should reflect this intent and specifically require that the exception apply only to physician office laboratories that do not accept referrals from physicians outside of the practice.

Another commenter believed that exempted group practice laboratories should meet the following two conditions:

First, the group practice laboratory should be fully financially integrated with the group practice, such that all group members and only group members share in laboratory expenses and income, and those expenses and income are distributed among group members in precisely the same manner and proportion as professional fees and expenses.

Second, the group practice laboratory should not be allowed to accept referrals of any tests from nongroup members.

This commenter believed that these restrictions would guarantee that the laboratory is in fact an extension of the group practice and not a distinct

business operating under the protection of the group practice.

On the other hand, another commenter recommended that we definitively state in the final rule that furnishing laboratory services on referral from outside sources will not disqualify a group practice laboratory from the in-office ancillary services exception if the laboratory meets all of the performance standards set forth in the definition of "group practice" in the statute and the proposed rule.

Response: There are two distinct issues that need to be addressed in responding to these comments. The in-office ancillary services exception in section 1877(b)(2) provides that the prohibition on referrals will not apply to those services that are furnished personally by the referring physician, a physician in the same group practice as the referring physician, or by individuals who are (as amended by OBRA '93 and effective on January 1, 1992) directly supervised by the physician or another physician in the same group practice. This exception further contains location and billing criteria. It is our belief that this exception was provided for those clinical laboratory services that are performed as an adjunct to the patient care services of the attending physician. As such, the solo physician, the group practice, or an entity that is wholly owned by the physician or group practice must bill for the services.

On the other hand, the general prohibition on referrals applies only to referrals for clinical laboratory services made by a physician to an entity with which he or she or an immediate family member has a financial relationship. Section 1877 does not prohibit either a solo practitioner's laboratory or group practice laboratory from accepting referrals from outside physicians who do not have a financial relationship with the laboratory. When the solo practitioner or group practice, however, accepts referrals from sources outside of its office practice, the office laboratory is also acting as an independent laboratory because these services are not performed as an adjunct to the patient care services of the attending physician. As a result, the laboratory must have a billing number from the Medicare carrier and directly bill for the services that are performed on referral.

A physician or group practice cannot bill for the laboratory services furnished to the patients of another physician as if they were the physician's or group's own patients, under the physician's or group's provider number.

To summarize, we do not find anything in section 1877 that would

prohibit a physician or group practice office laboratory from accepting referrals from physicians who do not have a financial relationship with the laboratory, physician, or group. However, if such referrals are accepted, they cannot be billed by the physician or group practice. Rather, billing must be done under a billing number that is assigned by the Medicare carrier to the laboratory itself.

We would also like to point out that, if a member of the group is either performing or supervising the laboratory services, the quantity of outside tests could affect the group's ability to qualify as a "group practice" under the definition in section 1877(h)(4). Under (h)(4)(A)(ii), substantially all of the services of physician members (who now include any physicians during the time they work for the group) must be provided through the group and be billed in the name of the group (beginning January 1, 1995, these services must be billed under a billing number assigned to the group). If group practice members spend too much time supervising laboratory tests that are billed under the laboratory's separate number, the group practice could fail to meet the "substantially all" test.

b. Independent Group Practice Laboratories

Comment: One commenter indicated that, while the point was not addressed in the proposed rule, we issued guidance to the carriers to deal with situations in which a group practice laboratory is also certified as an independent laboratory. The commenter wrote that we stated that the services must be billed differently depending on whether the test was referred for a patient of the group, or the test was referred from outside the group. The commenter suggested that it would be simpler for the groups and the government to have all services (physician, laboratory, and otherwise) billed to Medicare under one group billing number, regardless of the origin of the patient.

Response: We do not agree with this commenter. It has been an established Medicare policy that a laboratory a physician or group practice maintains solely for performing diagnostic tests for its own patients is not considered an "independent" laboratory. This means that the solo practicing physician or group practice can bill for in-office laboratory testing using the physician's or group practice's own billing number. Conversely, a physician providing clinical laboratory services to patients of other physicians is considered not to be furnishing "in-office ancillary" services

and is, therefore, doing business as an independent laboratory. Since this policy has been in effect for over a decade, we believe that physicians or group practices that have been accepting referrals from outside physicians have already established that the laboratory is a separate entity for those tests and they are familiar with the billing rules.

Furthermore, as previously explained, section 1833(h)(5)(A) indicates that payment may be made only to the person or entity that performed or supervised the performance of the tests. There are several exceptions to this rule, including one in which, if a physician performed or supervised the performance of the test, payment may be made to another physician with whom he or she shares a practice. This would apply, for example, if the two members are members of a group practice. Taking these factors into consideration, we affirm that physicians and group practices can bill, under their provider number, for clinical laboratory services performed only for their own patients. If the physicians' or group practices' in-office laboratory also provides reference work for patients of other physicians, that laboratory entity must bill for the services directly under its own number.

c. Furnishing of Tests

Comment: One commenter indicated that the final regulations should provide further guidance regarding the scope of the term "furnished." For instance, the commenter understood that we take the position that consulting services designed to assist a physician in interpreting test results are not considered a part of the furnishing of the clinical laboratory test; rather, these services are considered to be physicians' services. The commenter further understood that we take this position even though interpretation services are included in the Medicare payment for the laboratory service and Medicare makes no other payment for the physician's interpretation services.

Response: At § 411.353(a) in the proposed rule, we defined clinical laboratory services for purposes of section 1877 as those services described in the CLIA regulations at § 439.2. Thus, a service would be covered under section 1877 as a "clinical laboratory service" only if the service is considered a clinical laboratory service under CLIA.

Some services may be billed as, for example, physician's services but they would still be subject to CLIA (and, as a result, to section 1877) if they fall within the scope of services described in § 493.2. This is so regardless of how they are billed. Under § 493.2, a laboratory means a facility for "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 diagnosis, prevention, or treatment of any disease or impairment of, or assessment of the health of, human beings." In short, the services covered under CLIA and section 1877 are those conducted by these facilities and involving the examination of materials derived from the human body.

The commenter has asked specifically about consulting services designed to assist a physician in interpreting test results. We believe that CLIA covers the actual examination of materials, their analysis, and any interpretation and reporting of the results which are performed by a facility that qualifies as a laboratory, as defined in § 493.2. If a laboratory interprets certain test results or hires a consultant who takes the responsibility to interpret them in lieu of laboratory personnel, we believe the interpretation would qualify as a clinical laboratory service. (If a consultant only offers input or information which the laboratory will use in making its own interpretation, the input would not qualify as a clinical laboratory service.)

However, if a laboratory sends test results to an independent physician, any interpretation performed by the physician would not be performed by the laboratory facility. As a result, the services would not constitute part of the clinical laboratory test. If a physician hires a consultant to help interpret the results, the same rule would apply: the consultant's services would not constitute clinical laboratory services if the consultant is performing outside the auspices of a laboratory facility. The services would not be subject to CLIA or section 1877.

If, on the other hand, a physician or group practice hires a consultant to perform, analyze or interpret test results that are performed in the physician's or group's own laboratory, the interpretation would qualify as part of the services performed by a laboratory. These interpretive services would be subject to CLIA and, as a result, to section 1877. If the physician or group practice wishes to qualify under the in-office ancillary services exception, the physician or member of the group practice must supervise any non-physician consultant when he or she performs clinical laboratory services. In addition, the tests must meet the section 1877(b)(2) location and billing requirements.

d. Services an Outside Laboratory May Provide to a Physician's Office Laboratory

Comment: One commenter had concerns about services a laboratory outside the physician's office may provide a physician's office laboratory. The commenter wrote that the final CLIA regulations contain personnel standards that require laboratories performing moderately complex testing to have a laboratory director, a technical consultant, a clinical consultant, and testing personnel who meet certain standards. (See 42 CFR part 493.) In physician office laboratories, for the most part, one of the practice's physicians will function as the laboratory director and also may function in one or more other roles. In some circumstances, however, physicians have asked an independent laboratory entity to serve in, or assist the physician in carrying out the duties of, one of the required positions to the extent permitted under CLIA. For example, an independent entity might serve as the clinical consultant for a number of its physician customers as well as assist a physician in carrying out the duties of the technical consultant. The commenter requested a clarification in the final regulations that such services would not defeat a physician office laboratory's qualification for the in-office ancillary services exception, since the independent contractors will not be employees of the physician.

The commenter believed that, since all laboratories, including physicians' office laboratories, must meet the CLIA standards, the laboratory testing performed in these laboratories is covered under the provisions found in section 1861(s)(3). Since section 1861(s)(3) does not have an employment requirement, the commenter concluded that the physician does not have to employ the personnel as he or she would if the laboratory services were billed and covered as services performed incident to the professional services of the physician under section 1861(s)(2)(A).

Response: Regardless of the setting in which it is performed, if a service involves laboratory tests on human specimens by a laboratory as defined in § 493.2, the CLIA provisions apply. So we agree that the CLIA requirements apply to in-office laboratories of solo-practicing physicians and of group practices. It appears that the commenter is concerned about the requirement in the predecessor provision at section 1877(b)(2) that, in order for the in-office ancillary services exception to apply, services, when not furnished by a

member physician, must be performed by individuals who are *employed* by the physician or the group practice. The employment requirement was eliminated by OBRA '93 retroactively to January 1, 1992. Therefore, under amended section 1877(b)(2), referrals for services to be furnished by any individuals who are directly supervised by the referring physician or, in the case of group practices, by another physician in the same group practice, are excepted. In other words, the in-office ancillary services exception applies to a physician or group practice that has outside contractors furnishing laboratory services, as long as the physician or group practice physicians directly supervise these individuals. In addition, as mentioned previously, a contracting physician may be considered a "member" of a group practice. As a member, the contractor could perform the services without supervision or directly supervise other individuals who perform clinical laboratory services.

Also, in this regard, we have taken the position in the past that clinical laboratory testing performed in physicians' offices is covered only if furnished by the physicians or if the requirements are met for coverage of services incident to the professional services of the physicians under section 1861(s)(2)(A) (see section 2070 of the Medicare Carriers Manual (MCM)). One of the requirements has been that persons performing services incident to the services of a physician must be employed by the physician. However, section 1861(s)(3) states, in pertinent part, that "medical and other health services" covered by Medicare include "diagnostic laboratory test[s]." Section 1861(s)(3) does not exclude diagnostic tests performed in physicians' offices or clinics. The only restriction on coverage under section 1861(s)(3) is set forth in the language following section 1861(s)(14), which states that "[n]o diagnostic tests performed in any laboratory * * * shall be included within paragraph (3) unless such laboratory" meets the CLIA certification requirements or has a certificate of waiver. Because section 1861(s)(3) relates more specifically to laboratory testing than section 1861(s)(2)(A), and because most laboratory testing performed in a physician's office is subject to CLIA, we now take the position that it would be appropriate to provide coverage of these services under section 1861(s)(3). (We are in the process of changing the MCM to reflect this position.) This means that the employment requirement does not have

to be met for purposes of coverage or for purposes of application of the in-office ancillary services exception.

Furthermore, we note that section 1877(e)(8)(B) provides an exception for physicians who contract with an entity outside of their office for items or services, providing the items or services are furnished at a price that is consistent with fair market value. Fair market value is defined in section 1877(h)(3) as meaning the value in arm's-length transactions, consistent with the general market value.

We believe this exception permits a physician to contract with a laboratory outside of his or her office for certain services and to continue to refer testing to that laboratory, providing the services meet the requirements for fair market value. Therefore, an independent laboratory entity will be able to provide personnel to assist a physician in carrying out the CLIA requirements.

Accordingly, from the circumstances described by the commenter, the following conclusions emerge:

- In order to comply with the CLIA requirements, a physician or group practice may contract with a laboratory for the services of various physicians or other personnel. In these cases, as long as the direct supervision requirement is met, application of the in-office ancillary services exception is not jeopardized by the fact that the personnel performing the CLIA-related activities are not employed by the physician or group practice.

- Physicians' referrals to the laboratory with which they contract for the performance of CLIA-related activities will not be prohibited if the contract meets the "fair market value" requirement of the exception found in section 1877(e)(8)(B).

e. Location

Comment: One commenter believed the location requirements of the in-office ancillary services exception arbitrarily distinguish between group practices and solo practitioners. The commenter stated that a referring solo physician, as well as a group practice, should be able to qualify under this exception if the laboratory is located in a building used for centrally furnishing clinical laboratory services. The commenter believed there is no remedial purpose served by requiring that a laboratory with which a solo practitioner has a financial relationship be in the same building as his practice, while permitting a laboratory with which a group practice has a financial relationship to situate the laboratory in a separate building.

Response: We believe that, in creating the exception in section 1877(b)(2) and entitling it "in-office ancillary services," the Congress meant to except situations in which a physician refers patients to the practice's own laboratory located in the physician's practice office, or nearby. As a result, the statute requires that the services be furnished in a building in which the referring physician furnishes physician's services unrelated to clinical laboratory services.

Congress, however, has apparently always regarded the same building requirement as too restrictive for a group practice. Before the enactment of OBRA '93, section 1877(b)(2)(A)(ii)(II) allowed a group practice to refer to a laboratory in another building that was used by the group practice for the centralized provision of the group's clinical laboratory services. OBRA '93 liberalized this provision even more, amending it to allow a group practice to refer to another building that is used for some or all of the group's clinical laboratory services, no longer requiring that the services be performed in a "centralized" laboratory. This provision is effective retroactively to January 1, 1992.

Because group practices can have practice offices in many locations, the Congress appears to believe that it could be difficult to locate the group's laboratory close to all of them. The legislative history for the OBRA '93 amendment points out that a number of group practices own and operate satellite facilities in communities other than the community in which the main clinic facility is located. (H.R. Rep. No. 111, 103d Cong., 1st Sess. 545 (1993))

We have not created an exception under section 1877(b)(4) for solo practitioners who refer to laboratories that are located in buildings other than the ones in which they practice. That is so because we believe the services would cease to be in-office ancillary services if they are referred to an outside location and the solo practitioner might be less likely to directly supervise the services. Also, we have seen no evidence that such an exception would be free from any risk of patient or program abuse.

3. Prepaid Health Plan Enrollees

Under § 411.355(c) of the proposed rule, the prohibition on referrals does not apply to services furnished by one of the following organizations to its enrollees:

- An HMO or a CMP that has a contract with us under section 1876 and 42 CFR part 417, subpart C.
- A health care prepayment plan that has an agreement with us under section

1833(a)(1)(A) and 42 CFR part 417, subpart D.

- An organization that is receiving payments on a prepaid basis for enrollees through 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).

OBRA '93 amended section 1877(b)(3) to also include services furnished by a qualified HMO (within the meaning of section 1310(d) of the Public Health Service Act) to an individual enrolled with the organization.

Comment: One commenter indicated that the HMO exemption appears to be available only for a narrowly defined group of HMOs. The commenter recommended broadening this exemption because HMOs employ utilization review criteria and these criteria serve as a disincentive to overutilize services.

Response: As mentioned above, OBRA '93 provided an exception for referrals to qualified HMOs for the provision of services to enrollees of the HMO. This exception would apply to referrals for Medicare beneficiaries to Federally-qualified health maintenance organizations (FQHMOs) without requiring the FQHMO to enter into a contract under section 1833 or 1876.

Comment: One commenter indicated that the final regulation should permit staff physicians of a Medicare-contracting HMO or competitive medical plan (CMP), or a health care prepayment plan (HCPP) operated under an agreement with HCFA, to refer Medicare beneficiaries to their affiliated clinical laboratories, regardless of whether the beneficiary is enrolled as a member of the HMO/CMP/HCPP.

This commenter presents the case of an entity that contracts with us to furnish covered services to Medicare beneficiaries as an HCPP under section 1833(a)(1)(A). Medical services furnished by the HCPP are predominantly provided at clinic locations by employee and independent contractor physicians. The commenter believed that the proposed regulation would require the clinics to establish two different protocols for their laboratory services: one for their HCPP enrollees and one for Medicare eligible patients who are not enrolled as members of the HCPP, and on whose behalf Medicare pays on a fee-for-service basis ("fee-for-service patients"). The commenter believed this distinction is artificial and could result in different levels of care for certain classes of Medicare beneficiaries. The distinction

should, in the commenter's opinion, be eliminated.

Additionally, the commenter believed that providing a broader exception for referrals by HMO, CMP, or HCPP staff physicians is consistent with the statutory exemptions for services furnished by these organizations. The HMO, CMP, or HCPP exception recognizes that managed care plans may properly organize and operate their own clinical laboratories in the interest of serving their patients efficiently and economically. Those organizations may require their physicians to refer certain clinical laboratory services for both enrolled members and fee-for-service patients to their affiliated laboratories.

Even HMOs, CMPs, and HCPPs that engage physicians to practice in facilities owned and operated by the HMO, CMP, or HCPP may furnish services to Medicare beneficiaries who are not enrolled as members. Often this occurs when a patient "walks in" to the HMO, CMP, or HCPP clinic or when a relative accompanies a person who is enrolled in the plan.

The commenter believed that no purpose would be served by requiring physicians in HMOs, CMPs, or HCPPs that operate clinical laboratories to refer services for Medicare beneficiaries who are not enrollees to another laboratory. The commenter stated that these nonenrollee patients should be entitled to expect the same level of care as enrollees.

Response: As we have noted earlier, OBRA '93 added to the list of prepaid plans in the section 1877(b)(3) exception an organization that is a qualified HMO (within the meaning of section 1310(d) of the Public Health Service Act). The statute specifically excepts from the physician referral prohibition only services furnished by the listed organizations to their enrollees. Our proposed and final regulation reflect this statutory limitation. We decline to add services furnished to non-enrollees as an additional exception under section 1877(b)(4). When HMOs, CMPs, and HCPPs are reimbursed by Medicare on a fee-for-service basis, we believe that there still exists an incentive for these organizations to overutilize services. The Secretary cannot create an additional exception unless she determines that there is no risk of patient or program abuse.

However, physicians who are employed by HMOs, CMPs, and HCPPs may still be able to refer non-enrolled patients to the laboratories that are affiliated with these organizations under other exceptions in the statute. For example, if the physicians only receive

compensation from these organizations under an employment agreement or personal services contract, they can refer to the organizations' laboratory if they meet the requirements in section 1877(e)(2) or (e)(3).

F. Exceptions to Referral Prohibitions Related to Ownership or Investment Interest

1. Publicly-Traded Securities

In proposed § 411.357(a), we provided that physicians who hold an ownership or investment interest in certain entities may make referrals to those entities if the following requirements are met:

- The physician purchased ownership of the entity in the form of investment securities (including shares or bonds, debentures, notes or other debt instruments) on terms generally available to the public.

- The ownership or investment interest is in a corporation that meets the following conditions:

- + It is either listed for trading on the New York Stock Exchange or the American Stock Exchange or is a national market system security traded under an automated interdealer quotation system operated by the National Association of Securities Dealers.

- + It had, at the end of its most recent fiscal year, total assets exceeding \$100 million. These assets must have been obtained in the normal course of business and not for the primary purpose of qualifying for this exception.

As we have discussed elsewhere, OBRA '93 modified section 1877(c) in several ways. First, investment securities no longer have to be those purchased on terms generally available to the public; they must only be those which "may be purchased" on terms generally available to the public. Second, the securities can be those listed on additional exchanges. Third, the investment securities no longer have to be in a corporation with \$100 million in total assets at the end of a fiscal year; now the holdings of the corporation must be measured in terms of "stockholder equity," and the amount has been modified from \$100 million to \$75 million. This amount can now either be measured at the end of the most recent fiscal year or be based on the corporation's average during the previous 3 fiscal years. Finally, OBRA '93 extends the exception to apply to certain mutual funds.

Under the effective date provisions of OBRA '93, the amended version of section 1877(c) was not effective until January 1, 1995. SSA '94 revised this effective date provision to make the

amended version of section 1877(c) effective retroactively to January 1, 1992; however, the revised effective date provision states that, prior to January 1, 1995, the amended § 1877(c) does not apply to any securities of a corporation that meets the requirements of § 1877(c)(2) as they appeared prior to OBRA '93. Section 1877(c)(2), prior to OBRA '93, contained the requirement that a corporation have \$100 million in total assets.

Comment: One commenter supported our proposed requirements. The commenter believed that the additional requirement concerning the purpose in obtaining assets will help eliminate certain obvious sham transactions that followed the passage of section 1877. The commenter suggested the inclusion of additional language requiring that these entities have \$50 million in shareholder equity. Such a threshold, according to the commenter, could help to ensure that the company has actual, hard assets, rather than simply "phantom" assets that are offset by significant liabilities.

Response: After consideration of the comments we received on this issue (see below), we have decided that it would be extremely difficult to prove exactly what a corporation intended when it decided to acquire assets; that is, to sort through a corporation's financial records to try to separate business purposes from nonbusiness purposes. We further believe that it would be difficult to define what is meant by "acquiring assets during the normal course of business." Therefore this final rule does not specify that the assets must have been obtained in the normal course of business and not for the primary purpose of qualifying for the exception.

We agree that the commenter's suggestion for "shareholder equity" is a good one, but we do not believe that the Congress meant to refer to this concept when it included the term "total assets" in the statute. That is so because the OBRA '93 amendments specifically replaced the concept of "total assets" with "stockholder equity," a change the legislative history describes as a modification of the law and not a clarification or explicit expression of what was already implicitly present in the law. Also, the fact that SSA '94 appears to make the \$100 million-total-asset-standard and the \$75 million-stockholder-equity-standard apply simultaneously until January 1, 1995 suggests that they are two different concepts. Beginning on January 1, 1995, the "stockholder equity" standard will prevail.

Comment: Another commenter wished to emphasize the requirement that, in order to qualify for the exception, the general public must have the same opportunity to buy and sell the entity's stock as physician-investors. As noted in the proposed rule, physician-partners in a laboratory should not be permitted to exchange their partnership shares for stock in a new corporation, which is then publicly traded at some later date. The commenter was aware of one entity that has purchased physician-owned laboratories in just this manner. Therefore, the commenter believed that we should emphasize that such conduct is a clear violation of the regulation.

Response: The requirement at issue in the regulation was derived from section 1877(c), as it appeared prior to OBRA '93. Section 1877(c) used to require that investment securities be those *which were purchased* on terms generally available to the public. OBRA '93 amended this provision (the amendment is now retroactively effective as a result of SSA '94) to say that the investment securities are those which *may be purchased* on terms generally available to the public. We will interpret the amended provision and other provisions in OBRA '93 in a proposed rule covering all of the designated health services.

Comment: A few commenters indicated that they disagree with the proposed requirement that the \$100 million in assets must have been obtained in the normal course of business and not for the primary purpose of qualifying for this exception. The commenters believed there is no evidence that the Congress intended to deny protection to entities that meet the \$100 million asset test in part or in whole by acquiring assets for the purpose of qualifying for the exception spelled out explicitly in section 1877(c). The commenters suggested that the purchase of an independent clinical laboratory by a corporation intending to include the purchase in the total assets needed to qualify for this exception is not clearly an example of a corporation trying to circumvent the law through a sham transaction. One commenter went on to state that any corporation and physician involved in a good faith purchase and sale of a clinical laboratory in order to comply with the law would be unfairly penalized by the proposed language.

A few commenters urged that we eliminate the statement in the preamble advising the OIG to treat as a circumvention scheme any effort by an entity to obtain \$100 million principally for the purpose of meeting the "\$100 million in total assets" test.

Response: As mentioned in a previous response, we are withdrawing this interpretation and requiring that the corporation meet one of the following criteria: (1) it has, at the end of its most recent fiscal year or, on average during the previous 3 fiscal years, stockholder equity exceeding \$75 million or (2) until January 1, 1995, it had, at the end of its most recent fiscal year, total assets exceeding \$100 million, irrespective of how those assets were obtained.

The statement that the commenters have asked us to eliminate appears in the preamble to the proposed rule at 57 FR 8600 in the discussion on OIG regulations. Since we are not including a requirement about how the assets are obtained, we are not including language related to this issue in the final rule.

Comment: One commenter indicated that a major ambiguity appears in this exception when one considers how to treat physician investors who have acquired shares prior to the time the laboratory was publicly traded. As written, the statutory exemption might be interpreted not to protect such previously acquired shares since, by definition, they were not acquired in a transaction involving the general public.

The commenter requested that the final regulations specify that, once the laboratory meets both of the exemption's tests (that is, the stock exchange listing and the level of assets criteria), physicians who acquired their shares before this time be permitted to refer patients under certain conditions. That is, physicians can refer provided they own only shares with rights identical to those generally available to the public through trading on one of the specified exchanges.

Response: As we have pointed out in earlier responses, the requirement in the proposed regulation has been modified to reflect the statute, as amended by OBRA '93. OBRA '93 amended this provision (the amendment is now retroactively effective as the result of SSA '94) to say that the investment securities are those which *may be purchased* on terms generally available to the public.

Comment: One commenter requested that we use the same definition of public company that it believes is used by the Securities and Exchange Commission (SEC); that is, the definition used under General Accepted Accounting Principles. The commenter believed that use of this commonly accepted definition is in accord with the "public company" intent of the legislation and will maintain the "bright line" between referrals that can and cannot be influenced by ownership position.

Response: The American Institute of Certified Public Accountants, Inc., defines a public enterprise as a business enterprise—

- Whose debt or equity securities are traded in a public market on a domestic stock exchange or in the domestic over-the-counter market (including securities quoted only locally or regionally); or
- That is required to file financial statements with the SEC.

An enterprise is considered to be a public enterprise as soon as its financial statements are issued in preparation for the sale of any class of securities in a domestic market. (Commerce Clearing House, Professional Standards, AC Section 1072, 024(h).)

We do not believe that this definition adds any clarity to the very specific requirements found in the law; that is, for purposes of section 1877(c), a corporation is an entity that is listed for trading on the New York Stock Exchange or on the American Stock Exchange, or any regional exchange in which quotations are published on a daily basis, or foreign securities listed on a recognized foreign, national, or regional exchange in which quotations are published on a daily basis, or is a national market system security traded under an automated interdealer quotation system operated by the National Association of Securities Dealers.

Comment: One commenter suggested we allow the use of a consolidated balance sheet to show that the \$100 million asset test is met.

Response: A consolidated balance sheet is used for financial reports for a group of affiliated corporations, eliminating intercorporation debts and profits and showing minority stockholders interest. It also is used when, under certain circumstances, multiple related entities must report balances in a combined fashion instead of separately.

Since the statute excepts investment interests in a corporation with a minimum amount of assets (or, under OBRA '93, stockholder equity), we do not believe it is appropriate to aggregate the assets of multiple corporations on a consolidated balance sheet.

In the preamble to the proposed rule (57 FR 8597), we stated that the \$100 million in assets requirement applies only to the corporate entity that furnished the clinical laboratory services, and it does not include assets of any related corporations. This statement is misleading in that it applies only when the stock ownership giving rise to the financial relationship is held in the corporate entity that furnishes clinical laboratory services; it is

incorrect when applied to stock ownership in a corporation that does not itself furnish clinical laboratory services. In the latter case, the assets requirement would apply to the parent corporation (the corporate entity in which the stock is held), not to the subsidiary laboratory corporation.

Therefore, we are clarifying that only the assets of the corporation in which the physician or immediate family member's stock is held may be counted to determine whether the \$100 million asset requirement (or \$75 million in stockholder equity requirement) is met under section 1877(c)(1).

Comment: One commenter indicated that we should permit the grandfathering of financial transactions that were entered into to meet the intent of the legislation with regard to the \$100 million asset test if they were entered into before the effective date of the regulations. The commenter believed that such grandfathering would ease accounting and reporting requirements. Further, the commenter suggested that the final regulations should apply to an organization's fiscal year beginning after the effective date of the rule.

Response: As discussed earlier in this preamble, we are withdrawing our interpretation concerning how a corporation had to have obtained its assets.

In regard to the commenter's suggestion that the final regulations should apply to an organization's fiscal year beginning after the effective date of the rule, we disagree. Section 1877(c)(2), prior to its amendment by OBRA '93, required that a corporation have, at the end of the corporation's most recent fiscal year, total assets exceeding \$100 million. The amended version of this provision requires that a corporation have, at the end of the corporations' most recent fiscal year, or on average during the previous 3 fiscal years, stockholder equity exceeding \$75 million. These statutory provisions require an assessment of a corporation's assets or equity based upon a past year or years. These provisions were effective retroactively to January 1, 1992. We do not believe they can be interpreted to require compliance in the fiscal year occurring subsequent to the publication of this final regulation.

2. Rural Laboratories

In proposed section 411.357(b), we stated that an ownership or investment interest in a laboratory that is located in a rural area will not prohibit the physician owners from making referrals if the following criteria are met:

- The laboratory testing that is referred by a physician who has an

ownership or investment interest in the rural laboratory must either—

- + Be performed on the premises of the rural laboratory; or
- + If not performed on the premises, the laboratory performing the testing must bill the Medicare program directly for the testing.

- The majority of tests referred to the rural laboratory must be referred by physicians who have office practices located in a rural area.

As mentioned in response to a previous comment, we have amended the standards for this exception by eliminating the requirement that a majority of tests referred to the rural laboratory must be referred by physicians who have office practices located in a rural area. Instead, we are adopting the standard required by OBRA '93 that substantially all of the clinical laboratory services furnished by the entity are furnished to individuals residing in such a rural area.

a. General

Comment: One commenter indicated support for our formulation of the exception applicable to laboratories located in a rural area. The commenter was aware of a number of laboratories that were established in rural areas but that serve physician-owners and patients located in large metropolitan areas.

Another commenter stated that this exception protects against abuses by laboratories in rural areas, such as the setting up of a "shell" laboratory with a rural address. This commenter also supported the proposed rule's mandate that at least 51 percent of the tests referred to a rural laboratory be referred by rural doctors. The commenter believed this requirement should help to ensure that the laboratory is in fact serving rural beneficiaries.

On the other hand, a third commenter proposed that the final rule adopt an expanded definition of rural area that would include towns or similar State governmental subdivisions if the population is below 10,000 people and a laboratory located in the area meets the 2 additional requirements set out in the proposed rule. As an additional criterion, the commenter suggested that governmental subdivisions meeting this population standard could be defined as "rural" only if the number of outpatient laboratories in the area was no more than two. The commenter believed that this additional criterion would identify those laboratories that are clearly essential to serving the patient needs of the community.

Response: We agree with the first two commenters and believe that the OBRA

'93 amendment imposing the requirement that "substantially all" of a rural laboratory's services be performed for residents of the rural community indicates that the Congress is aware of and is concerned about the potential for abuse in this area.

What the third commenter urges is recognition of a laboratory entity as a rural provider, despite the fact that the entity is located within a metropolitan statistical area (MSA), if the suggested conditions are met. While we recognize that there may be some laboratory entities located in MSAs that, by virtue of being located in small towns within an MSA, have experiences similar to laboratories located in rural areas, we believe that it would be difficult in any given case to prove that the laboratory's situation actually parallels the situation in a rural area. In addition, it would be difficult and burdensome to make these determinations on a case-by-case basis. Further, at this time, we have no evidence that opening this exception to "nonrural" laboratories would be free of any risk of program or patient abuse, the standard that must be met under section 1877(b)(4).

b. Percentage of Tests and Direct Billing

Comment: One commenter argued that the exception for clinical laboratories in rural areas is too stringent. The commenter was concerned that the proposed requirement that more than 50 percent of the tests performed be referred by physicians whose practices are located in rural areas may present an undue burden on already existing rural laboratories. Those rural laboratories may be forced to close because their viability comes from nonrural business. Thus, the commenter recommended grandfathering existing rural laboratory practices.

Response: Although we have changed the proposed rule, the rule still requires that "substantially all" of a laboratory's services be furnished as rural business. As we explained previously, we believe to meet this standard that at least 75 percent of the clinical laboratory services must be furnished to individuals who reside in a rural area. Section 1877 does not contain an overall "grandfather" clause which would allow laboratory facilities that existed prior to its effective date to continue to accept prohibited referrals just because the laboratories predate the statutory provision. In addition, the statute does not routinely excuse certain referrals because it would be a burden for a facility to alter its business practices in order to fit within an exception. We believe that, instead, the specific

purpose of the statute is to require laboratory facilities to alter their practices in order to avoid abusive or potentially abusive financial relationships. Our approach in the proposed and final regulation for this provision reflects that purpose.

Furthermore, we do not believe that we can specifically except from the prohibition rural laboratories whose viability depends on non-rural business. We do not know at this time how many rural laboratories would have extreme difficulty meeting the requirements in the proposed regulation. Also, as described in previous comments, the situation described by the commenter can result in "shell" laboratory arrangements or otherwise be subject to patient and program abuse.

Comment: One commenter recognized the need to prohibit circumvention schemes by urban laboratories through the rural exemption, but thought that the proposed criteria may have a negative impact on a legitimate rural laboratory as follows: The criteria require laboratory testing referred by an investor physician to be performed on the premises or, if referred to another laboratory, that the testing be billed to Medicare directly by the laboratory performing the tests. This provision would prohibit rural laboratories from referring a limited number of tests to other laboratories and billing for the tests, in accordance with present statutory and regulatory requirements concerning shell laboratories.

One commenter indicated that, if a rural laboratory is not able to bill for reference work, it will be forced to collect patient information and forward it to the reference laboratory. This is necessary to enable the reference laboratory to bill Medicare. The rural laboratory will still be collecting the specimens for forwarding to the reference laboratory, but without compensation. The commenter also maintained that the rule will threaten the ability of small rural laboratories to maintain investment and employment while, on the other hand, the rule rewards large laboratories that already have the advantage of lobbying strength that can affect legislation. Also, the rule will not save the taxpayer any money, as good diagnostics for both treatment and preventive medicine are not a function of who bills Medicare for the tests.

This commenter suggested the following alternatives:

- Eliminate the condition that rural laboratories must perform in-house laboratory testing in order to bill Medicare directly.
- Revise the conditions to read: "if all tests are not performed on the premises, 80 percent of referrals must be made by physicians who have office practices in rural areas and 67 percent of all tests must be performed on the premises, otherwise the laboratory performing the testing must bill the Medicare program directly."

Response: We agree that the requirements we proposed for ownership in a rural laboratory are different from those found in the so called "shell laboratory" provision (section 1833(h)(5)(A)). Under the shell laboratory provision, payment may be made to a referring laboratory for the services of a reference laboratory in any of the following circumstances: the referring laboratory is located in, or is part of, a rural hospital; the referring laboratory is wholly owned by the reference laboratory; the referring laboratory wholly owns the reference laboratory; both the referring laboratory and the reference laboratory are wholly owned by the same entity; or not more than 30 percent of the clinical diagnostic laboratory tests for which the referring laboratory (other than a laboratory described in the "wholly owned" provision) receives requests for testing during the year in which the test is performed are performed by another laboratory. These provisions apply to the payment of Medicare-covered clinical diagnostic laboratory services generally. Section 1877 and these regulations contain additional specific requirements that apply to referrals for clinical laboratory services by physicians who have a financial relationship with the laboratory.

In the proposed rule, we stated that laboratory testing that is referred by a physician who has an ownership or investment interest in the rural laboratory must either be performed on the premises of the rural laboratory or, if not performed on the premises, the laboratory performing the testing must bill the Medicare program directly for the testing. Section 1877(d)(2) specifically provides the exception for referrals for clinical laboratory services if the laboratory furnishing the service is in a rural area. We do not believe the exception is satisfied if the rural laboratory in turn refers the work to a laboratory in a nonrural area.

In addition, we do not see this requirement as conflicting with the more general shell laboratory provision, because our requirement applies specifically to the testing ordered by a physician who has a financial relationship with the laboratory. Thus, all other testing referred to the rural laboratory would be subject to the more lenient provisions of section 1833(h)(5)(A) mentioned above. We continue to support this position. It is our firm belief that the Congress provided the rural provider exception in order that beneficiaries living in rural areas would have access to clinical laboratory services that might not be available without the financial investments of local physicians. Without the safeguards included in this regulation, we believe it would be possible to defeat the purpose of the exception.

c. Future Reclassification of Rural Areas

Comment: One commenter indicated that the final rule should provide that laboratories that currently qualify under the rural exception will not be disqualified in the future based on metropolitan statistical area (MSA) reclassification. This clarification will provide stability to legitimate rural laboratories and avoid future uncertainty and future "fireside" sales.

Response: We do not believe the language in section 1877(d)(2) is susceptible to the suggested "clarification." The statute specifically requires that a rural provider be located in a rural area as defined in section 1886(d)(2)(D).

Thus, a provider must be located in such an area, even if the MSAs are at some point reclassified for prospective payment purposes. In addition, we do not believe we should provide an additional exception for a rural provider whose area has ceased to be rural, since we have no evidence that the exception would be free from all risk of program or patient abuse.

3. Hospitals Outside of Puerto Rico

The OBRA '93 amendments to section 1877 substantially changed the provisions that directly concern physician/hospital relationships. Listed below is a table explaining the provisions prior to OBRA '93 and after OBRA '93, as they are in effect until January 1995; the table also reflects amendments made by SSA '94.

| Before OBRA '93 | OBRA '93 |
|--|--|
| Exceptions for Ownership/Investment and Compensation | |
| 1877(b)(4) exception relating to hospital financial relationships (ownership/investment and compensation) unrelated to provision of laboratory services. | OBRA '93 omitted, but SSA '94 reinstated until 1/95. But see 1877(e)(4) below. |
| 1877(d)(3) exception for hospital ownership | 1877(d)(3) unchanged. |
| Exceptions for Compensation Arrangements | |
| 1877(e)(2) exception for employment and service arrangements with hospitals. | Omitted by OBRA '93; SSA '94 reinstated until 1/1/95 |
| 1877(e)(4) exception for physician recruitment by a hospital | 1877(e)(2) exception for bona fide employment only, with any employer 1877(e)(3) exception for personal service arrangements with remuneration from any entity. 1877(e)(4) exception for remuneration from a hospital to a physician if not related to provision of clinical laboratory services. Still present, as 1877(e)(5). 1877(e)(7) exception for compensation between a group practice and a hospital for services furnished under an arrangement. |

Generally, the prohibition in section 1877(a)(1) on physician referrals excepts physicians who furnish services in certain situations or settings described in section 1877(b) (for example, in-office or HMO settings). In addition, under section 1877(a)(2), a financial relationship with an entity is defined as an ownership or investment interest in the entity except for such interests described in sections 1877(c) and (d). A financial relationship is also defined as a compensation arrangement between a physician (or immediate family member) and an entity, except for the arrangements described in section 1877(e). Of these provisions, the following exceptions directly concern physician/hospital relationships if the hospital either is not located in Puerto Rico or is not a rural provider.

- Under section 1877(d)(3), an exception is provided for referrals for clinical laboratory services to be furnished by a hospital located outside of Puerto Rico, even if the referring physician (or immediate relative) has an ownership or investment interest in the hospital, provided the referring physician is authorized to perform services at the hospital and the ownership or investment interest is in the hospital itself and not merely in a subdivision of the hospital.

- Under section 1877(e)(2), a physician who receives payment from any employer, including a hospital (or who has an immediate relative who receives such payment) will not be prohibited from making referrals to the hospital for clinical laboratory services on the basis of this payment if the employment of the physician or family member is bona fide and for identifiable services. In addition, the terms of the

employment must be for fair market value with no ties to the volume or value of referrals, and be commercially reasonable. Finally, the arrangement must meet any additional requirements imposed by the Secretary.

- Under section 1877(e)(3), a physician who receives (or whose immediate family member receives) remuneration from any entity, including a hospital, under a personal service arrangement will not be prohibited, on the basis of this remuneration, from making referrals to the entity for clinical laboratory services if the arrangement meets the following conditions:
 - + The arrangement is for at least 1 year, set out in writing, signed by the parties, and specifies the services covered.

- + The arrangement covers all of the services to be furnished by the physician (or immediate family member) to the entity.

- + The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement and the compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value and, except in the case of certain physician incentive plans, is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

- + The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.

- + The arrangement meets any other requirements imposed by the Secretary.

- Under section 1877(e)(4), a physician who receives remuneration

from a hospital will not be prohibited from making referrals to the hospital on the basis of that remuneration if the remuneration does not relate to the provision of clinical laboratory services.

- Under section 1877(e)(5), a physician who receives remuneration from a hospital that is intended to induce the physician to relocate to the geographic area served by the hospital in order to be a member of the medical staff of the hospital will not be prohibited from making referrals to the hospital if the following conditions are met:

- + The physician is not required to refer patients to the hospital.

- + The amount of remuneration under the arrangement is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician.

- + The arrangement meets any other requirements imposed by the Secretary by regulation.

- Under section 1877(e)(7), certain group practices may have an arrangement with a hospital to furnish clinical laboratory services that are billed by the hospital. The physicians may make referrals to the hospital for the furnishing of clinical laboratory services, as long as the following conditions are met:

- + Services provided to a hospital inpatient are furnished under an arrangement under section 1861(b)(3).

- + The arrangement began before December 19, 1989, and has continued in effect without interruption since that date.

- + With respect to the clinical laboratory services covered under the arrangement, substantially all of these services furnished to patients of the

hospital are furnished by the group under the arrangement.

+ The arrangement is set out in writing, specifies the services to be provided, and the compensation for the services under the agreement.

+ The compensation paid over the term of the agreement is consistent with fair market value and the compensation per unit of services is fixed in advance and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

+ The compensation provided is under an agreement that would be commercially reasonable even if no referrals were made to the entity.

+ The arrangement meets any other requirements imposed by the Secretary by regulation.

a. Joint Ventures Not Related to the Hospital Laboratory

Comment: One commenter suggested that the condition found in proposed § 411.357(b)(3)(ii) concerning "ownership or investment in * * * a hospital that * * * does not relate (directly or indirectly) to the furnishing of clinical laboratory services" could be construed as precluding a physician who has a financial interest in another hospital/physician joint venture that is unrelated to the clinical laboratory from referring to the hospital laboratory. This commenter recommended that the final rule clarify that physicians with financial interests in other hospital-physician joint ventures will not be precluded from making referrals to the hospital laboratory.

Response: The proposed provision that the commenter asked us to clarify was based on the predecessor provision of section 1877(b)(4), which excepted a physician's financial relationship (ownership/investment interest or compensation arrangement) with a hospital if the relationship did not relate to furnishing clinical laboratory services. This provision was eliminated from the statute by section 13562 of OBRA '93, but was reinstated until January 1, 1995 by section 152(c) of SSA '94. The amended section 1877 also contains, in paragraph (e)(4), a new provision which excepts remuneration from a hospital to a physician if the remuneration does not relate to the provision of clinical laboratory services. Section 1877(e)(4) is retroactively effective beginning January 1, 1992, and remains in effect after January 1, 1995.

As for joint ventures, an exception for an ownership or investment interest held *with* a hospital may not be necessary. That is because section 1877(a)(2) defines a prohibited financial

relationship of a physician *with an entity* as an ownership or investment interest *in the entity*. In the case of a joint venture held with a hospital, if the physician has no ownership or investment interest *in* the hospital, a prohibition based on ownership would not apply at all. That is, even though a physician may own a venture with a hospital, as separate partners, that does not mean that the physician actually owns any part of the hospital.

To determine whether a physician has an ownership interest in a hospital, we must define what constitutes a "hospital" for purposes of section 1877. Under the Medicare statute, section 1861(e) defines a "hospital" as an institution, but we have never specifically defined what constitutes an "institution." Although section 1861 dictates what services and functions a "hospital" must provide to qualify as one, it does not appear to mandate any requirements relating to a hospital's corporate structure.

Hospitals often are structured in complex configurations as the result of tax laws and in response to a variety of business concerns. These configurations make defining a "hospital" almost impossible to do on a case-by-case basis. As a result, we are establishing a test that we believe will be relatively easy to apply. For purposes of section 1877, we are defining a "hospital" as 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. We believe these arrangements, by their very nature, involve situations in which hospitals contract with outside entities because they cannot or do not wish to provide the services themselves.

For example, a hospital might be a parent corporation that provides administrative services but that furnishes patient care primarily through a variety of subsidiaries such as a home health agency, a laboratory, or a radiology unit, each of which is independently incorporated. If the hospital bills Medicare for services provided by a subsidiary, then we regard the subsidiary as part of the hospital. A physician, as a result of this structure, could own a part of the hospital if he or she owns some of the remaining interest in the laboratory or other subsidiary, even if the physician does not own any of the parent corporation.

If a physician owns part of the hospital by virtue of owning some

portion of a separately incorporated subsidiary, then the physician's referrals to the hospital's laboratory could be prohibited (absent some exception). However, if the physician owns part of the hospital by virtue of owning some portion of a separate corporation that provides services other than clinical laboratory services, the exception in section 1877(b)(4) could apply until January 1, 1995. That is, the physician would have a financial relationship with the hospital (an ownership interest in the hospital) that does not relate to the provision of clinical laboratory services.

If, in contrast, a physician has an ownership interest in the hospital as a whole, we believe that this interest is indirectly related to the provision of clinical laboratory services. That is because, in most cases, a hospital's revenues will reflect the revenues earned by its clinical laboratory. It is for this reason that we included in proposed § 411.357(b)(3)(ii) the concept of ownership or investment interests that relate "directly or indirectly" to the furnishing of laboratory services.

Even if a physician has no ownership interest in the hospital (either in its operating entity or in a subsidiary), referrals to the hospital laboratory might still be prohibited, however, if the joint venture is structured so that there is some compensation passing between the hospital and the physician. If the hospital provides remuneration to the physician, that remuneration will result in prohibited referrals, unless an exception applies. Referrals would not be prohibited under section 1877(e)(4) and § 411.357(g) of this final rule if the remuneration is unrelated to the provision of clinical laboratory services; for example, the hospital and the physician might jointly own a free-standing CAT scanning facility. Any remuneration that flows from the hospital to the physician would be excepted if the remuneration relates only to the CAT scanning operation. This result, however, will change when the prohibition on referrals is extended to other designated health services beginning on January 1, 1995.

Comment: There were several other comments relating to the exceptions that apply to financial relationships between physicians and hospitals. Some commenters maintained that there is a conflict between the exception set forth in section 1877(b)(4) and the proposed regulatory exceptions. The argument is that this section of the law establishes a general exception for financial relationships with a hospital if the relationship does not relate to the provision of clinical laboratory services

but that a parallel exception was not included in § 411.355, the title of which is "General exceptions to referral prohibitions related to ownership and compensation." Instead, the commenters pointed out, the proposed rule contains separate exceptions, one for "ownership or investment interests" and one for "compensation arrangements." In the view of these commenters, these regulatory provisions are not consistent with section 1877(b)(4), and they recommended that the regulations be revised so that § 411.355 reflects the content of section 1877(b)(4).

Another commenter had several questions about proposed § 411.357(b)(3)(i) and what is meant by an ownership interest in a distinct part or department of a hospital. The commenter stated that most hospitals are incorporated entities, being either a for-profit or not-for-profit corporation and that parts or departments are assets of the incorporated entity and cannot be owned separately. This being the case, the commenter asked the following:

- How can a physician own an interest in a distinct part of a corporation or was the intention to refer to ownership of entities related to a hospital?
- Why should ownership in an entity related to a hospital cause referrals from a physician to be prohibited if the related entity is not a clinical laboratory (for example, a hospital owns 60 percent of a subsidiary that is not a clinical laboratory and the physician owns 40 percent).
- Why should the facts of this example result in a situation that is any more subject to abuse than one in which a physician has general ownership in the hospital and is authorized to perform patient care services at the hospital?

Response: The first set of commenters maintained that there was a conflict between the exception set forth in section 1877(b)(4) and the proposed regulatory exceptions. We believed that the combination of the provisions at § 411.357(b)(3)(ii) of the proposed rule and § 411.359(g) of the proposed rule effectively incorporated the section 1877(b)(4) provision. We had considered including the content of these two regulatory provisions under one provision in § 411.355, as was suggested in the comment, but that section of the regulation addresses services that can qualify for an exception, whereas section 1877(b)(4) addresses financial relationships that can qualify. Since under section 1877(a) all financial relationships are either ownership/investment interests or

compensation arrangements, we included the section 1877(b)(4) exception under both § 411.357 (which applies to ownership/investment exceptions, and is now § 411.356) and § 411.359 (which applies to exceptions for compensation arrangements, and is now § 411.357).

We believe the commenters' dissatisfaction with our method for incorporating section 1877(b)(4) may stem from the way we drafted the provision in § 411.359(g). We now believe that this proposal deviates from the statute. We discuss this issue and our solution for it in our response to the next comment.

As a result of OBRA '93, as amended by SSA '94, the ownership/investment aspect of section 1877(b)(4) applies only until January 1, 1995. Some aspects of the compensation exception continue in effect, since OBRA '93 incorporated them into section 1877(e)(4).

The second comment asked, in regard to proposed § 411.357(b)(3)(i) and section 1877(d)(3), how a physician can own an interest in a distinct part of a corporation when hospitals are one incorporated entity. As we explained in an earlier response, we believe that a "hospital" can consist of any separate legally-organized operating entity plus a variety of subsidiary, related, or other entities if the hospital bills for the services furnished to its patients by those entities. In drafting section 1877(d)(3), Congress itself perceived that a hospital can consist of separately owned, subdivided parts and that a physician could own an interest in either the hospital itself or only in a subdivision. We are defining "hospital" for purposes of this regulation, to reflect this concept.

The commenter has also asked whether the intention of the exception in section 1877(d)(3) was to refer to ownership of entities related to a hospital. Although the statute does not explicitly say this, it does say that the exception will not apply if a physician's ownership interest is merely in a subdivision of the hospital, rather than in the hospital itself. We believe that a subdivision can be a related entity. We have interpreted such entities, in response to other comments, as parts of a hospital if the hospital bills for services furnished by these entities to hospital patients (excluding situations in which services are furnished for a hospital "under arrangements"). A physician with an interest in a joint or related entity would not have an ownership interest in the hospital at all if the hospital did not bill for the services furnished by the joint or related entity.

The commenter has also asked why ownership in a related entity should cause referrals from a physician to be prohibited if the entity is not a clinical laboratory (for example, if the hospital owns 60 percent of a non-laboratory entity and the physician owns 40 percent). If the entity in this situation is part of the hospital, any referrals by the physician to the hospital laboratory would not qualify for the exception in section 1877(d)(3). To qualify for this exception, the physician's ownership interest must be in the hospital itself and not in a subdivision. However, the physician's referrals could qualify for the exception in section 1877(b)(4) which, until January 1, 1995, excludes any ownership interest in a hospital, provided the ownership interest does not relate to the provision of clinical laboratory services.

Finally, the commenter has asked why the facts in the example should be more subject to abuse than one in which a physician has a general ownership in the hospital and is authorized to perform patient care services there. Section 1877(d)(3) specifically requires that, to take advantage of this exception, a physician must have an ownership interest in the hospital itself, and not in a subdivision. We must reflect this requirement in the regulation, and have incorporated it into the final rule at § 411.356(b)(3). We have not broadened this exception to apply to any other ownership interest in a hospital because we have seen no evidence that such an expanded exception would be free of the risk of program or patient abuse.

Comment: There were two comments relating specifically to proposed § 411.359, which contains exceptions for certain compensation arrangements. One commenter asked under what authority we had limited the broad exception in section 1877(b)(4). Under that exception, the commenter pointed out, any financial relationship with a hospital is excepted (ownership/investment interest or compensation arrangement), as long as the relationship does not relate to the furnishing of clinical laboratory services. As such, the commenter questioned why this exception was not included under proposed § 411.355, which covers general exceptions that apply to both ownership/investment and compensation relationships. The commenter believed that, in covering section 1877(b)(4) under § 411.359(g), we had limited the exception so that it no longer constitutes the broad exception, for all financial relationships, included in the statute.

The commenter referred to the fact that the exception in § 411.359(g) is

entitled "other arrangements with hospitals" and indicated that the provision is drafted so that this exception applies to compensation arrangements between a hospital and a physician (or family member) other than those arrangements described in §§ 411.359 (a) through (d). (These arrangements in paragraphs (a) through (d) include rental of office space, employment and services arrangements with hospitals, physician recruitment, and isolated transactions. To qualify for these exceptions, physicians and entities must meet a variety of conditions.) The commenter pointed out that, under section 1877(b)(4), the only condition is that a financial relationship cannot be related to the furnishing of clinical laboratory services.

The commenter has read the proposed rule to mean that the exception in § 411.359(g) applies *only if* the compensation arrangement is not one of the ones described under paragraphs (a) through (d). Thus, for example, a hospital may have one or a variety of arrangements with a physician who is performing outpatient surgery on a patient at the hospital. These arrangements could include the rental of office space, employment or service arrangements, physician recruitment arrangements, or isolated transactions. The commenter believed that if a physician had one or more of these arrangements but could not meet the conditions to qualify for an exception, the exception in § 411.359(g) would automatically be foreclosed. That is, if the physician's financial arrangement was one already described in § 411.359 in paragraphs (a) through (d), then it could not be covered by paragraph (g), which applies only to financial arrangements other than those in paragraphs (a) through (d).

The commenter feared that the proposed rule could result in situations in which the hospital's laboratory would refuse to accept the physician's Medicare patient for laboratory work, with the result that the patient could not receive needed medical care at the hospital. The commenter questioned our authority to limit the statutory exception in section 1877(b)(4) and asked that we, at a minimum, add an exception for emergency laboratory work that would apply whenever, in the judgement of the physician, laboratory tests are needed quickly.

Another commenter recommended that the exception addressed in proposed § 411.359(g) be broadened to permit a direct or indirect financial relationship between a physician and a hospital or hospital affiliated organization or entity.

Response: In drafting § 411.359(g), we intended to cover any compensation arrangements that were not described in §§ 411.359 (a) through (d), including those that were the kinds of arrangements described in those provisions but that did not meet the conditions specified in them. We agree with the first commenter that the way we drafted § 411.359(g) is ambiguous and can cause confusion. As a result, we have made § 411.359(g) an independent exception, as it is in the statute.

We have also made several other changes to this provision to reflect amendments to the statute. As we have discussed in other responses, OBRA '93 eliminated section 1877(b)(4), which excepted any ownership/investment interest or compensation arrangement with a hospital that does not relate to the provision of laboratory services. The relationship could be between a physician and a hospital or an immediate family member and a hospital. SSA '94 reinstated section 1877(b)(4) until January 1, 1995. OBRA '93 also added paragraph (e)(4) to section 1877, retroactive to January 1, 1992. This new provision differs somewhat from paragraph (b)(4) in the sense that it retains only the compensation aspect of the exception. In addition, it applies only to remuneration from a hospital to a physician (not to a family member) if the remuneration does not relate to the furnishing of laboratory services.

The commenter also believed that we should provide an exception for referrals by physicians whenever, in the judgment of the referring physician, laboratory tests are needed quickly to treat a patient whose condition will worsen or be put at risk absent prompt laboratory results. We believe that section 1877 and this final regulation provide sufficient exceptions to ensure, in almost all cases, that patients should not be in the position of having their health threatened because of the general referral prohibition. In addition, the commenter's recommendation would give physicians total discretion that could be subject to abuse.

We do not agree with the suggestion that relates to broadening the exception in proposed § 411.359(g) so that it would apply to permit a direct or indirect financial relationship between a physician and a hospital affiliated organization or entity. The current authority in section 1877(e)(4) limits the exception to remuneration provided by a hospital, and not some other entity. We have interpreted the term "hospital" to include related or affiliated organizations or entities in situations in which the hospital bills for services

provided to hospital patients by the organizations or entities (except when the services are provided "under arrangements"). However, we do not believe that expanding the exception to other, non-hospital organizations or entities would necessarily be free of the risk of patient or program abuse.

Comment: One commenter asked that we explain what is meant by the phrase "does not relate to the furnishing of clinical laboratory services," as used in proposed § 411.357(b)(3)(ii) and § 411.359(g). The commenter wanted to know whether a physician who is not authorized to perform patient care services at a for-profit hospital but who has an ownership interest in the hospital is considered to have a financial relationship that is related to the provision of laboratory services. The physician receives dividends based on the business profits earned by the hospital. These dividends may in part depend on the provision of laboratory services.

Response: The commenter has asked about a physician with an ownership interest in a hospital. The commenter has apparently correctly perceived that, because the physician is not authorized to provide patient care services in the hospital, the exception in section 1877(d)(3) and in proposed § 411.357(b)(3)(i) would not apply.

For purposes of the exception in section 1877(b)(4) and proposed § 411.357(b)(3)(ii), the commenter has asked whether the physician's ownership interest in the hospital relates (either directly or indirectly) to the furnishing of clinical laboratory services. We would consider the physician's ownership interest as related to the provision of clinical laboratory services. We base this conclusion on the fact that general ownership in a hospital includes an interest in the hospital laboratory. This exception could apply if the physician had an ownership interest in a subdivision of the hospital which did not provide clinical laboratory services. We would like to point out that, as the result of OBRA '93 (as amended by SSA '94), the exception in section 1877(b)(4) relating to ownership and investment interests is no longer in effect, beginning on January 1, 1995.

b. Ownership and Compensation

Comment: One commenter requested that the final rule clarify that a physician who meets the exception relating to an ownership or investment interest in § 411.357(b)(3) of the proposed rule not also be required to meet the exception relating to compensation arrangements in proposed

§ 411.359(g) in regard to arrangements that are incident to the physician's ownership. Examples of such arrangements are the initial offer to allow the physician to acquire the ownership interest, dividends paid to the physician as an owner, or the opportunity to enter into a stockholders agreement that would provide for the buyout of the physician's ownership on death, disability, retirement, etc., or that provides the hospital with a right of first refusal to buy the physician's ownership interest in a hospital.

Response: We believe that the commenter has asked about compensation arrangements that are inherent in certain ownership/investment situations for which there are exceptions under the proposed regulation. We believe that a return on equity (for example, dividends) that a physician gets as a consequence of being an owner is not considered a compensation arrangement.

We take this position because section 1877 is designed to prohibit referrals to an entity whenever a physician has a financial relationship with that entity. The purpose is to prevent physicians from realizing a financial gain or some other benefit from making those referrals. The Congress specifically defined "financial relationship" to include two distinct components: an ownership/investment interest and a compensation arrangement. By this, we believe the Congress meant to encompass two mutually exclusive concepts: (1) Investment/ownership interest and whatever potential compensation or value they have or may bring to the owner, and (2) all other arrangements that result in some compensation.

Since we believe that potential compensation from an ownership/investment interest is already factored into the investment/ownership exceptions, it would make little sense to review the resulting compensation against the exceptions for compensation arrangements. For example, it would make little sense to say that a physician can invest in publicly traded securities under the ownership/investment exception in section 1877(c), yet preclude the physician's referrals because the compensation he or she receives from these investments does not fall within any of the compensation exceptions. As a result, the prohibition on referrals should apply only when a physician has a compensation arrangement that results from something other than an excepted ownership or investment interest. It is to these compensation arrangements, which do not stem from an ownership or

investment interest, that the compensation exceptions apply. Thus, we agree that a physician would not be required to qualify for both exceptions in order to refer laboratory tests to the laboratory in which he or she has an ownership interest.

G. Exceptions to the Referral Prohibition Related to Compensation Arrangements

1. Rental of Office Space

Section 411.359(a) of the proposed rule describes the exception under which the rental of office space does not constitute a financial relationship subject to the prohibition on referrals. The exception applies as long as payment made by a lessee to a lessor is made under the following conditions:

- There is a rental or lease agreement that meets the following requirements:

- + The agreement is set out in writing and is signed by the parties.

- + The agreement identifies the premises covered by the agreement and specifies the space dedicated for the use of the lessee.

- + The term of the agreement is at least 1 year.

- + If the agreement is intended to provide the lessee with access to the premises for periodic intervals of time, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of the intervals, their precise length, and the exact rent for the intervals.

- + The agreement provides for payment on a periodic basis of an amount that is consistent with the fair market value of the rented or leased premises in arm's-length transactions.

- + The agreement provides for an amount of aggregate payments that does not vary (directly or indirectly) on the basis of the volume or value of any referrals generated between the parties.

- + The terms of the agreement would be considered to be commercially reasonable even if no referrals were made between the lessee and the lessor.

- If an interested investor (either a physician or immediate family member) has an ownership or investment interest in the rented or leased office space, the arrangement meets the following conditions:

- + The rented or leased office space is in the same building in which the physician's practice or the physician's group practice is located.

- + All of the requirements described in paragraphs (a)(1)(i) through (a)(1)(vii) of § 411.359 are met.

Section 1877(e)(1) as enacted by OBRA '89 was significantly changed by OBRA '93. Section 152(c) of SSA '94 amended the effective date provision for

OBRA '93 so that the amendments to the rental exception are effective retroactively to January 1, 1992. The OBRA '93 provisions for the rental of office space provide that payments made by a lessee to a lessor for the use of a premises shall not be considered a compensation arrangement if—

- The lease is set out in writing, signed by the parties, and specifies the premises covered by the lease.

- The space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee, except that the lessee may make payments for the use of space consisting of common areas if such payments do not exceed the lessee's pro rata share of expenses for such space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using such common areas.

- The lease provides for a term of rental or lease for at least 1 year.

- The rental charges over the term of the lease are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

- The lease would be commercially reasonable even if no referrals were made between the parties, and

- The lease meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

Comment: A number of commenters raised questions about the meaning of the "same building" requirement in section 1877(e)(1)(B). Prior to OBRA '93, section 1877(e)(1)(B) stated that, "in the case of rental or lease of office space in which a physician who is an interested investor (or an interested investor who is an immediate family member of the physician) has an ownership or investment interest, the office space is in the same building as the building in which the physician (or group practice of which the physician is a member) has a practice." Several commenters also questioned the meaning of the terms "investor," "interested investor," and "disinterested investor" in section 1877(h) (5) and (6).

Response: OBRA '93 amended section 1877(h) to eliminate the terms "investor," "interested investor," and "disinterested investor." In addition, OBRA '93 eliminated the "same building" requirement in section 1877(e)(1)(B), effective January 1, 1995.

SSA '94 amended the OBRA '93 effective date provision so that the revised version of section 1877(e)(1) is retroactively effective to January 1, 1992. As a result, these terms are not reflected in this final rule.

2. Isolated Transactions

Under § 411.359(d) of the proposed rule, referrals by physicians involved in isolated financial transactions, such as the one-time sale of property, qualify for an exception if certain conditions are met and there is no other financial relationship between the entity and the physician for 1 year before and 1 year after the transaction.

Comment: Many commenters believed that the 1 year requirement creates substantial and unnecessary problems.

If a laboratory were to purchase assets from a physician on a one-time basis, it would not be able to accept future Medicare referrals from this physician if there were any previous relationship between the laboratory and the physician.

Response: We attempted in the proposed regulation to quantify and define an "isolated transaction" by adding the 1-year requirement. However, because commenters felt that this requirement creates substantial problems, we have decided to replace it with what we believe is a simpler and clearer standard. To define "isolated," we have eliminated the requirement that there can be no financial relationship between the parties for 1 year before the transaction, and we have shortened the period after the transaction. We have replaced this with the requirement that there can be no other unexcepted financial relationship between the parties for 6 months after the "isolated transaction." That is, if the two parties enter into a compensation arrangement within the 6-month period that qualifies for another exception, such as the employment or personal services exception, or if one of the parties qualifies for one of the ownership exceptions, the original transaction can still qualify as an "isolated" one.

We have also added a definition of "transaction" to make it clear that we regard an isolated transaction as one involving a single payment. If a financial relationship involves long term or installment payments (such as a mortgage), each payment constitutes a separate transaction, and would result in an ongoing financial relationship. (Individual payments between parties generally characterize a compensation arrangement. However, debt, as described in the statute in section 1877(a)(2), can constitute an ownership

interest that continues to exist until the debt is paid off.)

3. Service Arrangements With Nonhospital Entities

Under proposed § 411.359(e), which reflects section 1877(e)(3) before it was amended by OBRA '93, referrals by a physician who has an arrangement to provide specific identifiable services to an entity other than a hospital would not be prohibited if the services are furnished—

- By the physician acting as the medical director or as a member of a medical advisory board of the entity in accordance with a Medicare requirement;

- As physicians' services to an individual receiving hospice care for which Medicare payment may only be made as hospice care; or

- As physicians' services to a nonprofit blood center.

The arrangement must satisfy certain requirements that also apply to employment and service arrangements with hospitals.

As discussed in section I.D.6.d. of this preamble, section 1877(e)(3) was amended by OBRA '93 and now provides that certain personal service arrangements with any entity will not be considered compensation arrangements for purposes of section 1877(a)(2)(B). This provision applies to remuneration paid by any entity to a physician, or to an immediate family member, for furnishing personal services. The exception applies if certain conditions are met. Finally, section 152(c) of SSA '94 amended section 13562(b)(2) of OBRA '93 (the effective date provision for OBRA '93) to create a new paragraph (D). This new effective date provision says that section 1877(e)(3), as amended by OBRA '93, is in effect beginning on January 1, 1992; however, until January 1, 1995, it does not apply to any arrangement that meets the requirements of section 1877(e)(2) or (e)(3) as they were in effect prior to the OBRA '93 amendments.

Comment: One commenter indicated that under the CLIA regulations (42 CFR part 493) laboratories must have physicians who act as laboratory directors, rather than medical directors. Thus, the commenter believed the regulations should be modified so that it is clear that a laboratory does not have a compensation arrangement if it pays a physician to act as the laboratory director of the entity.

Response: Under the revised provision in section 1877(e)(3), remuneration from an entity to a physician for the provision of the physician's personal services will not

prohibit the physician from referring clinical laboratory services to the entity providing the following conditions are met:

- The arrangement is set out in writing, signed by the parties, and specifies the services covered by the arrangement.

- The arrangement covers all of the services to be furnished by the physician (or an immediate family member of the physician) to the entity.

- The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement.

- The term of the arrangement is for at least 1 year.

- The compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value, and except in the case of a physician incentive plan described in section 1877(e)(3)(B), is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

- The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.

- The arrangement meets any other requirements the Secretary imposes by regulations as needed to protect against Medicare program or patient abuse.

Comment: One commenter indicated that there appear to be a number of relationships between clinical laboratories and physicians that are not specifically covered by proposed § 411.359 but would be protected by the fraud and abuse safe harbors. The commenter suggested that the final rule be expanded to specifically state that an arrangement would not violate the physician referral rule if it fits within a safe harbor under the fraud and abuse regulations.

Response: As mentioned in the preamble of the proposed rule and in the response to other comments, the anti-kickback and safe harbor provisions of the law and the section 1877 prohibition are intended to serve different purposes. The safe harbor provisions have been specifically designed to set forth those payment practices and business arrangements that will be protected from criminal prosecution and civil sanctions under the anti-kickback provisions of the statute. Conversely, section 1877 prohibits a physician's Medicare referrals for clinical laboratory services to entities with which the physician (or a family member) has a financial relationship when those referrals are not

specifically excepted under section 1877. Because of these distinctions, the provisions of the regulations implementing these laws will not exactly correspond. Additionally, we note that, under the amendments created by OBRA '93 (particularly in the new sections 1877(e)(2) and (e)(3)), many more relationships between physicians and laboratories are now excepted from the effects of the prohibition on referrals.

Comment: One commenter indicated that a justifiable distinction cannot be drawn between the employment of a physician (or family member) by a hospital, which in some cases would be excepted under § 411.359(b) of the proposed rule, and employment of a physician (or family member) by a nonhospital laboratory, which could not be excepted under proposed § 411.359.

Response: Section 1877(e)(2), as amended by OBRA '93, recognizes bona fide employment relationships without drawing a distinction between a hospital laboratory and nonhospital laboratories. Under the new provision, for purposes of section 1877, any amount paid by an employer to a physician (or an immediate family member of the physician) who has a bona fide employment relationship with the employer for the provision of services does not constitute compensation, providing the following conditions, set forth in § 411.357(c), are met:

- The employment is for identifiable services.
- The amount of the remuneration under the employment—
 - + Is consistent with the fair market value of the services;
 - + Is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician (although certain productivity bonuses are allowed); and
 - + The remuneration is provided under an agreement that would be commercially reasonable even if no referrals were made to the employer.

H. Additional Exceptions

Under section 1877(b)(4), the Secretary is given the authority to define financial relationships beyond those specified in the law that could be exempt from the prohibition on referrals if the Secretary determines, and specifies in regulations, that they do not pose "a risk of program or patient abuse." (Section 152(c) of SSA '94 amended the effective date provision for OBRA '93 to reinstate section 1877(b)(4), as it appeared prior to the enactment of OBRA '93, until January 1,

1995. The original version of (b)(4) provided an exception for financial relationships with a hospital which are unrelated to the provision of clinical laboratory services. As a result, we believe that there are two versions of section 1877(b)(4) in effect until January 1, 1995.) In the proposed rule, we requested recommendations about financial relationships that do not pose a risk of program or patient abuse. We received suggestions for additional exceptions, all of which are discussed below. In particular, the issue of shared laboratories was raised in the context of various business and practice arrangements, most often with respect to such shared arrangements between physicians.

1. Comments Relating to an Exception for Shared Laboratories

Comment: A few commenters strongly objected to the formulation of any special exception for shared laboratories. The commenters maintained that these arrangements could easily be used as a sham to circumvent the purposes of the law. They believed that a group of physician investors could set up a single laboratory to which they all refer testing. Each physician could then obtain his or her own CLIA number for the laboratory and bill separately for these services, thus making the detection of these schemes extremely difficult. Moreover, the commenters wrote that outside practitioners would also be allowed to refer their testing to any one of these physicians. Such an arrangement, in these commenters' view, is little more than a continuation of the physician-owned laboratory under a different name and is a way for physician-owners to circumvent the terms of section 1877.

Response: We share the concerns raised by these commenters, and we agree that a separate exception cannot be justified. CLIA certifies each laboratory by location. It does not certify individuals. Therefore, a laboratory that registers for CLIA will register once and receive one CLIA registration number. Each shared laboratory location is to have one CLIA certificate regardless of the number of physicians conducting or supervising testing in that laboratory, and only one registration and compliance fee and proficiency testing enrollment and survey is required. Testing performed in the physician's office that contains the shared laboratory may be included under the shared laboratory certificate. Physicians who perform laboratory testing in their own offices, in addition to performing tests in a shared laboratory, must have

a separate certificate for their office laboratory.

As we understand it, there are a variety of circumstances that involve shared office space in general and shared laboratories in particular. Examples of shared laboratories range from laboratories shared by two or more solo practicing physicians to larger laboratories that are shared by hospitals, other health care facilities, and group practices. In effect, these commenters believed that to establish an exception for practicing physicians who share a laboratory would thwart the intent of the statute to end potential and actual overutilization of laboratory services.

In the example presented by the commenters, several physicians set up a laboratory separate from any of their practices, share in the costs of its operation, and bill individually for services furnished to their own patients. (The commenters also stated that physicians who are not owners refer patients for tests.) Since the physicians each appear to have an ownership or investment interest in the laboratory, they would be precluded from referring to the laboratory, unless they qualify for an exception.

It is not clear from the example, but if each physician does not have a practice in the same building as the laboratory and does not directly supervise the laboratory personnel who are performing the services for the physician's patients, the supervision and location requirements of the in-office ancillary services exception in section 1877(b)(2) would not be met. Furthermore, as discussed in greater detail in response to the next comment, we do not believe that it would be possible to develop an exception to accommodate these circumstances that would meet the statutory test contained in section 1877(b)(4); that is, that there be no risk of program or patient abuse.

Nonetheless, we want to clarify that the in-office ancillary exception could apply if each of the individual physicians involved separately met the supervision, location, and billing requirements of section 1877(b)(2). For example, physicians A, B, and C each have their own offices in the same building. Each physician directly supervises the laboratory technician when the technician is performing services for the physician. In addition, each physician bills for services furnished to his or her own patients. We also want to provide an example of a situation that would not qualify for the in-office exception. For example, ten individual physicians each have their own office on different floors in a building and the laboratory they share is

located in the basement of the building. The physicians do not directly supervise the laboratory technician when the technician is performing services for the physicians. In addition, the laboratory bills for services furnished to the patients of the physicians.

In the first example, as long as the requirements of section 1877(b)(2) and § 411.355(b) are met, it would not matter if the physicians pooled resources to cover the costs of the space occupied by the laboratory or for the cost of the equipment or overhead. We emphasize that the in-office ancillary services exception has been amended by OBRA '93, effective retroactively to January 1, 1992. Before this amendment, the services under this exception had to be furnished by the referring physician or by another physician in the same group practice. Alternatively, services could be furnished by employees of the referring physician or of the physician's group practice, provided the employees were "personally supervised" by the referring physician or another physician in the group practice. This requirement has been changed by OBRA '93 to eliminate the requirement that only a physician's or group practice's employees can furnish services. Also, the term "personally supervised" has been changed to require that a technician's or other individual's services be "directly supervised" by the referring physician or by another physician in the group practice.

For purposes of this exception, we are explicitly defining "direct supervision" using the longstanding Medicare definition of this term. Under this definition, the physician must be present in the office suite and be immediately available to provide assistance and direction throughout the time a technician is performing services. We believe it is appropriate for us to define this term in this final rule with comment period, rather than in a new proposed rule. We have several bases for this conclusion.

First, we believe that the Secretary's definition for this term is interpretive. Interpretive, nonsubstantive agency promulgations fall into the Administrative Procedure Act (APA) exception to notice and comment rulemaking. See 5 U.S.C. 553(b)(A).

In defining "direct supervision," we are merely explicating the Congress' desires rather than adding substantive content of our own. That is, the definition is a clarification of what is implicitly in the statute. A rule that clarifies a statutory term is the classic example of an interpretive rule. Interpretive rules are those that merely

clarify or explain existing law or regulations. They serve an advisory function, explaining the meaning given by the agency to a particular word or phrase in a statute or rule it administers.

The term "direct supervision" is a longstanding term of art with a very particular meaning in the Medicare program. It appears in section 2050.2 of the Medicare Carriers Manual, Part 3—Claims Processing, which describes services that are "incident to" a physician's professional services. This definition has appeared in the manual since the 1970's. It has, over the years, affected the many physicians who bill for services or supplies that are furnished as an integral, although incidental, part of a physician's personal professional services in the course of diagnosis or treatment of an injury or illness. The same definition appears in the regulations at § 410.32(a), which states that, in general, diagnostic x-ray tests are covered only if performed under the "direct supervision" of certain physicians or by certain radiology departments. Congress, in using this term of art, has adopted and ratified the Secretary's definition.

We believe that in changing "personally supervised" to the familiar "directly supervised," Congress was intending to make clear that it wished to incorporate a concept that the agency and the provider community have long understood. For example, physicians are quite familiar with this term because they can only bill for nonphysician services that are "incident to" their own services if the nonphysician services are performed under "direct supervision." As such, we have reiterated in this regulation our long-standing definition for this term. The definition is a clarification of what the Secretary believes "direct supervision" means and has always meant; it does not add to the statute any additional substantive requirements.

We are aware of only one paragraph of legislative history for OBRA '93 that attempts to explain the meaning of the term "direct supervision." The Conference Report for OBRA '93 states that—

[T]he conferees intend that the requirement for *direct supervision by a physician* would be met if the lab is in a physician's office which is personally supervised by a lab director, or a physician, even if the *physician is not always on site*. [Emphasis added.] H.R. Rep. No. 213, 103d Cong., 1st Sess. 810 (1993).

We believe that this explanation provides no insight into the Congress' purpose in using the term "direct supervision." That is, it purports to explain what constitutes direct

supervision, yet defines it by allowing a physician to "directly supervise" without even being present. This appears to us to be at total variance with the Medicare program's longstanding requirements for "direct supervision," and with the statute, which specifically requires that the referring physician or another physician in the same group practice have *direct* involvement with individuals performing laboratory tests. In addition, the statute is very specific about who must directly supervise; it does not say that a laboratory director who is not a group member can provide this supervision instead of a solo or group practice physician.

Also, it appears to us that the legislative history is inconsistent. If "direct supervision" is interpreted to allow a laboratory director to supervise individuals who are furnishing services, this could have the effect of creating an exception for shared laboratories. The very same conference report points out that the House Energy and Commerce Committee introduced a provision that would have added an exception for shared laboratories. The conference agreement, however, specifically rejected this amendment. H.R. Rep. No. 213, 103d Cong., 1st Sess. 810 (1993).

Even without the "interpretive" exception, we believe that there would be good cause to waive notice and comment for this particular term. Title 5 U.S.C. 553(b)(B) authorizes agencies to dispense with certain procedures for rules when they find "good cause" to do so. Under section 553(b)(B), the requirements of notice and comment do not apply when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest."

We believe that waiting to define "direct supervision" in a future notice of proposed rulemaking would be both impracticable and contrary to the public interest. To begin with, some of the amendments added by OBRA '93 relating to clinical laboratories have a retroactive effective date. The provision containing the "direct supervision" requirement is effective retroactively back to January 1992. The retroactive effective date for some provisions relating to clinical laboratory services, but not others, demonstrates the Congress' desire to expedite their implementation. Although an expedited timeframe alone may not justify a "good cause" exception, we believe it is a crucial factor when considered in conjunction with the entire set of circumstances.

The in-office ancillary services provision establishes an exception to the referral prohibition that is critical to

the many solo and group practice physicians who wish to be excepted for referrals for their own in-office ancillary services. These physicians have had no way to be certain, from January 1992 until the publication date of this interim final rule, whether they qualify for the in-office ancillary services exception. They cannot know if they do until it is clear that they are "directly supervising" any individuals who perform laboratory tests. In short, a portion of the statute cannot be implemented without interpretation, although some form of "supervision" has been required since January 1992.

Defining "direct supervision" in this interim final rule avoids piecemeal promulgation of the statute for critical provisions such as this one. The in-office ancillary services exception is an important one that affects many physicians in a variety of situations, including those involved in shared laboratories. We have received a tremendous number of inquiries on how shared laboratories fit within the statutory scheme. We cannot provide a definitive answer to many of these inquiries until we define "direct supervision." Without certainty, physicians and entities affected by this provision will continue to be confused about how to handle their highly complicated financial relationships. They may divest themselves unnecessarily of interests that we believe the Congress meant to excuse when it created the in-office ancillary exception.

Any uncertainty over the meaning of "direct supervision" could also damage our ability to enforce section 1877. If we take no action and delay enforcement of the referral prohibition because of uncertainty about the "direct supervision" requirement, we could be allowing over-utilization of services by physicians who have financial relationships with an entity and who continue to make prohibited referrals to that entity.

Finally, we are providing a comment period following publication of this interim final rule. We will carefully consider all comments we receive on the definition of "direct supervision" and publish our responses to these comments in a final rule.

The long-standing definition of "direct supervision" makes the proximity of the laboratory to each physician's office important. That is, in the first example, the laboratory must be situated in a way that each of the three physicians would be able to directly supervise the services of the individual performing the testing when the testing is being performed for the physician's

own patients. This means that it is possible for a physician to have his or her office practice in a location separate from the laboratory as long as the laboratory is in the same building in which the physician practices and he or she fulfills the direct supervision requirement by being in the office suite when the tests are performed.

Finally, the exception in section 1877(d)(2) and § 411.356(b)(1) for clinical laboratory services furnished in a laboratory located in a rural area applies to shared laboratories. This exception, however, applies to referrals that would otherwise be prohibited only because of ownership or investment interests. The exception does not apply if the referring physician has a compensation arrangement with the rural laboratory. Therefore, if physicians share ownership in a laboratory located in a rural area but have no compensation arrangements with the laboratory (for example, remuneration between the physicians and laboratories other than return on investment), referrals by the physicians to the rural laboratory would not be prohibited provided the criteria mentioned above are met.

Comment: A majority of commenters regard the absence of a "shared laboratory" exception to be a serious oversight. These commenters indicated that shared clinical laboratories are very common, especially among younger physicians still building their solo practices and among providers in rural or medically underserved areas, whose populations could not otherwise support an independent laboratory testing facility. Other commenters indicated that an exception to permit physicians to make Medicare referrals to their shared laboratories would eliminate the discrimination that exists in the proposed regulations in favor of group practices and individually practicing physicians who can afford to purchase their own laboratory equipment solely for their own use. The commenters suggested that an exception could be added to permit referrals when all of the following factors are present:

- The shared arrangement involves a fixed and limited number of physician practices. The maximum may be specified by the Secretary.
- The arrangement involves only physicians who occupy the same office space or who practice in contiguous offices in the same building.
- The physicians in the arrangement refer only their own patients to their shared laboratory, which would not accept Medicare referrals from other physicians.

- The tests are done by the physicians' employees and are directly supervised by the physicians, or the physician personally performs the laboratory test for his or her own Medicare patients.

- No physician in the arrangement may be required to maintain a specific level or volume of laboratory referrals.

- The services are billed by one of the following:

- + The physician performing or supervising the service.

- + An entity that is wholly owned by the physicians who are parties to the shared office laboratory agreement.

- The shared-office must not loan funds or guarantee a loan for any physicians who share in the costs of the laboratory and who are in a position to refer to the laboratory.

- The agreement under which the shared-office laboratory operates does not contain "noncompetition clauses" that prevent physicians who share in the costs of the laboratory from investing in other laboratories.

- The shared-office laboratory must not furnish its items or services to referring physicians who have an ownership interest in the shared-office laboratory or share in the costs of the laboratory differently from other physicians. (By this, we believe the commenter meant that tests referred by owner physicians are not given priority.)

- Physicians who share in the costs of the shared-office laboratory must disclose their interest to their patients when ordering tests from the laboratory.

- Operation of the laboratory must be the joint responsibility of the physicians and/or practice groups with actual costs shared on a per test basis.

- Shared physician office laboratories must demonstrate that the laboratory simply passes actual costs through to the participating physicians and group practices with no accumulation or distributions of net earnings.

Response: As evidenced by the number of comments concerning this issue and the detail contained in suggestions for an exception, it is clear that there is great concern about this matter. Nonetheless, the Congress, while it was deliberating over the changes it would make in section 1877 by enacting OBRA '93, considered an exception for shared laboratory facilities but chose not to enact it. (See H.R. Rep. No. 213, 103d Cong., 1st Sess. 809-810 (1993)). The Secretary does have the authority to establish a shared laboratory exception if she determines that there would not be a risk of program or patient abuse.

Unfortunately, notwithstanding the arguments for establishing such an

exception, there is not sufficient basis in the rulemaking record to support an exception that meets the statutory standard. For that reason, we believe that Congress should provide further clarification or specific statutory authority in this area.

- The first suggestion made by the commenters was that a shared laboratory be limited to a fixed number of physicians. In our view, however, any attempt to select a number (three, five, ten, and so on) would be arbitrary. That is because we do not currently have data that would support making a distinction based on the number of physicians involved. We see no rational basis on which to establish or impose a limit.

- The second suggestion is to limit the exception to physicians who occupy the same office space or whose offices are contiguous in the same building. As explained in the response to the last comment, depending on how the physician's office space and the shared laboratory space are physically arranged, the in-office ancillary services exception provided in § 411.355(b) could apply. But we emphasize that the direct supervision and billing requirements must also be met.

- With respect to the remaining points, even if considered cumulatively, they do not clearly describe a situation in which there could be no program or patient abuse. Physicians could still have the opportunity to overutilize services with the possibility of profit that is inherent in any ownership arrangement. We are not suggesting that all physicians who might wish to participate in shared laboratory arrangements would overutilize laboratory tests. We do not believe, however, that there is a basis for concluding that the arrangements pose no risk of patient or program abuse.

Comment: One commenter indicated that, if the Secretary establishes an exception for shared laboratories, physicians involved in shared laboratory arrangements could be required to attest in writing that they meet the criteria required by the Secretary. This requirement would be like the one in the proposed regulation requiring that physicians attest in writing to their Medicare carrier that they meet the group practice exception.

Response: To clarify one point, we required only one attestation in the proposed rule; that is, that a group practice attest in writing, to the appropriate Medicare carrier, that the group complied with the standard we proposed to use to determine whether substantially all of the patient care services of group member physicians are furnished through the group as was

required by section 1877(h)(4)(B) (now section 1877(h)(4)(A)(ii)). There are other standards that a group practice has to meet in order to qualify, but we did not propose that they be the subject of an attestation procedure.

In any case, as explained above, we do not believe that a separate exception for shared laboratories is justifiable.

Comment: One commenter suggested that multiple group practices within the same building be allowed to refer patients to one central laboratory that was created for the patients of the group practices.

Response: What is described here may be a laboratory owned by several group practices that does testing for patients of each group. In effect, the laboratory would be an independent entity that is shared by several group practices in the sense that it does business with each of its group practice owners. (A second possibility is that the laboratory is owned by one group to perform testing for its own patients but also accepts referrals from other groups or other outside sources. This latter situation is discussed elsewhere in this preamble.)

As we have explained in earlier responses to comments, we are not providing a general exception for shared laboratories such as the one described by the commenter. The physicians in the multiple group practices could refer to the laboratory, provided that each referral meets the requirements of the in-office ancillary services exception in section 1877(b)(2). This means that the services must be personally performed by or directly supervised by the referring physician or another member of that physician's own group practice and the services must be billed by the referring physician, the group practice, or an entity wholly owned by the group practice or referring physician.

There is no evidence from the commenter's description that the group physicians personally perform or directly supervise the laboratory services. Also, if this is the case, the group practices cannot individually bill for the services under section 1833(h)(5)(A), which generally allows payment only to the person or entity that performs or supervises the performance of clinical diagnostic laboratory tests. If the laboratory bills, the services will not meet the billing requirement in section 1877(b)(2).

2. Specialized Services Laboratory

Comment: One commenter requested an exception for referrals for "specialized services." This exception would permit the establishment of laboratories by groups of individual

practitioners within a common area of expertise.

The exception would apply when there is a public health need for specialized clinical services not readily available in a geographic region.

According to the commenter, general laboratories may lack the equipment or the expertise to meaningfully analyze samples from patients suffering from particular diseases. The commenter stated that the cost of specialized services could be lowered by making them readily available to patients who would otherwise incur unnecessary costs and delays because samples have to be shipped to laboratories not reasonably close to them. The commenter stated, as an example, that laboratories that usually handle normal blood specimens typically fail to calibrate their laboratory equipment for renal patients who express blood values that depart significantly from the norm. In the commenter's view, the technicians at general laboratories tend to be inexperienced at processing these abnormal samples. In turn, this causes dialysis patients to incur unnecessary expense and endure needless delays and incorrect test results. The commenter also stated that laboratories that are not expert in evaluating renal blood samples tend not to report patient values, including cumulative historical laboratory results, to dialysis clinics in the same detailed manner as laboratories that specialize in renal patients.

Response: As mentioned previously, a physician's Medicare referrals to a laboratory owned by that physician will not be prohibited if the laboratory is located in a rural area (as defined in new § 411.356(b)(1)). Therefore, physicians with an ownership interest in a specialized laboratory that is located in a rural area are not prohibited because of that investment from referring Medicare patients to the laboratory. We believe that it is likely to be in rural areas that specialized equipment or technical expertise would be in short supply.

Furthermore, we believe the CLIA certification that is now required for any laboratory that performs tests on human specimens will tend to induce those laboratories that fail to calibrate their equipment or operate in other ineffectual ways to improve their performance or risk going out of business. For example, under CLIA, laboratories are subject to proficiency testing and personnel requirements. Failure to comply with accepted standards can result in serious sanctions. Thus, we do not agree that a special exception is warranted because

some laboratories may not properly conduct tests.

3. Laboratories Shared With Hospitals

Comment: One commenter requested that we create an exception for a shared laboratory facility owned by an organization or hospital that is exempt from taxation under section 501(c)(3) of the Internal Revenue Code if the laboratory is used in common under a written agreement with a group practice and if the group practice constitutes all or substantially all of the staff of the organization or hospital. The commenter stated that the requirement that the entity that owns the laboratory be tax exempt under section 501(c)(3) of the Internal Revenue Code provides significant protection against patient and program abuse. (To qualify for and maintain tax-exempt status, an organization must be a corporation, or a community chest, fund, or foundation, organized and operated exclusively for a community purpose such as for religious, charitable, scientific, public safety, literary, or educational purposes. No part of the net earnings of the organization can inure to the benefit of any private shareholder or other individual. Failure to meet these requirements, or failure to continuously maintain them, results in the denial or loss of tax-exempt status.)

The commenter believed that the conditions associated with tax-exempt status would prevent physicians from having an ownership interest in the laboratory from which they could receive financial benefits in the form of dividends or other distribution of earnings, as a result of their referrals. Consequently, there would be no incentive to order an excessive number of clinical laboratory tests. The commenter pointed out that payment for unreasonable or excessive compensation would also be prohibited by the restriction on private inurement.

Response: It is not clear from this comment exactly what the financial relationship is between the tax-exempt hospital/organization and the group practice physicians. We will first assume that it is the hospital or organization only that owns the laboratory and the physicians receive compensation from the hospital/organization for providing staff services. This relationship will not prohibit referrals to the hospital's laboratory provided the compensation meets the requirements of one of the exceptions in section 1877. For example, section 1877(e)(2) (for bona fide employment relationships with an entity) or (e)(3) (for personal service arrangements with an entity) could apply. An additional

exception appears in section 1877(e)(7), which exempts certain group practice arrangements with a hospital when a group practice provides services for which the hospital bills.

If, on the other hand, the group practice physicians have an ownership interest in the laboratory, they would be referring to a laboratory in which they have a financial interest under section 1877(a)(2), even if they do not receive dividends or earnings. The physicians could refer to their own laboratory, provided they meet the in-office ancillary services exception in section 1877(b)(2) and § 411.355(b) of this regulation. If the laboratory is rural, then the ownership relationship would be exempt under section 1877(d)(2). If the physicians have an ownership interest in a tax-exempt hospital itself, their relationship could be exempt under several hospital-specific exceptions.

Because there are a number of exceptions available for situations involving compensation between a hospital or other organization and a physician, or for ownership in a hospital, we believe that a specific blanket exception for laboratory facilities associated with a tax-exempt organization or hospital would be unnecessary. Also, we are not convinced that such an exception would be free from any risk of patient or program abuse. For example, a non-profit or tax-exempt organization can own a for-profit laboratory entity. Without further details and evidence, we would not grant such an exception.

Comment: One commenter indicated that an exception should be added for referrals to a laboratory facility that is shared by a hospital and a clinic. The commenter provided the following information. The clinic is a group practice. The shared laboratory is located on hospital premises, and the hospital owns the laboratory space. The clinic leases space from the hospital in an amount proportional to testing on the clinic's patients. Clinic staff manage the laboratory, and the clinic employs all the laboratory personnel. The clinic and hospital each own some of the laboratory equipment. As such, each entity essentially leases from the other entity the equipment needed to perform testing on its own patients. The laboratory is not a separate legal entity, but simply an arrangement that permits the clinic and hospital to work together. The parties entered into this arrangement in 1973 and it has been in effect since that time. Each party is responsible for billing and collecting fees related to laboratory services provided to its respective patients. The

agreement provides that the clinic and hospital would coordinate management, planning, budgeting, and accounting for the laboratory services. The commenter indicated that an exception should be allowed for referrals to a laboratory facility that is shared by a hospital and a clinic (group practice) where the parties divide expenses on a basis that reasonably approximates the costs associated with the tests performed for each party's patients and each party bills for and retains revenues associated with the testing of its own patients.

Response: The commenter has asked for a specific exception for arrangements in which a laboratory facility is shared by a hospital and a group practice clinic. The commenter has described an arrangement which involves a variety of ownership and compensation arrangements, each of which could cause the group practice physicians' referrals to be prohibited. However, as a result of the additional exceptions included in section 1877 by OBRA '93, we believe that most of the relationships described by the commenter could be excepted. As such, a separate exception would be unnecessary.

The commenter first describes several compensation arrangements between the hospital and the group practice. The group practice rents the laboratory space and some equipment from the hospital. (The laboratory is not a separate legal entity and is located on the hospital's premises, so we assume it is part of the hospital.) The hospital, in turn, rents some of the equipment from the group practice. These arrangements should not preclude the physicians' referrals if they meet the exceptions in section 1877(e)(1) (A) and (B), which exempt rental arrangements provided certain conditions are met.

The group practice also provides certain services to the hospital by managing the laboratory and employing the staff. We assume that the group practice is receiving some compensation, in some form, from the hospital for these services. This compensation would not trigger the referral prohibition if the arrangement meets the requirements in the bona fide employment exception in section 1877(e)(2) or qualifies for the exception for personal services arrangements in (e)(3). Alternatively, the relationship might be exempted under the exception in section 1877(e)(7) for certain group practice arrangements with a hospital under which the group provides clinical laboratory services which are billed by the hospital. In this case, the group practice appears to provide most, if not all, of the actual laboratory services while the hospital apparently bills for

its own patients. To qualify for this exception, the group must meet the definition of a group practice in section 1877(h)(4) and meet the requirements under section 1877(e)(7).

Finally, there are certain indications that the group practice may have some form of ownership interest in the laboratory entity (although it may not be a separate legal entity). The group pays rent for the space, manages the laboratory, employs all of the laboratory staff, owns some of the equipment, bills for its own patients, and retains the revenues associated with the testing of its own patients. In order for the group practice to refer to its own laboratory, it must qualify as a group practice under the definition in section 1877(h)(4), and meet the requirements of the in-office ancillary services exception in section 1877(b)(2).

Comment: Several commenters indicated that a number of group practices and the hospitals with which they are affiliated have for many years operated a laboratory facility that serves both hospital patients and the group practice's office patients. Under the terms of the agreement between the group and the hospital, the laboratory is operated under a shared services agreement, rather than as a true joint venture or under an "under arrangement" contract. The revenues, costs, profits, and losses resulting from services to hospital patients are attributed to the hospital and the revenues, costs, profits, and losses resulting from services provided to the group practice's office patients are attributed to the group practice. The commenters recommended a new exception that would be limited to teaching hospitals and would apply to clinical laboratory services furnished by a laboratory that is—

- Owned or operated by an organization or hospital that participates in an approved medical training program; and
- Used in common under a written arrangement with a group practice whose physician members constitute all or substantially all of the active medical and teaching staff of the organization or hospital.

Response: This comment is very similar to the previous comment. That is, it involves an arrangement between a hospital or organization and a group practice to share a laboratory facility. The commenters, however, do not address the specifics of the arrangement, so we cannot tell exactly how the situation will be affected by section 1877. In addition, it is not clear why the commenters limited their recommendation for a new exception to

just arrangements between teaching hospitals and group practices. However, as we pointed out in our response to the last comment, we believe that a new exception is unnecessary after OBRA '93 for most situations in which hospitals and other organizations share their laboratories with physicians.

In the commenter's example, for instance, the group practice physicians constitute all or substantially all of the active medical and teaching staff of the hospital or organization. The compensation that these physicians receive from the hospital or organization for their services should not prevent the physicians from referring to the hospital's laboratory, provided the arrangement meets the requirements under section 1877(e)(2) (for bona fide employment relationships) or (e)(3) (for personal services arrangements). The group practice physicians also appear to have some ownership interest in the laboratory, since they refer their own office patients there and the revenues, costs, profits, and losses of the group's office patients are attributed to the group. The group practice physicians can refer their own patients to each other, provided they meet the requirements of the in-office ancillary services exception in section 1877(b)(2).

Comment: One commenter indicated that there are large multi-specialty group practices that own clinics located adjacent to inpatient hospitals and the clinics share certain ancillary facilities, including laboratories, with the hospitals. In some cases, the ancillary services building literally becomes the bridge between the clinic and the hospital, so that a hospital patient enters the ancillary facility from the hospital, and a clinic patient enters the same facility from the clinic. Such a facility would be under the common control of both the clinic and the hospital, and both entities would share in the cost of personnel, space, equipment, supplies, and other operating expenses. The commenter questioned whether the physician group is entitled to treat such a shared facility as "in-office." The commenter believed that if the services furnished at the facility do not qualify for the in-office ancillary exception, the physician group's referrals for those services would be prohibited since the cost sharing agreement between the hospital and clinic would constitute a compensation arrangement under the statute. The commenter requested that we provide an additional exception to accommodate arrangements of this nature that meet all of the following conditions:

- The shared laboratory facility, the group practice, and hospital (or other

entity) are part of the same medical center campus.

- The costs of operation of the shared facility are shared on the basis of utilization originating from each part, so that each party pays only its own costs, and does not subsidize the provision of laboratory services to the other.

- The creation or continuation of such a shared facility arrangement is not conditional or otherwise related to the volume or value of referrals of patients between the clinic and hospital (or other entity) for other, nonlaboratory, covered Medicare services.

Response: The comments we have received on the issue of hospitals or similar organizations which share laboratories with group practices have revealed to us the complexity of many of the financial relationships involved in these arrangements. In some situations, one or both parties actually own the physical facility and/or its equipment, one party may pay rent to the other, and each party may provide the other with certain services both in the laboratory and in a practice context. It is impossible for us to analyze each and every configuration. However, as we pointed out in earlier responses on this issue, OBRA '93 has created additional exceptions which should address many of the interrelationships involved in these situations. We encourage hospitals and other organizations to analyze their own particular circumstances in light of these exceptions.

In regard to the particular situation raised by this commenter, the commenter describes a situation in which a laboratory is under the common control of both a group practice clinic and a hospital, each of which share in the cost of personnel, space, equipment, supplies, and other operating expenses. The commenter appeared to be concerned, primarily, about whether the in-office ancillary services exception would apply to services furnished in the laboratory for the patients of the group practice. The commenter provided few other details about ownership of the hospital or laboratory or whether there is any compensation passing between these parties.

The in-office ancillary services exception in section 1877(b)(2) does not appear to dictate any particular ownership arrangements between group practice physicians and the laboratory in which the services are provided. We believe that the group practice can take advantage of this exception and that members can refer to each other in the laboratory provided that the group meets the definition of a "group practice" under section 1877(h)(4) and

meets the requirements in section 1877(b)(2). Under section 1877(b)(2), the services must be furnished by the referring physician or a group member or must be directly supervised by a group practice member. In addition, the services must be billed by the referring physician, the group practice, or an entity wholly owned by the group practice.

Comment: One other commenter indicated that, if an exception is provided for contracts for services described "under arrangements" as described in section 1861(w), the language should be broad and not limited only to those circumstances in which the arrangement between the parties meets the safe harbor for personal services and management contracts provided for in the anti-kickback rules (42 CFR part 1001). According to this commenter, this limitation would pose several problems. First, the personal services and management contracts safe harbor would require that the aggregate amount of compensation be set in advance and not vary based on the volume or value of tests performed. This would mean that the parties would have to establish in advance a flat yearly fee for laboratory services. Even a fee schedule would not qualify for the safe harbor. A flat aggregate fee arrangement would be of concern to the hospital because it would place the group practice physicians at risk for the provision of clinical laboratory services that are the hospital's obligation. Under this arrangement, the physicians would have a financial incentive to order too few laboratory services for hospital inpatients and outpatients in order to make the arrangement as profitable as possible. To ensure that hospital patients receive optimum quality health care services, the hospital would not want the physicians to have a financial disincentive to order medically necessary laboratory services. The hospital would also be concerned that this contractual disincentive may have liability implications for the hospital in the event of a misdiagnosis of a hospitalized patient allegedly because the appropriate diagnostic testing was not ordered.

The safe harbor for personal services and management contracts also requires that contracts for less than full-time services be specific about the frequency and timing of the services being furnished. This commenter believed that a hospital in this situation must clearly expect that the group practice laboratory will furnish services for the hospital on an as needed basis when the patient and the patient's attending

physician require the laboratory service for appropriate diagnosis. Thus, the commenter concluded that this safe harbor criterion also could not be met.

Response: The commenter has described a situation in which group practice physicians both order and provide laboratory services to hospital inpatients and outpatients under an arrangement. We believe the commenter is correct in concluding that the section 1877 prohibition applies to both Part A inpatient hospital services as well as to Part B services.

The definition of "referral" found in section 1877(h)(5)(A) applies, by its terms, to items or services for which payment may be made under Part B of the program. Section 1877(h)(5)(A) is entitled "Physicians' Services," which are separate from inpatient hospital services and are always covered under Part B. Section 1877(h)(5)(B), on the other hand, covers "Other Items," and is not limited to Part B items and services. This provision states that, except for specific exceptions listed in (h)(5)(C), "the request or establishment of a plan of care by a physician" that includes clinical laboratory services constitutes a "referral" by a "referring physician." We believe this provision is difficult to decipher. Nonetheless, it appears to contemplate that physicians have made a "referral" in either a Part A or Part B context if they establish a plan of care for an individual that includes clinical laboratory services.

In the "inpatient hospital" context, we believe that most patients will receive clinical laboratory services as part of their "plan of care." We consider that anytime a physician orders anything, it is "pursuant to a plan of care" on the physician's part, even if not formally called that. In addition, we believe that the Congress fully intended to encompass Part A inpatient hospital services within the section 1877 referral prohibition. One of the designated health services that has been added to the prohibition effective January 1, 1995 (by section 1877(h)(6)(K)) is "inpatient and outpatient hospital services."

The commenter has asked about a specific exception for services furnished under arrangements. OBRA '93 amended section 1877 to establish such an exception in new paragraph (e)(7). This provision creates a limited exception for compensation that derives from an arrangement between a hospital and a group under which services are furnished by the group but are billed by the hospital. The provision specifies, in (e)(7)(A)(i) that, with respect to services furnished to an inpatient of a hospital, the arrangement is pursuant to the provision of inpatient hospital services

under section 1861(b)(3). Section 1861(b)(3) defines what constitutes "inpatient hospital services," and specifically includes certain services furnished to inpatients "under arrangements." Among other requirements in section 1877(e)(7), the arrangement must have begun before December 19, 1989, and have continued in effect without interruption since that date. Also, the compensation paid over the term of the agreement must be consistent with fair market value and the compensation *per unit* of services must be fixed in advance and not take into account the volume or value of referrals. Therefore, this exception does not present the "aggregate compensation" problem discussed in the comment. Also, there are no additional requirements for details about the frequency or timing of services furnished under a less than full-time service arrangement.

In response to the commenter's concern about the safe harbor for personal services and management contracts, we caution that the anti-kickback safe harbor regulations implement different provisions of the Act than are implemented by these regulations. Therefore, physicians and laboratory entities are obligated to consider the safe harbor requirements separately from the requirements of this rule.

4. Rental of Laboratory Equipment

Comment: One commenter stated that laboratories often rent a variety of equipment to physicians that they need in connection with their practices. For example, a physician may want to rent a blood analyzer in order to perform simple laboratory tests in his or her office. Since laboratories often have extra equipment they rent, the laboratory that the physician uses for his or her reference work will likely be the laboratory from which the physician rents equipment. Laboratories typically charge some rental fee for this equipment if the equipment is not an integral part of the laboratory services furnished. These arrangements could, however, be considered a compensation arrangement that could jeopardize the physician's referrals to the laboratory. The commenter believed that, if the equipment is leased at fair market value and meets other requirements comparable to those set out in the provision related to the lease of office space, there is little risk of patient or program abuse. Thus, this commenter recommended that an additional exception be created for referrals by a physician who has a compensation arrangement with a laboratory through

an agreement under which the physician leases or has a role in leasing equipment from or to a laboratory.

Response: We agree with the commenter that, if a physician who is leasing equipment from a laboratory under controlled circumstances refers to that laboratory, this should not lead to program or patient abuse. Section 1877(e)(1)(B), which was added by OBRA '93 retroactive to January 1, 1992, excepts from "compensation arrangements" payments made by a lessee of equipment to the lessor for the use of the equipment if certain conditions (discussed earlier in this preamble at section I.D.7.b.) are met. These conditions are specified in § 411.357(b) of this rule.

5. Group Practice Affiliated Property Companies

In the impact analysis of the proposed rule (57 FR 8601), we discussed group practices with affiliated property companies that are owned by members of the group practice and that lease facilities or equipment to the group. We stated that the group practice would need to restructure if it wanted to continue to make Medicare referrals for clinical laboratory services. Technically, we regarded the lease of equipment by the property company to the group practice that operates a clinical laboratory as a compensation arrangement for which an exception was not provided in the proposed rule. In these cases, it was indicated that the prohibition on referrals would apply, which would require the group physicians to either purchase the equipment from the property company or divest their interests in the laboratory if they intended to continue to make Medicare referrals for clinical laboratory services.

Comment: According to one commenter, in some group practices, affiliated property companies serve as the vehicle for the retirement system for the equity partners in the group practice; that is, as vehicles for creating retirement income. This commenter recommended that we provide an exception for group practices that have affiliated property companies under circumstances in which there is no potential or incentive for program or patient abuse.

Response: What this commenter is concerned about is that the compensation arrangement between the affiliated property company and the group practice might prohibit referrals by the physicians of the group practice to their own in-office laboratory. In this situation, one or more of the group practice physicians who own the

property company receive remuneration from the group practice. In the impact analysis of the proposed rule (57 FR 8601), we indicated that a group practice probably would have to divest its interest in an affiliated property company if it intended to refer Medicare patients to its in-office laboratory. After reconsidering the matter, however, we do not believe that our initial interpretation was correct.

Section 1877(a)(1) of the Act prohibits a physician from making referrals to an entity that furnishes clinical laboratory services if the physician or immediate family member has a financial relationship with that entity. In the situation described by the commenter, the group practice physicians appear to have a financial relationship with the affiliated property company which rents equipment to their laboratory, in the form of an ownership interest. We also regarded as a compensation arrangement the payments which the group practice makes to the affiliated property company for renting the equipment. However, the physicians in this case do not have these financial relationships with an entity that furnishes clinical laboratory services; their relationships are with an entity that only rents equipment to the group practice. As a result, these relationships with the affiliated property company should not affect the physicians' ability to refer to their own laboratory.

Instead, the group practice physicians' referrals could be prohibited because they are referring to a laboratory that they own. Section 1877(b)(2) provides an exception for group practices which refer Medicare patients to their own laboratory for in-office ancillary services. These services must be furnished personally by a member of the group practice or an individual who is directly supervised by a member of the group practice, provided these services are furnished in the building where the group practice has its office or a building that is used by the group practice for furnishing some or all of the group's clinical laboratory services. This provision also has certain billing requirements. The conditions in this exception do not place limitations on the origin of the laboratory equipment that is used by the group practice.

Thus, we have determined that, if the in-office laboratory services are furnished in the manner described by section 1877(b)(2) and § 411.355(b), the nature of the physician's financial relationship with the in-office laboratory is irrelevant. As a result, we do not believe that an additional exception is necessary.

6. Faculty Practice Plan Exception

Comment: Several commenters suggested that a separate exception be developed to treat faculty practice plans associated with accredited medical schools as a separate and distinct type of group practice. These commenters indicated that it is not uncommon in a faculty practice plan environment for the physicians to receive their compensation from one entity (the medical school, for example). However, they may conduct their practice through a separate entity that might be a professional corporation, partnership, or simply a contractually organized billing service. In addition they may order their laboratory work from one or more related entities (for example, the teaching hospital, the university's research laboratory for highly specialized testing, in-office laboratories within faculty departments that may or may not be incorporated as professional corporations, etc.). Since there is no consistent organizational arrangement that characterizes a faculty practice plan, these commenters requested that we develop a separate provision that would treat faculty practice plans associated with accredited medical schools as a separate and distinct type of group practice. They have suggested that the definition of a group practice and the separate requirements of the in-office ancillary exception be applied at the level of the umbrella organization. That is, they believed each legal entity within the same academic setting should not be required to satisfy these provisions. In this manner, any physician who is a staff member of the umbrella organization would be permitted to refer Medicare patients to laboratories that are owned or operated by the umbrella organization.

Response: We believe that the amendments made by OBRA '93 make an additional exception unnecessary. We acknowledge that faculty practice plan physicians may be associated with many organizations in an academic setting, in terms of receiving compensation, furnishing patient care, teaching, and doing research. For example, the medical school may pay the plan to teach residents or care for patients. Even though faculty practice plans may operate in a variety of arrangements, the common theme appears to involve physicians or groups of physicians who are compensated by some part of an academic center for providing a variety of services, and who are concerned about whether they can refer patients to laboratories that belong to the academic center.

If the physicians in the plan are directly employed by the academic center, then their referrals should not be prohibited if the employment meets the standards in section 1877(e)(2) and § 411.357(c). If, alternatively, the physicians or group practice members provide services to the academic center under contract, the personal services provided by these physicians would not be compensation if the arrangement meets the requirements in section 1877(e)(3) and § 411.357(d). In short, we cannot see why a separate exception would be necessary.

Comment: One commenter indicated that, in general, faculty practice plans fall under one of three organizational structures, as explained below:

- A single entity: Many faculty practice plans are organized as a single legal entity that submits a single bill for all physician services across specialties using one common Medicare provider number and, thus, clearly meeting the statutory billing requirement for a group practice.

- Multiple entities by specialty, each billing by its own group provider number: Other faculty practice plans within medical schools and teaching hospitals are organized as multiple legal entities, usually professional corporations established by specialty, that submit multiple bills using a provider number for the respective specialty group.

- Multiple entities by specialty, billing by individual physician provider numbers: Still other faculty practice plans are organized by groups but will submit multiple bills for service by specialty, using individual physician provider numbers.

The commenter recommended, therefore, that the final regulations recognize that a variety of faculty practice plan structures associated with a medical school or teaching hospital exist and should be able to qualify for the in-office ancillary services exception at the level of the umbrella organization. The commenter recommended that we not apply the criteria separately to each legal entity within the same academic setting.

Within an academic setting, according to another commenter, physicians may receive compensation from a variety of entities. They may order their laboratory work from one or more of these entities, such as a teaching hospital, a research laboratory for highly specialized testing, or in-office laboratories within faculty departments. Since there are often indirect financial relationships between and among the various entities within an academic setting, the law appears to prohibit referrals by faculty physicians

between and among these entities. The research laboratory may provide a unique situation because, as the commenter pointed out, it generally performs a highly specialized range of laboratory tests that are not available elsewhere. Therefore, the commenter urged us to craft an exception in the final rule that allows these and similar nonabusive arrangements to continue in the academic setting.

Response: We believe that as long as the faculty practice physicians receive remuneration from the academic institution for their bona fide employment or under personal service arrangements that meet the criteria in sections 1877(e)(2) and (e)(3), the physicians should not be prohibited from making referrals to laboratories that are owned by the academic institution.

7. Special Exception for Group Practices

Comment: We stated in our proposed rule that within the definition of "group practice" substantially all (at least 85 percent) of the patient care services of group practice physicians must be furnished through the group and be billed in the name of the group. Further, amounts received for those services must be treated as receipts of the group. One commenter stated that there are situations in which group practices will be unable to meet the "substantially all" requirements of section 1877(h)(4), or whatever percentage of patient care services is adopted in the final regulations. The commenter offered the example of 15 independently practicing physicians who have primary offices in one part of a city and establish a group practice clinic in a medically underserved area in the same city. Each physician spends 1 day a week at the clinic. In this case, only 20 percent of the services of the physicians in the group would be furnished through the group. This would be insufficient to meet the requirement of proposed § 411.351 that at least 85 percent of the aggregate services furnished by all physician members be furnished through the group practice.

The commenter recommended that an exception be added to the regulations that would allow group practices in medically underserved urban areas to furnish clinical laboratory services without being required to meet the "substantially all" requirement. In this commenter's view, this exception would tend to increase the availability of medical care in those urban areas currently deprived of adequate medical services without creating patient or program abuse.

Response: We note that the Congress has determined that there is a shortage of adequate medical care in locations designated as health professional shortage areas (HPSAs) under section 332(a)(1)(A) of the Public Health Service Act. In order to avoid discouraging group practice physicians from providing services in HPSAs, we are redefining the "substantially all" criteria in the definition of a group practice in § 411.351 in two ways. First, we are excluding from the "substantially all" test group practices that are located only in certain HPSAs. We have defined the term HPSA in reference to the definition of the term under the Public Health Service Act. Section 332(a)(1)(A) of the Public Health Service Act defines the term HPSA to include so-called "geographic HPSAs," that is, "an area in an urban or rural area (which need not conform to the geographic boundaries of a political subdivision and which is a rational area for the delivery of health services) which the Secretary determines has a health manpower shortage and which is not reasonably accessible to an adequately served area."

The Secretary has established criteria for designating areas having shortages of a number of types of health professionals, including primary medical care (which includes general or family practice, general internal medicine, pediatrics and OB/GYN), dental, mental health, vision care, podiatric, and pharmacy professionals. For purposes of this regulation, if an area is a primary care HPSA, any group practice located solely in that HPSA (regardless of whether it provides services of the type classified as primary medical care) will be exempt from the "substantially all" test. Since HPSAs do not exist for a number of specialty areas (for example, oncology, dermatology, neurology), if an area is a primary medical care HPSA, we believe that it is likely that there is a shortage of other types of professionals. Therefore, any group practices that are located solely in such an area and provide services of any type will be exempt from the "substantially all" calculation.

In addition, if an area has been designated an HPSA for one of the other types of professional services, such as vision care, any group practice located solely in the HPSA and providing services that are of the type related to the HPSA designation, such as ophthalmology services, will be exempt from the "substantially all" calculation. On the other hand, if an area is an HPSA for vision care professionals (and for no other type of professional services), group practices providing services

unrelated to vision care in that area will not be exempt from the "substantially all" calculation. There appears to be no justification to exempt such group practices from the "substantially all" calculation in these cases, since there may not be a shortage for such services.

Our second change to the "substantially all" criteria involves group practices located outside an HPSA, but whose members provide services in an HPSA. These outside group practices must continue to meet the "substantially all" test, even if their members provide services in an HPSA. However, we are excluding from the "substantially all" calculation for those groups outside an HPSA any time spent by group members providing the appropriate services in a particular type of HPSA (as described above), whether that time in the HPSA is spent in a group practice, clinic, or an office setting. We have amended § 411.351 ("Definitions") to reflect these concepts. We have also included a definition of "HPSA" in that section.

8. Ambulatory Surgical Center Exception

Comment: One commenter indicated that the Secretary should provide an exception for laboratory services performed in an ambulatory surgical center (ASC). Specifically, the exception should be provided if—

- Any ownership interest of the physician is in the ASC as a whole; and
- Any compensation relationship of the physician with the ASC does not relate to the provision of clinical laboratory services.

Response: We do not entirely agree with this comment. ASC facility services are services that are furnished by an ASC in connection with a covered surgical procedure and that would otherwise be covered if furnished on an inpatient or outpatient basis in a hospital in connection with that procedure. Medicare regulations at § 416.61 describe the scope of facility services. Generally, clinical laboratory services are not considered to be facility services. That is because, under § 416.61(b), ASC facility services do not include items and services for which payment may be made under other provisions in 42 CFR part 405, such as physicians' services, laboratory services, and x-ray or diagnostic procedures (other than those directly related to performance of the surgical procedure). As a result, there are a limited number of diagnostic laboratory tests that are considered ASC facility services and which are included in the ASC rate. We agree with the commenter that referrals for laboratory tests that are performed in

an ASC and included in the ASC rate should be excepted because there is no incentive to overutilize these services.

On the other hand, some ASC's have onsite laboratories that perform and bill for other laboratory testing furnished to ASC patients. Before enactment of CLIA, these laboratories were certified as "independent laboratories" and billed Medicare directly for their services. These laboratory facilities are now required to be certified under CLIA and continue to bill the Medicare program for the laboratory testing performed on the ASC premises, since general laboratory testing is not considered to be part of the ASC facility rate. We believe that, if the onsite laboratory facility is owned or operated by the ASC, referrals to the laboratory for general laboratory testing by a physician who has a financial relationship with the ASC should be prohibited, unless another statutory exception applies.

9. Home Care and Hospice Exception

Comment: One commenter indicated that home health agencies (HHAs) and hospices receive referrals from physicians to provide an array of services in the home. Currently, HHAs and hospices do not bill the Medicare program separately for laboratory services; instead, they bill for a home visit or the per diem hospice charge. The commenter made the following two recommendations:

- The regulations should clearly state that the prohibition does not apply to referrals to entities that do not bill Medicare separately for laboratory testing.
- Another exception should be developed to specify that the Medicare rules governing physician interest in HHAs would also apply to those entities in relation to laboratory services ordered by physicians. Thus, a physician's interest in a clinical laboratory would be permitted if the interest is less than 5 percent.

Response: As discussed earlier, OBRA '93 expanded the list of services subject to the prohibition to include 10 additional services. Because the list of services subject to the prohibition includes home health services, we do not believe an exception for laboratory services provided by home health agencies is warranted.

We agree with the commenter that referrals for laboratory tests that are performed by a hospice and are included in the per diem hospice charge should be excepted because a per diem amount does not reflect the number of tests performed. As a result, we are providing an exception in § 411.355 for laboratory services that are provided by

a hospice and billed as part of the per diem rate.

We disagree with the commenter's second recommendation. Section 1877 prohibits referrals to an entity by a physician who has a financial relationship with that entity. A financial relationship consists of an ownership or investment interest in the entity, regardless of the extent or degree of that ownership interest. Therefore, if a physician owns 5 percent or 95 percent of an entity, he or she is prohibited from making referrals to that entity, unless some exception applies. We will not grant an extra exception for ownership interests that are less than a particular percentage or that involve HHAs. That is because we do not have any evidence upon which to base a percentage or to ensure that the exception would be free from any risk of program or patient abuse.

10. Rural Laboratory Compensation Arrangements

Section 1877(d)(2) provides that ownership or investment by a physician in a rural provider of clinical laboratory services will not prohibit referrals by the physician to that rural provider.

Comment: One commenter stated that the statutory exception for rural laboratories is of little value since it provides only an exception to the ownership or investment interest test and still leaves the rural laboratory subject to the compensation arrangement test. Thus, the commenter recommended that the final rule contain an exception for compensation arrangements between a rural laboratory and a referring physician.

Response: Because of the OBRA '93 amendments to section 1877, we do not believe the exception recommended by the commenter is necessary. Section 1877 now contains exceptions that we believe will cover many compensation arrangements between physicians and laboratories. In addition to the section 1877(d)(2) ownership exception for rural laboratories, section 1877(e)(2) provides an exception if a laboratory compensates a physician as the result of a bona fide employment relationship, and section 1877(e)(3) provides an exception for remuneration from an entity to a physician under a personal services arrangement between the physician and entity. Finally, there are other additional exceptions relating to various other compensation relationships that a physician might have with a laboratory. For example, under section 1877(e)(8), a physician can purchase clinical laboratory services from a laboratory, or other items and services from a laboratory at fair market

value, without triggering the prohibition. These exceptions apply to relationships with all laboratory entities, including those located in rural areas, provided the conditions set forth in the statute and this final regulation are met.

11. Case-by-Case Exemptions

Comment: One commenter indicated that we should institute a process by which a laboratory may request an exemption from the law on an individual basis, based upon a determination by the Secretary that enforcement of the prohibition against the laboratory would not be in the public interest. The commenter suggested that narrow guidelines should be established for the types of laboratories that would be eligible to apply for this exemption. Thus, in the commenter's view, the administrative burden would not be prohibitive. The commenter proposed that, in order to be eligible for review, that any one of the following criteria be met:

- The laboratory is wholly owned by one referring physician or one group practice. This requirement would exclude the physician joint venture type laboratories, which this commenter believed are the entities intended to be regulated by the law.
- Referrals to a laboratory by physicians who have financial relationships with the laboratory do not exceed a specified percentage of the total laboratory volume. The commenter suggested that the referrals be limited to 40 percent of the laboratory's total volume, consistent with the Medicare anti-kickback investment safe harbor volume criterion. (See 42 CFR part 1001.)

- A laboratory located in a town or similar-type population center with a population of 10,000 or under should be eligible for exemption review if it is the sole outpatient provider of certain laboratory services within that locality. This would recognize that localities that are within an MSA may, in fact, be small towns lacking adequate outpatient laboratory services.

Response: We do not agree that we should implement such a process. Section 1877(b)(4) specifies that, in addition to the exceptions described in the statute, the section 1877(a)(1) prohibition will not apply with respect to any other financial relationship which the Secretary determines, and specifies in regulations, does not pose a risk of program or patient abuse (emphasis added). The statute speaks in terms of excepting particular financial relationships according to rules that would apply to any person or entity that

has such a relationship. It does not authorize "case by case" exceptions.

In addition, we do not believe that the guidelines suggested by the commenter to single out those who are eligible for case-by-case review would provide a guarantee against patient or program abuse. It is not clear to us why the review should only be available when a laboratory is wholly owned by one referring physician or one group practice. The commenter's second guideline would allow a laboratory entity to derive 40 percent of its business from referrals by physicians with whom the entity has a financial relationship. We do not believe that this standard would, in any way, satisfy the requirement under section 1877(b)(4) that exceptions beyond those specified in the law pose no risk of program or patient abuse. We simply do not see how a standard excusing any percentage of referrals would guarantee no risk of abuse.

Finally, we understand that it might be possible that a laboratory located within an MSA could have its existence threatened if it cannot accept referrals from physicians with whom it has financial relationships. The commenter did not, however, identify any specific localities, so we cannot tell how likely it is for this to occur. In any case, any such exception must be shown to comply with the "no abuse" criterion, and the commenter has provided us with no evidence that such an exception would be free of abuse. For these reasons, we are not adopting this suggestion.

12. Physician Ownership of Public Companies

Section 411.357(a)(2) of the proposed regulation provided an exception for a physician's or family member's ownership in a publicly owned corporation, provided that the ownership interest met certain requirements. Among these were the requirement that the corporation have, at the end of its most recent fiscal year, total assets exceeding \$100 million. This requirement reflected section 1877(c)(2) of the statute. OBRA '93 amended the statute to require, instead, stockholder equity exceeding \$75 million at the end of the corporation's most recent fiscal year or on average during the previous 3 fiscal years. SSA '94 made this amendment effective retroactive to January 1, 1992. However, it also provided that, until January 1, 1995, a corporation could still meet the requirement in the exception if it qualified under the pre-OBRA '93 standard.

Comment: One commenter suggested that we create an exception allowing physicians to own shares in clinical laboratories that satisfy the first test of the statutory public-company exception (having publicly-traded securities on the specified national securities exchanges) whether or not the company has \$100 million in assets (as required in proposed § 411.357(a)(2)), under certain conditions.

The conditions suggested were that: (1) The total physician ownership of each class of securities of the entity is less than 20 percent, and (2) no one physician's ownership of any class of securities of the entity represents more than 5 percent of the class. The commenter believed that such ownership would not pose a risk of abuse under Medicare. For example, the stock of Laboratory Corporation A, which has assets of \$50 million, is owned by the following individuals. Laboratory Corporation A has only one class of stock.

| Individual | Per-centage |
|-----------------|-------------|
| Dr. Abe | 5 |
| Mr. Brown | 17 |
| Dr. Car | 5 |
| Mr. Dorr | 17 |
| Dr. Else | 5 |
| Mr. Frank | 17 |
| Mr. Green | 12 |
| Mr. Hann | 12 |
| | 100 |

In this example, no one physician owns more than 5 percent of the stock of Laboratory Corporation A and the total physician ownership is 15 percent. The commenter stated that these facts should allow the owner-physicians to refer to Laboratory Corporation A because, in the commenter's view, since the majority of stockholders are nonphysicians, the physicians have no incentive to overutilize laboratory testing to increase the value of their investments. The commenter concluded, therefore, that there would not be the risk of patient or program abuse.

Another commenter suggested that we create an exception for public companies similar to that of the safe harbor for investment interest under the anti-kickback statute. Generally, the commenter suggested that the exception should follow all of the requirements found in 42 CFR 1001.952(a), "Investment interests safe harbor."

Response: The second comment is related to the first, in that one of the requirements found in § 1001.952(a)

also establishes a percentage limit on the amount of the investment. That is, § 1001.952(a)(2)(i) specifies that, in order to qualify for the safe harbor exception, "[n]o more than 40 percent of the value of the investment interests of each class of investments may be held * * * by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity."

While each commenter has made a good suggestion, we do not have any data supporting the first commenter's assumption that a limit of 5 percent ownership of a class of securities by individual physicians and a limit of up to 20 percent ownership of a class of securities by all physicians poses no risk of abuse. We believe that the Congress was very deliberate in establishing the requirements for the exception based on ownership or investment in publicly traded securities that is found in section 1877(c). Further, as pointed out in an earlier response, in order to establish additional exceptions, we must determine that the financial relationship does not pose a risk of program or patient abuse. To adopt the suggested approaches, we would, for example, be required to justify why a total of 20 percent physician ownership in a company would be abusive while a total of less than 20 percent physician ownership in a company would not be abusive. We do not have data to justify such a distinction.

13. Compensation Exception

Comment: One commenter proposed that an additional exception to the prohibition on referrals be added to address certain compensation arrangements between clinical laboratories and physicians. This commenter stated that, under a typical contractual arrangement between a clinical laboratory and a physician, the physician pays a reasonable fee to a laboratory to provide a service in an area in which the physician or his or her office personnel lack expertise. Some examples would be assisting the physician to establish a billing service, providing management services, and hosting educational seminars. The commenter suggested that this exception could contain the following elements:

- The agreement must be in writing and be signed by all of the parties.
- The agreement must be for identifiable services, which must be clearly set forth in the agreement.
- Compensation must be consistent with fair market value for these services.

- The compensation must be considered commercially reasonable even if no referrals were made.

- The amount of compensation for the services must not vary based on the volume or value of any referrals of business by the physician.

- The services must be offered by the clinical laboratory to all physicians.

- There must be no requirement on the part of the physician to refer patients.

As described, this situation involves a payment by the physician to the laboratory under the terms of a contract.

Response: We agree that physicians incur a legitimate cost when they must provide certain services, such as continuing medical education for themselves and their staff members. In addition, the physicians should be able to determine where they can best get these services. The commenter has asked that we add a new exception to the prohibition on referrals to address certain compensation arrangements in which a physician pays a reasonable fee to a laboratory to provide a service in an area in which the physician or his or her office personnel lack expertise. We believe that an additional exception under the authority of section 1877(b)(4) is not necessary. Section 1877(e)(8), as added by OBRA '93, provides an exception for payments made by a physician to any entity as compensation for items and services (other than clinical laboratory services) if the items or services are priced at fair market value. This provision is effective retroactively to January 1, 1992, and is included at § 411.357(i) of this rule.

Comment: A few commenters noted that a laboratory encounters a problem, for the following reasons, if it has an employee who is related to a physician who refers work to the laboratory. The referral prohibition is triggered not only by physicians who themselves have financial relationships with a laboratory entity but also by a physician's immediate relatives who have financial relationships. As a result, the laboratory's payment to an employee can constitute a compensation arrangement and, under the proposed rule, the laboratory would not be permitted to accept referrals from that physician. The commenters suggested that, as long as the employer has a bona fide employment relationship with the employee, there is no reason to question these employment arrangements. The commenters suggested that, with an added exception, the laboratory would be able to avoid the burdensome process of polling its employees to determine if they have a relative who is a referring physician.

Response: Section 1877(e)(2), as amended by OBRA '93, establishes a new exception for bona fide employment situations between an entity and a physician or an immediate family member of a physician. The conditions for the exception are as follows:

- The employment arrangement is for identifiable services.

- The amount of the remuneration under the employment—
 - + Is consistent with the fair market value of the services, and
 - + Is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician.

- The remuneration is provided under an agreement that would be commercially reasonable even if no referrals were made to the employer.
 - + The employment meets such other requirements as the Secretary may impose by regulations as needed to protect against program or patient abuse.

Finally, the employees may be paid a productivity bonus based on services they personally performed.

V. Analysis of and Responses to Public Comments on the Interim Final Rule With Comment Period—Reporting Requirements for Financial Relationships Between Physicians and Health Care Entities That Furnish Selected Items and Services

Section 152(a) of SSA '94 amended the reporting requirements in section 1877(f) of the Act. As amended, section 1877(f) specifically applies to not only physicians with an ownership or investment interest in an entity, but to physicians who have a compensation arrangement with an entity as well. SSA '94 also eliminated the Secretary's authority to waive the reporting requirements for certain States or services, although the Secretary continues to have the right to determine that an entity is not subject to the reporting requirements because it provides services covered under Medicare very infrequently. In addition, the reporting requirements continue to not apply to designated health services furnished outside of the United States.

The SSA '94 amendments apply to referrals made on or after January 1, 1995. However, section 1877(f) does not apply to referrals at all, but instead requires providers of Medicare covered items and services to report certain information about their financial relationships with physicians at such times as the Secretary specifies. As such, section 152(d), the effective date provision for the SSA '94 amendments,

is silent on when the amendments would apply to a provision that has no nexus with referrals. If section 152 is silent on this issue, we believe that the effective date is the date of enactment of the amendments, which is October 31, 1994. We have incorporated the amendments to section 1877(f) into § 411.361, to apply to any future reporting that we require.

Below we summarize and respond to comments we received in response to the interim final rule with comment period that was published in the **Federal Register** on December 3, 1991 (56 FR 61374). We received timely comments from five organizations.

Near the end of calendar year 1991, we developed a questionnaire titled "Survey of Financial Relationships Between Physicians and Selected Health Care Entities" (form HCFA-95) and forwarded it to selected hospitals, ESRD facilities, suppliers of ambulance services, entities furnishing diagnostic imaging (including magnetic resonance imaging, computerized axial tomography scans, ultrasound, and other diagnostic imaging services), parenteral and enteral suppliers, and entities furnishing physical therapy services. (This survey was also known as the "Ten State Survey.") This process was a collection of information concerning the financial interest arrangements of any entity that furnishes selected items and services for which payment may be made under Medicare. The survey was to be completed by all entities furnishing the above listed covered items and services to Medicare beneficiaries. The scope of the survey was limited to entities in the following 10 States: Connecticut, Pennsylvania, West Virginia, South Carolina, Florida, Michigan, Ohio, Texas, Arkansas, and California.

Surveys were sent to those entities that submitted claims to the Medicare intermediary or carrier for more than 20 items or services in any of the selected categories during calendar year 1990. Originally, an entity was required to return the survey not more than 30 days after the entity received it. Shortly after December 3, 1991, the date contractors were instructed to send the surveys via overnight, certified mail, the response time was extended from 30 days from the date of receipt to 60 days from the date of receipt.

Two commenters applauded our citing the need for the survey because of the potential for abusive behavior in situations where the referring physician has an ownership interest in the facility to which he or she refers patients. A discussion of other comments and our responses to them follow.

Comment: One commenter suggested that requiring the completed survey to be submitted before or at the same time that the comments on the interim final rule were due made the opportunity to comment meaningless.

Response: We agree that the timing of the deadlines for the completed survey and the comments on the interim final rule could be regarded as having had the effect of reducing a commenter's ability to have an impact on that particular survey. As we pointed out in the preamble to the interim final rule, however, section 4207(k) of OBRA '90 authorized the Secretary to issue interim final regulations for the amendments to the Medicare statute. In the preamble, we explained the pressing need for the interim final rule in order for us to fulfill several legislative requirements within their prescribed deadlines. These included carrying out the survey requirements of section 1877(f), as amended by OBRA '90, obtaining adequate information from health care entities in time to apply the payment provisions in section 1877, as amended by OBRA '90, and preparing the statistical profile required by OBRA '89, as amended by OBRA '90.

The purpose of the interim final rule was primarily to notify the public of the decisions the Secretary had made on the few items of discretion left to the Secretary under OBRA '90, such as the selection of the States in which the survey would be administered (the legislation prescribed a minimum of 10 States). In addition, we do not regard the opportunity that was provided to comment on the interim final rule as meaningless. Section 1877 allows the Secretary to collect the survey information in such form, manner, and at such times as she specifies, as long as it is first collected no later than October 1, 1991. The Secretary will take the comments into account if she decides to survey the entities again.

Comment: One commenter suggested that we extend the time for responding to the survey by 60 days and announce the extension publicly.

Response: As noted, we did provide for an automatic extension of 30 days, allowing a total of 60 days for response. We provided 19 representative specialty societies, for example, the American Medical Association, the American Hospital Association, and the American College of Radiology, with this information to alert their members. In addition, we alerted Medicare contractors who, in turn, alerted providers via updates in their routinely distributed bulletins and newsletters.

Comment: One medical specialty association had received several

complaints from its members concerning the question of who must report the ownership interest and what information must be reported. The association stated that the definition of "entity" (physicians, suppliers, or providers) in the instructions was too broad.

Response: The statute at section 1877(f) required, prior to SSA '94, that "[e]ach entity providing covered items or services for which payment may be made under [Medicare] shall provide the Secretary with the information concerning the entity's ownership arrangements, * * *." (Emphasis added.) The statute does not define an "entity." Thus, we could include within this concept any individuals or groups that provided Medicare covered items or services. We surveyed every entity, regardless of type, that provided more than 20 services in 1990 from the minimum set of services (hospital services, ambulance services, etc.) covered by the statutory requirement for this study. The use of the terms "physicians, suppliers, or providers" in our survey instructions was meant to cover all types of entities that had provided more than 20 services during 1990 of the types listed in the legislation.

Comment: One commenter wrote that there was no question on the survey that distinguished between those physicians who have an ownership interest in a facility and those who do not, like hospital-based radiologists. The commenter recommended that information relative to hospital-based practices be extracted and excluded from the study as it could produce a flawed database.

Response: We are not certain of the point this commenter wanted to make. Our survey form clearly distinguished between physicians with an ownership interest in an entity and physicians compensated by an entity, such as hospital-based radiologists. After receiving these survey forms, we matched data from the forms to Medicare claims data to determine referral patterns to entities that had submitted these survey forms. Since we also had information for each entity billing the program relating to whether the patient was referred to the entity by a physician with an ownership interest or by a physician compensated by the entity, the study was able to determine the referral patterns to that entity in a totally objective manner.

Comment: Two commenters wrote that the regulations would result in unreasonably burdensome reporting obligations for certain health care entities. The commenters believed that

the collection of useless information will thwart, rather than support, legitimate monitoring efforts. Examples of information that the commenters believed was unnecessary was identifying *all* physicians in a teaching hospital, considering the size of the facility, the number of salaried staff and faculty, and the time and effort required to collect, organize, check, and report the required data.

Response: The scope of the data collection activity was expansive in order to ensure that the Congress had sufficient information on utilization rates by physician owned and non-owned entities to consider in its legislative activities. While this may have appeared to be more data than could be effectively used, we believed a more narrow data collection effort would have resulted in the Congress having insufficient facts when considering legislative alternatives. Surveyed entities were expected to make good faith efforts to complete the surveys accurately, completely, and timely. In addition, we granted extensions to the 60-day response period on a case-by-case basis.

Comment: One commenter opposed the requirement that hospitals report compensation/remuneration arrangements, because the requirement exceeds the scope of section 1877(f) of the Act.

Response: Prior to SSA '94, section 1877(f) did not specifically provide us with the authority to require that hospitals report compensation/remuneration arrangements. Section 1877(f) required that entities report only the ownership or investment interests of physicians. As we pointed out in the preamble to the interim final rule, however, we believed that other parts of section 1877, the payment provisions of the Medicare statute, and section 6204(f) of OBRA '89, as amended by OBRA '90, implicitly required us to collect this information.

As we pointed out at 56 FR 61376, we need the information on compensation/remuneration arrangements in order to enforce the general prohibition, in section 1877, against physicians referring to laboratories with which they have a financial relationship, including a relationship based on a compensation arrangement. Without the reporting requirement, we would not have sufficient information to make payment determinations. Also, we would not have had the data we needed to prepare the statistical profile required by section 6204(f) of OBRA '89, as amended by section 4207(e)(4) of OBRA '90. This provision required us to produce a profile that covered all of a physician's

direct or indirect financial interests. As we explained earlier, beginning October 31, 1994, § 152(a) of SSA '94 amended § 1877(f) to explicitly require that a reporting entity provide information concerning the entity's ownership, investment, and compensation arrangements.

Comment: One commenter suggested that the imposition of civil monetary penalties on reporting entities that fail to report compensation/remuneration arrangements in a timely manner exceeds our statutory authority.

Response: Section 1877(g)(5) provides a civil money penalty when a person fails to meet the reporting requirements of section 1877(f). Section 1877(f), prior to OBRA '93, concerned information related to ownership interests only. However, as the result of the changes made in § 1877(f) by § 152(a) of SSA '94, entities are now required to provide information about ownership, investment, and compensation arrangements. As a result, we now have the authority to impose a civil money penalty when an entity fails to provide any of these kinds of information.

Comment: One commenter from California suggested that reporting employee information would place a hospital in jeopardy of violating certain State laws and State regulations.

Response: As we stated in an earlier comment, we have interpreted section 1877, the payment provisions of the Medicare statute, and section 6204(f) of OBRA '89 as requiring that reporting entities provide us with information about all of their financial relationships with a physician or a physician's family member. The statute at § 1877(f) now requires this information for all ownership, investment, and compensation arrangements. If this explicit Federal requirement conflicts with State law or State regulations, the Federal law and Federal regulations prevail.

VI. Provisions of This Final Rule

We have extensively rearranged the regulations from what we proposed and have added numerous OBRA '93 provisions as amended by SSA '94. Because of these many changes, we are including, in section VI.C., a list identifying whether the requirements in this final rule derive from OBRA '93, SSA '94, the proposed rule, or comments on the proposed rule. In addition, we identify below the changes from the December 1991 interim final rule and the March 1992 proposed rule.

A. Proposed Rule—Physician Ownership of, and Referrals to, Health Care Entities That Furnish Clinical Laboratory Services

Based on our analysis of the comments, we are adopting the provisions as set forth in the March 1992 proposed rule, with the following changes. The reason for a change either has been discussed in section IV of this preamble, the change is a result of the provisions of OBRA '93 or SSA '94, or the change merely conforms the regulations to the statute.

- In § 411.1 ("Basis and scope"), we added that section 1877 of the Act sets forth limitations on referrals and payment for clinical laboratory services furnished by entities with which an immediate family member of the referring physician has a financial relationship. This change was made to conform the regulation to the statute.

- As a result of the comments we received, we revised the definition of "compensation arrangement" at § 411.351 ("Definitions") to clarify that it applies to direct and indirect arrangements.

- We revised the definition of "group practice" at § 411.351 as follows:

- + Revised the "substantially all" threshold to 75 percent of the total patient care services of group practice members, measured as "patient care time."

- + Expanded and moved, to a new § 411.360, the requirements related to the group practice attestation statement.

- + Provided an exception to the "substantially all" requirement for those services furnished through a group practice located solely in certain areas designated as HPSAs under § 411.351. Also specified in this section that when members of a group practice that is located outside an HPSA spend time providing services in certain HPSAs, that time is not used to calculate the outside group's "substantially all" standard.

- We removed the definitions of "interested investor" and "investor" from § 411.351.

- We revised the definition of "remuneration" at § 411.351 to provide that forgiveness of debts, certain payments, and the furnishing of certain items, devices, and supplies are not considered remuneration if they meet specified conditions.

- We added a definition of "clinical laboratory services," "direct supervision," "hospital," "HPSA," "laboratory," "members of the group," "patient care services," "physician incentive plan," "plan of care," and "transaction" to § 411.351.

- We revised § 411.355 (“General exceptions to referral prohibitions related to both ownership/investment and compensation”) to do the following:
 - + For purposes of the in-office ancillary services exception in § 411.355(b), require that individuals furnishing services be “directly” supervised by the referring physician or by another physician in the same group practice. (The proposed rule had required that services be provided by an employee who was “personally” supervised by these physicians.)
 - + Include among the locations where the service may be furnished a building that is used by the group practice for the provision of some or all of the group’s clinical laboratory services. (The proposed rule had required that the building be used by the group practice for centrally furnishing the group’s clinical laboratory services.)
- We added the following services to the general exceptions listed under § 411.355 (“General exceptions to referral prohibitions related to both ownership/investment and compensation”):
 - + Services furnished by a qualified HMO (within the meaning of section 1310(d) of the Public Health Service Act) to individuals enrolled in the organization (new § 411.355(c)(4)).
 - + Services furnished in an ASC or ESRD facility or by a hospice and included in the ASC rate, ESRD composite rate, or per diem hospice charge, respectively (new § 411.355(d)).
- We revised proposed § 411.357, now designated as § 411.356, (“Exceptions to referral prohibitions related to ownership or investment interests”) to—
 - + Revise the requirements relating to publicly-traded securities, as specified in section 1877(c) of the Act (as amended by OBRA ’93 and SSA ’94), to include securities which “may be purchased” on terms generally available to the public, which can be those traded on additional stock markets, and which can be in corporations that had the following:
 - Until January 1, 1995, total assets at the end of the corporation’s most recent fiscal year exceeding \$100 million, or
 - Stockholder equity exceeding \$75 million at the end of the corporation’s

- most recent fiscal year, or on average during the previous 3 fiscal years
 - + No longer specify, with regard to the corporation’s assets, that these assets must have been obtained in the normal course of business and not for the primary purpose of qualifying for the exception;
 - + Expand the exception to include mutual funds that constitute ownership in shares in certain regulated investment companies, if the companies had, at the end of their most recent fiscal year, or on average during the previous 3 fiscal years, total assets exceeding \$75 million.
 - + Until January 1, 1995, retained the exception for a hospital located outside of Puerto Rico based on the condition that the referring physician’s ownership or investment interest does not relate to the furnishing of clinical laboratory services.
 - + Revise the requirements relating to rural providers, as specified in the proposed rule, to delete paragraph (ii), which added the requirement that the majority of tests referred to the rural laboratory are referred by physicians who have office practices located in a rural area.
 - + Revise the requirements relating to rural providers, as specified in the proposed rule, to include the requirement that substantially all of the tests furnished by the entity are furnished to individuals residing in a rural area.
- We revised proposed § 411.359, now designated as § 411.357, (“Exceptions to referral prohibitions related to compensation arrangements”) to do the following:
 - + Revise (a)(1) to reflect new requirements specified by OBRA ’93 for the rental of space.
 - + Remove proposed paragraph (a)(2), which contained requirements related to a physician who has an ownership or investment interest in a laboratory and who also rents or leases space to the laboratory.
 - + Add an exception for rental of equipment under certain conditions (new § 411.357(b)).
 - + Add an exception for certain group practice arrangements with a hospital (new § 411.357(h)).
 - + Add an exception for payments by a physician to a laboratory or other

- entity in exchange for certain items and services (new § 411.357(i)).
 - + Replace proposed § 411.359(b) (“Employment and service arrangements with hospitals”) and proposed § 411.359(f) (“Salaried physicians in a group practice”) with a new § 411.357(c) (“Bona fide employment relationships”). New § 411.357(c) is based on the exception at section 1877(e)(2) of the Act.
 - + Replace proposed § 411.359(e) (“Service arrangements with non-hospital entities”) with a new § 411.357(d) (“Personal service arrangements”). New § 411.357(d) is based on the exception at section 1877(e)(3) of the Act.
 - We added a new § 411.360 that requires that a group practice submit annually a statement attesting that it met the “substantially all” test set forth, under the definition of “group practice,” in § 411.351 of this rule. This section also specifies how a newly-formed group practice meets the “substantially all” criterion.
- In addition to the above changes, we have made technical changes. For example, in proposed § 411.355(c)(1), we cross-referenced part 417, subpart C. Subpart C has been redesignated by a new rule. The applicable provisions being cross-referenced are now under subparts J through M. We have also made editorial changes that do not affect the substance of the provisions.

B. Interim Final Rule With Comment Period—Reporting Requirements for Financial Relationships Between Physicians and Health Care Entities That Furnish Selected Items and Services.

The interim final rule with comment published on December 3, 1991, is revised to incorporate the amendments to section 1877(f) made by SSA ’94, to apply to any future reporting that we require. However, providers will not be held to the reporting requirements under section 1877(f) until we develop and issue the proper form and accompanying instructions booklet. Until that time, we will use audits and investigations as the primary tools to evaluate compliance with these provisions.

C. Source of Final Regulations.

| Final regulations | Source |
|------------------------------------|----------------------------------|
| § 411.1 Basis and scope | Proposed § 411.1. |
| § 411.350 Scope of subpart | Proposed § 411.350, SSA ’94. |
| § 411.351 Definitions | § 411.351. |
| Clinical laboratory services | Comments. |
| Compensation arrangement | Proposed § 411.352 and comments. |
| Direct supervision | Comments and OBRA ’93. |

| Final regulations | Source |
|--|--|
| Employee | Proposed § 411.351. |
| Entity | Proposed § 411.351. |
| Fair market value | Proposed § 411.351. |
| Financial relationship | Proposed § 411.351. |
| Group practice | Proposed § 411.351, OBRA '93, and Comments. |
| HPSA | Comments. |
| Immediate family member | Proposed § 411.351. |
| Laboratory | Comments. |
| Members of a group | Comments. |
| Patient care services | Comments. |
| Physician incentive plan | OBRA '93. |
| Plan of care | Comments. |
| Referral | Proposed § 411.351 and Comments. |
| Referring physician | Proposed § 411.351. |
| Remuneration | Proposed § 411.351 and OBRA '93. |
| Transaction | Comments. |
| § 411.353 Prohibition on certain referrals by physicians and limitations on billing. | Proposed § 411.353. |
| (a) Prohibition on referrals | Proposed § 411.353(a). |
| (b) Limitations on billing | Proposed § 411.353(b). |
| (c) Denial of Payment | Proposed § 411.353(c). |
| (d) Refunds | Proposed § 411.353(d). |
| § 411.355 General exceptions to referral prohibitions related to ownership and compensation ... | Proposed § 411.355. |
| (a) Physicians' services | Proposed § 411.355(a). |
| (b) In-office ancillary services | Proposed § 411.355(b) and services OBRA '93. |
| (c) Services furnished to prepaid health plan enrollees | Proposed § 411.355(c). |
| (c)(1) HMO or CMP under section 1876 | Proposed § 411.355(c)(1). |
| (c)(2) Prepaid plan under section 1833(a)(1)(A) | Proposed § 411.355(c)(2). |
| (c)(3) An organization receiving payments through a demonstration project | Proposed § 411.355(c)(3). |
| (c)(4) A qualified HMO within the meaning of section 1310(d) of the Public Health Service Act. | OBRA '93. |
| (d) Services furnished in an ASC or ESRD facility | Comments. |
| § 411.356 Exceptions to referral prohibitions related to ownership or investment interests | Proposed § 411.357. |
| (a) Publicly-traded securities | Proposed § 411.357(a) and OBRA '93. |
| (b) Mutual funds | OBRA '93. |
| (c) Specific providers | Proposed § 411.357(b). |
| (c)(1) Rural laboratories | Proposed § 411.357(b)(1) and Comments. |
| (c)(2) Hospitals in Puerto Rico | Proposed § 411.357(b)(2). |
| (c)(3) Hospitals outside of Puerto Rico | Proposed § 411.357(b)(3), OBRA '93, SSA '94. |
| § 411.357 Exceptions to referral prohibitions related to compensation arrangements | Proposed § 411.359. |
| (a) Rental of office space | OBRA '93. |
| (b) Rental of equipment | OBRA '93. |
| (c) Bona fide employment | OBRA '93. |
| (d) Personal service arrangements | |
| (d)(1) General | OBRA '93. |
| (d)(2) Physician incentive plan exception | OBRA '93. |
| (e) Physician recruitment | Proposed § 411.359(c). |
| (f) Isolated transactions | Proposed § 411.359(d), Comments, OBRA '93. |
| (g) Arrangements with hospitals | OBRA '93. |
| (h) Group practice arrangements with a hospital | OBRA '93. |
| (i) Payments by a physician | OBRA '93. |
| § 411.360 Group practice attestation | Comments. |
| § 411.361 Reporting requirements | Existing § 411.361 and SSA '94. |

VII. Collection of Information Requirements

Regulations at § 411.360 contain information collection or recordkeeping requirements or both that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). The information collection requirements concern those group practices attempting to meet the definition found in section 1877(h)(4) and require them to attest that, in the aggregate, at least 75 percent of the total patient care services furnished by all physician members are furnished through the group and are

billed under a billing number assigned to the group. Public reporting burden for this collection of information is estimated to be 1 hour per response. A document will be published in the **Federal Register** after approval is obtained. Organizations and individuals desiring to submit comments on the information collection and recordkeeping requirements should direct them to the OMB official whose name appears in the **ADDRESSES** section of this preamble.

VIII. Regulatory Impact Statement

A. Introduction

The provisions of this final rule with comment period implement section 6204 of OBRA '89 and section 4207(e) of OBRA '90, which concern a limitation on certain physician referrals. In addition, the rule contains revisions to our March 1992 proposal, based on comments submitted by the public. This final rule also incorporates the new expansions and exceptions created by OBRA '93, as amended by SSA '94, that are related to referrals for clinical laboratory services and have a

retroactive effective date of January 1, 1992. This final rule with comment, by prohibiting physician referrals for clinical laboratory services by physicians who have certain ownership, investment, or compensation arrangements with the entity furnishing the service, is meant to eliminate the ordering of unnecessary laboratory tests.

According to the OIG report cited in the March 1992 proposed rule (57 FR 8589), at least 25 percent of the nearly 4500 independent clinical laboratories, at the time of the report, were owned in whole or in part by referring physicians. The same OIG report revealed that Medicare patients of referring physicians who own or invest in these laboratories received 45 percent more clinical laboratory services than all Medicare patients. The OIG estimated in its report that the "increased utilization of clinical laboratory services by patients of physician-owners cost the Medicare program \$28 million nationally in 1987." (Financial Arrangements Between Physicians and Health Care Businesses, (May 1989))

We believe the majority of physicians and clinical laboratories do not currently make referrals that are prohibited by this rule. In addition, we believe that, in response to the statutory provisions, many physicians and laboratories took necessary steps, before January 1, 1992, to ensure that their investment and employment activities did not restrict their ability to make referrals. Therefore, any estimate of the aggregate economic impact of this rule will be purely speculative. We believe the statute itself will have a continuing deterrent effect on physicians' aberrant referral patterns and investment interests.

B. Regulatory Flexibility Act

Consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), we prepare a regulatory flexibility analysis unless the Secretary certifies that a rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, we consider all hospitals, physicians, and clinical laboratories to be small entities.

In addition, section 1102(b) requires the Secretary to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b), we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

We expect that a few entities may be affected to varying degrees by this final rule. Relative to the potential impact on these entities, the following discussion is provided.

1. Impact on Physicians and Physician Groups

Physicians reportedly find it inefficient and inconvenient to split their laboratory referral business among multiple laboratories; the physician who uses one laboratory for private-pay patients is likely to use that same laboratory for all of his or her patients. Therefore, it is conceivable that, absent this rule, a physician could seek an ownership or investment interest in a laboratory, or a compensation arrangement with a laboratory, in order for the physician to share in the profits of the laboratory to which he or she makes referrals. In these cases, the prohibition on referrals might apply, which will require the physician to either dispose of his or her interest in the laboratory or stop referring Medicare patients to that laboratory.

As discussed at length earlier in this preamble, some physicians who have independent practices maintain a physician office laboratory with other physicians in shared premises, with shared equipment, shared employees, a shared administrator who has the power to hire and terminate employees on behalf of the physicians, and shared overhead costs. For the most part, these shared office space arrangements are not eligible for the in-office ancillary exception found in section 1877(b)(2) and, therefore, the prohibition on referrals does apply. Thus, the physicians must each separately meet the in-office ancillary services requirements, form a group practice meeting the definition of section 1877(h)(4) of the Act, dispose of their interest in the shared laboratory facility, or stop referring Medicare patients to that laboratory facility.

Also as discussed earlier, in response to OBRA '93 changes, we have added exceptions to the prohibition on referrals that we believe recognize existing medical practice, are reasonable, and will not result in program abuse.

As a result of public comments we received in response to the proposed rule, we are revising the definition of "group practice" (§ 411.351) by lowering the "substantially all" threshold from 85 percent to 75 percent of the total patient care services of group practice members. This change will allow groups of physicians additional flexibility in hiring part-time and temporary physicians, without the

group jeopardizing its standing as a group practice.

2. Impact on Laboratories

As mentioned earlier in this impact statement, the report from the OIG to the Congress indicated that at least 25 percent of the nearly 4500 independent clinical laboratories were owned in whole or in part by referring physicians. The same report found that Medicare "patients of referring physicians who own or invest in these laboratories received 45 percent more clinical laboratory services than all Medicare patients * * *." Other studies found equivalent correlations involving physician self-referrals. However, we are unable to estimate with any degree of accuracy how existing physician laboratory owners will react to the provisions of the law and this rule or how the utilization of laboratory services will change. Nevertheless, given the extensive reach of section 1877 of the Act and these final regulations and the substantial penalties that are provided for violations of the prohibition on referrals, we believe that laboratories and physicians have been restructuring their relationships to ensure compliance with the statute and will continue to do so.

3. Impact on Hospitals

Sections 411.356 (b)(2) and (b)(3) include exceptions related to the prohibition on referrals for ownership or investment interests in certain hospitals. Sections 411.357 (c), (d), (e), (g), and (h) include exceptions related to the prohibition on referrals for compensation for services performed or supervised by physicians. Because we believe that a large number of the financial relationships between physicians and hospitals are covered by these exceptions, we do not believe hospitals will be significantly affected by this rule. In addition, hospitals in Puerto Rico and many hospitals in rural areas are excluded from this rule under § 411.356(c).

For the reasons stated above, we have determined, and the Secretary certifies, that this final rule with comment will not result in a significant economic impact on a substantial number of small entities or on the operations of a substantial number of small rural hospitals. We are, therefore, not preparing analyses for either the RFA or section 1102(b) of the Act.

In accordance with the provisions of E.O. 12866, this regulation was reviewed by the Office of Management and Budget.

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, 1395nm, 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 HCFA.

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

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-in-law, 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-for-service 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

program or to any individual, third party payer, or other entity for the clinical laboratory services performed under that referral.

(c) *Denial of payment.* No Medicare payment may be made for a clinical laboratory service that is furnished under a prohibited referral.

(d) *Refunds.* An entity that collects payment for a laboratory service that was performed under a prohibited referral must refund all collected amounts on a timely basis.

§ 411.355 General exceptions to referral prohibitions related to both ownership/ investment and compensation.

The prohibition on referrals set forth in § 411.353 does not apply to the following types of services:

(a) *Physicians' services,* as defined in § 410.20(a), that are furnished personally by (or under the personal supervision of) another physician in the same group practice as the referring physician.

(b) *In-office ancillary services.* Services that meet the following conditions:

(1) They are furnished personally by one of the following individuals:

- (i) The referring physician.
- (ii) A physician who is a member of the same group practice as the referring physician.
- (iii) Individuals who are directly supervised by the referring physician or, in the case of group practices, by another physician in the same group practice as the referring physician.

(2) They are furnished in one of the following locations:

(i) A building in which 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.

(ii) A building that is used by the group practice for the provision of some or all of the group's clinical laboratory services.

(3) They are billed by one of the following:

- (i) The physician performing or supervising the service.
- (ii) The group practice of which the performing or supervising physician is a member.
- (iii) An entity that is wholly owned by the physician or the physician's group practice.

(c) *Services furnished to prepaid health plan enrollees by one of the following organizations:*

(1) An HMO or a CMP in accordance with a contract with HCFA under section 1876 of the Act and part 417, subparts J through M, of this chapter.

(2) A health care prepayment plan in accordance with an agreement with HCFA under section 1833(a)(1)(A) of the Act and part 417, subpart U, of this chapter.

(3) An organization that is receiving payments on a prepaid basis for the enrollees through 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).

(4) A qualified health maintenance organization (within the meaning of section 1310(d) of the Public Health Service Act).

(d) *Services furnished in an ambulatory surgical center (ASC) or end stage renal disease (ESRD) facility, or by a hospice* if payment for those services is included in the ASC rate, the ESRD composite rate, or as part of the per diem hospice charge, respectively.

§ 411.356 Exceptions to referral prohibitions related to ownership or investment interests.

For purposes of § 411.353, the following ownership or investment interests do not constitute a financial relationship:

(a) *Publicly traded securities.* Ownership of investment securities (including shares or bonds, debentures, notes, or other debt instruments) that may be purchased on terms generally available to the public and that meet the requirements of paragraphs (a)(1) and (a)(2) of this section.

(1) They are either—

(i) Listed for trading on the New York Stock Exchange, the American Stock Exchange, or any regional exchange in which quotations are published on a daily basis, or foreign securities listed on a recognized foreign, national, or regional exchange in which quotations are published on a daily basis; or

(ii) Traded under an automated interdealer quotation system operated by the National Association of Securities Dealers.

(2) In a corporation that had—

(i) Until January 1, 1995, total assets at the end of the corporation's most recent fiscal year exceeding \$100 million; or

(ii) Stockholder equity exceeding \$75 million at the end of the corporation's most recent fiscal year or on average during the previous 3 fiscal years.

(b) *Mutual funds.* Ownership of shares in a regulated investment company as defined in section 851(a) of the Internal Revenue Code of 1986, if the company had, at the end of its most recent fiscal year, or on average during

the previous 3 fiscal years, total assets exceeding \$75 million.

(c) *Specific providers.* Ownership or investment interest in the following entities:

(1) A laboratory that is located in a rural area (that is, a laboratory that is not located in an urban area as defined in § 412.62(f)(1)(ii) of this chapter) and that meets the following criteria:

(i) The laboratory testing that is referred by a physician who has (or whose immediate family member has) an ownership or investment interest in the rural laboratory is either—

(A) Performed on the premises of the rural laboratory; or

(B) If not performed on the premises, the laboratory performing the testing bills the Medicare program directly for the testing.

(ii) Substantially all of the laboratory tests furnished by the entity are furnished to individuals who reside in a rural area. Substantially all means no less than 75 percent.

(2) A hospital that is located in Puerto Rico.

(3) A hospital that is located outside of Puerto Rico if one of the following conditions is met:

(i) The referring physician is authorized to perform services at the hospital, and the physician's ownership or investment interest is in the entire hospital and not merely in a distinct part or department of the hospital.

(ii) Until January 1, 1995, the referring physician's ownership or investment interest does not relate (directly or indirectly) to the furnishing of clinical laboratory services.

§ 411.357 Exceptions to referral prohibitions related to compensation arrangements.

For purposes of § 411.353, the following compensation arrangements do not constitute a financial relationship:

(a) *Rental of office space.* Payments for the use of office space made by a lessee to a lessor if there is a rental or lease agreement that meets the following requirements:

(1) The agreement is set out in writing and is signed by the parties and specifies the premises covered by the lease.

(2) The term of the agreement is at least 1 year.

(3) The space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee, except that the lessee may make payments for the use of space consisting of common areas if

the payments do not exceed the lessee's pro rata share of expenses for the space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using the common areas.

(4) The rental charges over the term of the lease are set in advance and are consistent with fair market value.

(5) The charges are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

(6) The agreement would be commercially reasonable even if no referrals were made between the lessee and the lessor.

(b) *Rental of equipment.* Payments made by a lessee to a lessor for the use of equipment under the following conditions:

(1) A rental or lease agreement is set out in writing and signed by the parties and specifies the equipment covered by the lease.

(2) The equipment rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee.

(3) The lease provides for a term of rental or lease of at least 1 year.

(4) The rental charges over the term of the lease are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

(5) The lease would be commercially reasonable even if no referrals were made between the parties.

(c) *Bona fide employment relationships.* Any amount paid by an employer to a physician (or immediate family member) who has a bona fide employment relationship with the employer for the provision of services if the following conditions are met:

(1) The employment is for identifiable services.

(2) The amount of the remuneration under the employment is—

(i) Consistent with the fair market value of the services; and

(ii) Except as provided in paragraph (c)(4) of this section, is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician.

(3) The remuneration is provided under an agreement that would be commercially reasonable even if no referrals were made to the employer.

(4) Paragraph (c)(2)(ii) of this section does not prohibit payment of

remuneration in the form of a productivity bonus based on services performed personally by the physician (or immediate family member of the physician).

(d) *Personal service arrangements—*
(1) *General.* Remuneration from an entity under an arrangement to a physician or immediate family member of the physician, including remuneration for specific physicians' services furnished to a nonprofit blood center, if the following conditions are met:

(i) The arrangement is set out in writing, is signed by the parties, and specifies the services covered by the arrangement.

(ii) The arrangement covers all of the services to be furnished by the physician (or an immediate family member of the physician) to the entity.

(iii) The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement.

(iv) The term of the arrangement is for at least 1 year.

(v) The compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value, and, except in the case of a physician incentive plan, is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

(vi) The services to be furnished under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.

(2) *Physician incentive plan exception.* In the case of a physician incentive plan between a physician and an entity, the compensation may be determined in a manner (through a withhold, capitation, bonus, or otherwise) that takes into account directly or indirectly the volume or value of any referrals or other business generated between the parties, if the plan meets the following requirements:

(i) No specific payment is made directly or indirectly under the plan to a physician or a physician group as an inducement to reduce or limit medically necessary services furnished with respect to a specific individual enrolled in the entity.

(ii) In the case of a plan that places a physician or a physician group at substantial financial risk as determined by the Secretary under section 1876(i)(8)(A)(ii) of the Act, the plan complies with any requirements the Secretary has imposed under that section.

(iii) Upon request by the Secretary, the entity provides the Secretary with access to descriptive information regarding the plan, in order to permit the Secretary to determine whether the plan is in compliance with the requirements of paragraph (d)(2) of this section.

(3) Until January 1, 1995, the provisions in paragraph (d) (1) and (2) of this section do not apply to any arrangements that meet the requirements of section 1877(e)(2) or section 1877(e)(3) of the Act as they read before they were amended by the Omnibus Budget Reconciliation Act of 1993 (Public Law 103-66).

(e) *Physician recruitment.* Remuneration provided by a hospital to recruit a physician that is intended to induce the physician to relocate to the geographic area served by the hospital in order to become a member of the hospital's medical staff, if all of the following conditions are met:

(1) The arrangement and its terms are in writing and signed by both parties.

(2) The arrangement is not conditioned on the physician's referral of patients to the hospital.

(3) The hospital does not determine (directly or indirectly) the amount or value of the remuneration to the physician based on the volume or value of any referrals the physician generates for the hospital.

(4) The physician is not precluded from establishing staff privileges at another hospital or referring business to another entity.

(f) *Isolated transactions.* Isolated financial transactions, such as a one-time sale of property or a practice, if all of the conditions set forth in paragraphs (c)(2) and (c)(3) of this section are met with respect to an entity in the same manner as they apply to an employer. There can be no additional transactions between the parties for 6 months after the isolated transaction, except for transactions which are specifically excepted under the other provisions in §§ 411.355 through 411.357.

(g) *Arrangements with hospitals.* (1) Until January 1, 1995, any compensation arrangement between a hospital and a physician or a member of a physician's immediate family if the arrangement does not relate to the furnishing of clinical laboratory services; or

(2) Remuneration provided by a hospital to a physician if the remuneration does not relate to the furnishing of clinical laboratory services.

(h) *Group practice arrangements with a hospital.* An arrangement between a hospital and a group practice under

which clinical laboratory services are provided by the group but are billed by the hospital if the following conditions are met:

(1) With respect to services provided to an inpatient of the hospital, the arrangement is pursuant to the provision of inpatient hospital services under section 1861(b)(3) of the Act.

(2) The arrangement began before December 19, 1989, and has continued in effect without interruption since then.

(3) With respect to the clinical laboratory services covered under the arrangement, substantially all of these services furnished to patients of the hospital are furnished by the group under the arrangement.

(4) The arrangement is in accordance with an agreement that is set out in writing and that specifies the services to be furnished by the parties and the compensation for services furnished under the agreement.

(5) The compensation paid over the term of the agreement is consistent with fair market value, and the compensation per unit of services is fixed in advance and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

(6) The compensation is provided in accordance with an agreement that would be commercially reasonable even if no referrals were made to the entity.

(i) *Payments by a physician.* Payments made by a physician—

(1) To a laboratory in exchange for the provision of clinical laboratory services; or

(2) To an entity as compensation for other items or services that are furnished at a price that is consistent with fair market value.

§ 411.360 Group practice attestation.

(a) Except as provided in paragraph (b) of this section, a group practice (as defined in section 1877(h)(4) of the Act and § 411.351) must submit a written statement to its carrier annually to attest that, during the most recent 12-month period (calendar year, fiscal year, or immediately preceding 12-month period) 75 percent of the total patient care services of group practice members was furnished through the group, was billed under a billing number assigned to the group, and the amounts so received were treated as receipts of the group.

(b) A newly-formed group practice (one in which physicians have recently begun to practice together) or any group practice that has been unable in the past to meet the requirements of section 1877(h)(4) of the Act must—

(1) Submit a written statement to attest that, during the next 12-month period (calendar year, fiscal year, or next 12 months), it expects to meet the 75-percent standard and will take measures to ensure the standard is met; and

(2) At the end of the 12-month period, submit a written statement to attest that it met the 75-percent standard during that period, billed for those services under a billing number assigned to the group, and treated amounts received for those services as receipts of the group. If the group did not meet the standard, any Medicare payments made for clinical laboratory services furnished by the group during the 12-month period that were conditioned upon the standard being met are overpayments.

(c) Once any group has chosen whether to use its fiscal year, the calendar year, or some other 12-month period, the group practice must adhere to this choice.

(d) The attestation must contain a statement that the information furnished in the attestation is true and accurate and must be signed by a group representative.

(e) A group that intends to meet the definition of a group practice in order to qualify for an exception described in §§ 411.355 through 411.357, must submit the attestation required by paragraph (a) or paragraph (b)(1) of this section, as applicable, to its carrier by December 12, 1995.

5. Section 411.361 is revised to read as follows:

§ 411.361 Reporting requirements.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, all entities furnishing items or services for which payment may be made under Medicare must submit information to HCFA concerning their financial relationships (as defined in paragraph (d) of this section), in such form, manner, and at such times as HCFA specifies.

(b) *Exception.* The requirements of paragraph (a) of this section do not apply to entities that provide 20 or fewer Part A and Part B items and services during a calendar year, or to designated health services provided outside the United States.

(c) *Required information.* The information submitted to HCFA under paragraph (a) of this section must include at least the following:

(1) The name and unique physician identification number (UPIN) of each physician who has a financial relationship with the entity;

(2) The name and UPIN of each physician who has an immediate relative (as defined in § 411.351) who

has a financial relationship with the entity;

(3) The covered items and services provided by the entity; and

(4) With respect to each physician identified under paragraphs (c)(1) and (c)(2) of this section, the nature of the financial relationship (including the extent and/or value of the ownership or investment interest or the compensation arrangement, if requested by HCFA).

(d) *Reportable financial relationships.* For purposes of this section, a financial relationship is any ownership or investment interest or any compensation arrangement, as described in section 1877 of the Act.

(e) *Form and timing of reports.* Entities that are subject to the requirements of this section must submit the required information on a HCFA-prescribed form within the time period specified by the servicing carrier or intermediary. Entities are given at least 30 days from the date of the carrier's or intermediary's request to provide the initial information. Thereafter, an entity must provide updated information within 60 days from the date of any change in the submitted information. Entities must retain documentation sufficient to verify the information provided on the forms and, upon request, must make that documentation available to HCFA or the OIG.

(f) *Consequences of failure to report.* Any person who is required, but fails, to submit information concerning his or her financial relationships in accordance with this section is subject to a civil money penalty of up to \$10,000 for each day of the period beginning on the day following the applicable deadline established under paragraph (e) of this section until the information is submitted. Assessment of these penalties will comply with the applicable provisions of part 1003 of this title.

(g) *Public disclosure.* Information furnished to HCFA under this section is subject to public disclosure in accordance with the provisions of part 401 of this chapter.

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: January 16, 1995.

Bruce C. Vladeck,
Administrator, Health Care Financing Administration.

Dated: May 10, 1995.

Donna E. Shalala,
Secretary.

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